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COLLEGE OF HEALTH SCIENCES

DEPARTMENT OF MEDICAL LABORATORY SCIENCES

Evaluation of medical laboratory performance by using Quality indicators, customer satisfaction and KAP of laboratory professionals at Tikur Anbessa Specialized hospital, Addis Ababa, Ethiopia.

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College of Health Science

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This is to certify that the thesis prepared by; MEKDELAWIT BIRHNU entitled:

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List of Abbreviations/Acronyms

AA	Addis Ababa
AAC	acceptable
AFCSH	Armed force comprehensive specialized hospital,
CBC	Complete cell count
CBHI	Community-based health insurance
CLSI	Clinical Laboratory Science
EAS	Ethiopian Accreditation Service
ELE	Electrolyte
ER	Emergency
ENT	Ear, nose, and throat
EQA	External quality assessment
ESI	Employee state insurance
GBPH	Govind Ballabh Pant Hospital
HCG	Human chorionic gonadotrophin
IHBAS	Human Behavior and Allied Sciences
ISO	International Organization for Standardization
KAP	Knowledge Attitude Practice
LIS	Laboratory Information System
OPD	Out patients department
QC	Quality Control
QI	Quality indicators
QM	Quality management
QMS	Quality management systems
QS	Quality standards
SMIMER	Surat Municipal Institute of Medical Education and Research
TASH	TIKUR ANBESSA Specialized Hospital
TAT	Turn around time
TB	Tuberculosis
TRF	Test Request Form
TTP	Total test procedure
WBC	White blood cell

RBC	Red blood cell
MCV	Mean cell volume
MCH	Mean corpuscular hemoglobin
MCHC	Mean corpuscular hemoglobin concentration
MPV	Mean platelet volume
PI	Performance indicators
PLT	Platelet

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Abstract

Background: Establishing and maintaining a standardized process in medical laboratories is the most important approach in providing quality results. However, there is very limited research-based information on the level of standardized laboratory performance in developing countries. Thus, the objective of this study is to evaluate medical laboratory performance by using Quality indicators, with customer satisfaction, and its associated factors in Tikur Anbessa specialized hospital, Addis Ababa, Ethiopia.

Methods: A cross sectional study was conducted from Oct 2021 to March 2022 in Addis Ababa at Tikur Anbessa specialized hospital (TASH). We assessed and monitored using various quality indicators at the five laboratory departments by adapting standardized format. The performance has evaluated by these indicators and compared with pre-set targets. Data was entered in Epidata and analyzed by SPSS version 23. The KAP level assessment was performed using 36 questions encompassing qualitative and quantitative aspects of quality practice in 45 participants. Self-administered pretested face-to-face interviews were performed and completed by a respondent without intervention of the researchers. which is a 5-point Likert scale, with 1 and 5 indicating the lowest and highest levels of satisfaction, respectively. And their weighted average was used to categorize the satisfaction level of the study participants in the laboratory service with a sample size of 900 patients and 164 physicians.

Result: Here we present the overall quality indicator of TASH as: 133,213(79.5%) tests were meet predefined target TAT. The most frequent reagents stock out were in clinical chemistry. service interruption at least occurred once to two times in a month; urine & parasitology department has the highest rate with 3(60%) tests interrupted for continuous six months. During the study period there have been three round EQA participation's and the feed-backs were satisfactory. The maximum sample rejection rate recorded is emergency department relatively from the five departments with 780(5.3%). The numbers shown that urine & parasitology, hematology, sections has the lowest sample rejection rate of 116(0.8%) and 416(0.8%) respectively. Moreover, the overall satisfaction with the laboratory service among the physicians and patients was 37.2% and 66.2% respectively. According to the overall scoring, 4.4% of the respondents had poor knowledge regarding quality assurance points, 77.8% of respondents had average knowledge, though only 17.8% had good knowledge, 23(51.1%) strongly agreed, and 22(48.9%) agreed on Quality assurance helps medical technologists and the laboratory attain a more accurate and precise result. 80% of participants often practice quality assurance. When compared to patients who got in touch with laboratory personnel who has better communication before and during sample collection, they were 2.17 times more likely to be satisfied than dissatisfied patient (AOR=2.17(1.346-3.510);P value=<.001).

Conclusion: The research demonstrates that TASH laboratory performs below the target objectives, specifically in customer satisfaction levels, TAT, and specimen rejection rates. Thus, the laboratory should strictly follow and evaluate quality indicators periodically, as they play a key role in reducing the risk of errors in clinical laboratories.

Key words: quality indicator, performance evaluation, associated factors, Ethiopia, Tikur Anbessa.

1. Introduction

1.1 Background

Quality indicators (QIs) are fundamental tools for enabling professionals to quantify the quality of all operational processes by comparing it against a defined criterion. This data should be collected over time to identify, correct, and continuously monitor defects and improve performance and patient safety by identifying and implementing effective interventions. The laboratory shall establish and periodically review QIs to monitor and evaluate performance throughout critical aspects of pre-, intra-, and post-analytical processes, according to the International Standard for medical laboratories accreditation (1).

Health-related indicators have evolved into two main types. The first indicator might be classified as having a primary utility for driving improvement and might include operational benchmarking and external quality assurance for comparison with peers. These should be used to monitor progression and improvement as well as having a function of providing a cause for investigation to explain deterioration or outliner status. The second form of indicator has a more corrective function for performance management and accountability. For laboratory medicine, quality indicators or performance measures may be developed to evaluate any stage of the total laboratory testing process, (e.g, hospitals and point-of-care settings) (2).

A continuous comparative performance-monitoring program is important for setting more strong objectives and thus decreasing laboratory process failures (3). Laboratory medicine QIs frequently concentrate on the effectiveness and performance of analytical procedures, recent data suggests that most curve bend mistakes occur outside of the analytical stage. and it has been shown that the pre- and post-analytical phases are more susceptible to the risk of error. Quality in laboratory has a huge impact on diagnosis and patient management as about 80% of all diagnoses are made on the basis of laboratory tests (4).

In all phases of total testing process (TTP), health laboratories use quality indicators based on the requirements of the International Organization for Standardization (ISO) 15,189:2012. The achievement of sustainable laboratory performance in accreditation has also been a major challenge in African countries and there are still gaps in strengthening laboratory services.

The majority of Ethiopian clinical laboratories provide sub-optimal service, and the quality of the service is severely compromised, which may lead to the occurrence of several laboratory errors (5).

One of the most important clinically supportive divisions of a hospital is the laboratory service. Regular evaluations of patient satisfaction with laboratory services are necessary to pinpoint areas for development (6).

Patient happiness has a favorable impact on clinical improvement, patient adherence and retention, work satisfaction, and physicians' ability to provide appropriate clinical treatment. On the other hand, patient discontent results from a mismatch between their expectations and the treatment they received. The level of professionalism and quality of service provided by the employees affects how satisfied patients are with clinical laboratory services, adequate information on how to collect a sample, as well as when and how to receive laboratory results, the amount of time it takes to receive lab results; whether ordered tests can be performed; how clean the lab is, and Laboratory location, accessibility, also toilets (7). One of the most significant measures of the quality of health care services is patient satisfaction. And this will assists in highlighting the TASH Laboratory's weaknesses.

1.2 Statement of the problem

The Institute of Medicine estimated that up to 98,000 deaths per year in US were attributed to medical errors. With approximately 60–70% of medical decisions related to diagnosis and treatment involving the laboratory, no other discipline is better positioned to the pivotal in the patient safety solution. Hence, it is obvious that laboratory errors may have a major adverse impact on patient care. Laboratory errors have a reported frequency of 0.012–0.6% of all test results which in turn has huge impact on diagnosis and patient management as 80–90% of all diagnosis are made based on laboratory tests (8).

The research at the laboratory of the government medical college and ESI hospital in Coimbatore, Tamil Nadu, India, showed that only 0.1 percent of 1000 forms had all the essential information, and the patient’s name was the only parameter that appeared in all of the laboratory request forms, and this too may be due to the refusal of request forms at the reception that have no name.

Information regarding the location of the patient ward and hospital number, which is necessary for locating the patient who may need a repeat of sample collection or a report of critical results, was missing; this may lead to unnecessary duplication of investigations and resource wastage.

The benefits of writing age on the request forms help, for example, with patient identification, interpretation of the results, and error detection. Though, inadequate clinical information may cause difficult in interpretation of results and its lead to misleading comments. Processing of incomplete filled laboratory request forms may lead to the misinterpretation of results and have a serious impact on patient health-care (9).

Also, quality gaps in laboratory tests in less-resourced countries are for example, the lack of a laboratory management infrastructure and quality management training curriculum which develops the competences of laboratory managers and quality coordinators, lack of access to or knowledge of current international standards, and an absence of national standard operating procedures that are based on these standards. Therefore, there are significant quality gaps in laboratories of resource-limited countries relative to international standards (10).

Some African healthcare professionals continue to experience serious issues due to skill and competency gaps. Like, The standard of healthcare in sub-Saharan Africa faces significant obstacles. Facilities' limitations and healthcare practitioners' performance frequently make it difficult to offer high-quality care. In addition, health care professionals claim that goal-setting and training initiatives are crucial for enhancing the standard of treatment delivered (11).

Evidence showed in the region of Amhara, Ethiopia showed that the risk of inappropriate care due to laboratory errors ranges from 6.4% to 12% and the incidence of further inappropriate investigations is much higher (19%). Poor laboratory performance that causes an error and delays in diagnosis, and treatment is an obstacle to optimal patient care, particularly in high volume patient care areas such as this Hospital (12).

Tikur Anbessa hospital laboratory has many challenges on producing high- quality test results in the most efficient and effective manner. One main drawback observed is a decrease in the overall quality of the care and service provided throughout the laboratory process, which is in pre-analytical, analytical, and post analytical has many factors.

Among those factors, insufficient supply, insufficient manpower, and most importantly lack of helpfulness from the higher management officials in providing and collaborating to have a better and expected standard laboratory setup is the challenge raised while assessing why the laboratory has not performed as it expected. A decrease in total quality and its negative effects on patient outcomes has caused economic and health loss. This study has shown possible impacts for maintaining quality. It also aimed to examine patient satisfaction with clinical laboratory services and relevant factors for patients across all departments.

1.3. Significance of the study

As a tertiary health care facility, the capacity as well as the quality of service needs to be at their maximum level. As an investigatory and professional service provider in this hospital, founded to be studied further and identify gaps. Since the aim of this study were to evaluate laboratory performance by using quality indicators in TASH Addis Ababa Ethiopia, Those gaps that are the main obstructions to providing quality lab results to patients are identified.

As for the professionals, participating in this research will increase the knowledge they have in this subject matter. In addition, this will help the managers to have base line information on the laboratory which will in the future help as a start-up for further improvement plan. Also, since there is no adequate research conducted in this topic issue here in Ethiopia particularly in this hospital, it will provide a wealth of information by demonstrating practical positive improvement, demonstrating the value of all laboratory departments' quality indicators.

2. Literature review

2.1 Evaluation of medical laboratory performance by establishing quality indicators.

In New Delhi, GBPH, a tertiary care hospital a study includes an evaluation of different quality indicators collected from the biochemistry laboratory during the period of 1 year, by Chawla R et, al (2010). A total of 84250 samples were received. The quality indicators were classified into the three phases. The most common cause for the rejection of samples was hemolysis, followed by an inappropriate ratio of anti-coagulant to blood for coagulation profiles, and clotted samples for coagulation studies. other indicators assessed were errors in the requisition slip such as illegible handwriting, incomplete patient identification, insufficient quantity of samples, the main problem encountered was random errors on the analyzer due to pipetting difficulties related to fibrin clots leading to repeat analysis, accounted for 12/1000 samples. The study implies that it is possible to compare laboratory functions with others by simply evaluating the prevalence of the various indicators (13).

In 2011 another study by Grecu DS, with a total of 168,728 samples and 88,655 test requests received in the emergency laboratory. They are able to discover the errors by establishing specific acceptance and rejection criteria. Pre-analytical errors were 0.8% of the total number of samples received that year. from the pre-analytical errors, in biochemistry 46.4% were hemolyzed samples, in hematology, 43.2% were clotted samples, 6.4% were not received in the laboratory, 2.9% showed an inadequate sample 0.7% were requests with errors in patient identification, 0.3% were samples collected in blood-collection tubes with wrong anticoagulant, and 0.1% were requests with test requests missing error. Most of the results indicated an optimum level of performance and they generalized that performance level in the pre-analytical phase of the testing process as good. Quality indicators in the study used to compare the performance of the individual laboratory with that of other laboratories, with the same parameter (14).

A study in India by Kulkarni S, et al, 2014, data was analyzed from a total of 39139 samples received in the 6 laboratories. The overall error rate was 2.72%. The error rate was further analyzed considering QIs categorized into the three phases: The error rate during the post-analytical phase was highest (1.75%) followed by (0.80%) error rates during the pre-analytical and analytical (0.16%) phases.

The assessment of the quality indicators in the laboratories shows that, as compared to the pre-analytical error the post-analytical phase was higher and analytical phases. Quality indicators play a key role in reducing the risk of errors in clinical diagnostics. Thus, the use of quality indicators to assess and monitor the quality system is an extremely valuable tool for improving the quality of laboratory services and patient care (15).

A retrospective study in Austrian, data from 167 laboratories in the years of 1999–2017, the performance for each parameter and trends of individual participants were compared with respect to certification or accreditation status of participants' quality systems and to laboratory type by Buchta C, et al. A total of 56,676 results were submitted by 182 participants. only a trend towards further reduction of error rates is recognizable considering ISO 9001 certification vs. ISO 15189 accreditation. There were no significant differences between hospital and independent laboratories whereas the lowest error rates were found in transfusion services (0.9%). laboratories with already good performance decide to introduce quality systems. According to study results, obligatory legal requirements and expert associations' guidelines are insufficient to ensure EQA results to an actually achievable extent. In contrast, quality systems according to ISO 9001 and ISO 15189 give a solid basis for higher analytical laboratory performance (16).

Also, in 2018 a retrospective study was carried out in India clinical Biochemistry laboratory SMIMER Hospital, Gujarat, a total of 9,07,611 tests performed on 3,17,212 samples was collected and analyzed for quality indicators one year period. Pre-analytical phase accounts for high error rates among all three phases of TTP. With the help of QIs, they found that the clinical Biochemistry laboratory accounts for significant error rates for analytical and post analytical phase too. They suggest procuring reagents which are manufactured by companies following international norms, with consideration of the budget escalation. Also, QC material and calibrators procured must have traceability. The study suggests that the laboratory departments and clinicians should reach to consensus related to define critical values of various parameters. All records pertaining to delayed report delivery, critical call outs to clinicians and technical staff training should be maintained. And that the laboratory needs to be equipped with fully functional LIS system to counter post analytical errors (17).

Inventory management performance for laboratory commodities in public hospitals of Jimma zone, Southwest Ethiopia a facility-based cross-sectional descriptive study, accompanied by a qualitative method was conducted in seven public hospitals in 2019 for two months. 225 bin-cards documents reviewed. Of the total estimated bin-cards only 30.4% of them filled accurately. Among major obstruction of inventory management, Budget constraints, absence of prompt administrative support, lack of staff commitment, and frequent shortages of commodities on the part of suppliers mentioned. In general, the hospitals had weak inventory management practices, showed by inaccurate records, stock-outs due frequent emergency orders, a high wastage rate while comparing with the national baseline statistics, and the storage conditions were below the standard (18).

The above literature's are manifestations of what medical laboratories majorly faces as a challenge all over the world including Ethiopia. Most commonly the research indicates different co factors in addressing a standard quality service. That research has been used as a tool in improving the laboratories performance by following a daily work activity and recommending appropriate solutions for the observed gaps. Likewise, this study will contribute major input mainly for Tikur Anbessa specialized hospital medical laboratory as well as the country in quality health service improvement and Efficiency gains can be achieved by reducing the error rate and by improving the laboratory’s layout and logistics.

2.2 Factors affecting laboratory quality performance

Study in Nigeria by Alash'le G. Abimiku, et,al (2010) identified factors which have impact on laboratory quality system. Among this, regarding quality assurance a high level of accuracy was maintained at sites following decentralization of EQA activities. Before the decentralization of EQA activities, 82.5% were performed with 100% accuracy, and 86.6% of the challenges were successfully completed. Following decentralization, 94.5% of the external proficiency were performed with 100% accuracy, and 98.3% of the challenges were successfully completed. Also, A strong foundation for laboratory support begins with clear policies and procedures, especially in developing countries where QA concepts are often lacking. Major limitations to establishing an efficient laboratory system to support activities in developing countries have been a lack of financial resources and a means to implement, manage, and monitor activities, this is particularly notice in the study (19).

In 2017, a cross sectional study was conducted using a questionnaire to assess factors affecting the quality of laboratory service at private and public health institutions in Addis Ababa. A total of 213 laboratory professionals participated, among those 131 participants had bachelor's degree. Majority, of the professionals did not attend any work-related training. Seventy-five respondents believed that their laboratories did not provide quality laboratory services and the major reported factors affecting provision of quality services were shortage of resources, poor management support, poor equipment quality, and high workload, lack of equipment calibration and lack of knowledge. Logistic regression analysis showed that provision of quality laboratory service was significantly associated with result verification, internal quality control, turnaround time, and shortage of equipment, communication with clinicians and lack of job description. the findings concluded that major factors that affecting provision of quality laboratory services were high workload, shortage of resource, poor management supports, poor staff motivation, lack of knowledge and skills, high workload, equipment failure and lack of calibration, shortage of supplies and reagents (20).

Observational descriptive study was conducted in 2017 at Dhulikhel Hospital-Kathmandu University Hospital is a tertiary care hospital, from the Department of Clinical Biochemistry Laboratory a total of 36,108 patients reports generated, among those almost 36% of reports exceeded the predefined TAT in case of stat tests, while around 7% of reports were out of

predefined TAT in case of routine tests. Among prolonged TAT, around 75% of reports were delayed due to various extra analytical reasons, mainly errors created by other departments over and beyond the laboratory itself. The finding concluded that reasons for prolonged TAT may vary with hospital to hospital depending upon different factors (21).

Cross sectional study was conducted in 2019 by Mebrat Gebreyesus in Addis Ababa armed force comprehensive specialized hospital, (AFCSH). The study implemented a structured questioner to collect data on two department test parameters TAT achievements aiming to evaluate the performance of Laboratory of AFCSH which is one of the quality indicators. In addition, information regarding factors contributing for poor or successful TAT was Also included in the study. Of a total of 422 laboratories test results were systematically selected the result showed that the hematology test has lower expected target time than chemistry tests. Dalliance of results is higher and different factors are indicated. Among those factors' KAP level of staff regarding TAT, workload, LIS and power interruption are shown. Based on the findings they recommended to manage the resource interruption and assigning additional personnel in laboratory in the morning time when flow is picking will somehow impact Achieving the recommended TAT (22).

In a study conducted at the Ethiopian Public Health Institute (EPHI), National HIV Molecular Reference Institute, Semi-annual Customer Satisfaction Survey with a retrospective review of records from routine laboratory activities From January 2016 to December 2017 Ababa, Ethiopia. Two surveys were conducted and in the first round clinician satisfaction was 85.7% (36/42). In the second survey, it was 91.9% (34/37). Almost all cases of patient satisfaction (95.0%, 37/39) and 88.4% (38/43) were satisfied with the 1st and 2nd surveys (23).

2.3 Conceptual framework

A conceptual framework for the current study which shows relation between quality indicators in Tikur Anbessa specialized hospital laboratory, Addis Ababa, Ethiopia, 2021-2022.

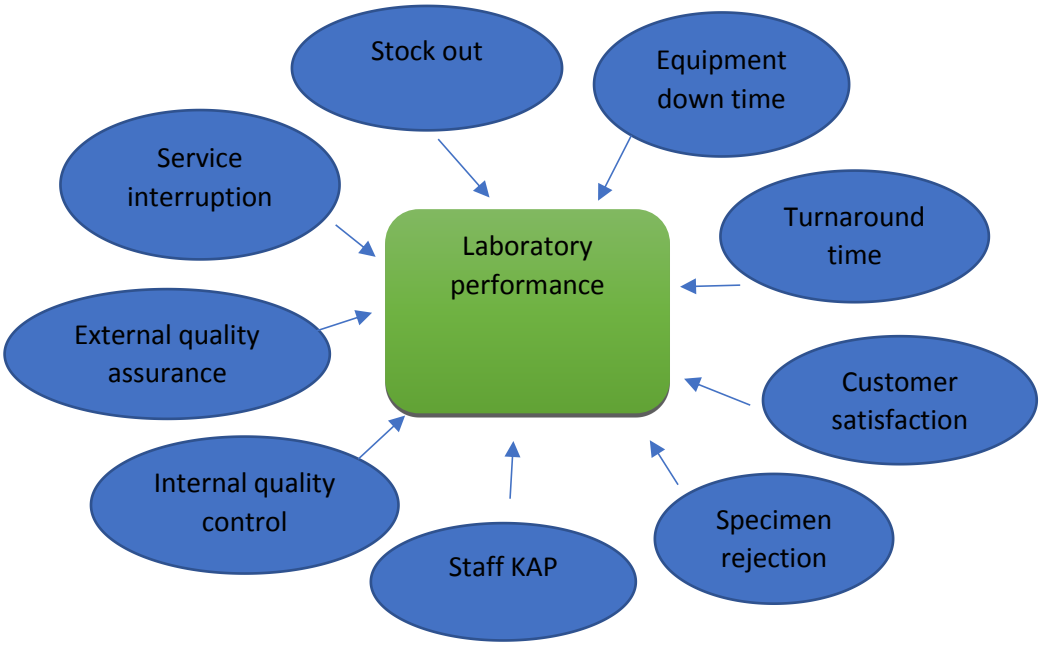


Figure 1: A conceptual framework to **e**valuate medical laboratory performance by using Quality indicators, customer satisfaction and KAP of laboratory professionals at Tikur Anbessa Specialized hospital, Addis Ababa, Ethiopia.

3. Hypothesis

- H1; there is difference between the current laboratory performance at Tikur Anbessa specialized hospital laboratory with the laboratory monthly quality performance target.

4. Objectives

4.1. General objective

The general objective of this study was evaluation of medical laboratory performance by using Quality indicators, customer satisfaction and KAP of laboratory professionals at Tikur Anbessa Specialized hospital, Addis Ababa, Ethiopia.

4.2. Specific objectives

- To evaluate laboratory's performance by using quality indicators in TASH laboratory, Addis Ababa, Ethiopia.
- To assess customer satisfaction on laboratory service in TASH, Addis Ababa, Ethiopia.
- To assess associated factors with client satisfaction on laboratory service.
- To asses' the KAP level of laboratory professionals towards laboratory quality assurance.

5. Materials and methods

5.1 Study area

The study was conducted in Addis Ababa Ethiopia at Tikur Anbessa Specialized Hospital (TASH). It is the largest referral hospital in the country. Among clinical service given in the institution laboratory is the core unit. The hospital laboratory has 2 sample collection areas (for OPD and emergency service), 6 rooms for testing, 1 room for sample processing, 1 room for media preparation, 2 cleaning rooms, 1 meeting hall, 2 administer offices: quality officer and laboratory head and 1 room for mini store. TASH laboratory serve for an average of greater than 120,000 tests per day. Since,May 11, 2022, the lab accredited by Ethiopian Accreditation Service(EAS) with in eight tests in hematology(WBC,RBC,PLT) and chemistry departments(AST,ALT,Urea,Creatinine,Glucose) with the requirements for quality and competence for a defined scope and the operation of a laboratory quality management system, with Accreditation no: M0071.

5.2. Study design and period

A hospital based cross sectional study was conducted from Oct 2021 to March 2022 using qualitative and quantitative data type to evaluate medical laboratory performance by using quality indicators, customer satisfaction and its associated factors at TIKUR ANBESSA Specialized hospital, Addis Ababa, Ethiopia.

5.3. Population

5.3.1. Source population

The source population was all tests done in Tikur Anbessa specialized hospital laboratory Addis Ababa, Ethiopia. Patients visited the lab from all department clinics of Tikur Anbessa specialized hospital Addis Ababa, Ethiopia during the study period. Physician's works in Tikur Anbessa specialized hospital Addis Ababa, Ethiopia.

5.3.2. Study sample

All clinical laboratory departments of Tikur Anbessa specialized hospitals Addis Ababa, Ethiopia. And laboratory staffs available during the study period.

Patients came to the lab during the study period with two or more than visitation days.

Physicians working in selected departments during the study period.

5.4. Inclusion and exclusion criteria

5.4.1 Inclusion criteria

- Routine lab tests having documented standard operating procedure
- All laboratory tests which were, not on and off during the study period of 6 months.
- Laboratory Professionals having a 6-month and more working experience.
- Physicians who are working in departments which require routine laboratory tests (internal medicine, dermatology STI, pathology, gynecology and obstetrics, ENT and head surgery, emergency and critical care, general surgery, neurology, urology, pediatrics)
- Clients having more than or equal two-time laboratory service.

5.4.2 Exclusion criteria

- Physicians who were not on duty during the study period.
- Lab personnel's who were temporarily not on work because of education..

5.5 Variables of study

5.5.1. Dependent variable

- Level of laboratory performance
- Physician Satisfaction
- Patient Satisfaction

5.5.2. Independent variables

- Internal & External quality assurance
- Specimen identification error
- Specimen rejection
- Turn-around time
- Stock out
- Equipment down time
- Service interruption
- KAP level assessment on professionals regarding quality assurance

5.6. Measurement and data collection

5.6.1. Sample size determination

In order to meet our objective, we used different sample size determination: For patients- we use single population proportion formula for calculate the sample size, n= $\frac{(Z_{\alpha/2})^2 P(1-P)}{d^2}$

Confidence level corresponds to a Z-score were 95% – Z score = 1.96, with a margin of error of +/- 5%, we take p=50%. Therefore the calculated sample size become, n =384, to maximize the sample size, we double up this by multiply it with 2. And + 10% contingency, then we get n=845. Method used to collect data is by convenient sampling.

Where; n=sample size, at 95% Confidence interval Z value (α=0.05) =1.96,

P= prevalence which is 0.5% (0.005)

$$\frac{\{(1.96)^2 \times 0.5\,(0.5)\}}{(0.5)^2}$$

For Physician – we involved physicians having above 6 months of working experience in the hospital and currently working in the selected departments stated in the inclusion criteria section. A total of 209 physicians were available in those departments. Of these 179 physicians is who fully meet the above study requirements. And 164 were involved, with 91.6% response rate.

For Laboratory professionals - All laboratory professionals working in TASH during the study period was participated in KAP level assessment. Accordingly, during the assessment time TASH had 45 laboratory professionals, and then we involved all 45, since all medical laboratory technologists currently working on TASH during study period are included with 100% response rate.

For quality indicators- The laboratory performance against the established criteria was assessed using follow-up observational tests that met quality markers over the study period (all tests conducted over a six-month period).

5.6.2. Data collection

Data was collected after permission is granted from the hospital and department. 5 data collectors in addition to the PI involved. Quality indicators (QI) categorized in pre-analytical, analytical, post-analytical phase and data were gathered using standardized format. For the KAP assessment, structured self-administered questioner disseminated to all laboratory technologists working in the laboratory during the study period.

In customer satisfaction survey (patients) visited the lab during study period in the selected two days of each week; a pre-tested, structured interviewer-administered questionnaire was used to collect the data. The questionnaire was written in English, translated into Amharic, and then returned to English to ensure uniformity. The questionnaire includes metrics of satisfaction that

were related to socio-demographic characteristics of the patients and different dimensions of laboratory services such as TAT, availability of requested laboratory tests, convenience of service hours, privacy, respect, courtesy and confidentiality, cleanness of the lab setup, service fee. Each feature of the laboratory service was rated by study participants on a five-point Likert scale (Very Dissatisfied=1 point, Dissatisfied =2 point, Neutral =3 point, Satisfied =4 point, and Very Satisfied = 5 point).

Exit interviews with patients were conducted. Patient satisfaction served as the study's dependent variable. As a result, indicator of the quality of medical care, patient satisfaction with laboratory services is defined as the patient's assessment of the treatment they received from the facility. Turnaround time, Test availability, Cleanness and location of Toilet, Information on payment, Payment amount, hospitality of laboratory professionals to patient, Information while sample collecting. waiting time to get service, confidentiality of lab results, queue process to get service, availability of service providers at their job, queue process to get service,

Physicians working in adult OPD, adult ER, adult ward, pediatric ER, pediatric OPD, pediatric ward, and staff clinic were included, and structured self-administered questioner disseminated to them with question related with quality service attainment. The qualitative data were collected using open ended questions along with the quantitative questionnaires.

5.7. Data quality assurance

In order to reduce the biases during data collection Training was given for data collector and supervisors. And data were gathered by skilled data collectors under the direction of the lead investigators. One month before the study period a pre-test done on 5% of the study population to assess clarity, understand ability and completeness of the questioner for all type of data collection tools. Data checked for completeness and double entered in the EPI data version 3.1 Software. Every day, the acquired data was examined for accuracy. To assure the quality of the data, each activity was controlled.

5.8. Data analysis and interpretation

Data files was prepared in EPI Data and then imported to SPSS for analysis. Statistical analyses performed using SPSS version 23 for client's satisfaction. The overall percentage rate of satisfaction by Likert scale was calculated as n=very satisfied + satisfied divided by very satisfied + satisfied + dissatisfied + very dissatisfied.

≥ mean value (2.6) = satisfied and ≤ mean (2.5) = dissatisfied. The neutral response was added to the dissatisfaction response because we are aiming for improvement and are taking into account every minor flaw.

Performance evaluation will be taken as, for clinical chemistry test TAT less and equal to 5 hour and 30 minute is termed as good performance and TAT greater than this is termed as poor performance. For hematology department test TAT less and equal to 5 hours and 51 minutes is termed as good performance and TAT greater than this is termed as poor performance. For microbiology department for different type of tests with distinct procedure interval, a minimum working time of 1 day up to 10day. TAT less or equal to the seated range for types of tests were termed as good performance, and TAT greater than seated range is termed as poor performance.

Emergency department (ER) department less than 1 hour is termed as good performance and urine & parasitology TAT less or equal to 5 hours is termed as good performance, and TAT greater than 5 hours is termed as poor performance for serology department. To measure the levels of various aspects of Knowledge, Attitude and Practice (KAP), the questionnaire was divided into three distinct modules. In each module, relevant questions asked to the respondents such as in Knowledge module, the emphasis was given to assess the level of knowledge of respondents for quality assurance. The analysis of three modules was done based on Likert scale analysis method. The other type of questions had 3 levels of scores, 0, 1, & 2 representing poor, average and good level of Knowledge, 1 & 0 representing positive, negative Attitude respectively. Participants said to have good knowledge are those who (score >9), average (6-9), low (<6), from the provided 12 questions. Also, to assess the attitude of technologists toward quality activities a five- point Likert scale was used to ascertain the level of agreement or disagreement for the statements (from 1 to 5, 1: strongly disagree, 2; disagree, 3; neutral, 4; agree, and 5; strongly agree). Evaluation is based on Statement which seems influence the testing process.

Data on patient satisfaction were subjected to binary logistic regression. Variables from the bivariate analysis that had a p-value of less than 0.2 were fitted into the multivariate model. The strength of the association was finally evaluated using adjusted odds ratios and their 95% confidence intervals, and variables with a p-value of 0.05 or less were deemed statistically significant.

5.9. Ethical consideration

The study protocol is reviewed, and ethical clearance obtained from the Department of Medical Laboratory Sciences, College of Health Sciences, Addis Ababa University. Support letter was written to the hospital to get permission to undertake the study. Ethical approval official in the hospital write a support letter to the laboratory.

5.10. Dissemination of result

First, the result of this study was submitted and presented to Addis Ababa University College of allied health science department of medical laboratory science. Also, the findings will be communicated and be utilized to improve service at all study sites. Finally it will be published in different journal including Addis Ababa University website. So that it will be accessible for the relevant needs.

5.11 Operational definitions

- Quality indicators: are tools to monitor and control efficiency of the system key segments, while the results collected serve as a basis for implementation of corrective measures and continuous quality improvement.
- KAP assessment is on a quality assurance based on laboratory quality indicators.
- Organ function test includes kidney (Creatinine & urea), liver function (alkaline phosphatase, Alanine transaminase, Aspartate aminotransferase), lipid profile (Total Cholesterol,Triglycerides, High-density lipoprotein cholesterol, Low-density lipoprotein cholesterol).
- Emergence testes are urine ketone and glucose test, CBC tests (Hgb, HCT, WBC, RBC, Platelet) blood film. Stock out is when inventory becomes unavailable and discounting of test for one day and more.
- Participants said to have good knowledge are those who (score >9), average (6-9), low (<6), from the provided 12 questions.
- Respondents were deemed to have a positive attitude if their scores were greater than or equal to the mean value of the sum of attitude-related items.And responders were considered to have a negative attitude if their responses fell below the mean value of the total knowledge assessment questions.
- Satisfied = $\geq$ mean value (2.6) And $\leq$ mean (2.5) = dissatisfied.

6. Result

6.1 description of study participants

In this study we include a total of 45 study participants from the laboratory professionals working in the hospital laboratory for KAP assessment. From the total of respondent, the majority, 28(62.2%) were male.

Most of the staffs have their first degree 27(60%).The majority of the study participants, 17(37.8%) have work experience of above 10 years. Table 1.

6.1.1 Socio Demographic profile of laboratory professionals working in TASH, Addis Ababa, Ethiopia.

Table 1 Socio-demographic characteristics of study participants, Ababa, Ethiopia, 2021-2022.

Variable	Count	percentage (%)
Age		
20-29	16	35.6
30-39	15	33.3
40-49	11	24.4
50-59	3	6.6
Sex		
Female	17	37.8
Male	28	62.2
Education attainment		
First degree	27	60
Masters	15	33.3
PhD fellow	3	6.7
Job description		
Department head	1	2.2
Quality officer	1	2.2
Safety officer	1	2.2
Section head	10	22.2
Laboratory technologist	32	71.1
Year of work experience		
2-4	4	8.9
5-7	14	31.1
8-10	10	32.2
Above 10	17	37.8

For the assessment of patient laboratory satisfaction, a total sample size calculated initially were 843, however, calculation gives an estimate of the minimum sample size, to compensate the non-response rate and to optimize; the number beef up to 900 patients were participated.

Of this 338(37.5%) were between 18-30 years age group. 475(52.8%) were male, regarding educational status 284(31.5%) of them don't read or write. the majority of respondents 548(60.9%) were user of CBHI for the service payment. Of patients participated in the survey the majority 348(38.7) were came from outside AA >50km summarized in table 2.

6.1.2. Socio Demographic profile of study participants.

Table 2: Socio-demographic characteristics of patient participated in this study, Ababa, Ethiopia, 2021-2022.

Variable		
Age	Frequency	Percent
≥17	197	21.9
18-30	338	37.5
31-50	256	17.1
51-60	87	21
Above 60	24	2.6
Total	900	100.0
Gender		
Male	475	52.8
Female	425	47.2
Total	900	100
Education status		
Don't read or write	284	31.5
Read and write only	88	9.8
Primary	150	16.7
Secondary	205	22.8
Higher education and Certified degree	173	19.2
Total	900	100
Payment method		
Out of pocket	290	32.2
CBHI	610	67.8
Total	900	100
Patient resident		
Addis Ababa	238	26.4
Outside AA<50km	314	34.9
Outside AA >50km	348	38.7
Total	900	100

In physician satisfaction on mainly in laboratory service survey 164 were included. majority of the participants were under the age group of 22-34. Among those, 112(68.3%) were Male. Their education status was 114(69.5%) residents, specialist 44(26.8%), and the rests were general practitioners. Physicians who were working in twelve different departments, it is further described in the table under (Table 3)

6.1.3 Socio Demographic profile of physicians participated in the study, Addis Ababa, Ethiopia, Oct - mar (2021-2022).

Table 3: Socio demographic characteristics of physicians participated in this study, Addis Ababa, Ethiopia, Oct - mar 2021-2022.

Variable		
Age	Frequency	Percent
22-34	154	93.9
35 -45	10	6.1
Total	164	100
Gender		
Female	52	31.7
Male	112	68.3
Total	164	100
Education status		
Specialize	44	26.8
Resident	114	69.5
GP	6	3.7
Total	164	100
Department		
Anesthesiology	13	7.9
Cancer treatment	1	0.6
ENT	6	3.7
ER critical care	14	8.5
General surgery	27	16.5
GYN/OBS	24	14.6
Internal medicine	21	12.8
Neurology	14	8.5
Pediatrics	26	15.9
Pediatrics surgery	7	4.3
Staff clinic	6	3.7
Urology	5	3
Total	164	100

6.2 General summarized performance of the Quality indicator

To evaluate and asses the laboratory quality performance in TASH, we used ten quality indicators. As bird view summary, we got a non-compliance performance in almost indicators, except EQA and patient satisfaction compared with the established indicator. The detail is presented in a specific sub sections as followed:

6.2.1. Turnaround time

In this study we had a six-month follow-up data in different sections of the laboratory. The findings shown as, in clinical chemistry a total of 167,669 test analyzed and 133,213(79.5%) tests were meet predefined target TAT, A total of 66,413 tests analyzed in hematology department and among this, 53993(81.3%) meet predefined TAT target. Emergency laboratory from a total of 27101 tests done 19556(72.2%) meet TAT target. Urine & parasitology from a total of 16775 tests performed 10298(61.3%) meet the target TAT. In serology department from 12627 different tests done in six month 8019(63.5%) were target meet rate, the rest 4608(36.45%) don't meet. In contrast the Microbiology department scores a TAT of 3664(96%) tests on time reporting out of 3816 total tests, shown in table 4.

Table 4: **Frequency of TAT target achievement during six months, in six departments in Tikur Anbessa specialized hospital, 2021-2022.**

Department	Assigned Target(85%)	Meet(*f*)	Percent	Don't meet(*f*)	Percent	Total test
Chemistry	142518	133,213	79.5	34456	20.5	167,669
Hematology	56451	53993	81.3	12420	18.7	66,413
Microbiology	3243	3664	96	152	4	3816
ER	23036	19556	72.2	7545	27.8	27101
Urine & parasitology	14259	10298	61.3	6477	38.6	16,775
Serology	10733	8019	63.5	4608	36.45	12627

6.2.2 Stock out

For a medical laboratory to operate effectively, they must have the commodities required for the testing services offered. This was also limited by the availability of reagents, supplies, and equipment this study shown mainly the reagent stock out in each six department. The most frequent reagents stock out were in clinical chemistry which are, OFT, ELE, CK/FE, HgA1C, GGT with (76 days) (31 days), (31 days) , (61 days) and (92 days) respectively. The lowest stock out rate was ELE and CK/FE test reagent. From the total reagent stock out occurred in hematology the highest were CBC (7days), and Retics (2 days), body fluid analysis (2 days).

Among the tests performed in the department of microbiology and interrupted due to stock out laboratory commodities on the study months were in a highest rate of blood culture bottle (182 days), also Indian ink (120 days) and KOH (31 days). Emergency Laboratory were providing eight test panel routinely but in the visited period for six months qualitative urine HCG test were discontinued because of under stock for test kits before resupply and rated as most of the total stock out 85.7%, the rest 14.3% is urine cup stock out. The department of urine and parasitology provides five tests panel routinely, among those during the study period more than half of the tests were interrupted, and those are, urine qualitative HCG, Hpylori Ag, occult test kits, for (182 days) each respectively. The lowest stock out rate were urine cup stock out for (2 days). Serology department from a total of six tests routinely provided, three of them stopped in different period of months, which are RF, WWF, HBV, with a percentage from the total stock out rate, (182 days), (91 days), (59 days) respectively in continual six month. Considering how many tests and for how many times the stock out occurred and service interrupted, urine & parasitology department has the highest rate of 63.3%. The monthly plan was none stock out occurrence, but the data proves otherwise, and recorded as below the target achievement, shown in table 5.

Table 5: Frequency of stock out during six months, in six departments in Tikur Anbessa specialized hospital, 2021-2022.

Department	Expected panel of test volume	Test not available/ Stock out	Stock out in days
Chemistry	OFT LIPID FBS ELE BILL AMYLASE Lipase CKMB UA CK/FE ALB TP fluid analysis HgA1C GGT	OFT ELE CK/FE HgA1C GGT	76 31 31 61 92
Hematology	CBC B/fluid Retics Morphology blood film ESR Bood group	CBC Retics Body fluid analysis	7 2 2
microbiology	urine culture blood culture body fluid culture Sputum culture CSF culture PUS Stool culture vaginal swab gram stain AFB wet smear KOH INDIAN INK	Blood culture Indian Ink KOH	182 120 31

Emergency	CBC Morphology blood film ESR Blood group UAA Stool microscopy HCG	HCG UAA	182 2
Urine&Parasitology analysis	HCG Hpylori Occult UAA Stool microscope	HCG Hpylori Occult UAA	182 182 182 2
Serology	HCV HBV CRP VDRL RF WWF	RF WWF HBV	182 91 59

6.2.3 Internal quality control

In clinical chemistry department internal quality control (IQC) has been performed every day. From fifteen type of test panel performed in six months 167,669(100%) passed the IQC. In hematology, quality control performed continuously only for three month. Which 21.4% pass out of a total of seven test panels in six months, The remaining 52201 (78.6%) were totally unperformed. From thirteen tests panel during a period of six month in microbiology department for none of them performed IQC. ER laboratory has performed and pass IQC in one month for one test 569(2.1%) out of seven tests in six months, the rest 26532(97.9%) is value for which IQC not done, due to a reason unavailability of commercially purchased QC. In both urine & parasitology department and serology, those provides 5, 6 tests respectively failed to do IQC the whole six months. The laboratory quality manual has a plan to achieve IQC 100% in all departments, yet the data were below monthly target plane except in chemistry department it has meet 100% achievement, further explained in table 6.

Table 6: Frequency of internal control during six months, in six departments in Tikur Anbessa specialized hospital, 2021-2022.

Department	IQC Pass	Percent	Not done	Percent	Total (n)
Chemistry	167,669	100	0	0	167,669
Hematology	14212	21.4	52201	78.6	66413
Microbiology	0	0	3816	100	3816
ER	569	2.1	26532	97.9	27101
Urine & parasitology	0	0	16775	100	16775
Serology	0	0	12627	100	12627

6.2.4 External quality assurance

The laboratory participated in inter laboratory comparison EQA periodically. During the study period there have been three round participation's. Chemistry department in round one received EQA's for about 26 different specific tests, among this 22 of them score 100% acceptable (ACC) grade. And the minimum result was 20% acceptance in Gamma glutamyl transferase. In round two from a total 24 EQA tests 20(83.3%) pass 100%. Hematology department evaluated in round one, with 11 single tests, among those 10(90.1%) were pass 100% except Blood parasite detection and identification, only 50% were pass. In second round the former test evaluated and grade elevated to 100%. Among the five evaluated tests in microbiology department on round one, 3(60%) pass 100%. Serology department evaluated with Anti-HIV-1/2 and the result achieved 100% pass. The set target to all departments was a minimum score of 80% pass. Detail discussed in table 7.

Table 7: Summery of external quality assurance done in six months of period, in Tikur Anbessa specialized hospital, 2021-2022.

Chemistry test participated	**Round 1** Result Acceptance rate	**Round 2** Result Acceptance rate	**Hematology test participated**	**Round 1** Acceptance rate
Albumin	100%	100%	Blood film	50%
Alkaline phosphatase	100%	100%	WBC	100%
Amylase	100%	100%	RBC	100%
Aspartate aminotransferase	100%	100%	Hemoglobin	100%
Bilirubin	100%	100%	Hematocrit	100%
Calcium	100%	100%	MCV, MCH, MCHC, RDW, MPV, platelet	100%
Chloride	80%	100%	**Round 2** Result Acceptance rate	
HDL	100%	80%	Blood film	100%
LDL	60%	100%	**Microbiology**	
Total cholesterol	100%	100%	**Round 1** Result Acceptance rate	
Creatin kinase	NA	100%	Primary culture	100%
Creatin	100%	100%	Colony morphology	NE
Gamma glutamyl transferase	20%	100%	Microscopic Examination	100%
Glucose	100%	100%	Identification	66.7%
Iron	100%	80%	Antibiogram	50%
Lactate dehydrogenase	100%	100%	AFB detection	100%
Lipase	80%	60%	AFB grading	NE
Magnesium	100%	80%	**Round 3** Result Acceptance rate	
Phosphorus	100%	100%	Primary culture	100%
Potassium	100%	100%	Colony morphology	0%
Total protein	100%	100%	Microscopic Examination	50%
Sodium	100%	100%	Identification	50%
Triglyceride	100%	100%	Antibiogram	100%
Urea	100%	100%	AFB detection	60%
Uric acid	100%	NE	AFB grading	NE
CK MB	100%	NE	**Serology Round 1** Anti-HIV-1/2	100%

NE; Not Evaluated

Note- rounds indicate time of participation feedback (Round 1 November, Round 2 Jan, Round 3 Mar)

6.2.5. Equipment downtime days (lost time)

Automated instrument downtime is a significant issue in laboratory service. This finding shows which department's downtime as high and somewhat common. To show the lost occurrence due to equipment downtime, lost time is calculated. In clinical chemistry from the total time of operation each day in six months lost time due to equipment down time were 0.5. Also, in hematology, for 7 days equipment was down in consequence of mainly by equipment failure 71.4%, the rest 28.6% were because of reagent stock out and lost time were 4 hours. And ER laboratory 50.5 lost time, in microbiology the blood culture machines down the whole six months and it was the highest number of lost times recorded. The two department's urine & parasitology and serology have no equipment down time in the same six months.

Four departments (100%) achieved the monthly target plan which is < 2 days in month Out of the six departments. The rest two departments fail to meet the target, illustrated in (Table 8).

6.2.6. Service interruption in days

Service interruption at list occurred once to two times in a month. Chemistry department in six months of service 5(33.3%) tests were interrupted for 77(42.3%) days, among those majority were due to reagent stock out 98.7%, the rest 1.3% is due to equipment failure. In hematology, microbiology, and ER departments 3(42.9%), 2(15.4%), 1(12.5%) test and averagely interrupted for 8(4.4%), 4(2.2%) and 182(100%) days respectively. In Urine & parasitology department 3(60%), serology 4(66.7%) test interrupted for 182(100%) days, further detail discussed in table 8. By this, those department tests account the highest level of interruption rate (Table 8).

Table 8: Frequency of equipment downtime and service interruption during six months, in six departments in Tikur Anbessa specialized hospital, 2021-2022.

Department	equipment downtime in days	Down time	Total time	service interruption in days	Percent	Total (days)
Chemistry	1	0.5	4368	77	42.3	182
Hematology	7	4	4368	8	4.4	182
Microbiology	182	4368	4368	4	2.2	182
ER	92	50.5	4368	182	100	182
Urine & parasitology	0	0	4368	182	100	182
Serology	0	0	4368	182	100	182

6.2.7. Number of samples rejected

All departments rejection rate was calculated from each total number of samples received and samples discarded according to the rejection criteria developed under sections. The highest sample rejection rate recorded is in emergency department relatively from the five departments with 780(5.3%). The numbers shown that urine & parasitology, hematology, sections has the lowest sample rejection rate of 116(0.8%) and 416(0.8%) respectively. Monthly target achievement rate were <2% of the total received sample, comparing with this all-department performance is explained in table 9.

6.2.8. Specimen identification error

Number of specimens with identification error calculated from a total sample received in six consequent months for each department. The total number of specimen identification error is in three critical identification error categories (mislabeled, requisition/specimen mismatch, unlabeled specimens). Specimen identification error rate were higher in ER laboratory 79(42.2%) from the total of six departments. Chemistry section 35(18.7%), hematology, microbiology, urine & parasitology, were 27(14.4%), 23(12.3%), 15(8.1%) respectively. The list was serology department with 8(4.3%). The monthly target plan was 0% of the total received sample. (Table 9).

Table 9: percentage of specimen identification error with samples rejected in six departments, in Tikur Anbessa specialized hospital, Oct-mar, (2021-2022).

Department	Total sample	Rejected sample	Percent	specimen identification error	Percent
Chemistry	54,025	635	1.2	35	18.7
Hematology	53,300	416	0.8	27	14.4
Microbiology	3647	44	1.2	23	12.4
ER	14,622	780	5.3	79	42.2
Urine & parasitology	14717	116	0.8	15	8
Serology	11404	344	3	8	4.3

6.3 Physician satisfaction on the laboratory service

Physician satisfaction on the laboratory service assessed with study participants of (n=164), using summarized 12 statements. The statements in this part of the questionnaires were related to the service provided by the laboratory. Participants were asked to rate their level of satisfaction along a five-point Likert scale. Among the study 164 participants, 84(51.2%) of them were dissatisfied with the presence of personnel in bench of work, 29(17.7%) were very satisfied, 32(19.5%) were satisfied, 19(11.6%) were very dissatisfied on this statement.

Regarding receiving results with agreed TAT, the majority of respondents 101(61.6%) were dissatisfied. About attitude and response of the staff 34(20.7%) very satisfied. with the highest number of 74(45.1%) dissatisfied response. Their perception on the Promptness and accuracy of test result 109(66.5%) of participants were dissatisfied. Having needed information on test report majority participants, 102(62.2%) was very satisfied. About On time notification during service interruption dissatisfied respondents were 94(57.3%), 31(18.9%) were satisfied. when they compare the lab with other labs they previously worked on. 37(22.6%) respondents' very satisfied. Among the respondents, n=38(23.2%) very satisfied on how complaints handling. With regards to the communication with lab staff n=85(51.8%) dissatisfied, n=35(21.3%) very satisfied.

Overall satisfaction with the laboratory service, were nearly the same with 37.2% rate further indicated in table 10.

Table 10: Physician satisfaction on the laboratory service in Tikur Anbessa specialized hospital, Addis Ababa, Ethiopia, 2021-2022.

Statements	Very satisfied (%)	Satisfied (%)	Dissatisfied (%)	Very dissatisfied (%)	Total
Presence of personnel at bench of work	29(17.7)	32(19.5)	84(51.2)	19(11.6)	164
Receiving result with agreed TAT	22(13.4)	27(16.5)	101(61.6)	14(8.5)	164
Attitude and response	34(20.7)	29(17.7)	74(45.1)	27(16.5)	164
Promptness and accuracy of test result	11(6.7)	30(18.3)	109(66.5)	14(8.5)	164
Needed info on test report	102(62.2)	41(25)	14(8.5%)	7(4.3)	164
On time notification during service interruption	21(12.8)	31(18.9)	94(57.3)	18(11)	164
Easiness and readability of lab report	34(20.7)	34(20.7)	77(47)	19(11.6)	164
The lab compared with other laboratories	37(22.6)	27(16.5)	64(39)	36(22)	164
Complaints handling	38(23.2)	31(18.9)	83(50.6)	12(7.3)	164
Communication with lab staff	35(21.3)	32(19.5)	85(51.8)	14(8.5)	164
Overall satisfaction with TASH	24(14.6)	41(25)	77(47)	22(13.4)	164
Overall satisfaction with the lab	19(11.6)	42(25.6)	82(50)	21(12.8)	164

6.3.1 Qualitative survey in physicians regarding laboratory service

In a question asked whether the test result report included all the information they need or it need some additional information be included.

Overall, regarding the test menu, many of the participants, especially those from the internal medicine department, suggested going to the lab to start a coagulation profile test. And in body fluid analysis, parameters like cell count with differential, glucose, and protein level are done but not reported properly and timely. Also, culture results and most microbiological tests are not reported on the laboratory information system (I Care), which is highly recommended by physicians working in surgery departments.

Furthermore, despite all departments promptly notifying unavailable tests, physicians have complained that patients were suffering as a result of the frequent returns.

There was also a TAT issue, particularly in those critical emergency department tests like Troponin, and some tests were only done in the morning to 4 a.m. local time, including HgA1c, a lipid profile, and a gene expert, which they asked the lab to accommodate with their manageable work schedule. Then with adjustment all above raised tests are done 24 hour, though lipid profile tests recommended to be performed in morning time it has been connivance to also done if the physician specifically inquire.

The other general question forwarded was would they recommend the hospital to other physicians on services given as a whole. And their answers were almost all the same, which was, unfortunately, No.the major reason for them saying this were the working environment is very tough because of the administration and lack of materials force them to give poor service with outdated equipment's. And most of them complained that due to lack of materials, skilled personnel are very frustrated.

6.4 Patient satisfaction on the laboratory

Table 11 summarizes the patient satisfaction level of Tikur Anbessa specialized hospital laboratory, the evaluating scale has 16 questions other that the socio-demographic request questions. In likert scale, The total mean score for patient satisfaction with TASH's laboratory services was 3.50. The range of the mean level of satisfaction with various laboratory services was 1.67 to 3.95. distance and location of the toilet, waiting room chair at the hospital, and queue to get the service, were with the lowest mean rating with 1.67, 1.83 and 1.92 respectively.

The highest mean ratings of satisfaction were given for the laboratory technician's efforts to maintain the confidentiality of the test results, competency of service provider at the laboratory, availability and accessibility of the staff of the laboratory in workplace during working hours, with mean value of 3.95, 3.64, 3.58 respectively as indicated in (Table 11).

Table 11: patient satisfaction in Tikur Anbessa specialized hospital laboratory, Addis Ababa, Ethiopia, 2021-2022.

Variable	VD	D	S	VS	Mean	SD	Satisfaction
How satisfied are you that the service was delivered on time as promised or on time?	11	25	377	487	3.49	.616	824(96%)
How satisfied are you with the availability and accessibility of the staff's workplace during working hours?	0	43	292	565	3.58	.583	857(95.2%)
How satisfied are you with getting the test ordered in the hospital?	26	231	565	78	2.77	.638	643(71.5%)
How satisfied are you with the information provided by the laboratory staff before and during the delivery?	26	741	100	33	2.16	.513	133(14.8%)
How satisfied are you with the respect and good reception shown by the laboratory experts who provide the service?	4	40	812	44	3.0	.333	856(95.1%)
How satisfied are you with the laboratory professional's efforts to maintain the confidentiality of the test results?	5	3	27	865	3.95	.301	892(99.1)
How satisfied are you the laboratory professionals who provide the service with treating patients equally?	9	12	456	423	3.44	.577	879(97.7%)
How satisfied are you with the service provider at the laboratory?	1	13	295	591	3.64	.516	886(98.5)
How satisfied are you with the queue to get the service on sample collection site?	146	682	67	5	1.92	.503	72(13.4%)
How satisfied are you with our work ethics?	7	55	625	213	3.16	.551	838(93.1%)
How satisfied are you with the reception and courtesy of our guests at the reception desk?	3	596	265	36	2.37	.566	301(33.4%)
How satisfied are you with the communication skills of the laboratory?	4	378	445	73	2.65	.631	518(57.5%)

How satisfied are you with the waiting room chair at the hospital?	258	551	75	16	1.83	.643	91(10.1%)
How satisfied are you with the distance and cleanness of the toilet?	368	475	47	10	1.67	.628	57(6.3%)
How satisfied are the providers who provide information about payment?	9	49	792	50	2.98	.387	842(93.6%)
How satisfied are you with the cost of laboratory service?	20	195	579	106	2.86	.635	685(76.1%)
Overall How satisfied are you with the service provided by the laboratory?	10	101	652	137	3.02	.556	789(87.6%)

VD- very dissatisfied, D-dissatisfied, S-satisfied, VS, very satisfied

6.5 Knowledge, attitude, and practice of the laboratory professionals on quality assurance in Tikur Anbessa specialized hospital

6.5.1 Knowledge on quality assurance in the laboratory

Table 12 shows level of Knowledge on quality assurance in the laboratory among laboratory professionals; participants were asked 15 questions and rated their level of agreement over a five-point Likert scale. A total of 45 respondents participated and asked each statement. For statement that quality assurance involves the pre-analytical, analytical, & post-analytical phases of the laboratory, 25(55.6%) of them strongly agree. In case of statement asked about whether Accreditation is the goal of quality assurance, 20(44.4%) the respondents were agreed.

With regards to the purpose of quality control materials being to calibrate laboratory instruments,12(26.7%) agreed. The majority of respondents 27(60%) agreed with statement that Quality assurance helps medical technologists and the laboratory attain a more accurate and precise result. More than half of the respondents 23(51.1%) strongly agreed on quality control is a day-to-day activity. The majority of respondents (48.9%) strongly agreed that it is every medical technologist's responsibility to achieve quality assurance in the laboratory. According to the overall scoring, 4.4% of the respondents had poor knowledge regarding quality assurance points, 77.8% of respondents had average knowledge, though only 17.8% had good knowledge, summarized in (Table 12).

Table 12: Knowledge assessment on quality assurance in Tikur Anbessa specialized hospital, 2021-2022.

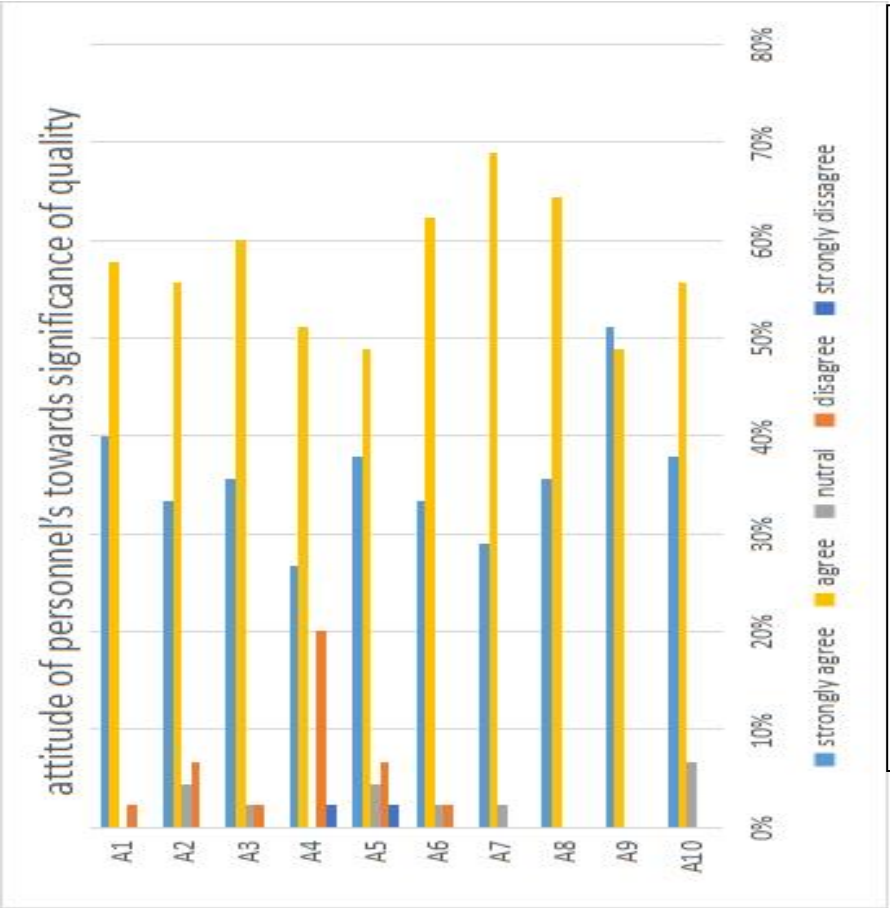
Statement	**Strongly disagree (%)**	**Disagree (%)**	**Neutral (%)**	**Agree (%)**	**Strongly agree (%)**	Total
1.quality assurance involves the pre-analytical, analytical, & post-analytical phases of the laboratory	11.1	0	0	33.3	55.6	45
2. A sensitive test has a low false-negative rate	6.7	13.3	2.2	55.6	22.2	45
3. Accreditation is the goal of quality assurance.	6.7	8.9	13.3	44.4	26.7	45
4. The standard deviation measures the accuracy of a laboratory tests.	4.4	11.1	20	42.2	22.2	45
5. Specificity is a measure of a test's ability to detect positive cases.	6.7	24.4	2.2	40	26.7	45
6. Specimen labeled with only the patient's name is acceptable.	35.6	35.6	4.4	22.2	2.2	45
7. The purpose of quality control materials (e.g., control samples) is to calibrate laboratory instruments.	31.1	33.3	2.2	26.7	6.7	45
8. Voltage fluctuations in a laboratory instrument area systematic and pre-detectable error.	8.9`	11.1	6.7	62.2	11.1	45
9. Quality assurance helps medical technologists and the laboratory attain a more accurate and precise result.	0	0	0	60	40	45
10. A test result is valid if one control value exceeds 3 standard deviations from the mean	28.9	44.4	0	26.7	0	45
11. Quality control is a day-to-day activity.	2.2	2.2	0	44.4	51.1	45
12. It is the responsibility of every medical technologist to attain quality assurance in the laboratory.	2.2	0	0	48.9	48.9	45

6.5.2 Attitude towards the significance of quality assurance in laboratory

Table 13 shows finalized findings on Attitude towards the significance of quality assurance in laboratory which is evaluated by using five-point Likert scale. A total of 45 Participants asked ten statements concerning quality assurance in the laboratory. On a statement asked whether Quality assurance reduces complaints from customers, 26(57.8) respondents agreed. The majority of respondents 25(55.6%) agreed, that quality assurance ensures customer satisfaction and customer loyalty. 27(60%) respondents agreed on a statement that quality assurance prevents error at an early stage. It was discovered that 23 respondents, or 51.1%, agreed with the assertion that using quality standards ensures reliable and accurate outcomes. The results showed that 31 respondents(68.9%) agreed with the statement that quality assurance promotes individual accountability and willingness to put up continued effort. compile in (Table 13).

Table 13: Attitude of the laboratory personnel's towards quality assurance in the laboratory in Tikur Anbessa specialized hospital, Addis Ababa,Ethiopia,2021-2022.

Statement	**Strongly disagree (%)**	**Disagree (%)**	**Neutral (%)**	**Agree (%)**	**Strongly agree (%)**	Total
A1. Quality assurance reduces complaints from customers.	0	2.2	0	57.8	40	45
A2.Quality assurance ensures customer satisfaction and customer loyalty	0	6.7	4.4	55.6	33.3	45
A3. Quality assurance prevents error at an early stage.	0	2.2	2.2	60	35.6	45
A4. The practice of quality standards ensures non-faulty and accurate results	2.2	20	0	51.1	26.7	45
A5. Specificity is a measure of a test's ability to detect positive cases.	2.2	6.7	4.4	48.9	37.8	45
A6. The quality management system in the laboratory cultivates collaboration between workers.	0	2.2	2.2	62.2	33.3	45
A7. Quality assurance encourages personal responsibility and willingness to maintain efforts.	0	0	2.2	68.9	28.9	45
A8. Quality management aids increase the quality of laboratory outputs.	0	0	0	64.4	35.6	45
A9. Quality management system encourages continuous improvement.	0	0	0	48.9	51.1	45
A10. Quality management system cultivates professional growth essentially an advantage to gain new skill and work experience.	0	0	6.7	55.6	37.8	45



A1= QA reduces complaints from customers.
A2= QA ensures customer satisfaction and customer loyalty
A3= practice of QS ensures non-faulty and accurate results
A4= The practice of QS ensures non-faulty and accurate results
A5= Specificity is a measure of a test's ability to detect positive cases.
A6= QM system in the laboratory cultivates collaboration between workers.
A7= QA encourages personal responsibility and willingness to maintain efforts.
A8= QM aids increase the quality of laboratory outputs.
A9= QM system encourages continuous improvement.
A10= QM system cultivates professional growth essentially an advantage to gain new skill and work experience.

Figure 2: Attitude of laboratory professionals on quality assurance in Tikur Anbessa specialized hospital, Addis Ababa, Ethiopia, 2021-2022.

6.5.3 Practices of medical laboratory professionals regarding quality assurance

practices of medical technologist in the laboratory with regarding quality assurance was evaluated as well and the total participants asked fourteen questions and given an option to rate their practice in a four-point Likert scale as written in the table below. The majority respondents practice quality assurance often 36(80%), 5(11.1%) of them sometimes.more than half a respondent 25(55.6%) often comply with the rule and regulation regarding quality assurance. Majority technologists 39(86.7%) identify the patient properly before proceeding to specimen collection. 37(82.2%) often prepare reagents and dilutions readily before the actual examination and testing.

In collecting the specimen at the right container, most of the respondents often practice this 38(84.4%), majority 41(91.1%) often uses the right preservatives or anticoagulants for the specimen and store it at the right storage condition.

Regarding TAT 23(51.1%) personnel's often takes into consideration. 35(77.8%) of the respondents often check whether the reagent expired or contaminated. Among the main practice performed in laboratory one is calibrating the machine, 20(44.4%) performs often, even though 8(17.8%) never have done It. 19(42.2%) often has a habit of reporting critical results attained immediately. The majority, 30(66.7%) often make sure that the test result interpreted correctly, contracted in table 14.

Table 14: Practice of the laboratory professionals in routine activity in the laboratory considering quality assurance In Tikur Anbessa specialized hospital, Addis Ababa, Ethiopia, 2021-2022.

Variables	**Never (%)**	**Rarely (%)**	**Sometimes (%)**	**Often (%)**	**Total**
1. How frequently quality assurance is used	2.2	6.7	11.1	80	45
2. Complying with the rule and regulations regarding quality assurance.	0	4.4	40	55.6	45
3. Identify the patient properly before proceeding to specimen collection.	2.2	2.2	8.9	86.7	45
4. Preparing reagents and dilutions readily before the actual examination and testing.	0	4.4	13.3	82.2	45
5. Collecting specimen at the right container.	6.7	0	8.9	84.4	45
6. Using the right preservatives or anticoagulants for the specimen.	2.2	2.2	4.4	91.1	45
7. Storing specimen at the right storage condition (temperature).	0	0	8.9	91.1	45
8. Taking into consideration the TAT (turnaround time).	0	4.4	44.4	51.1	45
9. Specimen get contaminated due to error in the laboratory.	13.3	44.4	40	2.2	45
10. Repeating the test due to error in the machine.	4.4	42.2	28.9	24.4	45
11. Checking reagents wither expired or contaminated.	0	11.1	11.1	77.8	45
12. Calibrating the Machine.	17.8	17.8	20	44.4	45

13. Ensuring tests result are interpreted correctly.	13.3	17.8	26.7	42.2	45
14. Ensuring tests result are interpreted correctly.	0	4.4	28.9	66.7	45

6.6. Associated factors with patient satisfaction on laboratory service.

To identify the association factors with patients satisfaction, bivariate logistic regression was used for possible satisfactory variables, those variables with a p-value of < 0.20, A multinomial logistic regression model was used to analyze the patient's socio-demographic data, which included education status, income level, and payment method.

The results showed that income level had a statistically significant association with the overall satisfaction of patients with clinical laboratory services.

Table 15: association of socio-demographic characteristics and overall satisfaction in TIKUR ANBESSA specialized hospital, Addis Ababa, 2021-2022.

Variable	Satisfied	Need improvement	COR(95%CI)	AOR(95%CI)	P-value
Education status					
Don't read or write	251	33	.775(.413-1.455)	1.668(.753-3.692)	
Read and write only	85	3	2.887(.818-10.190)	.711(.180-2.816)	
1-7	132	18	.747(.367-1.523)	1.720(.737-4.012)	
8-12	170	35	.495(.264-.929)	2.812(1.317-6.002)	.008
Higher education	157	16	1	1	
Income level					
None	116	38	.572(.279-1.173)	1.264(.526-3.038)	
Daily income	106	7	2.839(1.063-7.584)	.287(.094-.882)	
Farmer	76	3	4.750(1.284-17.571)	.194(.047-.799)	.047
500-1500	97	6	3.031(1.083-8.487)	.229(.072-.726)	
1501-3500	181	25	1.358(.644-2.859)	.470(.195-1.138)	
3501-5000	155	14	2.076(.910-4.733)	.341(.136-.853)	
Above	64	12	1	1	
Payment method					
Out of pocket	268	22	3.553(1.700-7426)	.395(.172-.909)	.172
CBHI	527	83	1	1	

7. Discussion

Performance indicators (PIs) play a crucial role as they allow for performance assessment (24). Test turnaround time (TAT) is one of the main quality indicators in the laboratory what we have assessed. Evaluating the monthly TAT performance has a high impact on assuring the service rendering. Accordingly, we tried to assess the quality indicator performance of using the six different departments of TASH .

In clinical chemistry a total of 167,669 tests analyzed and 133,213(79.5%) tests were meet predefined target TAT. Hematology department from a total of 66,413 tests 53993(81.3%) meet predefined TAT target. Whereas the study conducted in Addis Ababa armed force comprehensive specialized hospital from the established TAT for hematology test, only 37/169 (21.9%) met the target. And for clinical chemistry tests, only 41/253(16.2%) meet the target time, the observed discrepancy may be due the sample size difference (11). Although TAT achievement plan was ≥85%, Microbiology has the highest level of attainment with 96% rate This performance is comparable to report on a study of routine outpatient test with a TAT of 5.5 hours, where acceptable performance was very good performance above the set benchmark as only 1.02% of the results reported after the acceptable TAT (4). It might be due to the high workload that our finding showed a total of laboratory tests done in TASH departments, results were not released within the established TAT.

Also ensuring the appropriate stock level in the lab is very important work. The performance of inventory management for laboratory commodities may be evaluated by stock level. This study aims to assess this. For six months qualitative urine HCG test were discontinued because of under stock for test kit before resupply. In contrary, the average duration of stock out was 8.5 days in the study conducted in inventory management performance for laboratory commodities within public hospitals in Jimma zone, Oromia, Ethiopia by Befekadu A, and colleague (18). There is a need for uninterrupted supplies of essential test supply in order to reduce occurrence of longer stock out. Since, TASH's inventory system involves the pharmacist they need to be trained in commodities forecasting.

Quality control is a crucial component of laboratory management that laboratory directors take very seriously since it helps to ensure that we deliver accurate result to clinical management. Laboratory facilities are a crucial component of high-quality health care.

All laboratory activities could be mistake-prone. Unfortunately this study shown than almost all of the laboratory departments(83.3%) pass a problem that needs to be fixed before the results are released. This is mainly due to unavailability of commercially purchased quality control. This leads to an inconsistency in quality control performance (25).

The vast majority of mistakes in laboratory medicine today appear to be made in the pre-analytical stage of the testing procedure. Accurate patient identification and adequate labeling of blood collection tubes are essential steps in preventing diagnostic errors and poor patient care. In this study completeness of the test requests sent to the laboratory monitored, of the 151,715 specimens collected in 2021-2022 for continual six month 187 (0.12%) were identified as having patient identification errors. compared with a study at medical center in Taiwan Ning HC, et'al, 1023 (0.051%) were identified as having patient identification errors (26). considering the number total sample size and the study period both taken, the rate of this study consider to be higher.Though, since the higher rate 780(5.3%) were recorded in Emergency department where most of the requests are paper based, this can be avoided by using electronic identification systems in combination with automated sample labeling like other sections.

Effective laboratory management requires a realistic and precise estimate of the workload. In order to enhance performance in the laboratory, sufficient manpower and an optimized workload are necessary. Also in this study, there is some relation among the indicators; the TAT achievement is indicated to be higher in departments with a relatively lower number of tests performed.

This study assesses knowledge, attitudes, and practices of medical technologists on laboratory quality assurance programs in TASH with a survey questioner. Evaluating the KAP level will help to identify the gaps in manpower competency for addressing standard quality performance by continual refreshment training's.

This study revealed that 55.6% of the respondents strongly agreed and 33.3% agreed that quality assurance is involved in the three phases of the laboratory. As stated by Agarwal (2014), Quality assurance is an important management approach in the stages of the laboratory that involve patient identification, test ordering, specimen collection, testing, and transportation. However 44.4% agreed and 28.9% strongly agreed that accreditation is the goal of quality assurance.

The objective of quality assurance is to guarantee quality and reliable service, and at the same time, construct certainty in assembly quality requirements (ISO 9001's definition) (27).

Based on the overall KAP score regarding quality assurance 15.6% of the respondents had poor knowledge 71.1% of respondents had average knowledge, though only 13.3% had good knowledge. Based on the personals ideas regarding the importance and benefit quality assurance in the lab and according to the findings about 97.8% of them believed that customer satisfaction can be increased with quality assurance.

This also indicated in a study in Davao City by Danise D, and colleagues, with 94% agrees with the concept that a quality management system must be used to oversee all crucial activities involved in providing health services. This system must include a series of interrelated procedures that are designed to screen, assess, and improve the quality of treatment provided to patients (30).

The overall patient satisfaction level with clinical laboratory of TASH was 66.2%. This level of satisfaction is higher than result 59.7% reported by Abera RG, etal, in 2017 (28). However, direct comparison among these findings was difficult due to the use of different questioner and sample size. Subsequent studies needed using a consistent measurement for the lab in order to perceive the gaps continuously.

Overall physician satisfaction level among 164 physicians who participated in the survey, 37.2% (n = 23) were satisfied with the overall laboratory service. which is in line with study in Rwanda that showed nearly the same results obtained on Among 462 physicians who participated in the survey, 36.2% (n = 167) were satisfied with the overall laboratory service. (29).

In patient survey the higher rate of satisfaction was observed on the confidentiality of the test results mean value = (3.95), competency of the service provider at the laboratory mean value = (3.64) and personnel availability and accessibility of the workplace during working hours mean value = (3.58). Although the lower satisfaction rate were in distance and cleanness of the toilet mean value (1.67), waiting room chair mean value (1.83) and the queue to get the service mean value(1.92).

But, laboratory personnel communication skill (AOR=2.173(1.346-3.510); P-value = <.001, and manner of laboratory personnel's (AOR=.265(.119-.589) p-value <.001 were highly associated with the overall level of patient satisfaction in clinical laboratory services.

This is somehow related with a study done in Sri Lanka, with Higher rate of patient satisfaction on the cleanliness of facility, laboratory professional physical appearance, and confidentiality. Lower rate was availability of service provider explained about diagnostic test during sample collection and latrine accessibility and comfort (31).

7.1 Strength and limitation

In this study, relatively many quality indicators were used to evaluate laboratory performance. It has included twelve quality indicators. And the study period is large enough.

Due to the vast number of clients and departments, patients interviewed at the point of exit for one time. This would have been much preferred if there was a follow up interview to show improvement level.

8. Conclusion and Recommendation

8.1 conclusion

Laboratory quality indicators are underpinning and basic for the quality improvement in medical laboratory service, as their intent is to detect how well the laboratory process are working, allow for comparisons between the sated goal entities that encourage shared learning, enable assessments of improvement over time, and improve the efficiency and effectiveness of our targeted value. At large can help us to satisfy our customers.

Accordingly, this study evaluated the hospital laboratory performance. which shows that, TAT did not comply with the agreed time, as the objective was to generate at least 85% of the test results within the set time interval. and, also, fail to maintain customer satisfaction levels above 80% with laboratory service.

In addition, we did not achieve a plan to maintain the specimen rejection rate below 2% as an indicator of adequate training of personnel in specimen collection, transportation, and handling. The online system has a lower rate of specimen identification error than the paper-based method.

External quality assessments are used to verify personnel competence and method appropriateness. And the results showed that a much higher number was achieved than the set target of a minimum score of 80%. In the knowledge assessment, more than half of respondents had average knowledge.

In achieving fewer service interruption days, the majority of the departments have had good performances. Adhering to the laboratory quality management system has a significant impact on elevating the achievement plan.

The results of the study show that medical laboratory personnel needs training programs to get over the obstacles that have been found, which will make it easier to execute dependable medical laboratory services based on the ISO 15189 standard in the future.

It needs to be taken into account that the study was done a few months before the hospital laboratory implemented several adjustments and improvements that could have an impact on the results of the current study, such as, TAT, IQC, Stock out, improved communication with physicians.

8.2 Recommendation

The laboratory evaluation techniques described a comprehensive examination of the ability of TASH Laboratory to fulfill their mission requirements. Implementation of the techniques requires considerable managerial program, and technical expertise and a degree of common sense. The techniques employed conscientiously will confirm the ability or inability of TASH laboratory to perform satisfactorily. To this investigator knowledge, utilization of a combination of the above techniques has not failed to validate the status (satisfactory or unsatisfactory) of performance correctly.

One of the main measures of high-quality medical care and services is increasing patient satisfaction. In light of the results of this investigation, we suggest Continual evaluation of health services and additional research into other aspects of patient satisfaction, such as facility design, water and medication supply.

It is crucial to give managers on-the-job training to the professionals in the facility in order to increase their talent for improving patients' satisfaction. This is necessary to accommodate lab experts who love science and research but prefer to have little-to-no involvement with patients. And to advance their knowledge continually.

Additionally, ongoing advancements in science, technology, and organizational structure enhance knowledge and operational practices to establish better clinical approaches, calls for the discovery and usage of additional new quality assurance tools to validate and keep track of performance. In this situation, laboratory workers must be ready to handle both present and upcoming obstacles. Analyzing and evaluating the Monthly quality indicators in light of laboratory medicine's contribution to meeting clinical needs is important. And the establishment of a system for actively reporting and studying unsatisfactory incidents.

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Annexes

Annex I Information sheet in English Version

Title of the Research Project: Evaluation of medical laboratory performance by using Quality indicators, customer satisfaction and KAP of laboratory professionals at Tikur Anbessa Specialized hospital, Addis Ababa, Ethiopia.

Principal Investigator: Mekdelawit Birhanu (BSc, MSc candidate)

Name of the Organization: TASH, Addis Ababa University College of Health Sciences School of Medicine Department of laboratory.

Introduction

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

Purpose of the Research Project

We are asking you to take part in this study because we will try to evaluation of medical laboratory performance by using Quality indicators, customer satisfaction and KAP of laboratory professionals at Tikur Anbessa Specialized hospital, Addis Ababa, Ethiopia.

Confidentiality

Since there is no patient clinical history or personal information is reviewed, no need of confidentiality.

Potential benefits to subjects and/or to the society

There will not be any payment for your participation in this research study as compensation. However, based on the result your hospital will have an opportunity to have a much feedback on the essential gaps and also acknowledgment on the strong quality during project. In addition, participating in this study is adding reference information in the benefit of society beneficial

Participation and Withdrawal from the Study

The participation is voluntary and you have the right not to participate in this study. You may withdraw at any time and place without consequences of any kind.

Annex II

Informed consent form in English version

I had been informed that the objective of this study is to Evaluation of medical laboratory performance by using Quality indicators, customer satisfaction and KAP of laboratory professionals at Tikur Anbessa Specialized hospital, Addis Ababa, Ethiopia. The results of this study have an importance to have a clear insight in government hospital, and to be used as an input for the future development of strategies or guidelines for evaluating laboratory performance in Ethiopia. Principal investigator requested me to participate in the study that would require my willingness to provide the required data. Therefore, with full understanding of the importance of the study, I agreed voluntarily to provide the requested information.

I_____ hereby give my consent for providing the requested information.

Signature: _____ Date_____

Annex III

Informed consent Amharic version

ተገልጋዩን ስለአጠቃላይ አገልግሎት መጠየቂያ ፎርም

የተሳታፊዎች ስምምነት ማረጋገጫ

የሚስጥር ቁጥር ----------

የህክምናው ማዕከል ስም ----------

ከላይ የተጠቀሰው ተሳታፊ **በ ጥቁር አንበሳ ስፔሻላይዝድ ህክምና ማዕከል የላቦራቶሪ አገልግሎት በተመለከተ እና ተያያዥ ነገሮች** በሚለው ጥናት ላይ በቂ ገለጻ ተደርጎልኛል፡፡ ለጥናቱም የሚያስፈልገውን ቃለ መጠይቅ እንድሞላ ወይም እንደምጠየቅ ተገልጾልኛል፡፡የጥናቱንም አላማዎች በደንብ ተረድቻለሁ፡፡በቃለ መጠይቁ ላይ የገለጽኳቸው መረጃዎች በሙሉ በሚስጥር የተጠበቁ እንደሚሆኑ ተነግሮኛል፡፡ በጥናቱ ላይ ያለመሳተፍ ና ማንኛዉንም መረጃ ያለመየስጠት እንዲሁም በማንኛዉም ጊዜ ከጥናቱ ራስን ማግለል መብቴ የተጠበቀ እንደሆነተነግሮኛል፡፡

ስለዚህ ለዚህ ጥናት መረጃ ና የስምምነት ቃሌን የሰጠሁት ባጠቃላይ ሁኔታዉን በመረዳትና በፍጹም ፍቃደኝነት ነው፡፡ በተጨማሪም ጥያቄ ለመጠየቅ ተፈቅዶልኝ ለማወቅ የፈለኩትን ያህል ማብራሪያ አግኝቻለሁ፡፡ የዚህ ጥናት ተሳታፊ በመሆኔ የማገኘው የ ገንዘብ ጥቅም እንደሌለ ተረድቻለሁ፡፡

በአጠቃላይ እኔ ከላይ በመተማመኛ ቅፅ የተጠቀሱትን ሁሉም በሚገባ ና በተረጋጋ መንፈስ አንብቤዋለሁኝ፡፡ ስለዚህ በዚህ ጥናት ለመሳተፍ ፍቃደኛ መሆኔን በፊርማዬ አረጋግጣለሁ፡፡

ፊረማ ---------- ቀን -------/-----/----------

(.የስምምነት ቅፁን ማንበብ ለማይችሉ ተሳታፊዎች)

የአማካሪ ነርስ ስም ---------- ፊርማ---------- ቀን----------

Annex IV

Patent satisfaction questioner

ክፍል 1 የማ ህበራዊ ጉዳይ መ ረጃ መ ጠ የቂ ያ ቅፅ

እባክዎ በሚሰጡት መልስ ቁጥር ላይ ያክብቡ

የቃለ-መጠይቅ ጥያቄዎች	አማራጭ መልስ በኮድ	ተጨማሪ ሃሳብ ካለ
1. እድሜ ህ (ሽ) ስንት ነው?	1. 18 – 30 3. 41 – 50 2. 31 - 40 4. 51 – 60 5. ከ 60 በላይ	
2. ፆታ	1. ወንድ 2 ሴ ት	
3. የትም ህርት ደረጃ ዎ ም ን ያህል ነው?	1.መፃፍና ማንበብ የማይችል (ትችል) 2. መፃፍና ማንበብ ብቻ 3. ከ1 እስከ 7ኛ ክፍል 4. ከ8 እስከ 12ኛ ክፍል 5.ቴ.ሙ ያ/ኮሌ ጅ ዲ ፕ ሎ ማ/ ዩኒቨርሲ ቲ	
4. የጋብ ቻ ሁ ኔታ ዎ ም ንድነው?	1. ያላገባ/ች 2. ያገባ/ች 3. የፈታ/ች 4. ባል ሚ ስት የሞ ተበት/ባት	
5. ወ ርሃዊ ገቢዎ በአማ ካኝ ስንት ነው?	----------ብር	
6. በአሁን ሳዓት የት ነው የሚ ኖሩት?	1. አ/አበባ ው ስጥ 2. ከአ/አበባ ዉ ጪ (<=50km) 3. ከአ/አበባ ዉጪ (>50Km)	
7. አገለግ ሎ ት የሚ ያገኙ በት ክፍል	1. ተኝቶ ታ ካሚ ክፍል 2. ሰራ ተ ኞ ች መ ታ ከሚ ይ ክፍል 3. ተመ ላላሽ ታ ካሚ ክፍል 4. ድንገተኛ ክፍል	

ክፍል 2 ተገልጋዩን ስለአጠ ቃ ላይ አገልግሎ ት መ ጠ የቂያ ፎርም		
እባክዎ በሆስፒታሉ ባገኙት አገልግሎት እርካታ መጠን ለሚሰጡት መልስ ቁጥር ላይ ያክብቡ በጣም እረክቻለሁ- (5) እረክቻለሁ– (4) መካከለኛ – (3) አልረካሁም – (2) በጣም አልረካሁም –(1)		
1. አገልግሎቱ ቃል በተገባው ወይም በተቀመጠው የማጠቃለያ ሰአት ውስጥ መድረስ ምን ያህል ረክተዋል?	1. 2. 3. 4. 5.	
2. የላቦራቶሪ ክፍሉ ሰራተኞች በስራ ቦታ በስራ ሰአት መገኘት እና ተደራሽነት ላይ ምን ያህል ረክተዋል?	1. 2. 3. 4. 5.	
3. በዚህ ህክምና ማዕከል የታዘዙትን ምርመራዎች ከማግኘት አንፃር ም ን ያህል ረክተዋል?	1. 2. 3. 4. 5.	
4. የላቦራቶሪው ባለሙያዎች ናሙና ከመስጠት በፊትና በመስጠት ላይ በሚ ያደርሱት መረጃ ምን ያህል ረክተዋል?	1. 2. 3. 4. 5.	
5.አገልግሎቱን የሚሰጡት የላብራቶሪ ባለሞ ያዎች በሚያሳዩት ከበሬታና ጥሩ አቀባበል ምን ያህል ረክተዋል?	1. 2. 3. 4. 5.	
6. የላቦራቶሪው ባለሙያው የምርመራውን ውጤት ሚስጥራዊነት ለመጠበቅ በሚያደርገው ጥረት ምን ያህል ረክተዋል?	1. 2. 3. 4. 5.	
7. አገልግሎቱን የሚሰጡት የላብራቶሪ ባለሞያዎች ታካሚን በእኩል ማስተናገድ ላይ ምን ያህል ረክተዋል?	1. 2. 3. 4. 5.	
8. በላቦራቶሪ የናሙና ሰብሳቢው ወይም በአገልግሎት ሰጪው ብቃት ምን ያህል ረክተዋል?	1. 2. 3. 4. 5.	
9. አገልግሎቱን ለማግኘት በሚኖረው ወረፋ ምን ያህል ረክተዋል?	1. 2. 3. 4. 5.	
10. በባለሙያዎቻችን የስራ ስነ-ምግባር ምን ያህል ረክተዋል?	1. 2. 3. 4. 5.	

11. የ እንግዳ መ ቀበያ መስኮት ላይ ባሉ ባለሙ ያዎቻችን አቀባበል እና ትህትና ምን ያህል ረክተዋል?	1. 2. 3. 4. 5.	
12. በላቦራቶሪው ባለሙ ያ የመግባባት ክህሎት ም ን ያህል ረክተዋል?	1. 2. 3. 4. 5.	
13. በሆስፒታሉ ተራ መጠበቂያ መቀመጫ ወንበር መጠን እና ንፅህና ምን ያህል ረክተዋል?	1. 2. 3. 4. 5.	
14. በመፀዳጃ ቤቱ ርቀትና የቦታው ንፅህና ምን ያህል ረክተዋል?	1. 2. 3. 4. 5.	
15. ክፍያን በተመለከተ መረጃ የሚሰጡ ባለሙያዎች የመርዳት ተነሳሽነት ምን ያህል ረክተዋል?	1. 2. 3. 4. 5.	
16. በላቦራቶሪ የአገልግሎት ክፍያ ዋጋ ምን ያህል ረክተዋል?	1. 2. 3. 4. 5.	
17. በአጠቃ ላይ በማዕከሉ ላቦራቶሪ በተሰጥዎት አገልግሎት ምን ያህል ረክተዋል?	1. 2. 3. 4. 5.	

የቃለ-መ ጠ ይቅ ጥያቄዎች ለመመለስ፤ለመሙላት ላደረጋችሁልኝ እገዛና ጊዜያችሁን ሰጥታችሁ ስለተባበራችሁኝ እጅግ በጣም አመሰግናለሁ::

Annex V

Physician-satisfaction questions

1.Age	1. 24 – 34 3. 46 – 56 2. 35 - 45 4. 57 - 60 5. Over 60	
2.Sex	1. Female 2. Male	
3. educational status	1. GP 2. Resident 3. Specialize	
4. Department working	----------	
5. working experience	----------	

*Please rate the following questions by circling the number that best describes your experience.

Very Satisfied – 5 Satisfied – 4 neutral – 3 Dissatisfied – 2 very Dissatisfied – 1

1. How would you rate the presence of lab personnel at bench work?	1. 2. 3. 4. 5.	
2. How satisfied are you receiving laboratory reports within agreed TAT?	1. 2. 3. 4. 5.	
3. Attitude & Response of our Staff During your Visit at our Work place?	1. 2. 3. 4. 5.	
4. Perception on promptness and accuracy in reporting laboratory test results?	1. 2. 3. 4. 5.	
5. How satisfied are you with the ease of use and readability of the lab report?	1. 2. 3. 4. 5.	
6. having all needed information in the result? [yes/no] •If not, which additional information should, in your opinion, be included in the result report?	1. 2. 3. 4. 5.	
7. On time notification during service interruption?	1. 2. 3. 4. 5.	
8. How do you rate the service compared to other laboratories where you have worked?	1. 2. 3. 4. 5.	

9. Were your complaints handled effectively?	1. 2. 3. 4. 5.	
10. How satisfied are you with the communication between you and the laboratory staff? If not satisfied: could you, please be specific the departments or place?	1. 2. 3. 4. 5.	
11. Overall satisfaction with this hospital?	1. 2. 3. 4. 5.	
12. Overall satisfaction with this laboratory service.	1. 2. 3. 4. 5.	

Annex VI

Quality indicators tracking format

Section_____ Month_____ Year_____

Daily quality indicators tracking format

Section_____ Type of Test_____ Established TAT_____ Month_____ Year_____

Indicate if condition present or supply data for each day indicator is monitored.																															
Day		**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**	**20**	**21**	**22**	**23**	**24**	**25**	**26**	**27**	**28**	**29**	**30**	**31**
Stock out Indicate Item Affected																															
Test Volume																															
No of staff																															
IQC	Pass																														
	Fail																														
EQA	Pass																														
	Fail																														
No of Sample Rejected																															
Customer Satisfaction & Complaints (patient, physician)																															
Equipment down time																															
Service Interruption																															
Specimen identification error																															
Critical value reporting																															

Reviewed By _____ Signature _____ Date _____

Annex VII

KAP assessment on quality indicators

Part 1 Demographic questions

1. Age	1.20-29 years 2.30-39 years 3.40-49 years 4.50-59 years 5.above 60 years	
2. Sex	1. female 2. Male	
3. Educational attainment	1. diploma 2. First Degree 3. masters 4. PhD fellow	
4.Working experience	1. less than 2 years 2. 2 – 4 years 3. 5 – 7 years 4. 8_ 10 years 5. above 10 years	
5. Responsibility of work?	1. department head 2. Quality officer 3. safety officer 4. section head 5. Laboratory technologist	

Part 2 Knowledge on Quality Assurance in the Laboratory

Questioner	Strongly disagree	disagree	neutral	agree	Strongly agree
1. quality assurance involves the pre analytical, analytical, and post-analytical phases of the laboratory					
2. A sensitive test has a low false-negative rate					
3. Accreditation is the goal of quality assurance.					
4.The standard deviation measures the accuracy of a laboratory test					
5. Specificity is a measure of a test's ability to detect positive cases.					
6. Specimen labeled with only the patient's name is acceptable.					
7. The purpose of quality control materials (e.g., control samples) is to calibrate laboratory instruments.					
8. Voltage fluctuations in a laboratory instrument area systematic and predictable error.					

9. Quality assurance helps medical technologists and the laboratory attain a more accurate and precise result.					
10. A test result is valid if one control value exceeds 3 standard deviations from the mean.					
11. Quality control is a day-to-day activity.					
12. It is the responsibility of every medical technologist to attain quality assurance in the laboratory.					

Part 3 Attitude towards the Significance of Quality Assurance in the Laboratory

Statement	Strongly disagree	disagree	Neutral	Agree	Strongly agree
1. Quality assurance reduces complaints from customers.					
2.Quality assurance ensures customer satisfaction and customer loyalty					
3. Quality assurance prevents error at an early stage					
4. The practice of quality standards ensures non-faulty and accurate results					
5. Quality assurance results in efficient laboratory performance,					
6. The quality management system in the laboratory cultivates collaboration between workers.					
7. Quality assurance encourages personal responsibility and willingness to maintain efforts.					
8.Quality management aids increase the quality of laboratory outputs.					
9. Quality management system encourages continuous improvement.					
10. Quality management system cultivates professional growth essentially an advantage to gain new skill and work experience.					

Part 4 Practices questions of Medical Technologists inside the Laboratory

Questioner	Never	Rarely	Sometimes	Often
1. How often does your section practice quality assurance?				
2. How often do you comply with the rule and regulations regarding quality assurance?				
3. How often do you identify the patient properly before proceeding to specimen collection?				
4. How often are your reagents and dilutions readily prepared before the actual examination and testing?				
5. How often do you collect the specimen at the right container?				
6. How often do you use the right preservatives or anticoagulants for the specimen?				
7. How often do you store your specimen at the right storage condition? (temperature)				
8. How often do you always take into consideration the TAT (turnaround time)				
9. How often does your specimen get contaminated due to error in the laboratory?				
10. How often do you repeat the test due to error in the machine?				
11. How often do you check if you have expired or contaminated reagents?				
12. How often do you calibrate the machine?				
13. How often do you record and report the critical results attained immediately?				
14. How often do you ensure that the tests result is interpreted correctly?				

Declaration

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

M.Sc. Candidate: Mekdelawit Birhanu (B.Sc.)

Signature: _____

Date of submission: _____

This thesis has been submitted with approval as advisors.

Advisor: Abay Sisay (MSc, PhD fellow)

Signature: _____

Date: _____

Place: Addis Ababa, Ethiopia.