ADDIS ABABA UNIVERSITY

COLLEGE OF HEALTH SCIENCES

DEPARTMENT OF MEDICAL LABORATORY SCIENCES

Assessment of extra-analytical errors andassociated factors in Medical Laboratories of Government Hospitals in Addis Ababa, Ethiopia

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This is to recognize that the thesis prepared by cheru Degfe, entitled: "Assessment of extra analytical errors and associated factors in Medical Laboratories of Public Hospitals in Addis Ababa, Ethiopia" fulfills with the requirements of the University, and meets the accepted standards with respect to originality and quality**.**

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Abbreviations

AAU Addis Ababa University

AHB Addis Ababa Health Bureau

AIDS Acquired immune deficiency syndrome

AOR Adjusted Odds Ratio

EPHI Ethiopian public health institute

FMOH Federal Ministry of Health

HIV Human immune deficiency viruses

IOM Institute of medicine

IQC Internal quality control

LRFs Laboratory request forms

LQMS Laboratory Quality Management System

SOP Standard Operation Procedure

SPSS Statistical Package for Social Sciences

SRS Specimen Rejection Rate

QC Quality control

QIs Quality indictors

TAT Turnaround time

TQM Total Quality Management

UOG University of Gondar

US United States of America

WHO World Health Organization

Abstract

Background: Laboratory services are the back bone of current healthcare services, which is articulated in different phases that span pre analytical phase, analytical phase,and post analytical phases. Error can be any defect through the entire process of Laboratory services, from ordering request to reporting result. It may have harmful effects on patient managing, by contributing to wrong treatment, an increase in lengths of hospital stay, and unhappiness with healthcare services. Therefore, this study aimed to Assessment of extra analytical errors and associated factors in Medical Laboratories of Public Hospitals in Addis Ababa, Ethiopia

Objective: To Assess extra analytical errors and associated factors in Medical Laboratories of Public Hospitals in Addis Ababa, Ethiopia

Methods: A hospital based cross-sectional study was conducted inMedical Laboratories of Public Hospitals in Addis Ababafrom January-April 2020 to assess extra analytical errors and associated factors in medical laboratories.Data were collected from2401 laboratory requestforms (LRF) ordered within the study period and 169 lab professionals working in public hospitals.Data were entered and analyzed using SPSS version 23.Data analyzed using simple descriptive statistics, percentages, frequency and summarized using tables and text.The association between dependent variable and independent factors were assessed using Chi-square tests. P-value < 0.05 will be considered statistically significant.

Result: In this study, 2401 laboratory request forms were assessedand 169 lab professionals were interviewed. Out of the total errors 60.3% and 39.7% were recorded pre-analytic and post-analytical errors respectively. The physicianphone number and patient clinical data were missed in 97% and 88.3% respectively.Majority of the study participants were within the age group of 20-30 years (59.8%), Bachelor degree holders (62.7%) and have work experience of 6-10 years (39.1%).extra analytical errors in laboratory services were significantly associated with availability of written procedures for laboratory activities(adjusted odds ratio (AOR) =2.79, 95% CI =1.34, 5.86), Experience (3-5years)(AOR) =6.69, 95% CI =1.85, 24.19) andEducation (Degree)(AOR) =6.30, 95% CI= 2.17, 18.26).

Conclusion and recommendation: This study reported re high frequency of errors in the extra analytical phase. The information mostly absent in laboratory request forms assessed were physician phone number followed by clinical data of patients and excessive TAT. Extra analytical errors of laboratory can lead to misdiagnosis and mishandling of patients. So a continuous practice of measuringerrors andprovide capacity building, strengthening communication between laboratory staff and physicians, apply rejection practice in incomplete LRF and specimen were required to help in reducing extra analytical error of laboratory.

Key Words:Errors, post analytical errors, pre analytical errors, extra analytical errors, Laboratory request forms

1. Introduction

1.1. Background

Laboratory services are the back bone of modern healthcare sector (1).Laboratory services which is essential part of the clinical decision-making, is articulated in various phases that articulatedfromspecimens collection (preanalytical phase), sample analysis (analytical phase), reporting andinterpretation ofresults (postanalytical phase).Now day or modern medical practice is with time dependent on reliable clinical laboratory services (2). Laboratory services have been the major processes functioning to safe patient care in the recent healthcare sector. Howeveroccurrences of errors in the total testing processes impair the medical decision-making process (3). Healthcare is a relatively high risk area and the overall defect rate in healthcare in the United States is estimated to be 31-69 % (4)**.**

Laboratory testinginfluences 70% of medical diagnoses services. Errors may occur in any phase of the process. The effect of error during laboratory testing process can affect patient care in many ways such as long TAT, wrong result reporting, misdiagnosis and poor treatment (5). Laboratory errors are defect happening at any part of the laboratory phase, from ordering request to reporting and interpreting results (6).

Appropriatemonitoring of pre-analytical errors requires interdepartmental cooperation, since several sources of these errors fall outside the direct control of laboratory employees. Laboratory experts must be leaders in ensuring patient safety, both outside and inside the laboratoryservices (7).

The reporting of incorrect or inappropriate test results still occurs, perhaps even as frequently as in the past. Primarily comprise pre-analytical events related to sample collection and sample handling and post analytical procedures related to results reporting and interpretation(8).

Pre-analytical Error are an errors that occurring from physician order to analytic phase including inappropriate test request, order entry errors, misidentification of patient, wrong container, incorrectly labeled container, insufficientsample collection,unbalances sample/anticoagulant volume ratio, insufficient sample volume and labeling errors (9).

Post-analytical errors as errors that occur after the analysis activitycomplete. Andthat includeincorrect result reporting, no critical value notification, incorrect data entry, and long turnaround times (10).People are constantly watching for quality health products and services. The existence of this desire for quality has caused health facilities throughout the world to consider it as an essential component of any service and production process (11).

The forthcoming development and introduction of a nationalexternal quality assessment statement for Croatia for the extra- analytical areas of testing must be regarded as a great opportunity to improve the quality of the total testing process, in as much as those processes falling outside the analytical phase are much more important. This might be essential for identifying critical points in laboratory activity and to systematically monitor all laboratory processes to prepare for the administratively demanding process of accreditation (12).

Quality is defined as meeting or exceeding a customer's expectations. Quality Assurance requires identification of the causes of problems and their elimination through Quality Improvement (13). And quality in clinical Laboratory is “degree of fit” or compatibility between the laboratory system on the one hand and individuals who need to use these services on the other hand (14). It can be also defined as accuracy, reliability,and timeliness of reported test results. The laboratory results must be accurate,reliable,and reporting timely as possible to be useful in a clinical or public health setting (15).

Poor communication between laboratory professionals and clinicians is generally cited as a chief issue affecting quality during the pre and post-analytical phases (16).Laboratory turnaround time is assessed by determining the difference between recorded starting times (specimen collection time or laboratory sample receipt time) and end points (test reporting time) (17).Laboratoryquality inlaboratory medicine is the guarantee that each and every step in the total testing process isproperly performed, thus confirmingappreciated decision making and effective patient care (18). Therefore, the aim of this study was to assess extra analytical errors and its associated factor in the medical laboratory services of public Hospital in Addis Ababa Ethiopia.

1.2. Statement of the problem

Errors occur in Pre-analytical andpost-analytical phase have been account(46-68.2%) and (18–47%) respectively in laboratory medicine.According to literatures which embraces the process from the starting of laboratory test requests to the delivery of specimens in the laboratory; there is no enough data on errors during the extra analytical phase (19).The article review by Lippi et al. showed that the frequency of preanalytical errors comprises between 60 and 70% of all laboratory errors, thus approximately four-fold and threefold higher than errors occurring in the analytical (i.e.~15% of all errors) and post analytical phases (i.e.~20% of all errors) respectively. As was defined, the preanalytical phase encompasses a series of still manually-intensive activities which are performed mostly outside of the laboratory environment (20).

The extra-analytical phase has been defined as the "dark side of the moon" in laboratory medicinebecause it is unfamiliar and often overlooked by laboratory managers involved with quality assurance. Predominantly significant feature of this phase is lack of uniform standards and indicators adequate to ensure the excellence of phlebotomy, which is a serious procedure for obtaining good quality of blood specimens but often is not managed by laboratory personnel (21).

Pre-analytical and post analytical errors impairment an organization's status, reduce quality and safety in healthcare services, and contribute to a significant growth in unnecessary total operating costs, both for the hospital and laboratory (22).

Lack of quality and adequate equipment, non-adherence to standard operating procedures, no continuing professional development, unavailability of adequate supplies and reagents, no customer service management, no regular internal and external quality assessment activity, no diagnostic service for all requested tests, no result verification and review and laboratory safety were the major factorsaffect quality laboratory service (23).

Quality laboratory service or error free laboratory is an essential component of health care system; but in Sub-Saharan Africa such as Ethiopia, laboratories quality system remains weak due to several factors and it needs more attention to strengthen its quality system. Accurate, reliable, and timely Laboratory tests are required to diagnose illness, identify causative factors, monitor the effectiveness of treatment, and perform investigation for key diseases. And also

patient safety is influenced by the frequency and seriousness of errors that occur in the health care system (24).Error can be any defect during the whole process, from ordering laboratory request to reporting test result. It may have dangerous effects on patient management, by contributing to wrong treatment, an increase in lengths of hospital stay, and unhappiness with healthcare services. Therefore, this study aimed to assess extra analytical errors and associated factors in Medical Laboratories services of Public hospitals in Addis Ababa, Ethiopia

1.3. Significance of the study

This study was to assess extra analytical errorsand associated factorson laboratory diagnostic services. As such, the preanalytical and post analytical phases actually represents the most critical area to target for achieving major improvements in the total quality of laboratory diagnostics.Hence, the finding of this studywill be inputto all laboratory professionals, managers/ head and quality officer forimplementation ofquality management system in hospital laboratory and alsotobe aware of the quality status of medical laboratories and For giving useful baseline information to policy and decision makers, program managers for all efforts that will be made to improve laboratory quality in future. Moreover; it will be an entry point or base line data for further study in this subject matter.

2. Literature Review

The 2013 Francis report has increased the public focus on quality of care and highlighted the requirement to improve the patient experience through reduction of errors in healthcare provision. In theTotal Testing Process it has been reported that only 7–13% of errors actually occur in the analytical phase and that the most errors could be classified as either pre-analytical (46–68%) or post-analytical (18–47%)(25).sotherearechance of occurrences errors in any of these phases and there is necessary for studies of errors definitely in the extra-analytical phases of laboratory testing. Around70–80% of all health care decisions making affecting diagnosis, treatment, and follow-up of patients' investigations and laboratory errors may be associated with inappropriate patient care (26).

Aninternational survey conducted on the use of extra-analytical phase of laboratoryquality indicators by medical laboratoriesfrom the US, Australia, India, China, Brazil, South Africa and Curaçao. Almost all (98.7%) of responders believed that quality indicators and related performance criteria should be implemented in his/her clinical laboratorybut a smaller percentage (90.1%) was actually measuring one or more extra-analytical quality indicators.The list of the "Top Ten" most adopted quality indicators and the percentage of laboratories arethe following: hemolysis samples (82.4%); sample misidentification errors (81.5%); incorrect sample type (80.9%); patient misidentification errors (78.3%); incorrect fill level (75%); clotted samples (73.6%); turnaround times outside target (70%); unsuitable samples due to transportation and storage problems (67%); incorrect laboratory reports (61%) and test transcription errors (53%)(27).

The review article by Hammerling JA indicated that the information about frequency or prevalence of error in pre-analytical and post analytical phase of laboratory were observed among 46% - 68.2% and18.5% -47% respectively. Errors such as insufficient sample volume,misidentification of patient,incorrect order entry and labeling errors from analytical phase and error like improper data entry,failure in reporting anderroneous validation of analytical data from post analytical phase (28).

A Cross-sectional studyconducted in North India indicated that laboratory request forms wereanalyzed for the indicator of specific parameters to assessthe pre-analytical errors affecting

laboratory result. All of the request form have patient namebut othersparameters like age, date of request clinical data, were did not indicted by 1.41%, 23.13%, and 62.2% of the forms respectively.Andalso 89.25% of all forms were illegible and 76.60% of critical results were not communicated to the physician (29).

Similarly, another study conducted in NewDelhi on evaluating laboratory performance with quality indicators. Amongthose qualities indicators the researchers observed different parameters such ashemolysed (7%),lipemic(0.2%),insufficient quantity(0.6%),clotted samples (1.9%),andillegible handwriting (1%) from pre analytical phase. And alsofrom post analytical phase excessive turnaround time and Critical values reporting with (0.5%) and (11%) amount respectively (30).

Study done in NigeriaonEvaluation of laboratory request forms for incomplete datasuch as information regarding patient's age, gender, location (ward), name of attending clinician and working diagnosis was missing in 48.3%, 1.1%, 20.1%, 19.8% and (6.4%) respectively.But information regardingto patient's name and signatureof attending clinician was observed on all thelaboratory forms.And also Sample collection date and type of test required were not supplied in 5.6% and 1.5% respectively of all in LRFs (31).

Another retrospective, cross-sectional, and descriptive study was done inNigeria on examining laboratory request forms requested to hematology and blood transfusion lab sections at a hospital in Northwest Nigeria. So from this study the researchers were analyzed deferent findingssuch as, only patient name and location (ward) were filled completely for all patients.But Patient age, sex, request date, unit number, clinical information, and physician's name weremissing (1.9%), (1.2%), (0.5%), (1.4%), (0.2%) and (9.9%) amount respectively(32).

Studyconducted in Ghanaian tertiary hospital on evaluation oflaboratory requestforms submitted to the hematology laboratory. Out of all the required information on request form patient's age was not supplied on (25.6%), while patient's gender was present on 67.3% and others required information such as location or ward , clinical data , name of the physician and date of test was ordered was missing (47.8%), (22.7%) ,(44.6%) and (38.3%) respectively(33).

Different types of pre analytical error observed at clinical chemistry laboratory of GovindBallabh Pant Hospital, New Delhi, India byChawal R et al, such as 1469 specimens were rejected due to

different factors. Of the reasons of rejection: 1.1% was rejected due to hemolysis; 0.47% was specimens without proper requisition forms,Gross lipemia led to rejection of 0.14% and 0.45% had insufficient sample quantity (34).

On the other hand, a study in India that indicted after training, there was reduction in the frequency of errors before and after training the staff, with respect to Incorrect sample identification from 0.35% to 0.17%, missed samples from 0.06% to 0.04%, Sample from IV running area from 0.09% to 0.05%, Inadequate sample from 1.68% to 0.37%, Wrong timing of sample collection from 0.08% to 0.04% and Haemolysed Sample from 2.28% to 1.35%(35).

Study done in Niger Delta University Teaching Hospital observed deferent pre analytical error suchas forms did not fill the gender and age of the patient3.0% and 11.5% respectively. Patient location/ward and hospital number did not mentioned in laboratory request form 9.6% and 34.0% respectively. 25.5% of laboratory request forms also did not have the name of the attending Consultant and 15.5% did not have the name of the requesting Doctor(36).

The study conducted in Ethiopia Addis Ababa at St. Paul's Hospital Millennium Medical College on errors in the Hematology Laboratory with sample size of 2606 hematology requests was studied. And recorded deferent types of pre-analytical error such as missing name of patient 6(0.2), location/ ward name 19 (0.7%), type of request 91 (3.5%), request of date 166 (6.4%), gender 266 (10.3%), patient age 298 (11.5%), physician name 2215 (85%), physician signature 842 (32.3%) and clinical diagnosis 1827 (70.1%) were observed (37) .

Similar research done at St. Paul's Hospital Millennium Medical College on errors in Clinical chemistry laboratory with sample size of One thousand six hundred thirty three (1633) clinical chemistry laboratory request forms were examined. From this the researchers were observed deferent pre analytical and post analytical errors such asname of patient 8(0.5%), ward/clinic name 18 (1.1%), request date 159 (9.7%), gender 257(15.7%), age of patient 190 (11.6%), physician name1385(85%),clinical data1185(72.6%),inadequate samples 220(40.6%), hemolaysed 124(22.9%), and icterus samples 15(2.8%) from pre analytical phase and no communication of critical result 75(14%),sample delay 4(0.7%) and loss result 2(0.4%) from post analytical phase(38).

A recent study conducted in University of Gondar hospital, Ethiopia revealed that the prevalence of pre analytical and post analytical error were 89.6% and 7.7% respectively. The Information fully written on each laboratory request form was examined only 3(0.09 %) requisition papers were found to have complete data. Indicators of patient information in LRFs such as (99%) clinical data, (38.7%) address, 60(1.8%) requesting physicians name were not written on laboratory request forms. from post-analytical phase excessive turnaround time (8.6%) contributed to the majority of errors followed by unreported critical value cases 15(0.48%). All critical value cases were not reported or communicated to the concerned physician (39).

Another Studyconducted at central Oromiya, observe different types of pre analytical error such as no name of the clinician ordering the test, no clinical details and no ages of the patient in LRFs were 170 (22.5%), 135 (17.9%) and 16 (2.1%) respectively. While patient's gender almost all was present on 744 (98.7%) of Laboratory request forms. Specimens related pre-analytical error inappropriate quality of the blood specimens was the most common cause for unsuitable specimen 38 (5%) followed by insufficient volume of blood 34 (4.5%), mislabeling10 (1.3%), and unlabeled4 (0.5%).So the main reasons, for pre-analytical error as reported by the participants were lack of a procedure for ordering, preparing and applying of this process (40).

A cross sectional study done in Hawassa university hospital showed that from a total of 40 laboratory professionals intervened 32(80%), 18(45%) and 8(20%) do not reported result with predefined TAT, not attending training and do not participated in continues education program respectively(41).

Another study conducted in Addis Ababa public and private health facilities of factors affecting quality of laboratory service. That 213 laboratory professionals participated in the study and 62.4%, of laboratory professionals did not participating any work related training. 35.2% respondents believed that their laboratories did not deliver quality laboratory services andthe major reported factors affecting provision of quality services were high workload (41.1%) and lack of knowledge (23.3%). And (39.9%) laboratoryprofessional did notperform equipment calibration & maintenance as per instruction,(15.5%) of laboratory professionals did not verify laboratory results and (32.9%) of respondents claimed that laboratory results were not released within pre-defined turnaround time, (21.1%) of laboratory professionals not practiced as per

standard forLaboratory documentation (documents and records),(34.3%) of laboratory professionals did not monitor laboratory safety practices (24).

Study conducted at Gondar Public Health Facilities to assess quality of medical laboratory service provision and associated factors, the majority of the study participants, 63 (61.2%) was laboratory technologists and 61.2% of the participants reported that their laboratory did not provide quality laboratory service. Lack of quality and adequate equipment, non-adherence to standard operating procedures, no continuing professional development, unavailability of adequate supplies and reagents, no customer service management, no regular internal and external quality assessment activity, no diagnostic service for all requested tests, any result verification, and laboratory safety were the major factors significantly associated with poor quality laboratory service (23). Providing quality laboratory services cannot succeedunless continuous monitoring and focusing of extra analytical phases of laboratory and having a good communication with clinicians and laboratory staffs.From this perspective, it will be more realistic toassess extra analytical errors and associated factors in Medical Laboratories services of Public hospitals in Addis Ababa, Ethiopia.

3.Framework

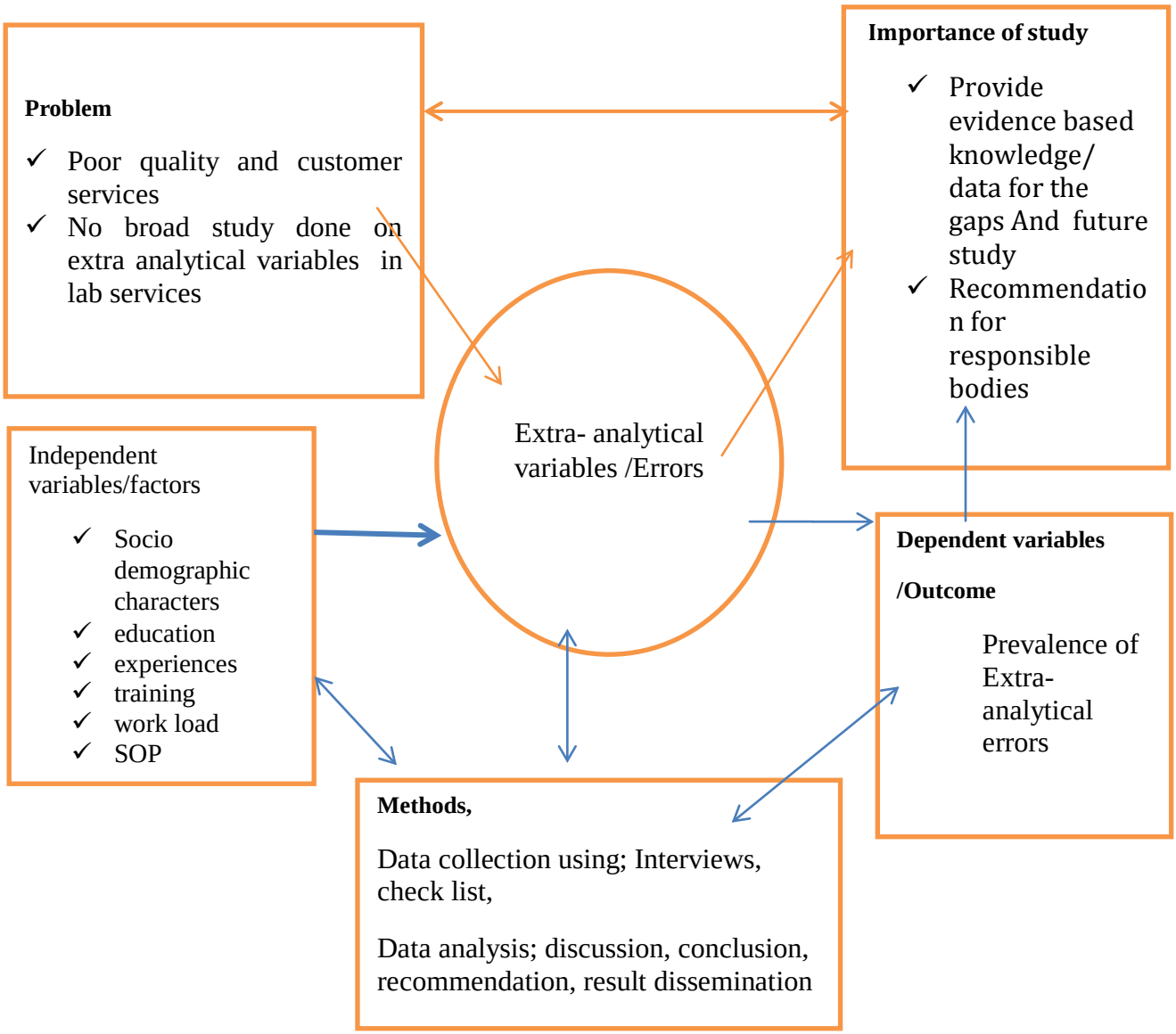

Fig-1 Conceptual framework of Assessment of extra analytical errors and associated factors in Medical Laboratories of Public Hospital in Addis Ababa, Ethiopia

4. Objectives of the study

4.1. General objective

To assess extraanalytical errors and its associated factorsinMedicallaboratoriesof public hospitals in Addis Ababa, Ethiopia fromJanuary2020 to April 2020.

4.2. Specific Objectives

- To determinemagnitude of extra analytical errors in medical laboratories of public hospitals inAddis Ababa
- To assessthe pre analytical errors related toLRFs with sample in medical laboratories of public hospitals in Addis Ababa
- To assess the post analytical errors in medical laboratories of public hospitals in Addis Ababa
- To identify factorsassociated withExtra analytical errorsin medical laboratories of public hospitals in Addis Ababa

5. Materials and Methods

5.1. Study area

The study was conducted inmedical laboratories of Public Hospitalsin Addis Ababa.Addis Ababais the capital city of Ethiopia, seat of African Union and Economic Commission. It is located in the geographic center of the country and covers a landmass of 540 sq. km. It is administratively sub-divided into 11 sub cities and 116woredawith total population of 3.6 million(42). The city has 14 public hospitals; sixunder Addis Ababa Health Bureau (AHB), sixunder Federal Ministry of Health (FMO), and twounder Ministry of defense providing teaching, specialized, and referral services(43).From 14 government hospitals, 1 hospital was excluded from the study for pre testing of questioners and the others13(thirteen)were included in the study.Hospitals in Addis Ababa are not only limited to providing services for the people residing in the city, but also to significant number of population in the surrounding areas outside the city and other regional states. As the city is the center of the country in many socio-economic aspects of peoples' life and due to the expectations that better health services are available in city of hospital services become overcrowded.

5.2. Study design and period

A cross-sectional study was conducted fromJanuary, 2020 to April, 2020,to assess extra analytical errors and associated factors in medical laboratoriesof public hospitals in Addis Ababa.

5.3. Population

5.3.1. Source population

All medical laboratory test ordered request forms and medical laboratory professionals working inPublic Hospitals of Addis Ababa.

5.3.2.Study population

All medical laboratory test ordered request forms and medical laboratory professionals working in Public Hospitals of Addis Ababa during the study period and fulfilling the inclusion criteria of the study.

5.4. Inclusionand exclusioncriteria

5.4.1. Inclusion criteria

All public hospitallaboratories those were voluntary to participate, laboratory professionals having a year of experiences and above willing to participate. Laboratory request formwhich were requested to department of serology, hematology,and parasitology and Chemistry laboratory byphysician.

5.4.2.Exclusion criteria

Employees who were not available during study periodand LRFs requested to emergency, pathology and microbiology lab section.

5.5. Study variables

5.5.1. Dependent variables

Percentage of Extra analyticalerrors

5.5.2. Independent variables

Age, Sex, Educational status,Experience, training of the professionals undertaking the procedure, continues education program,refreshing training, have procedure for each lab activities and workload

5.6. Sample size Determination and sampling method

5.6.1. Sample size determination

For Quantitative data type Sample size was calculated for lab request using the minimum sample size calculation formula for estimating single proportion assuming 50%, 2% margin of error and 95% CI due to lack of similar prevalence study in Ethiopia.

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

Where

n = Sample size

α = level of significance

z = at 95% confidence interval Z value (α = 0.05) =>Z α/2=1.96

p = Proportion of occurrence of the event estimated 0.5

d = Margin of error at (2%) (0.02)

$$n = \frac{1.96^2 * 0.5(1-0.5)}{(0.02)^2}$$

n=2401

As it can be seen from annex I, the sample size was allocated proportionately for 13(thirteen) public hospitals base on laboratory services an average patients daily, that consists of 280 LRF from Saint Paul's Hospital Millennium Medical college,309 from Black Lion Specialized Hospital,214 from Saint Peter TB Specialized Hospital,206 from ALERT Hospital,155 from Yekatit 12 Medical College, 177from RasDesta Memorial Hospital,125from Gandi Memorial Hospital,140from Zewditu Hospital,151 from Tirunesh Beijing Hospital,199 from Minilik Hospital,110 from Amanuel Hospital,169 from Armed Force Hospital, and 166 LRF from Police Hospital making a total sample size of 2401 LRFs.

Similarly, sample size of laboratory professionals were determined using single population proportions formula,assuming p=50%, level of significance =0.05 marginal of error (d) =5% due to lack previous similar study

$$sample\ size\ n = \frac{(\mathrm{Z}\ \alpha\ /2)^2 * p(1-p)}{d^2}$$

(Z α/2) =z-score at 95% confidence interval =1.96 the formula the sample size (n) was

$n=1.96^2*0.5*0.5/0.05^2=384$

Based on the profile of public hospitals the total study populations were 256 as can be seen from annex I which is less than calculated sample size and a correction factor was done based on the finite population formula (nf), therefore the sample size was

nf=n/1+n/N = 256/ (1+1/384) =154

Considering 10% for none response (15*10%=15.36), the sample size) was 154+15=169

As it can be seen from annex I, the sample size was allocated proportionately for 13(thirteen) public hospitals, that consists of 23 respondents from Saint Paul's Hospital Millennium Medical college,25 from Black Lion Specialized Hospital,16 from Saint Peter TB Specialized Hospital,15 from ALERT Hospital,14 from Yekatit 12 Medical College, 9 from RasDesta Memorial Hospital,7 from Gandi Memorial Hospital,12 from Zewditu Hospital,9 from Tirunesh Beijing Hospital,14 from Minilik Hospital,9 from Amanuel Hospital,7 from Armed Force Hospital, and 9 respondents from Police Hospital making a total sample size of 169 participants.

5.6.2. Sampling method

Simple Random sampling techniquefor lab professional and Systematic sampling forLRFs

5.6.3. Data collection procedure

After getting permission to conduct the study from the chief executives of hospitals, lab requestsof public hospital laboratorieswere divided proportionally according to their work load. Then the data was collected with close collaboration from health facility's Quality officer and heads of laboratory units.In this study, quality indicators observed the activity of each discipline of laboratory undertaken, namely: clinical chemistry, hematology, parasitology, and serology. When receiving the samples in the laboratories, quality indicators were documented in the lab after careful screening of the sample and accompanying test requisition forms by the laboratory technician to monitor pre-analytical phase. By using observational Checklist checked

completeness of TRFs (name, age, sex, registration no, location/ward, requesting physician's name and signature, clinical/diagnostic information, date and date of requesting), quality of sample haemolysed, clotted/lipemia/, not sufficient/inappropriate vials and quality indicators monitoredin post-analytical phase are checking reviews, documentation ,reporting/communication of critical result and result reporting with established TAT. When come to lab professionals structured questionnaire was used for data collection. It included different questions, such as Socio-demography, education background, work experience, communication, training and extra analytical error such as,laboratory request form without patient name, hospital number, patient sex and age, physician name and contact number, ward, request date and also error related to sample such as un labeling sample, insufficient volume, contaminated sample , clotted sample, samples lost, incorrect reporting and interpretation, result documentation, result report without TAT for the purposes of to know the factor that do not performed those activity as per standard. Trained and experienced laboratory technologists collectedthe data. The principal investigatorwas involvedin overall controlling activities of data collections and assisted data collectors during the process of data collection.

5.7. Data quality assurance

To ensure the quality of the data, the data collection tool was assessed by professionals for appropriateness and overall evaluation. The questionnaire and checklist was pre tested over 5 % of the sample size in AaBET Hospital. After the pre-test, some modifications of the questioner weremade for unclear and difficult questions. These pre-test data were not included in the analysis of this study. Training was given for three laboratory technologist data collectors by the principal investigator to clarify how to collect data. The completeness of the questionnaire and checklist rechecked at the end of the day by the principal investigator.

5.8.Dataanalysis andPresentation

In the study process, different types of raw data were collected processed, analyzed, and interpreted. A descriptive study carefully designed to ensure a complete description of the situation, making sure that there is minimum bias in the collection of data and to reduce errors in interpreting the data collected from the descriptive study. All data were coded and fed into SPSS version 23 statistical software. Descriptive statistics (frequencies and percentage) computed and summary results presented using text and tables and bivariate analysis were also used to assess

the presence of associations between dependent variable and the independent variables. Dependent variable is extra analytical errors; defined as occurrences of errors in pre and post analytical phase of laboratories services and the independent variables are socio demography variable Educational status, Experience, training of the professional undertaking the procedure, continues education program, refreshing training, and procedure for each lab activities. Binarylogistic regressions were conducted to control the confounding factors, and variables which had a p-value less or equal to 0.05 in bivariate analysis were included in the multivariate logistic regression model. Odds ratio with 95% confidence interval were used to measure the strength of association between independent variables and extra analytical errors of laboratory services.

5.9. Operational definitions

Extra analytical error -Occurrences of errors in pre and post analytical phase of laboratories servicesduring sample collection, preparation and result reporting and interpretation.

Preanalytical phase -processes that began from the clinicians request and include the examination request, preparation and identification of the patient, collection of the primary samples, transportation to and within the laboratory and end when the analytical analysisstart.

Postanalytical phase- is the last phase of the Total testing process. It comprises all steps that begin with the verification and review of the results, passing to the communication of the results and their interpretation by the attending clinician (44).

Service- Service is an activity of interaction between customer and service provider to provide solution of the customer problem (45).

Laboratory service Quality- the degree to which a set of inherent characteristics fulfills the requirement, aims to confirm the requirements of the customers to meet their expectations and to satisfy them, in terms of responsiveness, reliability, and safety (46).

Turnaround time-is defined as the usual amount of time between the timesa specimen is received within the laboratory and the result is accessible.

Error –is defined as failure of planned action to be finished as intended or use of a wrong plan to succeed an objective, happening at any part of the laboratory phase(47).

Laboratory request form (LRF) - is a communication ways ofbetween laboratories, physiciansand customers of laboratory service

Continuing education program- refers tothe classes and seminars that acquisition or improvement on job-related skills and knowledge. For example:-Postsecondary Degrees (associate, bachelor's or graduate,) ProfessionalCertification and On-the-job Training etc.

Specimen rejection rate (SRR)-This indicator is the percentage of specimen rejected and not tested due to some reasons. For example, blood clot, hemolysis, insufficient specimen, wrong bottle, wrong additive or spill sample, etc

5.10.Ethical consideration

The study was approved by the departmental research and ethical review committee (DRERC) of the department of medical laboratory science with protocol number DRERC/482/19/MLS and research ethics review committee of Addis Ababa Health Bureau andfrom eachsix under Addis Ababa Health Bureau (AHB), six under Federal Ministry of Health (FMO), and two under Ministry of defense before the study was commenced. There was a high degree of confidentiality during data collection and no name of professional and any health facility was mentioned. Andeach participant was informed about the purpose of the study, the right to refuse to participate in the study and anonymity and confidentiality of the information gathered.

5.11. Result dissemination

The result of this study was submitted to the Department of Medical Laboratory Science and will be presented. The findings will be submitted to Addis Ababa Health Bureau and each Addis Ababa public hospital and will be presented at national and international conferences, and it will be sent to publication in peer-reviewed journals and disseminated to the concerned bodies.

6. Results

6.1. Characteristics of the study participants

In our study, a total of 169 laboratory professionals were included from 13 public hospitals in Addis Ababa Ethiopia to assess factor that related with extra analytical variables. And the response rate was 100%. Among the participants 96(56.8%) were males. Majority of the study participants were within the age group of 20-30 years (59.8%), Bachelor degree holders (62.7%) and have work experience of 6-10 years (39.1%). Eighty four (49.7%) of the laboratory professionals did not participate in training of the professional undertaking the procedure and also 123 (72.8%) of laboratory professionals did not attend of laboratory refreshing training, (Table1).

Table1: Socio-demographic characteristics and attending of training and continuing education programof laboratory professionals working in public hospital in Addis Ababa Ethiopia (n=169)

Variable	Frequency, n (%)
Sex	
Female	73(43.2%)
Male	96(56.8)
Age group	
20 -30 years	101(59.8)
31 – 40	51(30.1%)
41 – 50	13 (7.7%)
51 – 60	4(2.4%)
Educational level (profession)	
Laboratory Technician	41(24.3%)
laboratory technologist	106(62.7%)
MSc	22(13.0%)

Working experience	
1-2 Years	48(28.4%)
3-5 Years	34(20.1%)
6-10 Years	66(39.1%)
>10 Years	21(12.4%)
Laboratory discipline	
General laboratory	43 (25.4%)
Clinical chemistry	40 (23.7%)
Hematology	35 (20.7%)
Parasitology	26(15.4%)
Immunology/Serology	18(10.7%)
Microbiology	7(4.1%)
Participated in training of the professional undertaking the procedure	
Yes	85(50.3%)
No	84(49.7%)
Participate on continuing education program in related to you work	
Yes	68(40.2%)
No	101(59.8%)
Attending of laboratory refreshing training	
Yes	46(27.2%)
No	123(72.8%)

6.2.Extra analytical factors in Medical Laboratories

In terms of pre analytical practice, findings from this study showed that 118 (69.8%) laboratory professionals said as they did not have written procedure for each laboratory activities and 71(42%) of the respondents also indicated that there was no record of rejected specimen in a log book due to work load and did not have registration log book. Similarly, 24.9% of the respondents replied rejected samples /requests were not communicated to responsible person. And also 49 (29%) and 77(45.6%) of the laboratory professionals did not collect sample according to SOP and did not reject an incomplete request respectively. Among post analytical quality indicators 80(47.3%) laboratory professionals did not verify laboratory results and 90(53.3%) of respondents claimed that laboratory results were not released within pre-defined turnaround time. Laboratory documentation (documents and records) systems were not practiced as per standard by 43 (25.4%) the laboratory professionals. Fifty three (31.4%) laboratory professionals also indicated that did not communicated or alert critical result laboratories for responsible person, is shown in (Table2&3).

Table2: pre-analytical variables activities reported by laboratory professionals working in public hospital in Addis Ababa, Ethiopia (n=169)

Variables	Frequency, n (%)
have written procedure for each laboratory activities	
Yes	118(69.8%)
No	51(30.2%)
have specific criteria for specimens rejection	
Yes	127(75.1%)
No	42(24.9)
recorded Each rejected specimen in a log book	
Yes	98(58%)

No	71(42%)
Reason for failure to record rejected specimen in a log book (N= 71)	
Work load	64(90.1%)
Have no log book	7(9.9%)
Communicate rejected sample /request toresponsible person	
Yes	127(75.1%)
No	42(24.9%)
Reason failure to communicate rejected sample (N=42)	
Work load	32(76.2%)
Lack of training	10(23.8%)
Reject an incomplete request	
Yes	92(54.4%)
No	77(45.6)
Reason failure to reject incomplete request (N=77)	
Work load	77(100%)
Reject unlabeled sample	
Yes	167(98.8%)
No	2(1.2%)
Did you reject Contaminated sample	
Yes	164(97%)
No	5(3%)
Do you rejected hemolyzed Sample	

Yes	165 (97.6%)
No	4(2.4%)
Collect sample according to SOP	
Yes	120(71%)
No	49(29%)
Reasons do not collect sample according to SOP (N=49)	
Work load	44(89.8%)
Lack of training	5(10.2%)
Prepare patients before sample collection	
Yes	111(65.7%)
No	58(34.3%)
Reason do not prepare patients before sample collection (N=58)	
Work load	50(86.2%)
Lack of training	4(6.9%)
Others	4(6.9%)

Table3: post-analytical variables activity reported by laboratory professionals working in public hospital in Addis Ababa, Ethiopia (n=169)

Variables	Frequency, n (%)
Record and document lab result	
Yes	120 (71.1 %)
No	49(28.9%)

Reason do not Record and document lab result (N=49)	
Work load	37 (75.5%)
Lack of training	10 (20.4 %)
Others	2 (4.1 %)
Interpreted result Correctly according to SOP	
Yes	130(76.9%)
No	39(23.1%)
Report result with TAT	
Yes	79 (46.7 %)
No	90 (53.3%)
Reason or challenge no Report result with TAT(N=90)	
Work load	81(90 %)
Others(do not have ward/ location)	9(10%)
Communicated or alert critical result	
Yes	116(68.6 %)
No	53 (31.4%)
Reason do not Communicated or alert critical result(N= 53)	
Work load	44(83.0%)
Others (no communication of ways)	9(17%)
Reviews or verified Laboratory result	
Yes	89(52.7%)
No	80(47.3%)
Reasons or challenges do not reviews or verified Laboratory result(N=80)	

Work load	64 (80%)
Lack of training	2(2.5%)
Others	14(17.5%)

6.3.Pre analytical errors related with request form

On the laboratory requisition forms were found to have not complete; such as clinical data 2121(88.3%), physician phone 2328(97%), physician name 720(30%),patient ward 675(28.1%) and date of request 241(22.9%) were not filled on the test request forms, is shown in (table4).

Table4: Frequency of pre analytical errors submitted test request forms in laboratoryat public hospitals from January2020 to April 2020, Addis Ababa, Ethiopia

Data type	Frequency	
	Yes, n (%)	No, n (%)
Patient name	2399(99.9%)	2(0.1%)
Hospital number	2384(99.3%)	17(0.7%)
Patient sex	2244(93.5%)	157(6.50%)
Patient age	2160(90.0%)	241(10.0%)
Physician name	1681(70%)	720(30%)
Patient clinical data	280(11.7%)	2121(88.3%)
Patient location / ward	1726(71.9%)	675(28.1%)
Date of requested	1851(77.5%)	550(22.9%)
Physician phone number	73 (3.0%)	2328 (97.0%)
Legible hand writing	2387(99.4%)	14(0.6%)

6.4.Pre-analyticalerrors related with samples

The otherfunding made during the study time was an assessment of sample quality indicators. A total2396 lab samples were submitted to the laboratories fordeferent laboratory tests. Type of specimens received in laboratory section ofurineand chemistry, hematology Serology, parasitology, coagulation and hormone with magnitude of 298, 769, 933, 118, 197, 22,and 59 respectively. 24(1.0%) were rejected. The most commonreasons forsample rejectionwereinsufficient volume of sample8 (0.3%), followed by hemolysis5(0.28%), and lack of labeling 5(0.2%).So the error calculated bellow based on those magnitudes of specimen types, as shown in (Table5).

Table5: pre analytical error for sample in laboratory at public hospitals from January 2020 to April 2020, Addis Ababa, Ethiopia.

Parameter	Frequency		
	Yes, n (%)	No, n (%)	Total
Hemolysis	5(0.28%)	1778(99.7%)	1783
Lipemic sample	24(1.3%)	1559(98.7)	1783
Insufficient volume of sample	8(0.3%)	2387(99.7%)	2396
No labeled	6(0.2%)	2391(99.8%)	2396
Request with no sample	5(0.02%)	2396(99.8%)	2401
Test not ordered/inappropriate test order	25(1.0%)	2376(99.0%)	2401

6.5.Post-analyticalerrors

In the post-analytical phasedifferent types of error were observedamong the recorded errors the highest amount was failure torecorded result1741 (73.3%)followed by failure to inform critical value result to concerned physician 11 (73%), and excessive turnaround time 1485(62%),as shown in (Table 6). Although most of laboratoriesdo not have functional laboratory information system (LIS) during our data collection time do you todifferentreasons.

Table 6:post-analytical errorsoflaboratories at public hospitals from January 2020to April 2020, Addis Ababa, Ethiopia

Parameter	frequency		
	Yes, n (%)	No,n (%)	Total
Excessive TAT	1485(62%)	897(38%)	2382
Not informed critical result	11(73%)	4(26.7%)	15
Review or verified result	776(33%)	1606(67%)	2382
Document and Recorded lab result	641(26.7%)	1741 (73.3%)	2382
Interpretations	2368(99.4%)	14(0.6%)	2382

Finally from total of 12234 errors was observed in pre- and post-analytical phases;particularly in the pre-analytical phase 7377(60.3%) and post analytical error 4857(39.7%).

6.6.Factors associated with extra analytical errors in laboratory services

The laboratory tests result can be affected by the completeness of laboratory request forms information’s provided and the qualities of specimen received to the laboratories.Regarding to factors that associatedwithpre and post analytical error oflaboratory services, our finding identified that high workload, lack of knowledge, lack of training,and lack of communication between lab personnel and physicianwere the major factors.Regardingpre analytical errorof laboratory services, 51(30.2%) laboratory professionals said that their laboratories did not have written procedure for each laboratory services activities and 71(42%)respondents showed that there were norecorded rejected specimens in a log book due to work load(64(90.1%)) and others

factors.In addition to this, 42(24.9%) respondents also reported rejected sample/requests were not communicated toresponsible persons due to workload32 (76.2%) and lack of training 10(23.8%). About factors that affecting the post analytical error inlaboratory services, our finding showed that 49(28.9%), 39(23.1%) and90 (53.3%) study participant did not Record and document lab result, did notReport result within TAT and did not communicate or alert critical result, respectively, due to several reasons such as:Work load,Lack of training and no ways of communicationTable 2&3.

Result finding generated fromLogistic regression analysis showed that extra analytical errors in laboratory services were significantly associated with unavailability of written procedures for laboratory activities(adjusted odds ratio (AOR) =2.79, 95% CI =1.34, 5.86), Experience (3-5years)(AOR) =6.69, 95% CI =1.85, 24.19) andEducation (Degree)(AOR) =6.30, 95% CI= 2.17, 18.26).Degree holder employees werefound 6.3 times more likely not to produce extra analytical errors than diploma holders.Laboratory professionals withExperience of 3-5years were found 6.69 times more likely not to produce extra analytical errors than lab professionals with experience of 1-2years.Similarly,Laboratory professionals, who did have written procedure for laboratory activities were 2.79times more likely not to produce extra analytical errors than those who did not have procedure for laboratory activities,shown in Table 7.

Table7: Association between extra analytical errors andcovariates in public hospitals laboratories, Addis Ababa, Ethiopia, 202

Independent variables		Extra analytical Errors		Crude odds ratio (95 % CI)	P value	Adjusted odd ratio (95 % CI)	P value
		Yes	No				
Education	Diploma	35	6	1		1	
	Degree	47	59	7.32(1.80, 11.98)	0.001	6.30(2.17, 18.26)	0.001**
	Masters	7	15	12.5(1.76, 23.49)	0.998	5.93 (0.73, 38.81)	0.998
Experience	1-2	32	16	1		1	
	3-5	14	20	7.62 (0.56, 9.48)	0.468	6.69 (1.85, 24.19)	0.004**
	6-10	40	26	1.3 (0.36, 1.80)	0.604	2.67 (0.94, 7.56)	0.065
	>10	4	17	8.5 (2.54, 9.46)	0.002	1.76 (0.19, 3.12)	0.704
TUP	Yes	28	57	1			
	No	59	25	0.21(0.45, 1.65)	0.656		
CEP	Yes	12	58	1		1	
	No	60	41	0.14(0.12, 3.94)	0.050	0.847 (0.23, 3.409)	0.702
RT	Yes	12	34	1			
	NO	82	41	0.18 (0.16, 2.02)	0.367		
PLA	Yes	67	51	1		1	
	No	25	26	1.37(1.09, 2.03)	0.008	2.79 (1.34, 5.86)	0.021**

*Key ** Significant association at α=0.05 and 1shows reference category*
TUP=Turning under the procedure CEP=continues education program
RT = Refreshing training PLA = have written procedure for laboratory activities

7. Discussion

Extra analytical errors are a common problem in the laboratory that compromises patient's monitoring and health care services.And the majority of laboratory professionals work under high workload without continuing education and training. Against this background, this study was focused on determining the frequency of extra analytical errors and its associated factor at public hospital laboratories in Addis Ababa, Ethiopia.

In this study patient name (99.9%) and hospital number (99.3%)were relatively well documented parameters appeared on all request forms. These results were in similar with findings from Ethiopia (39, 38, 37, and40), Indian (29),Nigeria (31, 32), andGhana (33). This was not amazing since it was very expected that the request would have been did not accepted if the patient's name and hospital number werenot mentioned. So this similarity is due to all clinicians focusingthese parameters highly than other parameters.

Gender of patients was not described in 6.5% of studied laboratory request forms.This error rate is higher than previous reports in Nigeria1.1 %(31)&1.2 %(32) but lower from Ghana32.7 %(33) and Ethiopiaat Addis Ababa by Tadesse H et al. 10.3% (37) &15.7 %(38). Reference values for some tests, such as chemistry test andhemoglobin concentration, differ with gender and age, underlining the need for their presence in request forms. Laboratoryrequest forms with no age of patients was observed in 10% of all forms inspected similar to studies done in Ethiopia AddisAbaba by Tadesse H et al.11.5 %(37) &11.6 %(38). These errorswere higher than reported errors rates in other studies fromEthiopia 0.6 %(39) & 2.1% (40), India1.32% (29) and Nigeria1.2 %(32)but lower than study done inNigeria 48.3% (31) and Ghana 25.6 %(33).This difference could be attributed to the workload on physicians, sample size, site of data collection, differencedue to attitude, and carelessness among physicians, lack of checking by the concerned body or inappropriate orientation about the effect of not complete information on laboratory request form on the quality of patient result.

Physician's phone number wasmissed in 97% of laboratory request forms.Name of physician' was missing 30% of the lab forms.This is higher than reported errors rates in other African studies (29, 31, and 32). Butalmost similar with the study in Ghana revealing missing of Physician's phone number in all assessed requests and 44.3% lack name of physician

(33).Critical results can be quickly communicated to the requesting doctor by telephone number or other communication system. So properly filing of Physician's phone number and name on laboratory request form is very important.

In this study28.1% of location/ward was missing in request forms but study done in Ethiopia at UOG Hospital(39) and at St. Paul's Hospital(37,38), Nigeria(32) and India(28) were very lowwith1,8%,0.7% 1.1,3.6% and 0.4%respectively.Othersimilar studies conducted in Nigeria (31) and Ghana (33) indicated 20.1% and 47.8% of laboratory request forms lack lection/ward,respectively. This difference might be due tosample size, site of data collection, attitudinal difference, work load,and training of hospital professionals.

The present study showed that 22.9% of the forms did not have the date of request.This finding is similar to study done in Niger21.5% (36) and Indian23.13% (29).But the study done in Ethiopia at UOG Hospitalreported as rate of error almost two times higher than the current finding46.9%(39).But study done in St Paul's Hospital Millennium Medical College6.4%(37) lower than to this finding. These differences due to sample size, site of data collected, attitudinal difference, work load and training states of hospital professional.

Significantly, 88.3% of laboratory request formsdid not mention patient clinical data. This result is inline with findings from Ethiopia 98% (39), 70.0 %(37), 72.8%(38))and Indian89.25% (29).But this study's errorrate was far higher than the study done in Ethiopia (40);Nigeria(31, 32) and Ghana (33)were error magnitude of 19.9%, 6.4%, 19%.1% and22.7% respectively.This dissimilarity may be due to not similar in work load,methods of data collection, sample size,the awareness of clinicians and commitment of health professionals.Absence of clinical information/clinical data or misleading information leads to extraneous and unnecessary additional tests.

In this study specimen rejectionof 0.28% observed due to hemolysis samples similar to study done in Nigeria (49).But studies was done in Ethiopia at Gondar by Ambachew S et al.(39), at Addis Ababa byTadesse H et al. (37)and (38)and India (34,30)reveallower proportions relative to the current finding.These differencesmight be due to several factors such as training status, sample size, work load, and also sample collection site differences. Hemolyzed samples due to

lack of training increased pressure with which blood was dispensed from syringes into sample tubes and did not flow correct procedure during blood collection.

In the current study,0.3%of the received specimens hadinsufficient volume forprocessing.This result is in line with findings in Ethiopia0.2 %(39) andIndia0.45 %(34). However, it is lower than previous studies conducted in Ethiopia48.9 %(37) and 40.6 %(38).Insufficient volumemay affectsome hematology and chemistry tests such as the 5 mL-draw heparin tube is only full with 3 mL of blood, the heparin concentration may be incorrectly raised and potentially interfere with some chemicalanalytes. In addition, insufficient blood draw of an EDTA tube may cause erroneous results for intact parathyroid hormone due to a chelation of the magnesium cofactor in some assays (4).The reason for hemolysis and not sufficient volume of blood in this study may be due to samples collected by nursing professionals and due to lack of training who did not recognize collecting samples by correct techniques or according to SOP.

In the current study, excessive turnaround time (62%) contributed to themajority of post-analytical errors. But studies donein others places of Ethiopia reported very low results, 3.5 %(37) and 8.6 %(39). This variation might be due to samplesize and work load.This high prevalence could be due to several factors such as workload, Lack of training, shortageof staff and absences of location or ward in LRF. From 169 lab professionals interviewed90(53.3%) were not reporting result withinTAT dueto workload (90%) and haven not ward / location(10%) in laboratory request forms.Lower than this finding was reported fromHawassa and Addis Ababa 70(32.9%) and 32(80%) of study results were not to be released within TAT respectively (41, 24).This variation may be due to study design; workload, sample size, and workflow passdissimilarity in the study organization.

Another significantside of thepost-analytical phase of laboratory testing procedure was critical value reporting.Ineffectiveness of critical values notification or the failure to provide notification within the target time might prove to be life threatening in certain cases (48). In thisstudy Critical results were perceived in 15(0.6%) of the total study sample. Of these, 73% were not communicated to the consideringphysicians.Similarly study done in Ethiopia at University of Gondar Hospital where 15(0.48%) were critical results and those all critical results did not communicated to the considering physicians (39). Which might due tolack awareness among laboratory staffs, unwritten parameter on laboratory request form like patient address,

ward/location and attending physicians name and phone numberand also there is no way of communication system. In this study from 169 lab professionals interviewed, 53(31.45%) did not notified or communicatedcriticalresult dueto work load and no ways of communication system,83% and17% respectively.

This study found out that checking of incomplete request and quality of sample, documentation system, and review or verified lab result, result reporting with TAT and communication of critical result were poorly implemented as per the standards. So poor extra analytical phase management system directly affects the extra analytical phase of laboratory services as well as patients and health care services.

Proposed model of TQM pointed out that education, training and motivation are major factors for implementation of quality system and non-trained professionals can be costly to the laboratory system due to inaccurate test results (51).Factor that affecting error prevalence is staff training. The study done by Sushma BJ and Shrikant C. indicted that after training the staff, there was reduction in the frequency of errors before and after training (35). In this study, from 169 lab professionals interviewed 84(49.7%) lab professionals repliedas they did not have training of the professional undertaking the procedures. So some of the errors observed in this study may be dueto this reason.Similarly,another study in India indicated that after formal training of lab personnel, medical and nursing staff thepre, and post analytical error were decreasing(30). Well documented standard operation procedures help laboratories to establish a well-functioning quality management system and client centered services that contribute to health care services (50).But this study found out that 51(30.2%) of laboratory professionals said as they do not have written procedure for each laboratory activities.So lack of procedure for each laboratory activities directly affects the extra analytical phase of laboratory servicesas well as patients and health care services. Additionally, this study also showed that extra analytical errors in laboratory services had statistically significant association withavailability of written procedure for laboratory activities(adjusted odds ratio (AOR) =2.79, 95% CI =1.34, 5.86), Experience (3-5years) (AOR) =6.69, 95% CI =1.85, 24.19) and Education (Degree) (AOR) =6.30, 95% CI= 2.17, 18.26). So focusing on those factors was important to improve extra analytical phase of laboratory services. And also it important to keep well documented written standard procedure

for laboratory activities to each working area and adapted to them by staff is also importantsystem to decline errors (26).

Finally, the findings made in this study confirm high prevalence of errors in pre- and post-analytical steps. Particularly in the pre-analytical phase (60.3%) and post analytical phase (39.7%) and none of requisition papers werecontain complete data.The results reported with magnitude of errors; pre-analytical 89.6%, and post-analytical 7.7% fromUOG Hospital,Ethiopiashowed small differences to this study (39).This difference may be due to workflow complexity, useor not use quality management system and system of error detection. It is clear that most errors occur in the extra analytical phase of laboratory. Issues such as specimen identification, appropriateness checking of laboratory requests forms, specimen handling, timely reporting of result and communication of critical result can no longer be considered insignificant because they strongly affect total quality of patientresult. This proposes better cooperation between clinician and laboratory professional and provision of training on extra analytical phase of laboratory.

8. Limitations and Strength of the study

8.1 Strength of the study

This study used both observational checklists for data collection related to Laboratory request form with sample and structured questioner for intervening lab professionals to assessed associated factor related to extra analytical errors.

8.2. Limitation of the study

The whole section of errors in extra analytical phases cannot be addressed like patient preparation; patient drug intake, diet, and timing of sampling and application of tourniquet have not been included. Another limitation was the incapacity to assess associated factors related clinician and the effect of extra analytical errors on patient health and the total healthcare system. These can be a possible for future study area. In the case of some quality inductors; such as hemolysis and icterus samples, checked by visual inspection may lead to interpersonal bias. Limited availability of literature in factor that associated with the extra analytical error made difficult in comparison to the findings.

9. Conclusionand Recommendations

9.1. Conclusion

In conclusion,thisstudy finding indicted high magnitude of errors in the extra analytical phase laboratory.The information mostly absent in laboratory request forms assessed were physician phone number followed by clinical data of patients and excessive TAT. Regarding to factors that associated with extra analytical error oflaboratory services, our finding revealed that high workload, lack of knowledge, lack of training, lack of communication between lab personnel and physician, have not written procedure for laboratory activitiesand lack of continues education programwere the major factors that affecting Extra analytical error of laboratory. These indicate essential to address shortcomings related to extra analytical phase of laboratory. Extra analytical error of laboratory can lead to misdiagnosis and mishandling of patients.

9.2.Recommendations

Based on thestudy result, the following recommendationswere made;

Continuous practice of measuring errors and provide capacity building,educated or inform the clinicianto fill properly all necessary patient information on laboratory request forms, keep well documented standard operation procedures (SOP) at working area and apply rejection practice in incomplete LRFs and specimen were required to help in reducing extra analytical error of laboratory.

Basic components of laboratory processing with an emphasis on the extra analytical phase of laboratory work movement/flow should be noticeable in the orientation training of all new staff, continues education program of lab personnel and other users of laboratory services(physicians, nurse and Health officer).

Improve and toleratecommonphysician-laboratory communication,periodical meetings to share knowledge and strengthen communication. Periodic complete laboratory audits on extra analytical error could be beneficial to reduce the extra analytical error in the laboratory.

Lab manager control all lab staff to record all extra analytical errors and their root causes as and when they happen. An analysis of documented lab errors and taking corrective actions to avoid such errors in future would go a long way to reduceextra analytical errors and thereby deliver reliable test results within the shortest possible Turnaround time (TAT).

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Annex's

Annex I:

Table -: Proportionate sampling of respondents of Public Hospitals, Addis Ababa, Ethiopia, 2019

Public Hospital	No of lab professional	Sleeted lab professional for interview	hospital laboratory serves an average patients daily	Selected request from form lab for analysis
SPHMMC	36	23	380	280
TASH	38	25	420	309
ALERT	23	15	300	206
SPTSH	24	16	250	214
AMSGH	14	9	150	110
Y12MC	21	14	210	155
MH	19	14	200	199
ZMH	17	12	190	140
GMH	11	7	170	125
TBGH	14	9	205	151
RDH	14	9	240	177
AFH	11	7	230	169
PH	11	9	225	166
Total	256	169	3260	2401

Annex I I: Information sheet

Purpose

I am conducting a research to assessment of extra analytical variables and associated factor on diagnostic services of medical laboratory in public hospitals, Addis Ababa. Your feedback on this research is important and will help to use extra analytical variables as tool for improving quality of diagnostic services.

Participation

I am asking you to voluntarily participate in this study. What is expected from you is to respond questions which may take 15 minutes.

Confidentiality

All the data obtained will be kept strictly confidential by using only code numbers which is filled by the investigators and locking the data.

Right to refuse

Since participation in this study is entirely voluntarily, you can refuse or withdraw to participate in this study at any time. Your refusal will not affect your job or services given in the hospital. If you have any question concerning the study you can ask with the following address

Principal investigator: cherudegfe

Address: Addis Ababa University College of Health science, Department Medical Laboratory Science.

Tel: 0948586832, Email ddress:cheru19d@gmail.com

Addis Ababa, Ethiopia

Annex III: Consent Form

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

Name of participant _____date ____ /____ /____ signature _____

Phone number_____

Name of data collector _____date _____/____/_____ signature _____

Annex IV: Public Hospitals in Addis Ababa

1-St, Paul Hospital Millennium medical College

2-Addis Ababa Burn, Emergency Hospital

3-Black Lion Comprehensive specialized Hospital

4-ALERT Hospital

5-Amanuel Mental specialized hospital

6-St, Peter Tb Specialized Hospital

7-Yekatit 12 Medical College

8-Menelik Hospital

9-Zewuditu Memorial Hospital

10-Ras Desta Damtew Memorial Hospital

11-Gahandi Memorial Hospital

13-Armed Force Hospital

14-Diffence Hospital

Annex IV: Questionnaire

Introduction

This questionnaire has been designed for the sole purpose of collecting data on the Assessment of extra analytical variables andtheir effect on Service Quality in Public Hospitalsin Addis Ababa, Ethiopia. The data collected will be treated with a very high degreeof confidentiality and it is meant for academic purposes only.

Part A: Demographic Profile

	Variables	Response /coding
1	Sex	Male …1 Female….2
2	Age in years	……. Year
3	Marital status	Never married ……..1 Married ……..2 Divorced …….3 Separated …….4
4	Education level (*Please tick where appropriate)*	Diploma...…….1 BSC……2 MSC……..3
5	How many years Work experience	1-2 years……..1 3-5 years……..2 6-10 years…….3 >10 years……4
7	What is Current position in the health institution	Laboratory head …….1 Quality officer……..2 Safety officer…….3 Section heads…….4 Operational staffs……5
8	what is your Laboratory discipline	General laboratory……1

		Clinical chemistry…….2 Hematology…… ….3 Parasitology……...4 Microbiology…….5 Immunology/Serology……6

Part B: Training

		Response /coding
1	Do you participated in training of the professional undertaking the procedure	Yes ……..1 No ……..2
2	Do you participate on continuing education program in related to you work	Yes …….1 No ……..2
3	Do you attending of laboratory refreshing training	Yes …….1 No ……2

Part C: pre- analytical variables

	Variables	Response /coding
1	Do you have written procedure for each laboratory activities	Yes……1 No …….2
2	Do have specific criteria for specimens rejection	Yes ……1 No ……2
3	Do you recorded Each rejected specimen in a log book	Yes…..1 No ……2
4	If the answer/response for Q 3 is no, what is the challenges	Lack of training …….1 Work load……2 Lack knowledge ……3 Other ……..
5	Do you take corrective actions for rejected sample /request?	Yes …..1 No ……2

6	Do you reject an incomplete request	Yes…..1 No…….2
7	If the answer/response for Q 1 is no, what is the reason	Lack of training …….1 Work load……2 Lack knowledge ……3 Other ……..
8	Do you reject unlabeled sample	Yes…….1 No…..2
9	If the answer/response for Q 3 is no, what is the reason	Lack of training …….1 Work load……2 Lack knowledge ……3 Other ……..
5	Do you rejected Contaminated sample	Yes …….1 No ……..2
6	Do you rejected hemolysis Sample	Yes…….1 No ……..2
7	Do you reject clotted sample	Yes ……1 No…….2
08	Do you collect sample according to SOP….?	Yes…….1 No……2
09	If the answer/response for Q8 is no, what is the reasons	Work load ……..1 Lack of knowledge ……2 Lack of training …….3 Other [specify]…….....
10	Do you reject insufficient sample	Ye……1 No……..2
11	Do you prepare patients before sample collection	Yes ……1 No……2

12	If the answer/response for Q10 is no, what is the reason	Lack of training ……..1 Work load…… …2 Lack knowledge ……3 Others ----------
13	How do you rate your laboratory pre-analytical error?	Very high …….1 High …….2 Low …….3 I don't know…….4

Part D: post-analytical variables

	Variables	Response /coding
1	Do you Record and document all data?	Yes …1 No ….2
2	If the answer/response for Q1 is no, what is the reason?	Work load ……..1 Lack of knowledge ……2 Lack of training …….3 Other [specify]…….....
3	Do you Interpreted result Correctly according to SOP?	Yes …..1 No …….2
4	If the answer/response for Q3 is no, what is the reason?	Work load ……..1 Lack of knowledge ……2 Lack of training …….3 Other……
5	Do you Report result timely?	Yes ……1 No ……..2
6	If the answer/response for Q5 is no, what is the reason?	Work load ……..1 Lack of knowledge ……2 Lack of training …….3 Other……

7	Do you Communicated or alert critical result	Yes ……1 No ……..2
8	If the answer/response for Q7 is no, what is the reason?	Work load ……..1 Lack of knowledge ……2 Lack of training …….3 Other…….....
9	Do you reviews or verified Laboratory result	Yes …..1 No …..2
10	If the answer/response for Q9 is no, what is the reason?	Work load ……..1 Lack of knowledge ……2 Lack of training …….3 Other…….....
11	Do you perform or do extra analytical activities of laboratory correctly	Yes …..1 No …..2

Part F: Observational check list to detect Pre-Analytical and post analytical Errors in Laboratory Testing

List of pre analytical error on lab request form	**Per total number of requests**	
	Yes	No
errors concerning patient name		
errors concerning hospital number		
errors concerning patient sex		
errors concerning patient age		
errors concerning physician name		
no physician's contact number		
errors concerning patient location		
errors concerning test ordered		

No ward/location where patient resides		
Number of requests with Illegible handwriting		
List of post analytical error	**Per total number of reported lab result**	
	Yes	No
Excessive TAT		
No Communication of Critical Results		
NoRecord and document		
No reviews or verified result		
List of pre analytical error on sample	**Per total number of sample**	
	Yes	**No**
samples hemolysis		
samples lipemic		
insufficient volume of samples		
Samples not labeled		
samples not labeled		

Declaration

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

M.Sc. candidate: Cheru Degfe (B.Sc.)

Signature: _____

Date of submission: _____

This thesis has been submitted with our approval as advisors.

Advisor: Zemenu Tamir(MSc, Phd cand, Ast. Professor)

Signature: _____

Date: _____

Place: Addis Ababa, Ethiopia.

Advisor: Abay Sisay (Msc, PhD Fellow.)

Signature: _____

Date: _____

Place: Addis Ababa, Ethiopia.