ADDIS ABABA UNIVERSITY
COLLEGE OF HEALTH SCIENCES
SCHOOL OF ALLIED HEALTH SCIENCES
DEPARTMENT OF MEDICAL LABORATORY SCIENCES

ASSESSMENT ON IMPLEMENTATION OF QUALITY MANAGEMENT SYSTEM AND THEIR CHALLENGES IN TIKUR ANBESSA SPECIALIZED HOSPITAL LABORATORY. ADDIS ABABA, ETHIOPIA

A THESIS SUBMITTED TO THE DEPARTMENT OF MEDICAL LABORATORY SCIENCES IN PARTIAL FULFILLMENT OF THE DEGREE OF MASTER OF SCIENCE IN CLINICAL LABORATORY SCIENCE (CLS) (CLINICAL LABORATORY MANAGEMENT AND QUALITY ASSURANCE SPECIALTY)

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DECLARATION

This is to certify that the thesis prepared by Daniel Beshah which is entitled with "**Assessment on implementation of quality management system and their challenges in Tikur Anbessa Specialized Hospital Laboratory, Addis Ababa, Ethiopia"** And submitted in partial fulfillment of the requirements for the degree of Master of Clinical Laboratory Sciences (Laboratory Management and Quality Assurance Specialty Track) complies with the regulations of the University and meets the accepted standards with respect to originality and quality.

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Approved by the Examining Board

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ACRONYMS

AIDS	Acquired Immunodeficiency Syndrome
ASLM	African society for laboratory medicine
BPR	Business process reengineering
CDC	Center of disease control and prevention
CLSI	Clinical and Laboratory Standards Institute
EHNRI	Ethiopian Health and Nutrition Research Institution
ENAO	Ethiopian National accreditation organization
EPHI	Ethiopian Public Health Institute
FDA	Food and Drug administration
HIV	Human immunodeficiency virus
ICT	Information communication technology
IQMS	Implementation of quality management system
ISO	International organization for standardization
LQMS	Laboratory quality management system
NCCLS	National Committee for Clinical Laboratory Standards.
NLAC	National laboratory accreditation committee
OPD	Outpatient department
PEPFAR	President‟s emergency plan for AIDS relief
PT	Proficiency testing
QC	Quality control
QMS	Quality management system
QSE	Quality system essential
SLIPTA	Stepwise laboratory improvement process towards accreditation
SLMTA	Strengthening laboratory management towards Accreditation
TASH	Tikur Anbessa Specialized Hospital
TAT	Turnaround time
TB	Tuberculosis
WHO-AFRO	World health organization-African Regional Office

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ABSTRACT

Background: Quality laboratory services and systems constitute the foundation for strengthening health care systems. Including Ethiopia, developing countries are on the way of establishing laboratory standards that are affordable and easy to implement and monitor in their facilities. This study was conducted to assess the laboratory starting from implementation of Quality Management System (IQMS), up to the final assessment.

Objective: The Objectives of the study is to assess implementation of quality management system and associated challenges in Tikur Anbessa Specialized Hospital, Addis Ababa, Ethiopia.

Method: Exploratory study was done by using available information, assessment data, questionnaire, in-depth interview and observational assessment from February 14/2013 – May 5/2014. All willing laboratory staffs were included in the research and non-probability purposive sampling technique was applied. Statistical analysis was carried out by using SPSS version 20.

Result: The progress of quality management system implementation after one year and three month from baseline assessment result of 41/250(16.4%) to final assessment result 95/250(38.0%) were 54(21.6%) with the mean value of 7.9 for12 QSE (P = 0.001).The identified challenges were staff Job dissatisfaction leads to staff demotivation, shortage of supportive staffs, lack of proper laboratory management, lack of Hospital management commitment, weakness of supporting (management) departments finance, purchasing, budget and maintenance departments, lack of budgets allocation for the laboratory, delay on purchasing system are critical challenges affecting the laboratory. Weakness in pharmacy supply chain management system, very poor store management, lack of mini store, lack of backup equipment and lack of equipment maintenance system are other challenging issues of laboratory. In appropriateness of sample collection area benches and sinks to keep samples and documents. Power supply problem were challenges of QMSI.

Conclusion: Majority participants were dissatisfied and demotivated in their work environment. The laboratory management was very week concerning awareness creation. There were major gap between upper management and laboratory department. Support from hospital management to the laboratory was very minimal. Weak inventory system, Finance, purchasing and budget department activities were major challenges. Main store that managed by pharmacy department does not have standard system and haven‟t close relationship with laboratory department.

1. INTRODUCTION

1.1. Background of the Study

Quality management system (QMS), as defined by the International Organization for Standardization (ISO) is coordinated activities to direct and control an organization with regard to quality [1]. The work of innovators, who articulated the concept of quality, helped it advance over a span of 80 years [2]. Quality ideas have evolved primarily in western industrial setting, usually through the interaction between regulatory bodies and commercial interests. These ideas are being adopted in medical sector where implementation of quality concept can help assure the best patient care [3].

QMS has taken a while for the dual managerial relationship between medical laboratory quality management activities and technical work to become comprehensively mapped out. It began in the United States in 1992, when the food and drug administration (FDA) convened a public workshop to solve the quality problems inherent in dealing with the HIV-AIDS virus contaminating the nation‟s blood supply [4]. In 1999, a National Committee for Clinical Laboratory Standards (NCCLS) subcommittee, representing laboratory, industry, and government perspectives, produced the first medical laboratory-specific QMS model known as GP26 [5].

In a QMS, all aspects of the laboratory operation, including the organizational structure, processes and procedures, need to be addressed to assure quality [2]. A well-defined quality system is a must for ensuring quality. According to International Organization for Standardization (ISO) explanation QMS is a part of overall quality management which aims at ensuring the consistency, reproducibility, traceability and reliability of the products or services. They define quality system as the organizational structure, responsibilities, procedures and resources needed for implementing quality management [6].

World health organization (WHO) Laboratory QMS Handbook elucidates all of the laboratory procedures and processes are organized into 12 quality system essentials (QSE). These QSE are a set of coordinated activities that serve as building blocks for quality management [2]. These QSEs, are 1)Documents and Records, 2)Organization, 3)Personnel, 4)Equipment, 5)Purchasing

and Inventory, 6)Process Control, 7)Information Management, 8)Occurrence Management, 9)Assessment: External and Internal, 10)Process Improvement, 11)Customer Service and Satisfaction and 12)Facilities and Safety. QSEs depict the necessary infrastructure in any organization, including healthcare organizations that provide care, treatment, and services to patients [7].

Study done in India by Tibbets et al stated that QMS in a laboratory is an integrated program involving all laboratory staff and management. It is a framework to operate and aiming for integration, consistency, increase in efficiency and continuous drive for improvement [3]. The WHO recognizes quality laboratory services as key to improving global health and reaching Millennium Development Goals. Strengthening the breadth of laboratory services accessible to clients and ensuring that results are accurate, reliable, reproducible, and rapid enough to be useful, is crucial to improve health outcomes [8]. It is, therefore, imperative that laboratory systems be strengthened within broader efforts toward health system strengthening [9].

Establishment of a formalized system to improve public medical laboratories throughout Africa occurred in several steps. A total of 120 experts and policy makers from 33 countries, including representatives from Cambodia, Haiti, India, Thailand, Vietnam and 28 Sub-Saharan African countries were invited in Maputo, Mozambique, from 22 to 24 January 2008 to reach a consensus on technical and operational aspects to guide the necessary steps and procedures for adequate national strategic plans for laboratories [10].

Later that year, in Senegal, the WHO African Regional Office (AFRO) laboratory network called for the establishment of a "step-wise" accreditation process. In July 2009, in Kigali, Rwanda, WHO-AFRO, together with US partners and a group of health experts and policymakers from 13 African countries, launched the WHO-AFRO step-wise laboratory accreditation program [8].The continent with partners Established WHO-AFRO Laboratory Accreditation Process 5 and laboratory management training programme, such as Strengthening Laboratory Management Towards Accreditation (SLMTA), and supported the launch of the African Society for Laboratory Medicine in 2011 [9].

The stepwise approach, using a 0- to 5-star scale is given to 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. Laboratories that achieve 95% or more will receive a 5-star rating [11].

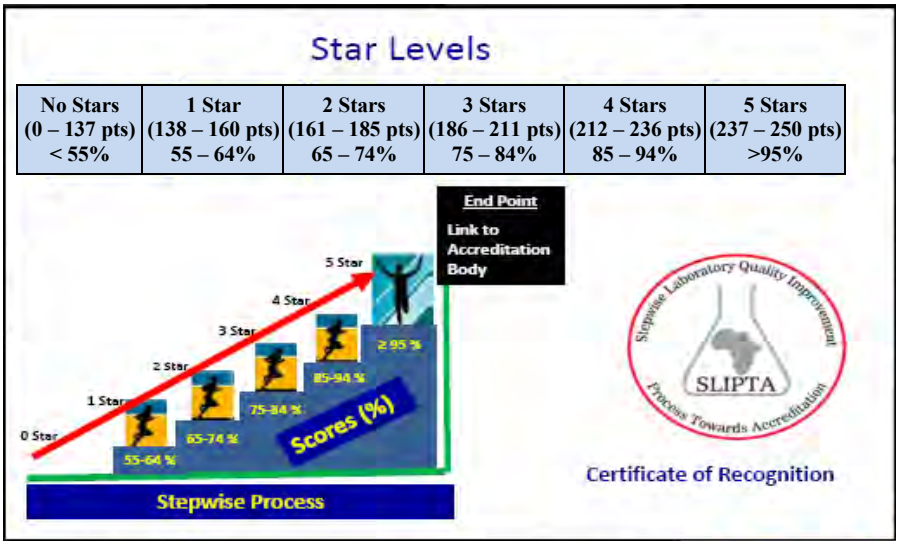

Figure 1: WHO-AFRO step-wise laboratory Quality improvement process towards accreditation (SLIPTA) [12].

Ethiopia was one of the first countries to develop its laboratory plan in 2005 with support from the Clinton Foundation and other partners. The plan, which has 14 strategic objectives, has since been implemented with leadership from the Ethiopian Health and Nutrition Research Institute (EHNRI) and support from the CDC/ PEPFAR; the Global Fund for AIDS, TB, and Malaria; and the Clinton Foundation [13].

The National Laboratory Accreditation committee (NLAC) was established by the EHNRI from the National Laboratory Technical Working Group in December 2009 to support public health laboratories to adapt and implement the WHO-AFRO laboratory accreditation program. NLAC reviews laboratory improvement progress based on the standardized WHO-AFRO quality improvement checklist. The level of improvement at each laboratory is scored by an external accreditation authority (WHO-AFRO or designated authority). Laboratories are rated from one to five stars based on their step-wise quality improvement. Laboratories that achieve the five star rating will be strongly encouraged to enroll in an established international accreditation scheme [8].

1.2. Statement of the problem

Laboratory testing is an essential component of improved health care. Diagnostics and clinical patient management have an interdependent relationship; laboratory data provide justification for clinical decision making, while clinical signs or the clinical management protocol often prompt laboratory testing [14]. Many therapeutic decisions rely heavily on data from health laboratories. Today‟s world cannot afford unreliable laboratory results, wasting precious time, precious samples, and too often, precious lives [15]. But in many low-resource settings, including many African countries, laboratory services have suffered from inattention and chronic under-development [9].

The World Health Organization estimates that fewer than 10% of malaria cases in Africa are properly diagnosed by using microscopy or rapid tests 14]. Especially, in sub-Saharan Africa, laboratory infrastructure and personnel are adversely affected by a lack of resources and prioritization, hampering laboratory systems. As a result, the accessibility of laboratory testing and the quality of available services remains a serious challenge [11].

According to Birx *D et, al.* explanation, the most difficult challenges facing national laboratory system in developing countries are: 1) acute shortage of workforce capacity, as seen with the limited number of trained and skilled personnel; 2) poorly maintained physical infrastructure and inadequate supply of electricity and water; 3) lack of equipment maintenance; 4) weak supply-chain management systems for consumables and reagents; and 5) lack of leadership and policies for standards [16].

The other Challenges indicated by Nkengasong J *et al.* in developing countries are lack of: 1) a framework for training, retaining and career development of laboratory workers; 2) specimen referral systems in an integrated, tiered national laboratory system network; 3) standards for quality management systems 4) laboratory information system; 5) biosafety and waste management system [17]. Supplies and reagents are one of the major challenges. Some of the greatest challenges are faced in product selection, quantification and forecasting [18].

Studies strongly recommend that, information systems allow the automation of internal quality management processes, using standard sample tests, Levey- Jennings charts and Westgard multi-

rule analysis. This simplifies evaluation and interpretation of quality tests and reduces the possibility of human error [19]. Fear of cost is one challenge for IQMS; however, high health care quality can lead to substantially lower costs. The pursuit of high quality provides a rational system for cost containment [20].

In addition Birx D et, al. commented that, in each resource-constrained setting, there are highly talented national scientists and international partners with sophisticated and well-equipped research laboratories but they are not participating in service giving laboratory QMS [16]. The other important barrier to the implementation of QMS is skepticism. There is a need to educate healthcare professionals about the potential benefits of QMS to resolve any skeptical attitude of healthcare professionals towards QMS [21].

Tikur Anbessa Specialized Hospital laboratory was not exceptional in light of the aforementioned problems in sub-Saharan Africa. So this research was aimed to address the level of QMS implementation and associated challenges that have been reported as outlined above. The study also investigates opportunities and other problems that affect the implementation of quality management system in the laboratory, with the aim of identifying gaps for corrective actions before the next assessment is effective.

TASH laboratory is one of those laboratories that had been implementing strengthening laboratory management system towards accreditation (SLMTA) collaborating with John Hopkins University and Addis Ababa Health Research Laboratory with total number of 34 government laboratories, from May 7, 2012 up to July, 7 2013 final date of assessment. Out of 34 health facilities three of them scored 3 stars, eight of them scored 2 stars, twelve of them scored one star and eleven of them scored 0 star including TASH Laboratory. Compared with the other institutions scoring zero star TASH laboratory has skilled staff and many options for required resources. So, this research questioned why TASH laboratory scored zero?

So this study majorly provides information on the challenges during implementation of quality management systems in the hospital and suggests improvement intervention for the next implementation.

1.3. Significance of the study

Patients need to benefit from the highest quality of clinical laboratory services. Moreover they should be protected from miss diagnosis, wrong treatment and prolonged illness. Public health care providers should also be trusted by the service they delivered. TASH laboratory also attempt to reduce patient defaulting that might be attributed to poor quality service. In addition as a teaching, research and tertiary level service providing center it is supposed to be a model and needs to get international recognition on best practice and simulate for innovation. So implementation of quality management is crucial.

The purpose of this study is, therefore, to assess level of implementation, gaps and challenges in the laboratory and give a useful insight/ recommendation to the hospital and laboratory to solve the problems and improve quality management system implementation to meet the expectations in five year national health strategic plan. Most public institution those cascade SLMTA were not successful so the principal investigator believes that the challenges and investigated solutions will be used in most governmental institutions as there may be shared challenges. Also it will be used as baseline for next studies since it was not done previously.

2. LITERATURE REVIEW

Minimizing the chance for Laboratory error and ensuring highest possible quality of testing and results are the major reasons to implement quality management system [22]. Studies in the United States and Europe in 2010 have demonstrated the majority of errors occur outside of the laboratory in the pre-analytical 46%-68% and post-analytical stages 18%-47%. The frequency of errors during the analytical stage is lower but remains significant, estimated to be between 7% and 12%, despite years of quality management regulation. In the United States, it is estimated that 6% to 12% of laboratory errors put patients at risk of inappropriate care and potentially of adverse events. [14]. Similar result was reported by Goldschmidt 12.5% of laboratory errors may have an effect on patient health [23].

One year study in San Raffaele Hospital Laboratory Italy showed a significant difference in the magnitude of errors detected between in- and outpatients. From total test results 0.60% for inpatients versus 0.039% error for outpatients was identified. [24].

A previous report from the College of American Pathologists (CAP) proficiency testing (PT) participating laboratories in US in 2007 indicates the possible causes of errors were 51% clerical, 24% technical, 12% methodological, 7% problem with PT materials, and 6% random errors observed [25]. In Ghana and Burkina Faso in 2012 on approved proficiency testing (PT) programs methodological 73% (246) Technical 4% (14) Clerical12% (41) PT Stability 7% (25) Random 4% (13) error were observed. These shows methodological errors were the major cause of unsatisfactory results in their laboratories [25]. In sub-Saharan Africa, methodological errors, and not clerical errors, accounted for the vast majority of errors. So efforts for accrediting laboratories are on the rise with the aim of improving quality laboratory services. [26].

In July 2009 survey of online registers of leading accreditation providers showed that internationally accredited laboratories in Africa were only 340. Out of the 340 laboratories, 312 (91.8%) of the accredited laboratories were in South Africa; only 28 (8.2%) were in the remaining sub-Saharan Africa. Of the accredited laboratories in South Africa, fewer than 30 (9.6%) were public sector and 282 (94.4%) were private sector laboratories [11].

In Ethiopia currently, there are only six internationally accredited laboratories: a disease-specific polio laboratory accredited by WHO, and International Clinical Laboratories accredited by Joint Commission International [13]. The rest four ALERT Centre Clinical Laboratory [27], Medical Biotech Laboratory [28], Hema Diagnostic Laboratory Plc [29], and Addis Ababa Health and Research Laboratory [30] are accredited by Ethiopian National accreditation organization (ENAO).

According to a study done in Lesotho, mentorship on implementation of QMS was exercised at four hospital laboratories, three districts and one central laboratory between June 2009 and December 2010. The average baseline score of the three district laboratories was 107.7 out of a possible 250 (43.6%) (range 109-138). At baseline, all three laboratories scored zero stars on the WHO-AFRO SLIPTA star scale. After six weeks of mentorship, the average score was 136.3 (54.5%) (Range 119–146). Whilst the scores were numerically not significantly higher than the baseline ($p = 0.25$), two of the three laboratories had shifted to a one star status on WHO-AFRO SLIPTA scale by six weeks. The scores at the start of the second mentorship engagement had remained stable (average 160.5; $p = 0.096$) and the one star status of the two laboratories was maintained. However, after an additional four weeks of mentorship, the average score was 182.3 (range 165–195), a significant increase of 74.7 points on average over the baseline scores ($p = 0.034$). Two laboratories had achieved two stars and the third had achieved a three star status [9].

While implementing SLIPTA in Lesotho, in two cohorts from January 2010- march 2012, twelve and nineteen laboratory supervisors and quality officers were enrolled in Cohort 1 and Cohort 2, respectively. These 31 participants represented 18 of the 19 laboratories nationwide. Two methods were used to implement SLIPTA: the traditional „three workshops" approach and twinning SLMTA with mentorship. The latter, with intensive follow-up visits, was concluded in 9 months and the former in 11 months. A standard data collection tool was used for site visits. Of the 31 participants across both cohorts, 25 (81%) graduated (9 from Cohort 1 and 16 from Cohort 2). At baseline, all but one laboratory attained a rating of zero stars, with the exception attaining one star. At the final assessment, 7 of the 25 laboratories examined at baseline were still at a rating of zero stars, whilst 8 attained one star, 5 attained two stars and 4 attained three stars. None scored above three stars. The highest percentage improvement for any laboratory was 51%, whereas the least improved dropped by 6% when compared to its baseline assessment. The most

improved areas were corrective actions (34%) and documents and records (32%). Process improvement demonstrated the least improvement (10%) [31].

In August 2009 the Ethiopian Health and Nutrition Research Institute (EHNRI) currently named Ethiopian Public Health Institute (EPHI) launched SLMTA on 24 health laboratories, which have completed the three phases of SLMTA trainings and improvement projects implementations including National External Audit, 1 laboratory has received Star 4 Level of accreditation. In addition to that, 2 laboratories have received 3 Star and 3 laboratories have received 2 Star. The remaining 8 health laboratories have received 1 Star of Laboratory Accreditation [32].

Addis Ababa regional health laboratory was one of the first batches to implement QMS. Baseline assessment conducted in June 2010, and the first phase of Strengthening Laboratory Management Towards Accreditation (SLMTA) training given which was followed by regular mentoring and coaching once a week with 4 to 5 hour stays at the facility. By November 2011, the Addis Ababa regional health laboratory received 4-star scale based on WHO criteria (up from a baseline of 0-star). The average turn-around time (TAT) declined from 5 to 3 days for CD4 test; from 28 to 5 days for DNA PCR, and from 35 to 15 days for viral load testing in 98% of samples. Test outlier rate dropped from 20% to 3% and over 85% of documents and records were customized and used. The rate of receipt of External quality assessment proficiency testing was 85%, 95%, and 100% for CD4, DNA PCR, and TB/HIV tests, respectively. Mean equipment downtime declined from 25% to 3% and stock-out from 12% to 0%. Sample rejection rate dropped from 25% to 3%, and wrong labeling from 15% to 2%. No service interruption was noticed from May 2010 to October 2011 [33].

A cross-sectional descriptive study was conducted on Logistics management information system (LMIS) practice for HIV/AIDS and TB laboratory commodities from September 2010-January 2011 at 43 selected public health facilities in Addis Ababa. However, majority of laboratory professionals were not trained in LMIS. Majority of the facilities (60.5%) were stocked out for at least one ART monitoring and TB laboratory reagents and the highest stock out rate was for chemistry reagents. Expired ART monitoring laboratory commodities were found in 25 (73.5%) of facilities. Fifty percent (50%) of the assessed hospitals and 54% of health centers were

currently using stock/bin cards for all HIV/AIDS and TB laboratory commodities in main pharmacy store, among these only 25% and 20.8% of them were updated with accurate information matching with the physical count done at the time of visit for hospitals and health centers, respectively [34].

A paper presented in Maputo Conference in 2009, explain some major challenges facing laboratory systems in resource-poor settings include dilapidated infrastructure, lack of human capacity, laboratory policies, and strategic plans; and limited synergies between clinical, teaching and research laboratories are factors that compromise the quality of test results and impact patient management [16].

In Ethiopia, a study which evaluates the QMS implementation status of selected CD4+ T cell count and AFB microscopy performing laboratories in Addis Ababa demonstrated poor performance as evidenced by the small proportion (about a quarter) of the assessed laboratories having one star level and above while the majority had zero. The study documented that there was a staff resistance towards the implementation of the QMS due to 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 [36].

Other than this recent study, as far as our knowledge goes, there is no published report in Ethiopia on the challenges of QMS implementation. The proposed research is focused on the gaps and challenges on implementation of quality management systems of the tertiary care largest teaching and referral hospital. As TASH is currently the only hospital for many of the specialty and sub-specialty services, which is also engaged in teaching and research, QMS implementation success in this premier hospital has added significance to do same in the other health facilities in the country. Moreover, the hospital is expected to play a leading role in clinical research which requires standard laboratory support. However, in contrary to the expectations, the hospital's laboratory is among those which do not have any star level. So the research is intended to show the importance of implementation of quality management system and challenges during implementation that helps to encourage for both managerial and technical staff to work together for the vision of the laboratory.

3. OBJECTIVES OF THE STUDY

3.1. General Objective:

- To assess implementation of quality management system in Tikur Anbessa Specialized Hospital. Addis Ababa, Ethiopia

3.2. Specific objectives:

- To compare IQMS baseline assessment with final assessment done by using WHO-AFRO checklist.
- To identify challenges on implementation of Quality management system in TASH laboratory.
- To identify opportunities to implement Quality management system in TASH laboratory.

4. HYPOTHESIS

Implementation of QMS and associated challenges on TASH Laboratory were similar to what has been seen in other health facilities in developing countries.

5. METHODS

5.1. Study area

The study was conducted in Tikur Anbessa Specialized Hospital laboratory which is located in Lideta sub city. TASH was established in 1973 "to serve the needs of the whole country as specialized referral hospital and as a medical university under Addis Ababa University by drawing its students from a cross-section of the country as well as foreign nations". TASH is the largest specialized hospital in Ethiopia, with over 700 beds, and serves as the training center for undergraduate and postgraduate medical students, dentists, nurses, midwives, pharmacists, medical laboratory technology, radiology technology, and others who shoulder the health problems of the community and the country at large [37].

The Hospital has 201 doctors, 627 nurses, 76 laboratory staff and more than 115 other health professionals dedicated to providing the health care services. The various departments" faculties and residents under specialty trainings in the School of Medicine provide patient care in the hospital. The hospital also has more than 1300 permanent and contract administrative staffs to support the hospital activities. In addition, almost all regional and federal hospitals in Addis Ababa are affiliated to the School of Medicine as clinical services and training sites [37].

Table 1: Tikur Anbessa Specialized Hospital Laboratory profile

Level	**Tertiary level referral specialized hospital laboratory**
Affiliation	Government
Laboratory Layout	4 sample collection rooms, 3 of them in OPD and 1 for pediatrics OPD. Sample collection rooms are in different places near to the case team. 6 rooms for testing, 1 room for sample processing, 1 room for media preparation, 2 rooms for cleaner, 1 room for meeting hall 1room for QA office and 1 room for lab head
Staff	1- MD, 3- MSc (specialist, 2 of them are PhD candidates), 34 Technologists, 13-Technicians, 3-data clerk, 6-phlebotomists, 5-equipment and reusable items cleaner, 6-porters, 5-laboratory cleaners = 76 staffs
Section	Chemistry, Hematology, Blood Bank, Serology, Parasitology and Urinalysis, Bacteriology, Sample Processing and Sample Collection Units
Average test	700,000 – 800,000 / year

5.2. Study period

The study was conducted from February 14, 2013 – May 5, 2014 G.C.

5.3. Study design

Descriptive study was done based on retrospective and prospective data‟s. Retrospective study was carried out by reviewing meeting minuets and WHO-AFRO SILPTA baseline assessment checklist results which were done by external assessor for comparison. Prospective analysis was done by using assessment checklist, questionnaire and in-depth interview questionnaires. Questionnaires were developed for laboratory department based on points identified from meeting minutes and implementation of QMS requirements. For other departments in the hospital, in-depth interview were developed based on the issues raised from meeting agendas and from system requirement. Since the aim of the study was to assess IQMS and factors affecting IQMS. In-depth interview were held in selected departments with heads who are working with laboratory personnel.

5.4. Source population

Tikur Anbessa Specialized Hospital staffs were source of population.

5.5. Study population

Tikur Anbessa Specialized Hospital laboratory staffs and department heads from different departments who had direct links with hospital laboratory system were selected. All Phlebotomists, porters, laboratory technicians and technologists who were involved during implementation phase were included.

5.6. Sampling Technique

All laboratory staff professionals were selected as respondents in the research while in-depth interview was done with other department heads who have been working closely with laboratory system. So non-probability and purposive sampling technique was used.

5.7. Inclusion and exclusion criteria:

5.7.1. Inclusion criteria:

All willing TASH laboratory staff involved during implementation phase were included, from other departments‟ voluntary heads or delegates that have link with the laboratory department were selected.

5.7.2. Exclusion criteria:

Laboratory staffs and other department heads that had not been worked in that specific duration of QMS implementation were not selected.

5.8. Sample size

One department head or delegated personnel from the departments which have link with laboratory department were selected as a sample.

Table 2: TASH Laboratory departments and respective sample sizes

No	Departments	Sample size
1	Laboratory professionals	All
For in-depth interview		
2	Hospital management head	1
3	Finance department head	1
4	Purchasing department head	1
5	Store head	1
6	Pharmacy department head	1
7	ICT department head	1
8	Budget department head	1
9	Property administration	1
10	Maintenance department head	1
11	Managing director	1
12	Physician	1
13	Matron	1
Total		**12**

5.9. Sampling procedures

- Convenient sampling technique was employed to include study participants who meet the inclusion criteria which are mentioned above.

5.10. Study Variables

5.10.1. Dependent variables

- Implementation of SLMTA in TASH laboratory
- Challenges on implementation of quality management system in TASH laboratory

5.10.2. Independent variable

- Experience
- Educational status
- Job satisfaction
- Motivation
- Incentive
- Knowledge about QMS
- Training
- Commitment on implementation
- Recourse/ supply chain management
- Mentorship during implementation

5.11. Data collection procedures

In this study, quantitative and qualitative, primary and secondary data were collected from selected participants and sources. The data collections were mainly focused on the objective of the study.

5.11.1. Prospective data collection

The first primary data sources were baseline and final assessment result using WHO-AFRO checklist (Annex I). Second primary data source were questionnaire (Annex II) which were relevant to the issue to be studied. The third primary data collection method were in-depth interview (Annex IV), which helps the principal investigator to investigate opportunities and challenges on implementation phase of QMS in the laboratory.

5.11.2. Retrospective data collection

Secondary data source was meeting minutes and final assessment result done by National assessors using the WHO-AFRO checklist standard (Annex I) for the comparison of principal investigator result.

Questionnaires for laboratory personnel‟s were developed both in Amharic and English to address all participants easily. In-depth interview questionnaire were prepared and response were documented in English. Questionnaire and in-depth interview data were collected including gender, age, profession, qualification and experience of participants. Extraction of main points from secondary data of meeting minutes was done in English. The data were collected in the facility during working hour from April 15– May 5, 2014 G.C.

Data quality was maintained starting from questionnaire preparation up to data collection and analysis. The questionnaires were pre-tested whether it achieves required objective or not before starting data collection and adjustment were made as necessary. Data collector was trained and informed prior to data collection. In addition, there was a daily follow up by the principal investigator.

5.12. Data Management

Data quality was ensured through use of standardized data collection formats and materials. Data were entered, cleaned and analyzed by using SPSS version 20 software for further processing. The data were stored in password protected computer and backup were saved by flash and CDs.

5.13. Data Analysis procedures

Results from WHO-AFRO checklist were analyzed with the paired t-test to compare baseline performance with performance after one year and three month. The quantitative data collected using different techniques were analyzed using simple descriptive statistics i.e. percentages, frequency, mean and the data collected was also compared using paired t-test statistical package. $P<0.05$ was taken as statistically significant. The qualitative data obtained from meeting minutes and in-depth interview, were summarized and discussed.

5.14. Data Analysis plan

Data was processed and analyzed both by descriptive and analytical methods. In the questionnaire, there are some questions with five ordered choices for detail understanding of each response. However, they were condensed in to three categories for ease of discussion. In case, the reader wants to see further clarification, the detail is provided in the table.

5.15. Operational Definitions

Assessment data: Evaluation result of the entire QA systematic evaluation of all laboratory procedures by WHO-AFRO checklist.

Questionnaire: is a type of consistency and completeness informational job aid used to assess laboratories.

In-depth interview: is a qualitative research technique that involves conducting intensive individual interviews with department heads to explore their perspectives on a particular idea.

Quality management system: Management system to direct and control an organization with regard to quality

WHO/AFRO Checklist: a checklist designed based on ISO 15189:2007 and CLSI Quality Management System: Approved Guideline (GP26-A4: 2011) use to assess laboratories.

5.16. Ethical considerations

This research received approval from the Department of Medical Laboratory Sciences, departmental research and ethics review committee (DRERC) and researcher received ethical clearance. Permission letter was obtained from the study site. A questionnaire (Consent form 1.3 or 2.3 and 1.4 or 2.4) filled after obtaining participant information to be agreed up on and signed on consent form (English and Amharic version). The researcher collected the primary and secondary data and no information, which may expose the identity of individuals, was collected, to ensure confidentiality. Response to questionnaires were recorded and analyzed.

6. RESULTS

6.1. Findings from quantitative study

Among a total of 76 TASH laboratory staff members, 66 of them were involved in the study. In case of in-depth interview all selected 12 department heads were participated. The overall response rate was 66 (89.2%) and 12 (100%) of the laboratory staff and other department heads of Tikur Anbessa hospital staffs respectively.

6.1.1. Participants socio demography characteristics

As it is indicated below, 72.72% of respondents‟ are between age 20-40. Total mean age of respondents is 36.14 years. Highest percentage of respondents, 22.7, 15.2 and 13.6 percent were senior medical laboratory technologist, Expert medical laboratory technologist and Junior medical laboratory technician respectively. On educational background the highest composition of respondents, (51.5%) are bachelor's degree holders which were followed by diploma holders 27.27%. (Table 3)

According to the table, 84.9% and 12.1% of respondents were section workers and section heads respectively. As indicated in the above table 3, least years of experiences are from one to two years which counted 15.15% and 25.76% were employee with highest years of work experience found to be 20 to 41 years. The major shares of respondents were from Sample collection unit (21.2%), Chemistry (18.2), Hematology (15.2%) and Bacteriology (15.2%). (Table 3)

Table 3: Socio demographic characteristics of TASH laboratory professionals participated in the study.

Variables	Frequency	Percentage (%)
Gender		
Male	39	59.1
Female	27	40.9
Total	66	100
Age group in years		
20-30	24	36.36
31-40	24	36.36
41-50	9	13.64
51-60	9	13.64
Total	66	100

Table 3 continued

Professional level		
Consultant med. lab. Specialist	1	1.5
Health specialist	3	4.5
Expert medical lab. Technologist	10	15.2
Chief medical lab. Technologist	3	4.5
Senior medical lab. Technologist	15	22.7
Junior medical lab. Technologist	6	9.1
Expert medical lab. Technician	1	1.5
Senior medical lab. Technician	3	4.5
Junior medical lab. Technician	9	13.6
Phlebotomist	6	9.1
Cleaner	1	1.5
Patient assistant	8	12.1
Total	66	100.0
Educational background		
Medical doctor and postgraduate	1	1.52
Post graduate	3	4.55
Degree	34	51.5
Diploma	18	27.27
Certificate	1	1.52
12th grade	5	7.57
Other	4	6.06
Total	66	100.0
Position in the organization		
Diagnostic Director	1	1.5
Lab head	1	1.5
Section head	8	12.1
Section worker	56	84.9
Total	66	100
Years of experience		
1-2year	10	15.15
3-5 years	16	24.24
6-10 years	8	12.12
11-20 years	15	22.73
20-41 years	17	25.76
Total	66	100
Participant working department		
Sample collection unit	14	21.2
Sample processing and reception	4	6.1
Blood bank	4	6.1
Parasitology	5	7.6
Hematology	10	15.2
Serology	4	6.1
Chemistry	12	18.2
Bacteriology	10	15.2
Laboratory head office	3	4.5
Total	66	100.0

6.1.2. Baseline and final Assessment result using WHO-AFRO Cheek list

The baseline assessment was done before starting QMS implementation. The assessment was done by supervisor and quality officer immediately after the first round training. The final assessment was done after 16 months of implementation. The result is displayed in Table 4 as follows.

Table 4: Comparison of IQMS baseline assessment with final Assessment result by using WHO-AFRO Cheek list in TASH laboratory from May 14, 2012- September 09, 2013

Quality System Essentials	**Total Points**	**Baseline Assessment score in No & %**	**Final Assessment score after 14 month in No & %**	**Progress in No & % in each QSE.**	**Final Assessment score after 16 month in No & %**	**Paired test P-Value**	**Assessment Progress in No & % in each QSE.**
1. Documents & Records	25	4(16%)	11(44%)	7(28%)	13(52%)	0.001	9(36%)
2. Management Reviews	12	2(16.7%)	3(25%)	1(8.3%)	3(25%)		1(8.33%)
3. Organization & Personnel	20	7(35%)	13(65%)	6(30%)	12(60%)		5(25%)
4. Client Management & Customer Service	10	1(10%)	5(50%)	4(40%)	5(50%)		4(40%)
5. Equipment	32	4(12.5%)	12(37.5%)	8(25%)	13(40.6%)		9(28.13%)
6. Internal Audit	5	0(0%)	1(20%)	1(20%)	1(20%)		1(20%)
7. Purchasing & Inventory	31	4(12.9%)	11(35.5%)	7(22.6%)	11(35.5%)		7(22.6%)
8. Information Management	14	3(21.43%)	4(28.57%)	1(7.14%)	5(35.7%)		2(14.3%)
9. Process Control and Internal & External Quality Audit	43	3(6.98%)	11(25.58%)	8(18.6%)	12(28%)		9(20.9%)
10. Corrective Action	8	0(0%)	0(0%)	0(0%)	1(12.5%)		1(12.5%)
11. Occurrence / Incident Management & Process Improvement	10	0(0%)	0(0%)	0(0%)	1(10%)		1(10%)
12. Facilities and Safety	40	13(32.5%)	17(42.5%)	4(10%)	18(45%)		5(12.5%)
TOTAL SCORE	**250**	**41(16.4%)**	**88(35.2%)**	**47(18.80%)**	**95(38.0%)**		**54(21.6%)**

No Stars	**1 Star**	**2 Stars**	**3 Stars**	**4 Stars**	**5 Stars**
(0 – 137 pts)	(138 – 160 pts)	(161 – 185 pts)	(186 – 211 pts)	(212 – 236 pts)	(237 – 250 pts)
< 55%	*55 – 64%*	65 – 74%	*75 – 84%*	*85 – 94%*	>95%

The final assessment done by assessors were 88(35.2%) and principal investigator 95(38.0%), with a difference of 7 marks in two months duration. The observed progress from cumulative baseline assessment score 41 (16.40%) to final cumulative assessment score 95(38.0%) was 54(21.6%) with the mean value of 7.92 and standard deviation of 5.885; P = 0.001 for all 12 QSEs. Laboratories that fail to achieve at least 55% on assessment will not be awarded a star ranking. Laboratories that achieve 95% or more will receive a 5-star rating [11]. Based on WHO-AFRO cheeklist grading [38], 95(38.0%) lies under zero star. To find one star the expected score should have been 143-165(55% - 64%) which was 48 points (17%) far from the assessment result.

The laboratory department has shown major improvements on Client Management and Customer Service from 10% to 50% (improvement by 40%), document and record from 16% to 52% (by 36%), and Equipment from 12.5 to 40.63% (by 28.13%). There least progress was observed on Occurrence / Incident Management and Process Improvement 0% to 10% (by 10.0%) and management review from 16.67 to 25.0% (by 8.33%) (Table 4).

6.1.3. Challenges on IQMS in TASH laboratory

6.1.3.1. Job satisfaction and Perceptions of laboratory personnel

Table 5 shows satisfaction of laboratory personnel and their perception about IQMS. Among the total participants, 51.5% of laboratory personnel were well satisfied on their profession, 18.2% of them were partially satisfied and 30.3% were not satisfied. On the other hand, 27.3% of participants were satisfied on their work environment and 27.3% were partially satisfied and the rest 44% of them were not satisfied. From the total 71.2% partially satisfied and dissatisfied respondents, major reason for job dissatisfaction were concerning wage /payment (25.53%) and managerial issue (disagreement with management) 19.15%.

Table 5: TASH Laboratory staffs' satisfaction and perception about IQMS

Questions	**Answers in Number**				
Job Satisfaction	**SA No. (%)**	**A No. (%)**	**PA No. (%)**	**DA No. (%)**	**SD** No. (%)**
Are you satisfied with your profession?	15 (22.7%)	19 (28.8%)	12 (18.2%)	17 (25.8%)	3 (4.5%)

Table 5 continued

Are you satisfied with your work environment?	**7 (10.6%)**	**11 (16.7%)**	**18 (27.3)**	**19 (28.8%)**	**10 (15.2)**
If no, please indicate the reason	Wage (Salary, Incentive)		12 (25.53%)		
	Managerial issue		9 (19.15%)		
	Education		1 (2.13%)		
	1and 2		7 (14.89)		
	2 and 3		1 (2.13%)		
	1and 3		4 (8.51)		
	ALL		10 (21.28)		
	Other		3 (6.38)		
	Yes No. (%)	No No. (%)			
Do you have knowledge about LQMS?	50 (75.8%)	16 (24.2%)			
Have you been trained about LQMS?	25 (37.9%)	41 (62.1%)			
Perception of participants	**SA No. (%)**	**A No. (%)**	**PA No. (%)**	**DA No. (%)**	**SD No. (%)**
Do you believe LQMS is important in the laboratory?	51 (77.3%)	11 (16.7%)	2 (3.0%)	0 (0%)	2 (3.0%)
Do you think LQMS needs more money/capital?	15 (22.7%)	28 (42.4%)	16 (24.2%)	5 (7.6%)	2 (3.0%)
Do you think LQMS needs more time?	15 (22.7%)	26 (39.4%)	19 (28.8%)	5 (7.6%)	1 (1.5%)
Do you think LQMS needs more effort?	36 (54.5%)	18 (27.3%)	7 (10.6%)	3 (4.5%)	2 (3.0%)
Do you believe LQMS helps to achieve laboratory goals?	49 (74.2%)	11 (16.7%)	3 (4.5%)	1 (1.5%)	2 (3.0%)
	Yes No. (%)	**No No. (%)**			
Do you believe LQMS can be implemented in your laboratory?	49 (74.2%)	17 (25.8%)			
Are you interested to implement LQMS in your laboratory?	63 (95.5%)	3 (4.5%)			
Are you participated to implement LQMS?	36 (54.5%)	30 (45.5%)			

Key: ** SA- strongly agree, A- agree, PA- partially agree, DA-disagree, SD-strongly disagree

Among the total participants 75.8% of personnel had knowledge about LQMS. Training coverage about LQMS was 37.9% and the rest 62.1% were not trained. Majority, 94% of participants believe LQMS is important for laboratory. As the above data explains, 65.1% of them agree on the need of additional expense for implementation of QMS. Most of participants 62.1% believe that implementation of LQMS needs more time. However, 28.8% partially agreed and the rest

9.1% said no additional time is needed; 81.8% participants said LQMS need more effort, 10.6% partially agreed and the rest 7.5% did not agree (Table 5).

Almost 90.9% participants believe that LQMS implementation helps the laboratory to achieve its goal. Concerning respondents‟ perception, 74.2% think LQMS can be implemented in the laboratory. Participants who have interest for LQMS implementation in their laboratory were 95.5%. However, during implementation 54.5% of respondents were participating and 45.5% of them did not participate on the IQMS (Table 5).

6.1.3.2. Personnel management

As show below, almost half (54.5%) of participants agreed there is sufficient manpower. According to those disagreed participants, shortage of supportive staffs (sample porter, clerks and equipment cleaner) are most mentioned. Half (50%) believe that laboratory personnels were working efficiently (Figure 2).

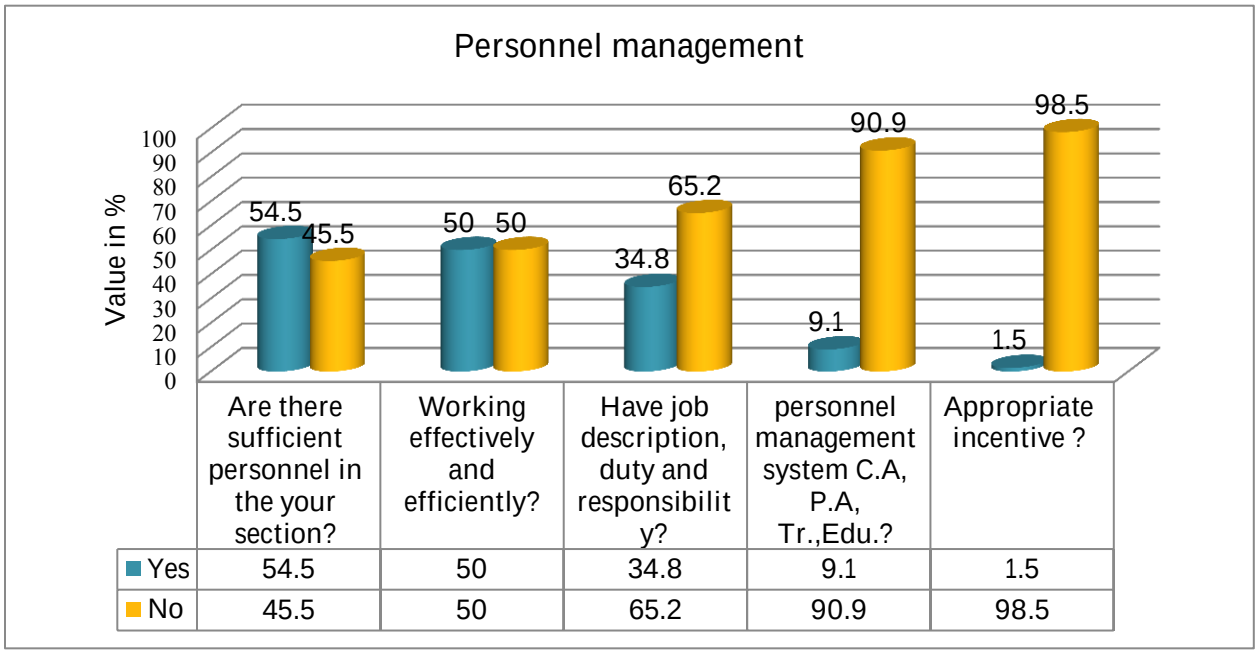

Figure 2: Questionnaires summary result of TASH laboratory staffs concerning personnel management in the laboratory.

Concerning job description, only 34.8% of participants reported that they have clear understanding of responsibility; 90.9% of participants disagreed on the existence of proper

personnel management, competency assessment, performance appraisal and training and education system in the laboratory whereas 9.1% agreed. Almost all (98.5%) participants agreed that there was no incentive mechanism for laboratory personnel (Figure 2).

6.1.3.3. IQMS Activities in the laboratory

Among total participants, 68.2% reported that the laboratory has quality assurance policy and procedures whereas those who reported the laboratory has safety guideline were 34.8 %; 71.2% have used guideline and procedure. From the total participants, 54.5% said the laboratory has organized document and recording system.

From all participants, only 22.7% reported laboratory has good laboratory information system. 66.7% agreed on implementation of internal and external quality control. As of 83.3% participants, there is no Inventory system for equipment and reagents in the laboratory. Similarly, 84.8% of participants have agreed on insufficient equipment"s availability and no backup system in the laboratory.

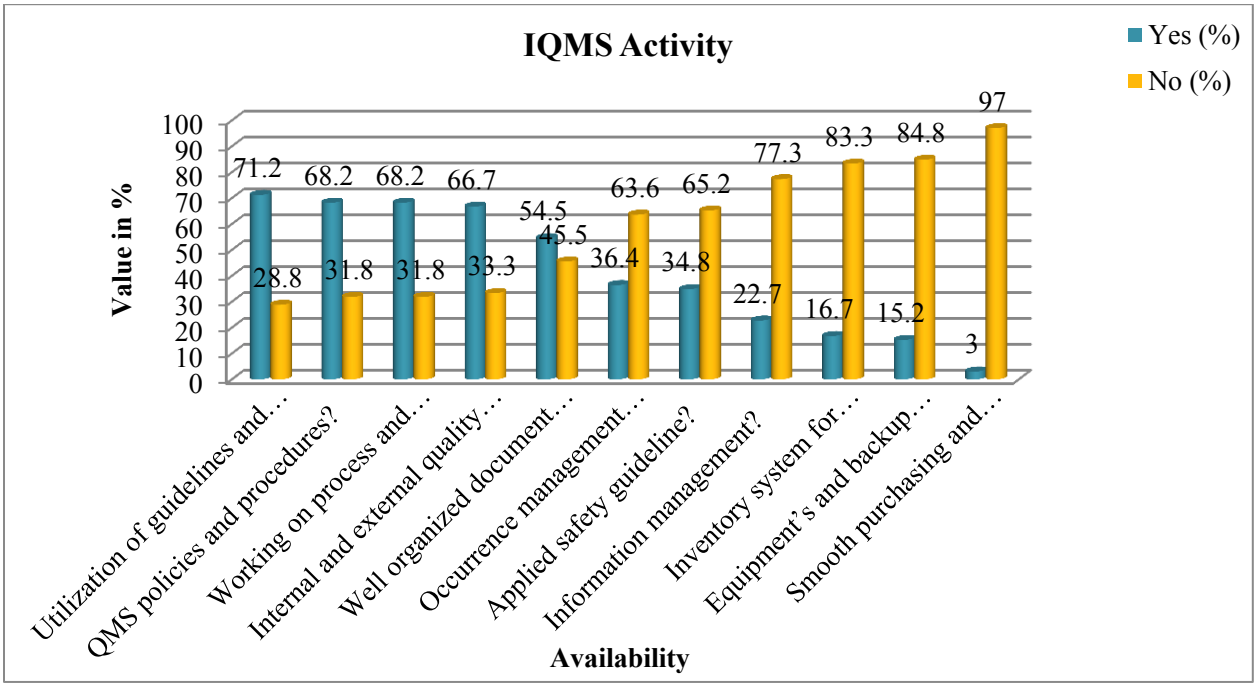

Figure 3: Activity of TASH laboratory personnel on IQMS

With exception of 3.0%, all participants agreed that there was no smooth purchasing and inventory system in the hospital. About 68.2% of participants believe that laboratory is working

on quality improvement. Of the participants, 36.4% said there is occurrence management system in the laboratory (Figure 4).

6.1.3.4. Performance of departments

6.1.3.4.1. Laboratory Management participation

As it is illustrated in the table below (Table 6), 63.6% of respondents have said laboratory management is effectively working on LQMS. On the other hand, 84.8% have responded that laboratory quality officer is working on LQMS effectively. Regarding the laboratory safety officer is concerned, only about half of the respondents agreed the responsible person works properly. Below half (42.4%) of the total respondents agreed laboratory supervisor takes care of his responsibility properly. As it is shown in Table 6, only 28.5% of respondents agreed that hospital management has awareness, interest and collaboration for implementation of LQMS.

Table 6: Department heads and hospital management performance on LQMS Implementation

Participation of lab. department	SA	A	PA	DA	SD
	No. (%)	No. (%)	No. (%)	No. (%)	No. (%)
As your expectation, does the laboratory head working on LQMS effectively?	3 (4.5%)	13 (19.7%)	26 (39.4%)	20 (30.3%)	4 (6.1%)
As your expectation does the laboratory quality officer working on LQMS effectively?	13 (19.7%)	27 (40.9%)	16 (24.2%)	8 (12.1%)	2 (3%)
As your expectation does the laboratory safety officer working his/her responsibility properly?	4 (6.1%)	9 (13.6%)	22 (33.3%)	20 (30.3%)	11 (16.7%)
As your expectation does the laboratory supervisor working his/her responsibility properly?	3 (4.5%)	10 (15.2%)	15 (22.7%)	24 (36.4%)	14 (21.2%)
Do you believe that the hospital management has awareness interest and collaboration for implementation of LQMS?	3 (4.5%)	6 (9.1%)	10 (15.2%)	26 (39.4%)	21 (31.8%)

6.1.3.4.2. Finance and purchasing department performances

The next table states respondent‟s response for questions related to finance and purchasing department performance. According to the table below (Table 7), 89.4% of respondents reported

that finance department is not fulfilling laboratory's demand. Also, the department is not giving fast responses for laboratory requests. Similarly, very high (92.4%) proportion of respondents has found purchasing department either not fulfilling laboratory demand or not giving fast response for laboratory request. As to the majority (63.6%) of respondents, resources are not available for implementation of quality management system.

Table 7: Finance and purchasing department performance according to laboratory demands

Performance of finance and purchasing	SA No. (%)	A No. (%)	PA No. (%)	DA No. (%)	SD No. (%)
Do you believe that finance department was fulfilling laboratory demand? Are they giving fast response for laboratory request?	0 (0%)	3 (4.5%)	4 (6.1%)	29 (43.9%)	30 (45.5%)
Do you believe that purchasing department was fulfilling laboratory demand? Are they giving fast response for laboratory request?	1 (1.5%)	2 (3.0%)	2 (3.0%)	26 (39.4%)	35 (53.0%)
Are there available resources for implementation of quality management system?	1 (1.5%)	5 (7.6%)	18 (27.3%)	28 (42.4%)	14 (21.2%)

6.1.3.4.3. Pharmacy department performance

As it is illustrated in the table, respondents have evaluated overall performance of pharmacy department as below the expectation. Accordingly, 77.2% of respondents have found the TASH Store is not working in the appropriate standard.

Also, about half (53%) of respondents have indicated store personnel are not available for laboratory staff all the time when they needed and higher proportion (69.7%) have stated that, pharmacy and laboratory department do not work closely. Similarly, 78.8 and 77.3% of respondents stated that, the Pharmacy is using standard protocol for the store management and does not continuously maintain their stock even their information is limited about appropriate supplies and reagents needed by the laboratory.

Table 8: The table below discusses pharmacy department work performance as evaluated by respondents

Performance of pharmacy	SA No. (%)	A No. (%)	PA No. (%)	DA No. (%)	SD No. (%)
Do you believe that the TASH Store (not pharmacy store) working in appropriate standard.	1 (1.5%)	3 (4.5%)	11 (16.7%)	35 (53.0%)	16 (24.2%)
Are the Store personnel available for laboratory staff all the time when they needed?	2 (3.0%)	6 (9.1%)	23 (34.8%)	23 (34.8%)	12 (18.2%)
Do you think the Pharmacy department has close relation with laboratory department?	1 (1.5%)	3 (4.5%)	16 (24.2%)	29 (43.9%)	17 (25.8%)
Do you think the Pharmacy know appropriate supplies and reagents needed by the laboratory?	0 (0%)	3 (4.5%)	11 (16.7%)	39 (59.1%)	13 (19.7%)
Do you think the Pharmacy maintain their stock without interruption?	1 (1.5%)	6 (9.1%)	8 (12.1%)	41 (62.1%)	10 (15.2%)
Does the Pharmacy using standard protocol for the store management?	0 (0%)	7 (10.6%)	18 (27.3%)	16 (22.7%)	25 (37.9%)

6.1.3.4.4. Laboratory information management system

The table below shows laboratory information management system application and performances.

Table 9: Laboratory information management system performance

Performance of ICT	SA No. (%)	A No. (%)	PA No. (%)	DA No. (%)	SD No. (%)
Is there ICT department representative/ delegated for laboratory department who can solve the problem happened in the laboratory?	0 (0%)	4 (6.1%)	10 (15.2%)	35 (53.0%)	17 (25.8%)
If the answer for above question is no are they available when the laboratory need support?	0 (0%)	1 (1.5%)	13 (19.7%)	34 (51.5%)	6 (9.1%)
Is there computerized hospital management information system (HMIS)?	0 (0%)	3 (4.5%)	10 (15.2%)	31 (47.0%)	22 (33.3%)
Is there computerized integrated LMIS, Is there suitable software used by the laboratory?	2 (3.0%)	4 (6.1%)	4 (6.1%)	32 (48.5%)	24 (36.4%)
If the answer for the above question is No, is LMIS is important for LQMS?	38 (57.6%)	13 (19.7%)	1 (1.5%)	7 (10.5%)	1 (1.5%)

The table shown above (Table 9), points out that, majority agreed that there is no ICT department representative/ delegated for laboratory department who can solve the problem happened in the

laboratory as 78.8% of respondents. Again majority agreed that the hospital doesn‟t have computerized hospital management information system (80.3%) and also there are no computerized integrated LMIS and suitable software used by the laboratory (84.9%). However, 78.8% believes LMIS are important for LQMS.

6.1.3.4.5. Maintenance and budget department performances

The following table assesses access and performances of maintenance and budget departments (Table 10). As it is clearly illustrated in the table, 83.3% of respondents agreed budget department is not working efficiently. In addition, laboratory department doesn‟t know its annual budget and cannot utilize according to the plan. On the other hand, laboratory department is not getting appropriate service from maintenance department according to 75.8% of respondents. Moreover, the department‟s service is characterized by the majority (71.3%) as unsatisfactory including absence of proper system for external equipment maintenance agreement.

Table 10: Maintenance and budget department performances

Performance of budget	SA No. (%)	A No. (%)	PA No. (%)	DA No. (%)	SD No. (%)
Do you believe budget department is working efficiently?	3 (4.5%)	3 (4.5%)	5 (7.6%)	28 (42.4%)	27 (40.9%)
Does the laboratory know their annual budget and utilize according to their plan?	2 (3.0%)	2 (3.0%)	6 (9.1%)	23 (34.8%)	33 (50.0%)
Do you get appropriate service from maintenance department?	2 (3.0%)	1 (1.5%)	13 (19.7%)	32 (48.5%)	18 (27.3%)
Are they available when they needed?	2 (3.0%)	4 (6.1%)	17 (25.8%)	28 (42.4%)	15 (22.7%)
Can they maintain laboratory equipment‟s, are you satisfied on service delivered by them?	1 (1.5%)	5 (7.6%)	13 (19.7%)	37 (56.1%)	10 (15.2%)
Is there proper system for external equipment maintenance agreement?	3 (4.5%)	3 (4.5%)	8 (12.1%)	28 (42.4%)	24 (36.4%)

6.1.3.4.6. Teaching and laboratory service integration

As it is clearly indicated in table 11 below, 87.9% of respondents have stated laboratory teaching department and laboratory service giving department are not integrated and do not work together. However, 86.4% of respondents believe integration of laboratory teaching and service

giving department will enhance IQMS. Likewise, according to 72.8% of respondents, laboratory staff does not have good communication with physicians and nurses concerning experience sharing and system improvement. Here under, teaching and laboratory service linkage and cooperative working environment related issues are addressed in table 11.

Table 11: Teaching and laboratory service integration and linkage

Communication of laboratory from other department	SA No. (%)	A No. (%)	PA No. (%)	DA No. (%)	SD No. (%)
Does laboratory teaching department and laboratory service giving department integrated and working together?	3 (4.5%)	2 (3.0%)	3 (4.5%)	31 (47.0%)	27 (40.9%)
If the answer for question above is no, do you think integration of laboratory teaching and service giving department will enhance IQMS?	25 (37.9%)	25 (37.9%)	7 (10.6%)	2 (3.0%)	2 (3.0%)
Does the laboratory have good communication with physicians concerning experience share and work improvement?	0 (0%)	5 (7.6%)	13 (19.7%)	31 (47.0%)	17 (25.8%)
Does the laboratory have good communication with nurses concerning system improvement? Eg in sample collection, result dispatching, …	1 (1.5%)	5 (7.6%)	22 (33.3%)	28 (42.4%)	10 (15.2%)

6.1.4. Hospital and Laboratory Facility

The environment of sample collection area facility was not appropriate and comfortable for working as 84.9% of respondents pointed out. Similarly, the laboratory do not have store with sufficient space to adequately store reagents and existing supplies. The laboratory area is not maintained in good condition (59.1%) and does not have a consistent power supply and/or a generator with a guaranteed supply (63.6%).

It was also found that, there is problem on running water, distilled or deionizer water supply, adequate numbers of power points (sockets) as 47.0% of respondents, 42.4% of them have also indicated that there is limitation of availability of functioning drainage, separate sinks for washing laboratory ware and staining, and for washing hands after being exposed to infected materials.

Table 12: Below table shows respondents‟ response to questions related to TASH laboratory facility.

Facility	Yes No. (%)	No No. (%)
Is the hospital facility comfortable for working environment?	25 (37.9%)	41 (62.1%)
Is the laboratory facility comfortable for working environment?	22 (33.3%)	43 (65.2%)
Is the facility sample collection area appropriate and comfortable for working environment?	10 (15.2%)	56 (84.8%)
Does the laboratory have mini store for reagents and supplies? Is that sufficient space to adequately store existing supplies?	10 (15.2%)	56 (84.8%)
Is the laboratory area maintained in good condition (e.g., clean, all trash removed, shelves are sturdy, etc.)? Including sample collection?	27 (40.9%)	39 (59.1%)
Does the laboratory have: a. Running water? b. Distilled or deionizer water?	32 (48.5%)	33 (50.0%)
Does the laboratory have a consistent power supply and/or a generator with a guaranteed supply? UPS?	24 (36.4%)	42 (63.6%)
Does the laboratory have an adequate number of power points (sockets)?	35 (53.0%)	31 (47.0%)
Does the laboratory have separate sinks for washing laboratory ware and staining, and for washing hands after being exposed to infected materials?	47 (71.2%)	19 (28.8%)
Does the laboratory have functioning drainage from laboratory sinks that are closed and that lead to either a septic tank or deep pit?	38 (57.6%)	28 (42.4%)
Does the hospital/ laboratory have functioning incinerator?	43 (65.2%)	23 (34.8%)
Are the laboratory floors, roof and walls in good condition without the need for repair?	46 (69.7%)	20 (30.3%)
Is the laboratory well lighted and ventilated? Are the windows and doors in good condition without the need for replacement or repair?	42 (63.6%)	24 (36.4%)
Does the laboratory have an indoor patient waiting area with seats?	8 (12.1%)	58 (87.9%)

6.2. Findings from in-depth interview

6.2.1. In-depth interview Participant socio demography summary

From total number of respondents participated in the in-depth interview, department heads that have directly link with the laboratory system, 7 (58.3%) were males and 5 (41.1%) were females. Age wise, participants range from 26-57 years with mean age of 42.43 and 66.7% were greater than 41 years. Educational backgrounds were 3(25.0%) masters, 7(51.8%) degree 1(8.3%) diploma and 1(8.3%) less than diploma.

6.2.2. Summarized idea of in-depth interview

The problems on dalliance of services were due many reasons. As most of them opinions they were not giving priority for the laboratory because they don,,t have knowledge about laboratory work and its demand. The other problem were job dissatisfaction. Even though most of them were satisfied on profession, majority were dissatisfied on work environments. High job dissatisfaction of employee creates negative influence on giving fast response for their internal customers. Problems stated as major causes for their job dissatisfaction were shifting work area due to BPR, managerial problem, low payment high workload and lack of incentives are the majors.

There was a problem on shortage of manpower in administrative offices due to BPR restructuring. There was no strong system to monitoring and utilize personnel resource. Most of departments don‟t have strong personnel management, like competency assessment, performance appraisal, training, education and attendance monitoring for their personnel. Most of them said there is minimal support from upper management.

As they explained there was less habit to use national or international standard for their work and lack of policy or written manual for their department contribute for poor service. Lack of well-organized document and recording system was the major challenge in their office so request letter and some other documents were lost. Some of the departments head offices had record and controlling system for letters requests and other circulating document. All departments don‟t have posted turnaround time (TAT) for their activities. So nobody will be responsible for dalliance of services. All had scarcity of equipment and consumable for their work. Most of them said that the organization did not have smooth purchasing and inventory system including finance and budget department that was the major obstacles they face.

6.3. Summarized points of meeting minutes

There were three types of regular meeting held in the laboratory. 1) laboratory management committee (diagnostic director, laboratory head, quality officer, safety officer, supervisor and section heads on Monday morning, 2) section head with section worker on Friday afternoon and 3) all staff on Friday afternoon on the last week of the month. Issues beyond section head were

discussed and decided by management committee. The laboratory management committee and all staff meeting minutes from 14/05/2012 - 05/07/2013 were revised to understand the major challenges of the laboratory. Issues repeatedly raised are discussed as follows.

About the facility

- One of frequently raised problem was inconvenient sample collection site that was given during BPR restructuring. Previously, sample collection laboratory was sufficiently ventilated, secured and have enough space for store rooms and emergency tests. But the current rooms which were given during BPR restructuring were:
    - Very small and not ventilated
    - that can‟t be locked hence difficult to put supplies and reagents in
    - Since it was not furnished for laboratory activity, there are no convenient laboratory benches and sinks to keep samples and documents.
    - No space to do emergency test
    - Inconvenient waiting area
- In newly renovated laboratory, microbiology department do not have KOH sample collection area and AFB working area.
- There were LMIS (polytec) at the time the laboratory was scattered in different floor. However, newly renovated laboratory do not include LMIS (polytec) which makes LMIS lead result dispatching very difficult. As a result, results get lost and TAT increases.
- Renovated laboratory does not have
    - Phone for internal and external communication
    - Internet for reference
    - Most sinks are not functional, even there is a room without sinks available
    - No mini store for laboratory purpose
    - No emergency exit

Equipment's related problems

- There was no external preventive and curative maintenance agreement, so lack of equipment maintenance were the major challenge.

- There was shortage of power stabilizer to avoid test interruption and for laboratory Equipment safety (to protect from damage during power fluctuation).
- Backup system is not available due to shortage of Equipment"s especially in clinical chemistry department

Shortage of reagents and supplies

- Shortage of reagents and supplies were the issues raised frequently in the meeting.
- Poor laboratory personnel interaction with pharmacy workers creates difficulty on continuous supply chain management system

Personnel management

- Shortage of manpower is being faced especially on supportive staff during PBR implementation.
- Shortage of Training and inappropriate usage of training.

Laboratory budget

- No separate budget is allocated for laboratory department. This results difficulty to plan and achieve hospital laboratory goals.

Hospital Management

- Lack of support from Hospital management. This issue was raised during the meeting held with laboratory department and hospital management. The other issue was complains on finance department that laboratory equipment and consumable purchases are not allowed.
- There have been repeated discussions about challenge on purchasing department. Most of the time there were no response for requests. Even request documents get lost.

Staff incentive

- There was par time payment that had been started from 11 years back and it was discontinued by the hospital management. This issue was raised eight times as a big discussion issue. The laboratory personnel were disappointed and discouraged.

Regular Meeting

- Unable to do regular meetings because of the staff being bored due to lack of response from the management. The management could not fix sustainable meeting program.

Referral linkage

- Challenge to develop referral linkage because of less payment compared with other institutions.

Training

- Though training is needed for all staffs, training given for the laboratory personnel is very minimal and the utilization is also not in the proper way.

7. DISCUSSION

7.1. Implementation of SLIPTA in TASH laboratory

This research aimed to assess implementation of quality management system and associated challenges in TASH laboratory. The evaluated improvement of quality management system implementation after fifteen month from baseline assessment result of 41/250(16.4%) to final assessment result 95/250(38.0%) were 54(21.6%) with the mean value of 7.92 for final assessment of the 12 Quality System Essentials (QSE), standard deviation of 5.885 (P = 0.001). The score progress attained was only around half way at least to reach 1star which is a minimum requirement.

change of assessment score of the final assessment result was 21.6% which showed in agreement with the study done in Lesotho, that shows the overall performance of 24 laboratories over the entire SLMTA period in which the most improved laboratory demonstrated an increase of 51% from its baseline to final assessments, whilst the laboratory that performed the least demonstrated a 6% in the assessments (due to staff departure) [31].

The change of score after final assessment has statistically significant difference from the baseline but it does not reach to the targeted value (>143points or >55%) for scoring at least one star. Our result showed similarity in terms of improvement between assessments; however, there is a difference on overall performance results and star level with the study done in Lesotho in which the results after 16 week duration and 10 week mentorship the cumulative mean results were 182.3(72.9%) (P=0.034) [9]. This was because the baseline assessment result of TASH lab were 41(16.4) and the Lesotho were 107.7 (42.8%); otherwise, the progress result were 30.1% of Lesotho and 21.6% TASH laboratory. The other possible explanations are the Lesotho research was done on impact of mentorship on WHO-AFRO SLIPTA program, and the mentorship was very strong and the laboratory personnel and hospital management were committed.

According to WHO-AFRO cheeklist grading 95(38.0%) points score zero star. Study done in Addis Ababa regional health laboratory on Implementation of SLIPTA after 18 months of duration, the laboratory reached 4-star scores from a baseline of 0-star [33] which opposes with our finding which shows no improvement in terms of star. This is because of strong support,

coaching once a week with 4 to 5 hour stays at the laboratory and assigned one full-time assistant mentor for a period of 18 months and there was strong leadership and staff commitment. In TASH laboratory there were 6 mentoring periods 5 hour stay per day in 14 months‟ duration of IQMS, these shows the mentorship schedule was not sufficient.

During baseline assessment Organizational and personnel (35%), and facility and safety (32%) were the highest scores whereas process improvement, corrective action and internal audit were the lowest zero score. Major improvements were seen on Client Management and Customer Service from 10% to 50% by 40%, document and record from 16% to 52% (by 36%) and Equipment from 12.5 to 40.63% (by 28.13%). There was least progress observed on Process Improvement 0% to 10% (by 10.0%) and management review from 16.67 to 25.0% (by 8.33%). Comparing with the research done in Lesotho the highest improvement was seen in corrective action 34%, in document and record 32% and least improvement seen in process improvement 10% [31]. Similarly document and record was the second highest improvement with second least results found in process improvement in our case. On another study there was high score in client management from an average of 58% to 100% and followed by 80% increment in management reviews and the least improvement were corrective actions from 25% to 67% in Lesotho [9]

The very low progress observed on management review was an activity that can be accomplished by lab management and available laboratory personnel. This implies lack of commitment in laboratory management. Similarly, in Occurrence/ Incident Management and Process Improvement expected tasks [38] are other areas that do not demand extra resource which could be done by laboratory personnel, so these is a sign of staff resistance towards changes that is similar with study done by Moges H. and Safadel N. [36, 39]. These suggest staff motivation alone could bring desired changes with little cost.

7.2. Challenges on IQMS in TASH laboratory

7.2.1. Job dissatisfaction

Laboratory personnel participating in this study, 51.5% of them were satisfied, but in terms of satisfaction on working environment 44% were dissatisfied. Even though most of the staffs were happy of being laboratory professional, most of them were not happy on working environment.

The same result was found in in-depth interview most of them were satisfied on their profession; however, many of them dissatisfied on their work environments. Highly motivated staff adheres more strictly to laboratory procedures defined by the Laboratory Quality Management System with the ultimate outcome of improving the quality of medical laboratory services [39]. Thus, necessitating to pay due attention to staff satisfaction issues to achieve the desired success in QMS implementation.

From the total 47(71.2%) partially satisfied and dissatisfied respondents, the major reason for dissatisfactions were their working environment, 12(25.53%) were due to wage (Salary, Incentive, par time payment), 9(19.15%) of them were on managerial issue (disagreed with management) and 10(21.28%) were due to all (wage, managerial, education) issues. During the in depth interview, major reason for dissatisfaction of department heads was managerial issues. This result is similar with that done in sub-Saharan Africa about career structure and benefits which was found to be highest source of staff satisfaction [17]. On the other study done in Tanzania the second and third highest rated categories for dissatisfaction were working environment /working conditions and benefits; 42% (95/224) and 38% (85/224) of the participants, respectively [40]. Almost all 98.5% participants have stated there is no incentive mechanism for laboratory personnel. The meeting agenda explains that the par time payment that used to be paid before 2013 for the last 11 years had been discontinued by the hospital management. It caused high job dissatisfaction in the laboratory personnel that creates lack of motivation of staff as incentive has been identified as one of the factors for dissatisfaction in earlier studies [36].

7.2.2. Staff Demotivation

In this study 50(75.8%) of the laboratory personnel have knowledge about LQMS and 61(94%) believe that LQMS is important for the laboratory and 49(74.2%) of them believe that they can implement LQMS in their setup. This shows less skeptical attitude on IQMS unlike the review done by Abdullah A. and Charles S [21]. In our study 63(95.5%) were interested/ happy to implement but only 36(54.5%) participated on IQMS and the rest 30(45.5%) did not participate on IQMS. These imply that TASH laboratory did not motivate the staff and utilized the manpower they have properly [36].

Lack of motivation was major challenges in the laboratory; 54(81.8%) of participants believe that IQMS needs more effort and 41(62.1%) of participant believe IQMS need more time and 43(65.1%) believe it needs more money. Participants know importance of QMS and they know that it needs more cost, effort and time. Study done by James B on cost and quality management for health care delivery, has clearly demarcated two major areas quality waste and productivity; he argue that high health care quality can lead to substantially lower costs [20].

7.2.3. Personnel Management

In terms of educational level and year of experience TASH laboratory staff has a good mix from Diploma up to doctorate level. From the total participants 54.5% said there were sufficient laboratory personnel, but the 45.5% said there were shortages. The departments that reported shortage of personnel were sample collection and sample processing departments. In addition, as confirmed from meeting minutes shortages of supportive staff were discussed in the meetings. On the third implementation phase, there was restructuring in the hospital because of BPR. As a result, porters/patient assistance and clerks of contract employees were discontinued from their work, and porters/patient assistance and clerks who were permanent workers were deployed to another place. That makes interruption of registration, TAT using sample tracking sheet etc. This implies BPR reformation activity was not aligned with laboratory QMS. This staff related work disruption supports research done by Gershy-Damet GM. which explains laboratories are affected by lack of personnel on accreditation process in sub-Saharan Africa [11].

Among total participants 50% of them believe that laboratory personnel were working efficiently and the rest half don‟t believe. Moreover, 34.8% of participants agreed that they have job description and the rest 65.2% were not agreed. Final assessment checklist showed that the laboratories had job description but only 34.8% of participants know their job description which was not signed by the staffs. Among participants 90.9% disagreed on proper personnel management, competency assessment, performance appraisal and training and education system in the laboratory. This was due to weak awareness and week laboratory personnel management system. These ideas were supported by perception questionnaire. Our finding was similar with other studies [16, 17] that showed lack of leadership in developing countries is one of the major challenges in QMS implementation.

7.2.4. QMS activities in the laboratory

Among participants those who said the laboratory has quality assurance policy and procedure were 68.2%. Among participants 65.2% said there is no safety guideline but 34.8% of them said that the laboratory has safety guideline. The checklist assessment showed that both manuals were available since 2011. These indicate that the laboratory has policy and manual but personnel don‟t have the same knowledge and information. The laboratory management is responsible to create awareness on IQMS.

7.2.5. Laboratory Management Activity

According to participants grading Laboratory head, safety officer and supervisor get similar results so the cumulative point on working efficiently 21.2% said they are efficient, 31.8% said partially efficient, majority of 46.95% said those mentioned above were not efficient. Response on the performance of quality officer was 60.6% said efficient, 24.2% said partially efficient, and 15.1% of them said not efficient. The assessment result show as least improvement (8.33%) was seen in management reviews. These results suggest that a laboratory delegate on this position has week performance, so it is expected to be efficient and hard worker [16, 36].

7.2.6. Support from Hospital management and other departments

Hospital management support is crucial for IQMS in the laboratory departments. Among participants who were asked about hospital management support 9(13.6%) said they support the laboratory, 10(15.2%) said as they support partially and 47(71.2%) said there is no support from hospital management. Other departments who were participated in the in-depth interview also disagreed on upper management support in which the same information was found. Study in Ethiopia shows, lack of full cooperation between the laboratory personnel and the upper managements will contribute to poor performance the IQMS [36]. There were major gaps in this regard.

Almost similar result was found on finance and purchasing department. According to the data, 89.4% of respondents said finance department is not fulfilling laboratory demand. Also, the department is not giving fast responses for laboratory requests. Similarly, very high (92.4%) proportion of respondents has found purchasing department neither fulfilling laboratory demand

nor giving fast response for laboratory request. Amazingly 100% of in-depth interview respondents said purchasing department was inefficient including respondent from the purchasing department. As to the majority (63.6%) of respondents, resources are not available for implementation of quality management system. Similar studies were done in sub-Saharan Africa and explained that laboratories in sub-Sahara were adversely affected by lack of resource [11, 16, 41].

On the other hand evidences on meeting minutes indicated that there were no clearly defined budgets for the laboratory, shortage of reagents and supplies, dalliance on purchasing system, loss of request paper were repeatedly mentioned. In addition on the efficiency of the budget department, the reported 55(83.3%) inefficiency of the budget department by our study participants suggests the need for special attention for Finance, purchasing and budget department, because these departments are back bones for all other departments. The research done in Iran has similar finding that improper budget allocation was identified as the major challenge in laboratories [39].

Regarding lack of mini-stores for reagents and supply storage, and supply management related issue the hospital management needs to work out as per guidelines and WHO-AFRO check list expectations [38].

7.2.7. Supply chain management

The finding that 46(69.7%) of participants agreed that pharmacy doesn‟t have close relationship with laboratory department and also could not meet the demand of the laboratory implies that the supply chain management system was very poor. Similar study was done in Ethiopia on utilization of the logistics recording and stock/bin cards usage revealed limited use and being stock out usually happens in hospitals [18, 34]. Laboratory main store quality control system should be maintained and ordered laboratory items should be done by laboratory personnel especially by delegated logistics officer.

7.2.8. Laboratory information system

There was neither assigned ICT person as reported by 78.8% for the laboratory nor availability to support (60.6%) when they are needed. Although computerized HMIS system is lacking,

majority (78.8%) believe LMIS is important for LQMS. LIS was other Challenges of developing countries [17] and a study done in Nairobi indicated the ineffective communication channels affected delivery service quality in public health sector [42], a finding which can be extrapolated.

7.2.9. Equipment management

Lack of equipment back up, external maintenance agreement and limited support from the maintenance department resulted a lower satisfaction on the hospital maintenance department 3(4.5%); partially satisfied were 13(19.7%) and majority of 50(75.8%) dissatisfied on the maintenance service. hence, increasing the maintenance capacity of the department as well as Equipment maintenance agreement should be done with external bodies (supplier or with laboratory equipment maintenance organizations) [16].

Regarding integration of laboratory teaching department and laboratory service, 75.8% participants believe that the integration will help the laboratory in the effort of implementing QMS. Integration is very important to capacitate the laboratory [16, 39]. The research explains experts can provide an excellent resource for the needed national laboratory system.

7.2.10. Hospital and Laboratory Infrastructure

Sample collection area facility was not appropriate and comfortable for working according to 84.9% of respondents. Laboratory was not maintained in good condition 39(59.1%) especially in sample collection area and power supplies problem was the whole laboratory issue. The problem was discussed repeatedly on meetings minutes, the room was very small, not ventilated, not secured, no space to do emergency test, Inconvenient for waiting area. Since it is not furnished for laboratory activity, there are no convenient laboratory benches and sinks to keep samples and documents [11, 16]. Power supply problem should be solved and main and mini store should be designed and renovated.

7.3. Opportunities for implement of QMS in TASH laboratory

- In terms of educational level and year of experience TASH laboratory staff has a good mix from Diploma up to doctorate level.
- There was less skeptical attitude on IQMS, which helps IQMS.

- There were policy manuals procedures and important documents in the laboratory for IQMS.
- Renovation of main laboratory was good opportunity for the laboratory.
- AS TASH laboratory is under AAU, integration with school of medical laboratory department will help to introduce new technology, training opportunity and capacity building on educational level of laboratory personnel.

7.4. Strength and Limitation of the study

7.4.1. Strength

- The study tried to address detailed problems in the laboratory since the research was done in a single institution.
- The possible solutions of the problems are proposed in recommendation part (also discussed with every problem identified).

7.4.2. Limitation

- Assessment done by researcher using WHO-AFRO checklist was after fifteen month of baseline assessment which have a difference of two month from final assessment done by external assessors.
- Questionnaire based interview was done after seven month of final assessment.

8. CONCLUSION

The evaluated improvement of quality management system implementation after fifteen month from baseline assessment result of 41/250(16.4%) to final assessment result 95/250(38.0%) were 54(21.6%) with the mean value of 7.92 for final assessment of the 12 Quality System Essentials (QSE), standard deviation of 5.885 (P = 0.001). The progress of quality management system implementation was not successful to move from the baseline zero star.

There was less skeptical attitude on IQMS, which is encouraging. Majority of participants were dissatisfied in their work environment; therefore, most of the staffs were demotivated. The laboratory personnel did not have same knowledge and information regarding available documents indicating the limitations of the laboratory management in awareness creation. There were major gap between upper management and laboratory department. Hospital management support to the laboratory is very minimal. Other departments who were participated on in-depth interview were also not comfortable on top management support.

Finance, purchasing and budget department system were the major challenge for laboratory. Strong inventory system should implement to overcome test interruption. Pharmacy department don‟t have close relationship with laboratory. Main store were managed by pharmacy department and was not working in standard system. There is no mini store in the laboratory. Purchasing system of equipment, consumable and reagents in laboratory department was not satisfactory.

9. RECOMMENDATION

- Laboratory departments should be autonomous and need to have its own budgets plan and achievement evaluation.
- Hospital management should be committed to support laboratory department.
- Staff satisfaction and motivation is very critical for implementation of quality management system, so the hospital management should work to maintain the staff satisfaction.
- Hospital reformation should be integrated with departments and consider the activities in the institution.
- LMIS are important for the institution.
- ICT personnel should be hired to the laboratory to establish and maintain LMIS system.
- Supply chain management of laboratory items is better to be handled separately from pharmacy.
- Purchased and ordered laboratory items should be done by laboratory personnel especially by delegated logistics officer.
- Awareness on IQMS and its benefits should be done for all staff.
- The laboratory sample collection area should be renovated for the purpose required.

10. REFERENCES

1. ISO 15189: 2007(E). Medical laboratories particular requirements for quality and competence 2007; 2: 1-48.
2. WHO. Laboratory Quality Management System: Handbook. Geneva, Switzerland: World Health Organization, 2011; 1: 7.
3. Tibbets MW, Gomez R, kannangai R, Siridharan G. Total quality management in clinical virology laboratory. *Ind. J. med micro, 2006, 24(4): 258-268.*
4. Berte L, Laboratory Quality Management: A Roadmap. USA Clinical Laboratory Medicine *Clin Lab Med* 2007, 27: 771–790
5. NCCLS. Application of a Quality Management System Model for Laboratory Services; Approved Guideline Third Edition GP26-A3. NCCLS, West Valley Road, Wayne, Pennsylvania USA, 2004. 24 (36).
6. WHO. Guidelines for establishment of Accreditation of Health laboratories. Strengthening Quality System in Health Laboratories. Nonthaburi, Thailand. world health organization June 2007;09
7. NCCLS: A Quality Management System Model for Health Care; Approved Guideline-Second Edition. HS1-A2. West Valley Road, Wayne, Pennsylvania USA, 2004; 24:37 1-92.
8. I- TECH. "step-wise" approach to laboratory quality improvement in the Amhara, tigray and afar region of Ethiopia. Upgrading laboratories towards WHO-AFRO laboratory accreditation. 2011; 1-2
9. Maruta T, Motebang D, Mathabo L, Rotz J, Wanyoike J, Peter T, Mathabo L. ' Impact of mentorship on WHO-AFRO Strengthening Laboratory Quality Improvement Process Towards Accreditation (SLIPTA), Ministry of Health and Social Welfare, Lesotho. *Afr. J. Lab. Med. 2012; 1(1): 61-8. http://dx.doi.org/10.4102/ajlm.v1i1.6*
10. WHO-AFRO. The Maputo Declaration on Strengthening of Laboratory Systems, Maputo, Mozambique: World Health Organization; January, 2008. Incited from: http://www.who.int/eportuguese/news/en/.

11. Gershy-Damet G-M, Rotz P, Cross D, Belabbes E H, Cham F, Ndihokubwayo J-B. et al. Improving the quality of laboratory systems in the African region. The World Health Organization African Region Laboratory Accreditation Process. *Am J Clin Pathol. 2010; 134 (3): 393–400.*
12. Teferi M. WHO/AFRO Stepwise Laboratory Quality Improvement Process Towards Accreditation (SLIPTA): ASLM 2012 Satellite Session. Advancing the laboratory profession and networks in Africa Cape Town, South Africa. December 2012. Incited from:http://www.stoptb.org/wg/gli/assets/documents/gli_acc_m1/5%20SLIPTA% 20for %20GLI%20Session.pdf
13. Nkengasong J, Mesele T, Orloff S, Y Kebede Y, Fonjungo P, Timperi R, and Birx D. Critical Role of Developing National Strategic Plans as a Guide to Strengthen Laboratory Health Systems in Resource-Poor Settings. American Society for Clinical Pathology. *Am J Clin Pathol* 009;131: 852-857.
14. Peter F, Rotz D, Blair H, Khine A, Freeman R, and Murtagh M. Impact of Laboratory Accreditation on Patient Care and the Health System, American Society for Clinical Pathology, *Am J Clin Pathol 2010;134:550-555.*
15. Bergeri I, Cognat S, Dolmazon V, Dubois P, Fitzner J, Fuchs F, et al. Laboratory Assessment Tool: World Health Organization WHO/HSE/GCR/LYO/ 2012; 2: 11-12.
16. Birx D, Souza M, and Nkengasong J. Laboratory Challenges in the Scaling Up of HIV, TB, and Malaria Programs. The Interaction of Health and Laboratory Systems, Clinical Research, and Service Delivery: *Am J Clin Pathol 2009; 131: 849-851 849. DOI: 10.1309/AJCPGH89QDSWFONS*
17. Nkengasong J, Nsubuga P, Nwanyanwu O, Gershy-Damet G-M, Roscigno G, Bulterys M. et.al. Laboratory Systems and Services Are Critical in Global Health, Time to End the Neglect? American Society for Clinical Pathology. *Am J Clin Pathol 2010; 134: 368-373.*
18. WHO. Specification & Quantification of Laboratory Equipment and HIV Essential Laboratory Commodities for Efficient Procurement of Laboratory Items, Tool on Essential Laboratory Commodities 2011,10-11

19. Vanessa S and Marta R. Information systems as a quality management tool in clinical laboratories: *Journal of Physics: Brazil Conference Series 90 (2007) 012005 doi:10.1088/1742-6596/90/1/012005*

20. James BC. quality management for health care delivery The Hospital Research and Educational Trust. USA Chicago, 1989; 9:1-73

21. Abdullah A. Charles S. Impact of Accreditation on the Quality of Healthcare Services: a Systematic Review of the Literature, Impact of Accreditation on health care. *Ann Saudi Med. 2011; 31(4): 407–416. doi: 10.4103/0256-4947.83204*

22. Blumen S, Naud S, Palumbo M, McIntosh **B**, Wilcke B. Measuring the Application of Quality System Essentials in Vermont Clinical Laboratories. *Labmedicine* 2011; 42(3), 152-157.

23. Goldschmidt HMJ, Lent RW. Gross errors and work flow analysis in the clinical laboratory. *Klin Biochem Metab 1995; 3: 131–40.*

24. Bonini P, Plebani M, Ceriotti F and Rubboli F. Errors in Laboratory Medicine, Clinical Chemistry Italy, 2002; 48(5): 691–698

25. Ibrahim F, Dosoo D, Kronmann K, Ouedraogo I, Anyorigiya T, Abdul H, et al. Good Clinical laboratory Practices Improved Proficiency Testing Performance at Clinical Trials Centers in Ghana and Burkina Faso. Johns Hopkins University, United States of America June 29, 2012; 7(6): 1-8

26. Wattanasri N, Manoroma W, and Viriyayudhagorn S. Laboratory Accreditation in Thailand, A Systemic Approach. American Society for Clinical Pathology. *Am J Clin Pathol 2010;134:534-540*

27. ENAO: Congratulates Alert Centre Clinical Laboratory, Published on: Saturday November 16, 2013. Insisted from http://www.enao-eth.org

28. ENAO: Congratulates Medical Biotech Laboratory, Published on: Tuesday January 07, 2014. Insisted from http://www.enao-eth.org

29. ENAO: Congratulates Hema Diagnostic Laboratory Plc, Published on: Tuesday January 14, 2014. Insisted from http://www.enao-eth.org

30. ENAO: Congratulates Addis Ababa Health And Research Laboratory, Published on: Tuesday January 14, 2014. Insisted from http://www.enao-eth.org

31. Mothabeng D, Maruta T, Lebina M, Lewis K, Wanyoike J, Mengstu Y. Strengthening Laboratory Management Towards Accreditation: The Lesotho experience. *Afr J Lab Med. 2012; 1(1), Art. #9, 7 pages. http://dx.doi.org/10.4102/ajlm.v1i1.9*

32. EHNRI (EPHI). Laboratories Upgrade towards WHO-AFRO Laboratory Accreditation. EPHI. 2013. Incited from, http://ehnri.gov.et/component/search/ Laboratories.

33. Eshete A, Zwedu S, Sherefedin B, Mekonen T, Tibesso G, Ruff A, Jerene D. Impact of mentoring and coaching on laboratory quality management systems development: the case of Addis Ababa Health Research Laboratory, Ethiopia. MOPE718 - Poster Exhibition: 2012

34. Desale A, Taye A, Belay G, Nigatu A. 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. 2013; 15:46. doi:10.11604/pamj.2013.15.46.1969*

35. Abaynesh T, Girma K. Quality of liver and kidney function tests among public medical laboratories in western region of Amhara national regional state of Ethiopia. *Ethiop J Health Sci. 2012: 22,(1) 19-26*

36. Mogese H. Laboratory Quality Management System Assessment of Level Ii Laboratories Providing CD4 Testing and AFB Microscopy Services In Addis Ababa, Ethiopia. Thesis submitted to Addis Ababa University 2013.

37. Addis Ababa University. Background information of the College of Health Sciences. Incited from:- http://www.aau.edu.et/index.php/colleges/3142.

38. WHO-AFRO Laboratory Accreditation Assessment checklist for Clinical and Public Health Laboratories 2009

39. Safadel N, Dahim P, Anjarani S, et al. Challenges of Implementing Iranian National Laboratory Standards. Reference Health Laboratories Research Center, Ministry of Health & Medical Education, Tehran, Iran. Iranian J Publ Health 2013, 42, (1): 125-128

40. Marinucci F, Majigo M, Wattleworth M, Damiano P, Bazle H, and Redfield R., Factors affecting job satisfaction and retention of medical laboratory professionals in seven countries of Sub-Saharan Africa. *Human Resources for Health 2013, doi:10.1186/1478-4491-11-38*

41. Petti A, Polage R, Quinn C, Ronald R, and Sande A, A Barrier to Effective Health Care. Laboratory Medicine in Africa: *Infectious Diseases Society of America* 2006: 42 (1): 377-382

42. Wanjau N, Muiruri W, Ayodo E. Factors Affecting Provision of Service Quality in the Public Health Sector: A Case of Kenyatta National Hospital Jomo Kenyatta University of Agriculture and Technology Nairobi, Kenya. *International Journal of Humanities and Social Science* 2012. 2(13): 114-125

11.ANNEXES

Annex I: The component of standard checklist of WHO-AFRO SLIPTA checklist

Table 13: QMS contents and points of WHO-AFRO SLIPTA checklist

Audit Score Sheet					
Section					Total Points
Section 1: Documents & Records					25
Section 2: Management Reviews					17
Section 3: Organization & Personnel					20
Section 4: Client Management & Customer Service					8
Section 5: Equipment					30
Section 6: Internal Audit					10
Section 7: Purchasing & Inventory					30
Section 8: Process Control and Internal & External Quality Audit					33
Section 9: Information Management					18
Section 10: Corrective Action					12
Section 11: Occurrence/Incident Management & Process Improvement					12
Section 12: Facilities and Safety					43
TOTAL SCORE					258
(0 – 142 pts) *< 55%*	1 Star (143 – 165 pts) *55 – 64%*	2 Stars (166 – 191 pts) *65 – 74%*	3 Stars (192 – 217 pts) *75 – 84%*	4 Stars (218 – 243 pts) *85 – 94%*	5 Stars (244 – 258 pts) *≥95%*

Annex II: English version of participant information sheet, consent and questionnaire

1.1. Participant information sheet

Department of Medical Laboratory Science, Collage of Health Sciences, Addis Ababa University, Addis Ababa, Ethiopia

Title of the research: Assessment on implementation of quality management system and associated challenges in Tikur Anbessa Specialized Hospital Laboratory, Addis Ababa, Ethiopia

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

Back ground

I am doing a research in partial fulfillment of the requirement of master"s degree in laboratory management and quality assurance specialty at Addis Ababa university school of medical laboratory science. The research is on implementation of quality management system in Tikur Anbessa Specialized Hospital laboratory (TASHL).

Quality management system is a "coordinated set of activities to direct and control an organization with regard to quality". A well-defined quality system is a must for ensuring quality. QMS is a part of overall quality management which aims at ensuring the consistency, reproducibility, traceability and reliability of the products or services.

The study will be conducted through standard checklist, questionnaire based interview and in-depth interview. Enclosed are questions that are very important for the study. You will be asked your socio-demography, knowledge about quality management system, opportunity and threats on implementation of quality management system in TASHL.

Aim of the study

The purpose of this study is to know the level of implementation of quality management system in the laboratory, to identify opportunity and challenges during implementation to give a useful insights and understanding of the problem to the hospital and laboratory management. The information you give could help as to find out the level of participation of staff and management,

barrier, challenges and possible solutions for the recommendation to improve laboratory quality management system.

Benefits for participants

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

Risks for participant

The proposed research does not have any drawback on the research participants and 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.

Assurance of Principal Investigator

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

Daniel Beshah (PI): Signature: _____ Date: _____

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

Principal investigator: Daniel Beshah email: danibeshah @gmail.com

Advisor: Tedla Mindaye (Bsc, MSc)

Aster Tsegaye, (BSc, MSc, PHD)

Tatek Gebreegziabher (Bsc, MSc)

1.2. Informed consent

I have been informed about the study which plans to assess implementation of quality management system in TASH, Addis Ababa, Ethiopia. The objective and the application of the study were briefly explained to me. I am also informed that all information contained within the

questionnaire is to be kept confidential. Moreover, I have been well informed of my right to refuse information, decline to cooperate and drop out of the study if I want. It is therefore with full understanding of the situation that I agreed to give the informed consent voluntarily to the researcher to give my idea/ knowledge for the mentioned study.

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

Participant code:_____ Signature: _____

Date: _____

1.3. Respondent Demography

Sex ☐ Male ☐ Female

Years of Experience _____ Age _____

Educational background ☐ Post graduate ☐ Undergraduate

☐ Diploma ☐ Certificate

☐ 12th Other _____

Department _____

Position in the organization _____

E.g. clinical chemistry dep. worker	*E.g. hematology dep. head*

Professional level _____

Eg; Senior medical laboratory technologist

1.4.Questionnaire in English

The following questions will help the principal investigator to identify the opportunity and challenge on implementation of QMS in laboratory, so please circle or mark on the answers.

Key:

Abbreviation	Full word	Point	Abbreviation	Full word	Point
SA	Strongly agree	5	SD	Strongly disagrees	1
A	Agree	4	yes	yes	1
PA	Partially agree	3	No	No	0
DA	Disagree	2			

No	Questions	Answers				
1. Perceptions						
1.1	Are you satisfied with your profession?	SA	A	PA	DA	SD
1.2	Are you satisfied with your work environment?	SA	A	PA	DA	SD
1.3	If the answer for question No 1.2 is PA, DA, SD, please indicate the reason. You can underline more than one.	• Salary • Incentive • Benefits • Managerial Issues			• Training • Education Other _____ _____	
1.4	Do you have knowledge about laboratory quality management system (LQMS)?	Yes	No			
1.5	Have you been trained about LQMS?	Yes	No			
1.6	Do you believe LQMS is important in the laboratory?	SA	A	PA	DA	SD
1.7	Do you think LQMS needs more money?	SA	A	PA	DA	SD
1.8	Do you think LQMS needs more time?	SA	A	PA	DA	SD
1.9	Do you think LQMS needs more effort?	SA	A	PA	DA	SD
1.10	Do you believe LQMS helps to enhance laboratory capacity and help to achieve laboratory goals?	SA	A	PA	DA	SD
1.11	Do you believe LQMS can be implemented in your department?	Yes	No			
1.12	Do you interested to implement LQMS in your laboratory?	Yes	No			
1.13	Did you participate to implement LQMS in your laboratory?	Yes	No			
1.14	If the answer for question number 1.13 is yes, what was your contribution on the implementation phase?	_____ _____				
2. Personnel						
2.1	Are there sufficient personnel in the laboratory department / in all section?	Yes	No			
2.2	If the answer for question number 2.1 is No, which department / sections have shortage of manpower?	_____ _____				
2.3	Do you think assigned personnel are working effectively and efficiently?	SA	A	PA	DA	SD
2.4	Do personnel in your office have job description, duty and responsibility based on service delivered?	Yes	No			
2.5	Is there personnel management system in your department? That has competency assessment, performance appraisal, training, education….	Yes	No			
2.6	Is there appropriate incentive for laboratory personnel?	Yes	No			
2.7	If your answer is yes, what type of incentive you get	• Bonus • Allowance (Transport, mobile card,…) • Education fee				

		• Appropriate payment for par time/ duty work • Other _____				
3. Activities						
3.1	Are there written quality assurance policies and procedures available in this laboratory?	Yes	No			
3.2	Do you have habit/ experience to follow guidelines and procedures?	Yes	No			
3.3	Do you have well organized laboratory documentation and recording with controlling system? Is there document and record master list?	Yes	No			
3.4	Does the laboratory undertake the internal and external quality control procedures?	Yes	No			
3.5	Does the laboratory have inventory system for equipment, reagent and supplies?	Yes	No			
3.6	Do you have sufficient equipment‟s and backup system?	Yes	No			
3.7	Does the organization have smooth purchasing and inventory system?	Yes	No			
3.8	Does the laboratory working on process and quality improvement?	Yes	No			
3.9	Does the laboratory have good information management?	Yes	No			
3.10	Is there practically applied safety guideline?	Yes	No			
3.11	Is there occurrence management system?	Yes	No			
3.12	Are there reference documents in or internet access in the laboratory?	Yes	No			
4. Performance of sections and departments						
4.1	As your expectation, does the laboratory management working on LQMS effectively?	SA	A	PA	DA	SD
4.2	As your expectation does the laboratory quality officer working on LQMS effectively?	SA	A	PA	DA	SD
4.3	As your expectation does the laboratory safety officer working his responsibility properly?	SA	A	PA	DA	SD
4.4	As your expectation does the laboratory supervisor working his responsibility properly?	SA	A	PA	DA	SD
4.5	Do you believe that the hospital management has awareness interest and collaboration for implementation of LQMS?	SA	A	PA	DA	SD
4.6	Do you believe that finance department was fulfilling laboratory demand? Are they giving fast response for laboratory request?	SA	A	PA	DA	SD
4.7	Do you believe that purchasing department was fulfilling laboratory demand? Are they giving fast response for laboratory request?	SA	A	PA	DA	SD
4.8	Are there available resources for implementation of	SA	A	PA	DA	SD

	quality management system?					
4.9	Do you believe that the TASH Store (not pharmacy store) working in appropriate standard.	SA	A	PA	DA	SD
4.10	Does the Pharmacy department have close relation with laboratory department?	SA	A	PA	DA	SD
4.11	Does the Pharmacy know appropriate supplies and reagents needed by the laboratory?	SA	A	PA	DA	SD
4.12	Does the Pharmacy maintain their stock without interruption?	SA	A	PA	DA	SD
4.13	Does the Pharmacy using standard protocol for the store management?	SA	A	PA	DA	SD
4.14	Are the pharmacy Store personals available for laboratory staff all the time when they needed?	SA	A	PA	DA	SD
4.15	Is there ICT department representative/ delegated for laboratory department who can solve the problem happened in the laboratory?	SA	A	PA	DA	SD
4.16	If the answer for question number 4.15 is no are they available when the laboratory need support?	SA	A	PA	DA	SD
4.17	Is there computerized hospital management information system (HMIS)?	SA	A	PA	DA	SD
4.18	Is there computerized integrated LMIS, Is there suitable software used by the laboratory?	SA	A	PA	DA	SD
4.19	If the answer for question number 4.18 is No, is LMIS is important for LQMS?	SA	A	PA	DA	SD
4.20	Do you believe budget department working efficiently?	SA	A	PA	DA	SD
4.21	Does the laboratory know their annual budget and utilize according to their plan?	SA	A	PA	DA	SD
4.22	Do you get appropriate service from maintenance department?	SA	A	PA	DA	SD
4.23	Are they available when they needed?	SA	A	PA	DA	SD
4.24	Can they maintain laboratory equipment‟s, are you satisfied on service delivered by them?	SA	A	PA	DA	SD
4.25	Is there proper system for external equipment maintenance agreement?	SA	A	PA	DA	SD
4.26	Does laboratory teaching department and laboratory service giving department integrated and working together?	SA	A	PA	DA	SD
4.27	If the answer for question number 77 is no, do you think integration of laboratory teaching and service giving department will enhance IQMS?	SA	A	PA	DA	SD
4.28	Does the laboratory have good communication with physicians concerning experience share and work improvement?	SA	A	PA	DA	SD
4.29	Does the laboratory have good communication with nurses concerning system improvement? Eg in sample collection, result dispatching, …	SA	A	PA	DA	SD
5. Facility						

5.1	Is the hospital facility comfortable for working environment?	Yes	No			
5.2	Is the laboratory facility comfortable for working environment?	Yes	No			
5.3	Is the facility sample collection area appropriate and comfortable for working environment?	Yes	No			
5.4	Does the laboratory have store for reagents and supplies? Is that sufficient space to adequately store existing supplies?	Yes	No			
5.5	Is the laboratory area maintained in good condition (e.g., clean, all trash removed, shelves are sturdy, etc.)? Including sample collection?	Yes	No			
5.6	Does the laboratory have: a. Running water? b. Distilled or deionizer water?	Yes	No			
5.7	Does the laboratory have a consistent power supply and/or a generator with a guaranteed supply? UPS?	Yes	No			
5.8	Does the laboratory have an adequate number of power points (sockets)?	Yes	No			
5.9	Does the laboratory have separate sinks for washing laboratory ware and staining, and for washing hands after being exposed to infected materials?	Yes	No			
5.10	Does the laboratory have functioning drainage from laboratory sinks that are closed and that lead to either a septic tank or deep pit?	Yes	No			
5.11	Does the hospital/ laboratory have functioning incinerator?	Yes	No			
5.12	Are the laboratory floors, roof and walls in good condition without the need for repair?	Yes	No			
5.13	Is the laboratory well lighted and ventilated? Are the windows and doors in good condition without the need for replacement or repair?	Yes	No			
5.14	Does the laboratory have an indoor patient waiting area with seats?	Yes	No			
6. Personal opinion						

6.1	What is your attitude towards accrediting this laboratory?	_____ _____ _____
6.2	According to your understanding what are the main causes for service interruptions in this facility?	_____ _____
6.3	Please mention challenges on implementation of LQMS.	_____ _____ _____
6.4	What remedy do you suggest?	_____ _____ _____

Annex III: Amharic Version of participant information sheet, consent and questionnaire

2. **(የተሳታፊዎች መረጃ ቅጽ፣ የፈቃደኝነት ማረጋጫ እና መጠይቅ ቅፅ)**

2.1. የተሳታፊዎች መረጃ ቅጽ

አዲስ አበባ ዩኒቨርሲቲ ጤና ሳይንስ ኮላጅ የህክምና ላቦራቶሪ ሳይንስ ዲፓርትመንት

አርስት፡ የጥ/አ/እስ/ሆ/ል ላቦራቶሪ ጥራትና ቁጥጥር ስርአት ዝርጋታ አተገባበር ላይ ነው፡፡

አጠቃላይ መረጃ፤ በጥናቱ በመሳተፍዎ ከልብ እያመሰገን ከመወሰንዎ በፊት፡- ይህንን ቅጽ በትክክል አንብቡ ወይም ሲነበብልዎ በትክክል ያድምጡ፤ እንዲሁም ግልፅ ያልሆነልዎትን ነገር በሙሉ በነፃነት ይጠይቁ::

መግቢያ

በአ/አ ዩኒቨርሲቲ የህክምና ፋካሊቲ በላቦራቶሪ ቁጥጥር ጥራትና ማረጋገጫ ት/ት ክፍል ውስጥ በድህረ ምረቃ ፕሮግራም ትምህርቴን ለማጠናቀቅ ጥናታዊ እሁፌን በመጻፍ ላይ እገኛለሁ፡፡ ጥናቱም በጥ/አ/እስ/ሆ/ል ላቦራቶሪ ላይ በጥራት ቁጥጥር ትግበራ ላይ ያተኮረ ነው፡፡

የጥራት ቁጥጥር ስርአት ማለት ማናቸዉም በላቦራቶሪ ዉስጥ የሚሰሩ ስራዎችን በመምራትና በመቆጣጠር ጥራት እንዲኖራቸዉ የሚስችል ሲሆን ይህም ሂደት ምርትን ወይም አገልግሎትን ቀጣይነት ተአማኒነት ተጠቂነት እና ትክክለኛነት አንዲኖረዉ ያደርጋል፡፡

ጥናቱንም ማከናውንበት መንገድ በመቆጣጠሪያ /ቼክሊስት/ ከተመረጡ አካላት ጋር በመጠይቆች በሚደረግ ቃለመጠይቅ መሰረት ነዉ፡፡ አሁን ለጥናቴ እጅግ በያግዙኝ ጉዳዬች ላይ ጥያቄ ላቀርብሎት ነዉ፡፡ ጥያቄዎቹም የእርስዎን ማንነት፤ ስለጥራት ቁጥጥር ያለዎትን እውቀት የቁጥጥር ስርአቱን ትግበራ ጥቅምና ሊያጋጥሙ የሚችሉትን ችግሮች ይመለከታል፡፡

የጥናቱ አላማ፤

የጥናቱ አላማ የጥራት ቁጥጥር ትግበራ የአሰራር ሂደት በምን ያህል እንደተተገበረ ለማወቅ በትግበራዉ ወቅት የነበሩ ምቹ ነገሮችን እንዲሁም ተግዳሮቶችን ለይቶ ማወቅ አና ለሚመለከተው አካል ችግሮቹን እንዲሁም የመፍትሄ ሃሳቦችን በማሳወቅ ችግሮቹ ተቀርፈው የጥራት ቁጥጥር ስርአቱ በአግባቡ እንዲተገበር መርዳት ነዉ፡፡

ለጥናቱ ተሳታፊዎች ያለው ልዩ ጥቅም፤ በጥናቱ ለሚሳተፉ ፍቃደኛ ተሳታፊዎች ምንም አይነት የገንዘብ ክፍያ የለውም::

በጥናቱ ተሳታፊዎች ላይ ያለው ጉዳት፤

በዚህ ጥናት ላይ በመሳተፍዎ ሊደርስብዎ የሚችል አንድም ጉዳት አይኖርም፡፡ በትናቱ ምክንያት የሚሰጥ መድሃኒት አካልን የሚጎዳ፤ ስብእናን የሚጎዳ የስነ ልቦና ችግር የሚያመጣ እንዲሁም ገንዘብዎን የሚያስወጣ ጥናት አይገለም፡፡

የመረጃ ሚስጥራዊ አጠባበቅ

የሚሰጡት መረጃ በጥናቱ ወቅትም ሆነ ከዛ በኃላ ባሉት ጊዜያት ሙሉ በሙሉ ሚስጥራዊነቱ የሚጠበቅና መረጃውም የሚያዘዉ በስም ሳይሆን በመለያ ቁጥር ይሆናል፡፡ በጥናቱ ላይ ያለመሳተፍ መብት አለዎት፡፡ ይህ መረጃ በጥንቃቄ የሚያዝ ይሆናል፡፡ በመጨረሻም የጥናቱ ውጤት ለሚመለከተዉ አካል ለጥናቱ አላማ ብቻ የሚገለፅ ይሆናል፡፡

ያስታውሱ፤ ስለዚህ ጥናት ማንኛውም ጥያቄ ካልዎት በማንኛውም ጊዜ ከዚህ በታች በተጠቀሱት አድራሻዎች መጠየቅ ይችላሉ፡፡

የዋና ተመራማሪው አድራሻ፤

- ዳንኤል በሻህ፣ የሕክምና ላቦራቶሪ ቴክኖሎጂ ዲፓርትመንት፣ የጤና ሳይንስ ኮሌጅ፣ አዲስ አበባ ዩኒቨርሲቲ- አዲስ አበባ፣ ኢትዮጵያ

ቁጥር	ጥያቄዎች ሌላ መልስ ካለዎት	መልስ			

- **ኢ-ሜይል**፣ danibeshah @gmail.com **ስልክ** ፣ +25191151317

2.2. **የፈቃደኝነት ማረጋገጫ ቅፅ**

ስለ ላቦራቶሪ ጥራት ቁጥጥር ትግበራ እና ትግበራዉ ላይ ያሉ ችግሮችን ማጥናት በሚል ርዕስ በሚደረገዉ ጥናት ላይ ለመሳተፍ መሆኑ፤ የጥናቱ ዓላማና ጥቅም ተገልጾልኛል፡፡ በመጠይቁ ላይ የምሰጠዉ የእኔ ሙሉ መረጃ በሚስጥር እንደሚያዝ ተነግሮኛል፡፡ በተጨማሪም ጥናቱ ዉስጥ አለመሳተፍ መብቴ እደሆነና በማንኛዉም ጊዜ ከጥናቱ በራሴ ዉሳኔ መዉጣት እንደምችልና በዚህም ምክንያት ምንም አይነት መጉላላት እንደማይደርስብኝ በሚገባ ተረድቻለሁ፡፡ስለሆነም ሁኔታዉን በሚገባ በማጤን በፈቃደኝነት ጥናቱ ላይ ለመሳተፍ ለተመራማሪዉ ፈቃደኝነቴን ሰጥቻለሁ፡፡ ማንኛዉንም ያልገባኝን ነገር የመጠየቅ ዕድል ተሰጥቶኝ ተስማምቻለሁ፡፡

እኔ _____ የተባልኩ ግለሰብ ይህን ሁሉ በማገናዘብ ምርምሩ ላይ የማዉቀቁን መረጃ ለመስጠት ተስማምቻለሁ፡፡ ፊርማ _____ ቀን _____

መረጃዉን ያስረዳዉ አካል _____ ፊርማ_____

2.3. የተጠያቂዉ ማንነት መግለጫ

በሆስፒታሉ ውስጥ ያለዎት ሃላፊነት _____

ጾታ ☐ ወንድ ☐ ሴት

የአገልድሎት ዘመን _____ እድሜ_____

የትምህርት ደረጃ ☐ ሁለተኛ ዲግሪ ☐ ዲግሪ

☐ ዲፕሎማ ☐ ሰርተፍኬት

☐ 12ኛ ☐ ሌላ _____

የስራ ማእረግ _____

ምሳሌ; ሲኒየር ሜዲካል ላቦርቶሪ ቴክኖሎጂስት

2.4. መጠይቅ ቅፅ በአማርኛ

ከዚህ በታች ያሉት ጥያቄዎች ይህንን ጥናት ለሚያደርገዉ ሰዉ የላቦራቶሪዉን ጥራት ቁጥጥር ስርአት አተገባበርን እና መልካም አጋጣሚዎቹን እንዲሁም ተጎዳሮቶቹን ለማወቅ እጅግ ጠቃሚ ስለሆኑ መልሶቹ ላይ እንዲያከቡአቸዉ እጠቃለሁ፡፡

ምፃረ ቃል	ሙሉ ቃል	ነጥብ	ምፃረ ቃል	ሙሉ ቃል	ነጥብ
በ.እስ	በጣም እስማማለሁ	5	በ.አል.	በጣም አልስማማም	1
እስ	እስማማለሁ	4	አዎ	አዎ	1
በከ.እስ	በከፊል እስማማለሁ	3	በከ	አይደለም	0
አል	አልስማማም	2	አይ		

	1. መረዳትዎን					
6.5	በስራዎት ዘርፍ ደስተኛ ነዎት?	በ.እስ.	እስ.	በከ.እስ	ኣል	በ.ኣል
6.6	በሚሰሩበትስ መስሪያ ቤትስ ደስተኛ ነዎት?	በ.እስ.	እስ.	በከ.እስ.	ኣል	በ.ኣል
6.7	መልስዎ በ.እስ፣ኣል፤በ.ኣል ከሆነ ምክንያቶን ይግለጹ	• ደሞዝ • ጥቅማ ጥቅም • የኣስተዳደር ችድር		• ስልጠና • ትምህርት • ሌላ _____		
6.8	ከዝህ በፊት ስለ የላቦራቶሪ ጥራት ቁጥጥር ስርኣት (ላጥቁስ) ኣተገባበር የሚዉቁት ነገር ኣለ?	ኣዎ	ኣይ			
6.9	ከዚህ በፊት የላቦራቶሪ ጥራት ቁጥጥር ስርኣት (ላጥቁስ) ስልጠና ወስደዋል?	ኣዎ	ኣይ			
6.10	የላቦራቶሪ ጥራት ቁጥጥር ስርኣት ለላቦራቶሪዉ ጠቃሚ ነዉ ብለህ ታምናለህ?	በ.እስ.	እስ.	በከ.እስ	ኣል	በ.ኣል
6.11	የላቦራቶሪ ጥራት ቁጥጥር ስርኣት ብዙ የገንዘብ ኣቅም ያስፈልገዋል ብለህ ታምናለህ?	በ.እስ.	እስ.	በከ.እስ	ኣል	በ.ኣል
6.12	የላቦራቶሪ ጥራት ቁጥጥር ስርኣት ብዙ ጊዜ ያስፈልገዋል ብለህ ታምናለህ?	በ.እስ.	እስ.	በከ.እስ	ኣል	በ.ኣል
6.13	የላቦራቶሪ ጥራት ቁጥጥር ስርኣት ብዙ ጥረት / ድካም ያስፈልገዋል ብለህ ታምናለህ?	በ.እስ.	እስ.	በከ.እስ	ኣል	በ.ኣል
6.14	የላቦራቶሪ ጥራት ቁጥጥር ስርኣት የላቦራቶሪን ግብ ያሳካል የላቦራቶሪንም ኣቅም ያሳድጋል ብለህ ታምናለህ?	በ.እስ.	እስ.	በከ.እስ	ኣል	በ.ኣል
6.15	የላቦራቶሪ ጥራት ቁጥጥር ስርኣትን በዚህ ላቦራቶሬ መተግበር ይቻላል ብለህ ታምናለህ?	ኣዎ	ኣይ			
6.16	የላቦራቶሪ ጥራት ቁጥጥር ስርኣትን በዚህ ላቦራቶሬ ለመተግበር ፍላጎት ኣለህ?	ኣዎ	ኣይ			
6.17	የላቦራቶሪ ጥራት ቁጥጥር ስርኣት ትግበራ ላይ ተሳትፈሃል?	ኣዎ	ኣይ			
6.18	በቁጥር 1.13 ላይ መልስህ ኣዎ ከሆነ የተሳተፍከዉ ምን ላይ እንደሆነ ግለጽ	_____ _____ _____				
	2. የሰዉ ኃይል					
2.1	በላቦራቶሪውና በስራ ክፍልህ ዉስጥ በቂ የሰዉ ኃይል ኣለ ብለህ ታስባለህ?	ኣዎ	ኣይ			
2.2	በቁጥር 16 ላይ መልስህ ኣይደለም ከሆነ የትኛዉ ክፍል ዉስጥ ነዉ እጥረት ያለዉ?	_____				
2.3	በዚህ ክፍል ዉሱጥ የተመደቡ ስራተኞች በብቃትና በጥራት ይሰራሉ ብለህ ታምናለህ?	ኣዎ	ኣይ			
2.4	በክፍልህ ዉስጥ የሚሰሩ ሰራተኞች የስራ መግለጫ፤ ስራ ክፍፍል ፣ የስራ ሃላፊነት ይሰጣቸዋል ብለህ ታስባለህ ?	ኣዎ	ኣይ			
2.5	በክፍልህ ዉስጥ ስልጠና ፤ ትምህርት ፤ ብቃት ፍተሻ ፤ ብልጫ ላላቸው ሰራተኞች የሚ የተደራጀ የሰው ሃይል ኣመራር ኣለ?	ኣዎ	ኣይ			
2.6	ለሽራተኛው የስራ ማትጊያ / ማነቃቅያ ኣለ ብለህ ታስባለህ ?	ኣዎ	ኣይ			
2.7	መላስህ ኣዎ ከሆነ ምን ኣይነት ማነቃቂያ ነው ያለው	• ቦነስ • የትራንስፖርት የማባይል የቤት…. • ጥሩ የትርፍ ሰኣት ክፍ • ሌላ _____				
	3. ተግባራት					
3.1	የጥራት ማስጠበቂ ፖሊሲ እና ኣፈፃፀም መመሪያ በላቦራቶሪው ዉስጥ ኣለ ብለህ ታምንለህ?	ኣዎ	ኣይ			

3.2	የጥራት ማስጠበቂ ፖሊሲ እና አፈፃፀም መመሪያዎቹን የመከተል ልማድ አለህ?	አዎ	አይ			
3.3	በላቦራቶሪዉ ዉስጥ የተደራጀ መረጃ አያያዝ እና የተደራጀ መረጃ አጠባበቅ ስርአት አለ ብለህ ታስባለህ?	አዎ	አይ			
3.4	በላቡራቶሪ ዉስጥ የዉስጥ ጥራትቁጥጥር ስርአት እንዲሁም ከላቦራቶሪዉ ዉጪ ካለ አካል ጋር የጥራት ቁጥጥር ምርመራ ይሰራል ?	አዎ	አይ			
3.5	ላቦራቶሪው የሪኤጀንት/ኬሚካሎች የመሳሪያ እና የመለዋወጫ እቃዎች የመቁጠሪያን የመቆጣጠሪ መንገድ አለዉ?	አዎ	አይ			
3.6	ላቦራቶሪው በቂ የመስሪያ እቃዎች እንዲሁም የሚሰሩት ሲበላሹ መቀየሪያ ሚሆኑ ማሽኖች አሉት?	አዎ	አይ			
3.7	ድርጅቱ የተስተካከለ እና የተመቻቸ የግዢ ስርአት አለዉ?	አዎ	አይ			
3.8	ላቦራቶሪዉ የአሰራር ጥራትን ለማሻሻል እየሰራ ነዉ ትላለህ?	አዎ	አይ			
3.9	ላቦራቶሪዉ ጥሩ/ዘመሃዊ የሆነ የመረጃ የመለዋወጫ መንገድ አለዉ ብለህ/ሽ ታምናለህ/ሽ?	አዎ	አይ			
3.10	ላቦራቶሪዉ እየተገበረ ያለዉ ቅድመ አደጋን የመከላከል አሰራር አለዉ?	አዎ	አይ			
3.11	ላቦራቶሪዉ የሚከሰቱ ችግሮችን የመፍቻ ስርአት አለዉ?	አዎ	አይ			
3.12	ላቦራቶሪዉ እዉቀት ማጎልበቻ መጽሐፍት እና የድህረ ገጽ (ኢንተርኔት) መጠቀሚያ መንገድ አለዉ?	አዎ	አይ			
4.	**የስራ አፈፃፀም**					
4.1	በርስዎ ግምት የላቦራቶሪው ማኔጅመንት በላቦራቶሪው የጥራት ቁጥጥር ላይ በትጋት እየሰራ ነው ብለው ያምናሉ?	በ.እስ.	እስ.	በከ.እስ	አል	በ.አል
4.2	በርስዎ ግምት የላቦራቶሪው የጥራት መኮንን በላቦራቶሪው የጥራት ቁጥጥር ላይ በትጋት እየሰራ ነው ብለው ያምናሉ?	በ.እስ.	እስ.	በከ.እስ	አል	በ.አል
4.3	በርስዎ ግምት የላቦራቶሪው የሥራ ደህንነት መኮንን ሥራውንና ኃላፊነቱን ባግባቡ እየተወጣ ነው ብለው ያምናሉ?	በ.እስ.	እስ.	በከ.እስ	አል	በ.አል
4.4	በርስዎ ግምት የላቦራቶሪው ተቆጣጣሪ ሥራውንና ኃላፊነቱን ባግባቡ እየተወጣ ነው ብለው ያምናሉ?	በ.እስ.	እስ.	በከ.እስ	አል	በ.አል
4.5	የሆስፒታሉ ማኔጅመንት አካላት ስለ ላቦራቶሪው አጠቃላይ የጥራት ሂደት ግንዛቤና አብሮ የመስራት ተነሳሽነት አላቸው ብለው ያምናሉ?	በ.እስ.	እስ.	በከ.እስ	አል	በ.አል
4.6	የሆስፒታሉ ፋይናንስ ክፍል ከላቦራቶሪው ጋር አብሮ የሚሰሩና ችግሮቻቸንን ያቃልላሉ ብለው ያምናሉ?	በ.እስ.	እስ.	በከ.እስ	አል	በ.አል
4.7	የሆስፒታሉ የግዥ ክፍል ከላቦራቶሪው ጋር አብሮ የሚሰሩና ችግሮቻችን አፋጣኝ ምላሽ ይሰጣሉ ብለው ያምናሉ?	በ.እስ.	እስ.	በከ.እስ	አል	በ.አል
4.8	ላቦራቶሪው የራሱ የሆነ የአቅርቦት አጠቃቀም ኡዲትና ፍሰት ቁጥጥር አለው?	በ.እስ.	እስ.	በከ.እስ	አል	በ.አል
4.9	የጥቁር አንበሳ ስፔሻላይዝድ ሆስፒታል የንብረት ክምችት ክፍል ስታንደርዱን በጠበቀ መልኩ እየሰራ ነው ብለው ያምናሉ?	በ.እስ.	እስ.	በከ.እስ	አል	በ.አል
4.10	ለላቦራቶሪ የፍጆታ ጥያቄስ ሁሌ ዝግጁ ናቸው?	በ.እስ.	እስ.	በከ.እስ	አል	በ.አል
4.11	የፋርማሲ ክፍል ከላቦራቶሪ ጋር የጠበቀ የሥራ ግንኙነት አለው?	በ.እስ.	እስ.	በከ.እስ	አል	በ.አል
4.12	ለላቦራቶሪ ክፍል የሚሆን ተገቢውን አቅርቦትና አስፈላገውን ኬሚካል አላቸው? የላቦራቶሪ ኬሚካልና ሌሎች አቅርቦቶች በደንብ ያውቋቸዋል ወይ?	በ.እስ.	እስ.	በከ.እስ	አል	በ.አል
4.13	የአገልግሎት መቆራረጥ እንዳይከሰት የክምችት ክፍላቸውን በየጊዜው ያሟላሉ?	በ.እስ.	እስ.	በከ.እስ	አል	በ.አል
4.14	ስታንደርዱን በጠበቀ መልኩ እየሰሩ ነው?	በ.እስ.	እስ.	በከ.እስ	አል	በ.አል
4.15	በላቦራቶሪ ውስጥ ለሚከሰት ችግር ከ ICT ክፍል የተመደበ አካል አለ?	በ.እስ.	እስ.	በከ.እስ	አል	በ.አል
4.16	መልስዎ አዎን ከሆነ፣ እርዳታ በሚያስፈልግበት ጊዜ ሊረዱን ዝግጁ	በ.እስ.	እስ.	በከ.እስ	አል	በ.አል

	ናቸው?					
4.17	ኮምፒዩተራዝድ የሆነ HMIS በሆስፒታሉ ውስጥ አለ?	በ.እስ.	እስ.	በከ.እስ	አል	በ.አል
4.18	በኮምፒውተር የታገዘ የLMIS, አገልግሎት አለ?	በ.እስ.	እስ.	በከ.እስ	አል	በ.አል
4.19	መልስዎ አይደለም ከሆነ፣ LMISን መጠቀም ለLQMS አስፈላጊ ነው ብለው ያምናሉ?	በ.እስ.	እስ.	በከ.እስ	አል	በ.አል
4.20	በርስዎ ግምት የበጀት ክፍል ባግባቡ ሥራውን እየተወጣ ነው?	በ.እስ.	እስ.	በከ.እስ	አል	በ.አል
4.21	ላቦራቶሪው የፀደቀለት ዓመታው በጀት አለው? ይህንን በጀት አውቆት በፕላንና ባግባቡ ይጠቀምበታል?	በ.እስ.	እስ.	በከ.እስ	አል	በ.አል
4.22	ከጥገና ክፍል ማግኘት የሚገባዎትን አገልግሎት እያገኙ ነው?	በ.እስ.	እስ.	በከ.እስ	አል	በ.አል
4.23	ሲፈለጉ በተፈለጉበት ሰዓትና ቦታ ይገኛሉ?	በ.እስ.	እስ.	በከ.እስ	አል	በ.አል
4.24	የላቦራቶሪ መሣሪያያዎችን የጠግናሉ? በሚሰጡት አገልግሎትስ እርካታ አለዎት?	በ.እስ.	እስ.	በከ.እስ	አል	በ.አል
4.25	ደንቡን የተከተለ የጥገና አገልግሎት ስምምነት ከውጭ ድርጅቶች ጋር አለ?	በ.እስ.	እስ.	በከ.እስ	አል	በ.አል
4.26	የላቦራቶሪው ትምህርት ክፍልና ዲያግኖስቲክ ክፍሉ ተባብረውና ተመጋጋቢ የሆነ አግልግሎት ይሰጣሉ?	በ.እስ.	እስ.	በከ.እስ	አል	በ.አል
4.27	መልስዎ አይደለም ከሆነ፣ ተባብረው ቢሰሩ ለላቦራሪው ጥራት ለውጥ ያመጣሉ ብለው ያስባሉ?	በ.እስ.	እስ.	በከ.እስ	አል	በ.አል
4.28	ላቦራቶሪው ከሐኪሞች ጋር የልምድ ልውውጥና ለተሻለ አገልግሎት የስራ ግንኙነት አለው?	በ.እስ.	እስ.	በከ.እስ	አል	በ.አል
4.29	ላቦራቶሪው ከነርሶች ጋር ለተሻለ አገልግሎት መልካም የሆነ የስራ ግንኙነት አለው?	በ.እስ.	እስ.	በከ.እስ	አል	በ.አል
5.	**ስለሆስፒታሉ**					
5.1	የሆስፒታሉ እና የሆስፒታሉ አወቃቀር ለስራ ይመቻል ብለዉ ያስባሉ?	አዎ	አይ			
5.2	የላቦራቶሪዉ ክፍል እና አወቃቀር ለስራ ይመቻል ብለዉ ያስባሉ?	አዎ	አይ			
5.3	የላቦራቶሪዉ ናሙና መሰብሰቢያ ክፍሎች አወቃቀር ለስራ ይመቻል ብለዉ ያስባሉ?	አዎ	አይ			
5.4	ላቦራቶሪዉ የምርመራ ኬሚካሎች እና የመለዋወጫ እቃዎች ማስቀመጫ በቂ ስፋት ያለዉ የላቦራቶሪዉ ክፍል /መጋዘን/ አለው?	አዎ	አይ			
5.5	ላቦራቶሪዉ በንጽህና ተያዘ፤ ፅዳቱና የእቃዎቹ አቀማመጥ ትክክል ነዉ?	አዎ	አይ			
5.6	ላቦራቶሪዉ የቧንቧ ዉሃ፣ የተጣራና ከንጥረ ነገሮች የጸዳ ዉሃ አለዉ?	አዎ	አይ			
5.7	ላቦራቶሪዉ የማይቋረጥ የዉሃ አገልግሎት፤ እንዲሁም የመብራት አገልግሎት UPS አለዉ?	አዎ	አይ			
5.8	ላቦራቶሪዉ በቂ የሃይል ማግኛ ሶኬቶች አሉት?	አዎ	አይ			
5.9	ላቦራቶሪዉ ለእጅ መታጠቢያ ለእቃ ማጠቢያ የሚሆን ቦታ /ሲንክ/ አለዉ?	አዎ	አይ			
5.10	ላቦራቶሪዉ ደረጃዉን የጠበቀ በናሙና የፍሳሽ ማስወገጃ መስመር እና ፍሳሹን ከብክለት ማስወገጃ ጉርጉዓአድ አለዉ?	አዎ	አይ			
5.11	ላቦራቶሪዉ ደረጃዉን የጠበቀ የተበከሉ እቃዎችን ማቃጠያ ስፍራ አለዉ?	አዎ	አይ			
5.12	የላቦራቶሪዉ ወለል፤ ጣሪያው እና ግርግዳዎች እድሳትን የማይፈልግና ንፁህ ነዉን?	አዎ	አይ			
5.13	የላቦራቶሪ ክፍሎቹ አየርና ብርሃን በበቂ ሁኔታ ያገኛሉ ?መስኮቶቹና በሮቹ ቅያሬ ሳያስፈሊጋቸው በጥሩ ሁኔታ ላይ ናቸው?	አዎ	አይ			
5.14	ላቦራቶሪው የተገልጋዮች ተራ መጠበቂያ የሚሆን መቀመጫዎች አሉት?	አዎ	አይ			

6. የግል የርስዎ አመለካከት						
6.1	ስለ ላቦራቶሪ አክሪዲቴሽን የርስዎ አመለካከት ምን ይመስላል?	_____ _____ _____ _____				
6.2	በርስዎ ግንዛቤ የዚህ ላቦራቶሪ አገልግሎት መቆራረጥ መንስኤው ምንድነው ብለው ያምናሉ?	_____ _____ _____ _____ _____ _____				
6.3	የላቦራቶሪን የጥራት ሂደት እንደሚፈለገው ላለማስኬድ እንቅፋቶቹ ምንድን ናቸው?	_____ _____ _____ _____ _____ _____ _____				
6.4	መፍትሔዎቻቸውስ?	_____ _____				

Annex IV: In-depth interview participant information sheet, consent and questionnaire

1.1. Participant information sheet

Title of the research: Assessment on implementation of quality management system and associated challenges in Tikur Anbessa Specialized Hospital Laboratory, Addis Ababa, Ethiopia
First of all we would like to thank you in advance for your cooperation and consent in participation in this study. Please read or listen carefully about the general information of the study. If you have any question regarding the study please ask freely.

Back ground

I am doing a research in partial fulfillment of the requirement of master"s degree in laboratory management and quality assurance specialty at Addis Ababa university school of medical laboratory science. The research is on implementation of quality management system in Tikur Anbessa Specialized Hospital laboratory (TASHL).

Quality management system is a "coordinated set of activities to direct and control an organization with regard to quality". A well-defined quality system is a must for ensuring quality. QMS is a part of overall quality management which aims at ensuring the consistency, reproducibility, traceability and reliability of the products or services.

The study will be conducted through standard checklist, focus group discussion and questionnaire based interview. Enclosed are questions that are very important for the study. You will be asked your socio-demography, knowledge about quality management system, opportunity and threats on implementation of quality management system in TASHL.

Aim of the study

The purpose of this study is to know the level of implementation of quality management system in the laboratory, to identify opportunity and threats/challenges during implementation to give a useful insights and understanding of the problem to the hospital and laboratory management. The information you give could help as to find out the level of participation of staff and management, barrier, challenges and possible solutions for the recommendation to improve laboratory quality management system.

Benefits for participants

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

Risks for participant

The proposed research does not have any drawback on the research participants and 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.

Assurance of Principal Investigator

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

Daniel Beshah (PI): Signature: _____ Date: _____

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

Principal investigator:- Daniel Beshah email: danibeshah@gmail.com

Advisor: Tedla Mindaye (Bsc, MSc)

Aster Tsegaye, (BSc, MSc, PHD)

Tatek Gebreegziabher (Bsc, MSc)

1.2. Informed consent

I have been informed about the study which plans to assess implementation of quality management system in TASH, Addis Ababa, Ethiopia. The objective and the application of the study were briefly explained to me. I am also informed that all information contained within the questionnaire is to be kept confidential. Moreover, I have been well informed of my right to

refuse information, decline to cooperate and drop out of the study if I want. It is therefore with full understanding of the situation that I agreed to give the informed consent voluntarily to the researcher to give my idea/ knowledge for the mentioned study.

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

Participant code:_____ Signature: _____

Date: _____

1.3. Respondent Demography

Sex ☐ Male ☐ Female

Years of Experience _____ Age _____

Educational background ☐ Post graduate ☐ Undergraduate

☐ Diploma ☐ Certificate

☐ 12th Other _____

Department _____

Position in the organization _____

E.g. clinical chemistry dep. worker	*E.g. hematology dep. head*

Professional level _____

Eg; Senior medical laboratory technologist

1.4. Questionnaire

The following questions will help the principal investigator to identify the opportunity and traits of implementation of laboratory quality management system (LQMS).

1) Are you satisfied by your profession? Yes No

2) Are you satisfied with your occupation/ work environment? If no, please indicate the reason; salary, benefits, managerial issues, training, etc. Yes No

3) Do you have knowledge about laboratory quality management system (LQMS)? Have you been trained about LQMS? Yes No

4) Do you believe LQMS is important in the laboratory? Do you believe LQMS can be implemented in TASH setup? Yes No

5) Are you interested and participated on implement LQMS in TASH laboratory? If the answer for question number 13 is yes, what was your contribution on the implementation phase? Yes No

6) Are there sufficient personnel in the laboratory department / in all section? If the answer for question number is No, which department / sections have shortage of manpower? Yes No

7) Do you think assigned personnel are working effectively and efficiently? Do personnel in your office have job description, duty and responsibility based on service delivered? Yes No

8) Are you applying any national or international standard system in your office? Eg. IOS 9001, 17025, 15189 or other. If the answer for question number 19 is yes, please write the name on the space provided. Yes No

9) Concerning your duty/job, are there written manual, policies and procedures available in your department? Do you have habit/ experience to follow manual policy, guidelines and procedures available in your office? Yes No

10) Do you have well organized documentation and recording system in your department? Do you have controlling system for official letters, requisition paper and other customer letters to be circulate in you section? Yes No

11) Does your organization set maximal time required for every activity? Yes No

12) Do you think the organization have smooth purchasing and inventory system? Do you have sufficient working equipment‟s and consumables for your department? Yes No

13) As your expectation is your customer‟s satisfied by the service your department delivered? Yes No

14) Do you believe that the hospital management has controlling and supporting your department? Yes No

15) Do you believe that finance department is working efficiently? Yes No

16) Do you believe that purchasing department was fulfilling laboratory demand? Are they giving fast response for laboratory request? Yes No

17) Do you believe that the TASH Store (not pharmacy store) working in appropriate standard. Yes No

18) Does the Pharmacy department delivered appropriate service for the hospital? Yes No
19) Is there ICT department representative/ delegated for your department who can solve the problem happened? If no, are they available when you need their support? Yes No

20) Is there computerized Hospital management information system (HMIS), is there suitable software used by the hospital? If no, is Hospital management information system (HMIS) is important for the hospital? Yes No

21) Do you believe budget department working efficiently? Is the Budget department allocated your annual budget? Yes No

22) Do you get appropriate service from maintenance department? Are they available when they needed? Are you satisfied on service delivered by them? Yes No

23) Is there proper external Equipment Maintenance system and agreement (if you have instruments need to maintain by external maintenance? Yes No

24) Is the hospital facility comfortable for working environment? Yes No

25) Is the office comfortable for working environment? Yes No

26) Does the laboratory have a consistent power supply and/or a generator with a guaranteed supply? UPS? Yes No

27) Does the laboratory have an adequate number of power points (sockets)? Yes No

Annex V: Dummy tables

Table 14: Socio demographic characteristics of laboratory professionals working in TASH facilities in Addis Ababa, 2013

S/No.	Variables	Number (frequency)	Percent (%)
1	**Gender**		
	Female		
	Male		
2	**Age group in years**		
	20-30		
	31-40		
	41-50		
	51-60		
3	**Professional level**		
	Expert medical laboratory technologist		
	Senior medical laboratory technologist		
	Junior medical laboratory technologist		
	Medical laboratory technician		
4	**Educational background**		
	MSc		
	BSc		
	Diploma		
	Working organization		
	Hospital		
	Higher clinic		
5	**Years of experience in laboratory field**		
	1-2year		
	3-5 years		
	6-10 years		
	>10 years		
6	**Years of experience in current organization**		
	1-2year		
	3-5 years		
	6-10 years		
	>10 years		
7	**Position in the organization**		
	Laboratory head		
	Section/department head		

	Laboratory expert		
	Quality officer		

Table 15: Detail assessment summary by standardize checklist

No	Questions	Answers in Number				
2. Perceptions						
7.1	Are you satisfied with your profession?					
7.2	Are you satisfied with your work environment?					
7.3	If no, please indicate the reason	Reasons will collect and interpret in number and in percent.				
7.4	Do you have knowledge about laboratory quality management system (LQMS)?					
7.5	Have you been trained about LQMS?					
7.6	Do you believe LQMS is important in the laboratory?					
7.7	Do you think LQMS needs more money?					
7.8	Do you think LQMS needs more time?					
7.9	Do you think LQMS needs more effort?					
7.10	Do you believe LQMS helps to enhance laboratory capacity and help to achieve laboratory goals?					
7.11	Do you believe LQMS can be implemented in your department?					
7.12	Are you interested to implement LQMS in your laboratory?					
7.13	Are you participated to implement LQMS in your laboratory?					
7.14	If the answer for question number 13 is yes, what was your contribution on the implementation phase?	Answer will summarize				
8 Personnel						
8.1	Are there sufficient personnel in the laboratory department / in all section?					
8.2	If the answer for question number 15 is No, which department / sections have shortage of manpower?	Answer will summarize				
8.3	Do you think assigned personnel are working effectively and efficiently?					
8.4	Do personnel in your office have job description, duty and responsibility based on service delivered?					
8.5	Is there personnel management system in your department? That has competency assessment, performance appraisal, training, education….					

9	**Activities**					
9.1	Are there written quality assurance policies and procedures available in this laboratory?					
9.2	Do you have habit/ experience to follow guidelines and procedures?					
9.3	Do you have well organized laboratory documentation and recording with controlling system? Is there document and record master list?					
9.4	Does the laboratory undertake the internal and external quality control procedures?					
9.5	Does the laboratory have inventory system for equipment, reagent and supplies?					
9.6	Do you have sufficient equipment‟s and backup system?					
9.7	Does the organization have smooth purchasing and inventory system?					
9.8	Does the laboratory working on process and quality improvement?					
9.9	Does the laboratory have good information management?					
9.10	Is there practically applied safety guideline?					
9.11	Is there occurrence management system?					
9.12	Are there reference documents in or internet access in the laboratory?					
10	**Performance**					
10.1	As your expectation, does the laboratory management working on LQMS effectively?					
10.2	As your expectation does the laboratory quality officer working on LQMS effectively?					
10.3	As your expectation does the laboratory safety officer working his responsibility properly?					
10.4	As your expectation does the laboratory supervisor working his responsibility properly?					
10.5	Do you believe that the hospital management has awareness interest and collaboration for implementation of LQMS?					
10.6	Do you believe that finance department was fulfilling laboratory demand? Are they giving fast response for laboratory request?					
10.7	Do you believe that purchasing department was fulfilling laboratory demand? Are they giving fast response for laboratory request?					
10.8	Are there available resources for implementation of quality management system?					
10.9	Do you believe that the TASH Store (not pharmacy store) working in appropriate standard.					
10.10	Are the Store personals available for laboratory					

	staff all the time when they needed?					
10.11	Does the Pharmacy department have close relation with laboratory department?					
10.12	Does the Pharmacy know appropriate supplies and reagents needed by the laboratory?					
10.13	Does the Pharmacy maintain their stock without interruption?					
10.14	Does the Pharmacy using standard protocol for the store management?					
10.15	Is there ICT department representative/ delegated for laboratory department who can solve the problem happened in the laboratory?					
10.16	If the answer for question number 66 is no are they available when the laboratory need support?					
10.17	Is there computerized hospital management information system (HMIS)?					
10.18	Is there computerized integrated LMIS, Is there suitable software used by the laboratory?					
10.19	If the answer for question number 69 is No, is LMIS is important for LQMS?					
10.20	Do you believe budget department working efficiently?					
10.21	Does the laboratory know their annual budget and utilize according to their plan?					
10.22	Do you get appropriate service from maintenance department?					
10.23	Are they available when they needed?					
10.24	Can they maintain laboratory equipment‟s, are you satisfied on service delivered by them?					
10.25	Is there proper system for external equipment maintenance agreement?					
10.26	Does laboratory teaching department and laboratory service giving department integrated and working together?					
10.27	If the answer for question number 77 is no, do you think integration of laboratory teaching and service giving department will enhance IQMS?					
10.28	Does the laboratory have good communication with physicians concerning experience share and work improvement?					
10.29	Does the laboratory have good communication with nurses concerning system improvement? Eg in sample collection, result dispatching, …					
11 Facility						
11.1	Is the hospital facility comfortable for working environment?					
11.2	Is the laboratory facility comfortable for working environment?					

11.3	Is the facility sample collection area appropriate and comfortable for working environment?					
11.4	Does the laboratory have store for reagents and supplies? Is that sufficient space to adequately store existing supplies?					
11.5	Is the laboratory area maintained in good condition (e.g., clean, all trash removed, shelves are sturdy, etc.)? Including sample collection?					
11.6	Does the laboratory have: a. Running water? b. Distilled or deionizer water?					
11.7	Does the laboratory have a consistent power supply and/or a generator with a guaranteed supply? UPS?					
11.8	Does the laboratory have an adequate number of power points (sockets)?					
11.9	Does the laboratory have separate sinks for washing laboratory ware and staining, and for washing hands after being exposed to infected materials?					
11.10	Does the laboratory have functioning incinerator and drainage from laboratory sinks that are closed and that lead to either a septic tank or deep pit?					
11.11	Are the laboratory floors in good condition without the need for repair?					
11.12	Is the roof maintained in good condition at all times to avoid sunlight and water penetration?					
11.13	Are the internal walls in good condition without the need for repair?					
11.14	Is the laboratory well lighted and ventilated?					
11.15	Are the windows and doors in good condition without the need for replacement or repair?					
11.16	Does the laboratory have firm built-in benches with leveled tops in good condition?					
11.17	Does the laboratory have firm shelves to store supplies and reagents?					
11.18	Does the laboratory have an indoor patient waiting area with seats?					
12 Personal opinion						
12.1	What is your attitude towards accrediting this laboratory?	Answer will summarize in discussion				
12.2	According to your understanding what are the main causes for service interruptions in this facility?	Answer will summarize in discussion				
12.3	Please mention challenges on implementation of LQMS.	Answer will summarize in discussion				
12.4	What remedy do you suggest?	Answer will summarize in discussion				

Annex VI: Organization Consent Form at which the research will done

General information sheet about the study

My name is Daniel Beshah employee of TASH in laboratory department and currently I am student of clinical laboratory science in the track clinical laboratory management and quality assurance program launched in Addis Ababa University College of health sciences school of medical laboratory science. Now, I am working a research thesis project and the aim of the study is to assess implementation of quality management system, opportunities and challenges during the implementation phase in TASH to give insight and recommendation for further improvement. It will also important for other government institution to take a lesson.

All the information, which you are being asked to provide in this questionnaire will be kept strictly confidential; and will be used only for study purposes, the interview is voluntary and you have the right to participate or not. However, your participation is important to full fill the study purpose.

I the undersigned name assure and no complain if the indicated title is performed in our institution for the sake of the sector‟s implementation of quality management system and consistent laboratory quality improvement.

In-depth intervew with different departments and questioner based interview will done. WHO-AFRO assessment result and meeting agenda (for development of questioner), will be used: To assess implementation of quality management system in TASH Addis Ababa, Ethiopia, 2013

Name of the hospital_____

Responsible person_____ Sign _____ Date _____

For any information you can contact

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2. Advisors:

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Annex VII: Declaration of the Author

I the undersigned, declare that this is my original work and has not been presented for a degree in this or any other university and all sources of materials used for this thesis have been acknowledged.

Name: Daniel Beshah

Signature _____

Place_____

Date of submission _____

This thesis has been submitted with my approval as University advisor.

1. Name: Tedlla Mindaye (BSC, MSC PhD fellow)

   Signature _____

   Place _____

   Date of submission _____

2. Name: Aster Tsegaye (PHD)

   Signature_____

   Place_____

   Date of Submission_____