ADDIS ABABA UNIVERSITY

SCHOOL OF GRADUATE STUDIES

FREQUENCY OF SPECIMEN REJECTION AND ASSOCIATED FACTORS AT ST. PAUL HOSPITAL MILLENNIUM MEDICAL COLLEGE, ADDIS ABABA, ETHIOPIA

BY:

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A thesis submitted to the School of Graduate Studies, Addis Ababa University in partial fulfilment of the requirements for the Degree of Masters in Clinical Laboratory Sciences (Clinical Laboratory Management and quality assurance)

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STATEMENT OF AUTHOR

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LIST OF ABBREVIATIONS

AAHB	Addis Ababa Health Bureau
AAU	Addis Ababa University
CBC	Complete Blood cell Count
ENAO	Ethiopian National Accreditation Office
EMLA	Ethiopian Medical Laboratory Association
ISO	International Standards Organization
LIS	Laboratory Information System
MOH	Ministry Of Health
NGO	Non Governmental Organization
SLIPTA	Stepwise Laboratory Improvement Process towards Accreditation

ABSTRACT

Introduction: Laboratory testing is an integral part of the clinical decision-making process, and results of laboratory testing often strongly influence medical diagnoses and therapies. Quality of specimen is an important factor that affects the accuracy and usefulness of laboratory results. The problem is high in resource poor countries like our country, Ethiopia. Identifying the types, frequency and associated factors influencing the quality of clinical samples is important for designing appropriate interventions to prevent their generation and hence improving the quality of laboratory service. Different literatures showed that more than 70% of errors in the laboratory occur in the pre analytical phase.

Objective: The purpose of the study is to determine the frequency of specimen rejection and associated factors of specimens submitted for different tests to the St. Paul hospital millennium medical college, Addis Ababa, Ethiopia.

Methods: Cross sectional study design was applied at St. Paul hospital millennium medical college medical laboratory. A total of 8063 specimens were collected during the study period. The quality of all specimens submitted to laboratory during data collection period were checked and inappropriate specimens were recorded in data collection checklist format. The data was entered and analyzed using SPSS version 16.0 software.

Result: Of 8063 total specimens submitted for testing to the laboratory of St. Paul hospital millennium medical college during the data collection period, 116(1.4%) were rejected. The most frequent reason for rejection was hemolysis of specimen, which occurred much more frequently than the second most cited reasons, clotted specimens and unlabelled specimens. Compared with their respective frequency of rejection of specimens by type of requested laboratory service, significantly more rejected specimens occurred in Hematology

and Serology departments. Compared with the respective frequency with which they collect the specimen, laboratory personnel had significantly fewer rejected specimens than Nonlaboratory personnel. The proportion of specimens that were rejected in emergency department and inpatient services were twice more than for the outpatient services.

Conclusion: Our finding shows the problems of specimens in the preanalytic phase and the factors involved in rejection of specimens, particularly with respect to specimen collections performed outside the laboratory walls by Nonlaboratory personnel who are not under the direct control of the laboratory; moreover, the finding shows that the rates of specimen rejection are higher for inpatients and ED than outpatients, owing to the performance of outpatient procedures by personnel under direct laboratory control.

1. INTRODUCTION

Laboratory testing is an integral part of the clinical decision-making process, and results of laboratory testing often strongly influence medical diagnoses and therapies. There is a long history of quality requirements in laboratory medicine, which have mainly concerned the analytic phase of this process. Owing to the substantial advances in technology, laboratory automation and analytic quality, there is increasing evidence that further quality improvements should be targeted to extra-analytic phases of laboratory testing. (1)

Laboratory errors may be defined as any defect from ordering tests to reporting results and appropriately interpreting and reacting on these. These errors can be occurred at pre analytical, analytical or post analytical stage of the laboratory process. Process analysis has demonstrated that laboratory errors occur primarily in the preanalytic phase, influencing patient outcomes and costs. Literature suggests that pre analytical errors account about 70% of the total errors encountered in the laboratory. (2)

Pre analytical phase is an important component of total laboratory quality. Current efforts towards the standardization of pre analytical phase have increased the awareness of the effect of this critical component on laboratory results. With this awareness and the introduction of strategies to recognize pre analytical errors, the goal of achieving total laboratory quality is finally within our grasp. (3)

After identifying the right patient, specimen collection, handling and processing are the main activities during the pre analytical phase. In case of specimen referral, for tests that are not available at the collection site or when there is equipment breakdown, specimen transportation and storage are also critical part of this phase. The quality of specimens including: optimal amount of specimen, specimen collection procedures, specimen

processing, transportation and storage conditions and other pre analytic variables affect laboratory results. (4)

The adequacy of a specimen is an important factor that affects the accuracy and usefulness of laboratory results. For this reason, most laboratories have guidelines for evaluating specimens submitted for laboratory testing. If specimens fail to meet these criteria of adequacy, it may be necessary to obtain another specimen from the patient, which causes delay, discomfort, and increased cost. (5)

Rejection of specimens has a lot of clinical consequences. For patients, we know that getting another vein-puncture is uncomfortable, and there can be complications such as hematoma. If a lot of extra blood is drawn from a patient, there is also the potential for iatrogenic anemia. Similarly, re-collecting a urine and stool sample carries risks. One reason is that the patient may not be able to produce more urine or stool right away, and of course for those patients who require catheterization, every time you put in a catheter you are potentially introducing bacteria, and the more the patient is catheterized, the greater the risk. (6)

The issue of specimen rejection has always plagued clinical laboratories and continues to be a growing concern. In many hospitals, nurses and other healthcare workers have replaced traditional teams of highly skilled phlebotomists. Often this decentralization occurs with little or no phlebotomy training for the new staff, as facilities make the flawed assumption that sticking patients to obtain blood is a simple procedure. In fact, a great deal of knowledge, skill, and experience is necessary to collect a quality blood specimen that yields the desired results. (7)

Specimens divided by which can easily be recollected from the patient (e.g., a lavender top tube) or not (e.g., cerebrospinal fluid). Irretrievable specimens may also be rare enough to be identified by other means. A recollected specimen does not harm the patient and is

diagnostically equivalent to the original. Examples: throat swab, urine, stool, sputum and blood. A recollected specimen has a potential to negatively impact care or will not represent the original (e.g., unique collections). Examples: cerebrospinal fluid, cord blood, bone marrow and pathology specimens. (8)

The laboratory in most cases has very little control on the collection of specimens for laboratory investigations. The education and awareness of the attendants, orderlies and nurses and attending physicians, who are involved in the collection and transport of the specimen to the laboratory is very important. On the other hand, the technicians must confer to the physician before rejecting any valuable specimens. Frequent staff discussions between the clinicians and the laboratory staff to bridge the gap are necessary to maintain appropriate quality control of lab findings. (9)

The quality of clinical samples is an essential part of the Preanalytical phase cycle of laboratory testing. While 70 % of laboratory errors occur in the Preanalytical phase, little attention is given to it. Wrong or improperly collected samples can lead to equipment breakdown or erroneous results that can in turn impact the quality of patient care. To avoid this, laboratories set rejection criteria to avoid processing unsuitable samples. However rejection of samples also translate into wastage of personnel time in collection, sample collection supplies and unnecessary inconvenience to patients who are re-subjected to additional sample collection; in addition to delays in producing result for test for timely care; hence the need to track frequency and reasons in order to address them. (10)

The concept of quality changed from perception to measurement. The laboratory Services can be viewed as bridging endeavour, linking the basic medical, biological & physical science with medical practice. The laboratory Services are committed to provide the right test result, at the Right time, on the Right specimen, from the Right patient, with result interpretation

based on correct reference data, and at the Right price. Thus keeping in mind the great importance of clinical laboratories in the practice of modern medicine today, it is imperative for the laboratories to be totally committed to quality. Laboratory service has set its Quality indicators and is monitoring it as a part of continual improvement. One of the Quality indicators is Sample rejections. (11)

Generally laboratory specimen rejection criteria includes: specimens that have incomplete or questionable patient demographic data (at least with two patient identifiers –full name and medical record number), absence of clinical information, discrepancy between specimen and request, unclear requested test, unlabeled or mislabelled specimens, clotted samples, overfilled tubes, insufficient quantity of specimen, inadequate sample, specimens that endanger the safety of those or delivering or receiving them, specimens that have questionable integrity in terms of improper collection, specimens that have delayed transportation, inappropriate transport temperature , specimens with bad storage condition and test requested is not available in the laboratory as specified in the laboratory service guide. (12)

The pre analytical phase comprises all of the processes occurring before the sample is analyzed in the laboratory. Although these areas are mostly beyond the legal authority of the clinical laboratory personnel, the credibility of the laboratories is at stake due to these errors. The laboratories have to bear the burden of the inconsistencies that result because of these pre analytical errors. This study will assess how often specimens are rejected and related factors in order to take appropriate measures to prevent their occurrence and produce consistent or correct results.

1.1.Statement of the problem

Laboratory tests are an essential part of the clinical care required to identify a patient's problem ranging between identification of an asymptomatic condition to confirming a diagnosis, tracking complications, monitoring therapy and determining prognosis (outcome) (13). Literatures are suggesting more than 60% of clinical decisions are based on laboratory test results. However, errors at all phases of the laboratory process are a major concern and needs identifying them and designing appropriate intervention to prevent them. More than 70% of errors in the laboratory occur in the pre-analytical phase. Difficulties to objectively monitor most of the pre-analytic variables which lie outside the direct control or supervision of the laboratory personnel call for effective educational and preventive policies. (1)

A recent study by Addis Z. et al in a tertiary care teaching Hospital which is recognized nationally as a four star hospital laboratory revealed that one or more of patient identification parameters were missed in 8.7% of the request papers. Name of the requesting physician and address of the sender were missed from 44.5% and 6.5% of the request papers. None of the requesting physicians mentioned the clinical information of the patients. Examination of the samples showed that 0.98%, 2.8% and 0.98% of the samples were hemolyzed, insufficient for analysis and clotted respectively (14).

On the other hand, a study in a tertiary care teaching hospital in Addis Ababa revealed among the requests sent to hematology laboratory, age and sex information was missing in 14.4% and 10.2% of the request forms, respectively (while reference ranges need to be supplied with the patient result are known to vary between gender and different age groups). 70.1% lack proper clinical details of the patient, 85% lack the name of the physician ordering the test. (15)

These studies shade some light that pre-analytic errors of all types are common in our health facilities. The finding by Zelalem Addis and his colleagues in particular is of a concern since close to 4% specimen related errors are detected in the hematology laboratory of this recognized 4 star laboratory and the situation might be worst in those with less or no stars. Thus, identifying the types, frequency and associated factors influencing the quality of clinical samples is important for designing appropriate interventions to prevent their generation and hence improving the quality of laboratory service.

1.2.Significance of the study

The evaluation of pre-analytical processes in the laboratory, with regard to sample rejection, allowed one to identify problem areas where improvement is necessary. Rejected samples due to factors out of the laboratory's control had a definite impact on patient care and can thus affect customer satisfaction. Clinicians should be aware of these factors to prevent such rejections. Although frequency and factors of specimen rejection varies between laboratories, this study gives an overview of how often specimens are rejected and what are the major factors for the rejection at St. Paul hospital millennium medical college, Addis Ababa. The study will help laboratory to identify the areas where improvement is necessary to minimize specimen rejection.

2. LITERATURE REVIEW

The ISO 15189: 2007 standard for laboratory accreditation defines the pre analytical phase as steps starting in chronological order, from the clinician's request, preparation of the patient, collection of the primary sample, and transportation to and within the laboratory, and ending when the analytical examination procedure begins. This clearly recognizes the need to evaluate, monitor and improve all the procedures and processes on specimens. (16)

Quality of specimens determines accuracy of test results that affects the patient outcomes and the health care service. Those specimens that don't fulfill acceptability criteria should be rejected. Analyses of inadequate specimens have unwanted clinical outcomes and adverse economical consequences. A patient might be diagnosed with a particular disorder, when he/she does not have it (i.e., false-positive test result obtained) or a patient with a true disorder might be missed (i.e., false-negative test result obtained). Both situations will cause adverse consequences for both patients and the health care system. (17). An evaluation conducted to review the incidence of laboratory errors at the University-Hospital of Padova showed that 19% of errors were correlated with further inappropriate investigations and subsequently, an unjustifiable increase in laboratory costs. (13)

Frequency of specimen rejection varies according to the nature of specimens ordered. The type of specimens could be CBC specimens, urine specimens, stool specimens, coagulation specimens, Microbiology specimens, serum etc. Lai X and colleagues reported that among 553,158 samples submitted to laboratory testing, in Hospital of Chongqing Medical University, 1,051 unqualified samples were identified (about 0.19%). From these rejected specimens, samples collected for coagulation tests were the predominant unqualified samples. They also identified the main causes of generation of unqualified samples were insufficient sample volumes and improper methods of mixing the samples. (18)

Different types of specimens have a variety of collection, processing and handling procedure. Specifically blood specimen is more vulnerable to errors. Jones et al noted that among 7,894,882 complete blood count specimens submitted for testing to 703 laboratories, of which 35,347 (0.45%) specimens were rejected. The most frequent reason for rejection was clotted specimen followed by insufficient quantity of specimen. They also discussed that when collected by type of professionals, in this regard, laboratory personnel had significantly fewer rejected specimens than other personnel groups. (19)

The analysis of Chawal R et al at clinical chemistry laboratory of Govind Ballabh Pant Hospital, New Delhi, India, showed that of the 96,328 specimen received for clinical chemistry tests, 1469 specimens were rejected due to different factors. Of the reasons of rejection: 0.74% was rejected due to hemolysis; 0.47% was specimens without proper requisition forms; and 0.23% had insufficient sample quantity. (20)

A study conducted at University hospital of Verona on pre analytical errors in a laboratory medicine department over a one-year period showed that out of 423 075 specimens received for different laboratory tests, 3154 (0.74%) specimens were rejected, and hemolysis and clotting were most frequently related to specimen rejection (21). In a recent hospital study done in America, clotted specimens were a recurrent cause of specimen rejection for inpatients (22).

A retrospective data analysis (2001-2005) done in Spain from 105 laboratories that summarized the main factors affecting pre analytical phase quality determined that from a total of 4,715,132 specimens received, 32,977 (0.699%) were rejected. 81% of rejections arose as a result of the following reasons: "specimen not received" (37.5%), "hemolysis" (29.3%), and "clotted sample" (14.4%). (23)

Most laboratories offer inpatient, outpatient and emergency testing and maintain a specimen collection area in the main laboratory for easy access by outpatients. A retrospective study conducted at the main laboratory at Prince Hamzah Hospital medical laboratory reported that the highest rate of specimen rejection was from inpatient service departments and the main reason of rejection was clotting (24). Many national and international programs to track laboratory quality have reported laboratory specimen rejection rates ranging from 0.3% in outpatient services to 0.83% in inpatient services (5).

A retrospective audit was conducted to investigate the rejection rate of routine blood specimens received at chemistry and hematology laboratories over a 2-week period at a tertiary laboratory in Cape Town. This study showed that from a total of 32,910 specimens received, 481 were rejected, giving a rejection rate of 1.46%. According to this study only 51.7% of rejected samples were repeated. This shows rejection of specimen had an impact on patient care. (25)

The effect of point of collection on proportion of specimen rejection was studied, at The Henry Ford Health System (HFHS), the largest health care provider in south-eastern Michigan, by Stark et al using retrospective study design and reported that a total of 1,364,117 specimens received, of which 0.74% (n =10,094) were rejected because of errors in the Preanalytical phase of laboratory medicine. Specimens rejected in emergency department and inpatient service were 2-fold and 5-fold higher, respectively, than for the outpatient service. This indicates specimens collected by physicians and nurses from inpatient service do not fulfill adequacy criteria of specimens for testing. (26)

A study conducted in 2006, at the University Hospital of Padova, for 3 months shows among a total of 51 746 specimens, 160 of which were confirmed as inappropriate for testing. Although there are many reasons for rejection of specimens, according to Carraro P et al., the

most commonly reported types of causes for specimen rejection are: a) missing sample and/or test request, b) wrong or missing identification, c) contamination from infusion route, d) hemolyzed, clotted, and insufficient samples, e) inappropriate containers, f) inappropriate blood to anticoagulant ratio, and g) inappropriate transport and storage conditions. (27)

Illegibility and completeness of requisition forms for laboratory testing cause misdiagnosis and rejection of the specimens. Chhillar N et al examined a total of 1513 request forms received during a 3 month period from February 2009 to April 2009 at a tertiary care Neuropsychiatry hospital in India reported that no possible diagnosis was provided on 61.20% of forms. They also recognized type of specimen was not mentioned in 61.60% of the forms and 89.25% of all forms were illegible. (28)

A cross sectional study done by Mehrotra DA et al in India showed that from a total of 2000 samples studied and followed, 5.3% samples were rejected. The rejection rate was higher among the hospitals run by charities than government. In all, the rejection rate was higher blood sample (9.1%) as compared to body fluid (8%), urine (6.8%), stool (5.3%) and sputum (3.3%) sample. The main reason of rejection was due to inadequacy of specimen collection by the paramedical staff. (29)

Retrospective study conducted at Prince Hamzah Hospital, Amman/Jordan over a six months period by Abed R; from January 1, 2011 to June 30, 2011 showed that the average rejection rate was 1.5%. The rate of specimen rejection was highest in the medical ward and clotted specimens were the commonest cause for rejection followed by wrong patent identification. (30)

A report by Mweene S et al in Zambia, from June 2011 to August 2012, at Kasama General Hospital showed 287 (1.0%) rejected samples out of a total of 27,543 received for testing, with a mean of 20 samples rejected per month. Reasons for rejection included: clotted whole blood sample (29.7%); no or insufficient sample (23.0%); hemolyzed blood samples (17.8%); use of inappropriate container (12.9%); labelling problems (10.5%) and other problems (6.0%). Overall, blood samples accounted for 95.5% of all rejected samples. (31)

A Study at G. B. Pant Hospital, New Delhi, India by Chawla R et al revealed that Of the 96,328 specimens received during the data collection period, 1469 samples were found unsuitable for further processing. This accounted for 1.52% of all samples collected in the laboratory. Rejections arose as a result of the following reasons: 0.74% was rejected due to hemolysis; 0.47% was specimens without proper requisition slips; and 0.23% had insufficient sample quantity. (32)

A retrospective study conducted by Upreti S et al at Chatrapati Shivaji Hospital on A total of 135808 samples received for testing, 1339 samples were found inappropriate for diagnosis, which approximately constituted 1 % of all samples. Highest numbers of samples were rejected due to misidentification that is 0.35 % and least number were rejected due to dilution of the samples that is 0.04 %. (33)

Mellkie M et al conducted institution based cross-sectional survey supplemented with non-participatory type observational study from February 2012 to September 2012 in laboratories of three governmental hospitals of Gamo Gofa zone, Southern Ethiopia. They included a total of 19 laboratory professionals working in the three governmental hospitals for the survey. They identified that highest proportions of undesirable practices were related to establishment

and adherence to serum/plasma/whole blood rejection criteria, measures taken when produced serum/plasma is too small for analysis, speed and duration of centrifugation. None of the socio-demographic and background information of participants we assessed was associated with undesirability of venous blood sample processing activities. (34)

A research done by Soni DS et al from India showed that sample rejection rate of the Microbiology Laboratory of tertiary care hospital in the month of July 2010 was 0.31%. After the training of the nursing staff as well as resident doctors regarding proper collection & transport of samples based on scientific principles, a decreasing trend in the sample rejection rate was observed, from 0.31% to 0.11 % in the 13 months duration of the study. (35)

The study by Shah KG et al in USA reported that Of the 615 samples collected, 155 samples (25.2%) were hemolyzed. The hemolysis rate of 25.2% for type and screen samples is higher than previously reported in the literature. The data suggest that the high rate of hemolysis in trauma patients was due to the residents lack of experience and skills required to obtain an adequate blood draw. (36)

Literatures regarding the rejection and acceptability of different laboratory specimen types are limited and have not been investigated in detail, in Ethiopia. None of the studies in Ethiopia reported the factors of specimen rejection. Though the study from Gondar University hospital gives clues for further detailed analysis in the other health facilities, there is no published literature in Ethiopia specifically studying the frequencies and associated factors of specimen rejection. So this study fills these gaps of the literatures.

3. OBJECTIVES

3.1. General objective

The objective of this study is to determine the frequency of specimen rejection and associated factors of specimens submitted for different tests to the laboratory of St. Paul hospital millennium medical college, Addis Ababa, Ethiopia.

3.2. Specific objectives

- To determine the frequency of rejection of specimens in St. Paul hospital millennium medical college, Addis Ababa, Ethiopia.
- To assess the reasons for rejection of specimens in St. Paul hospital millennium medical college, Addis Ababa, Ethiopia.
- To calculate the proportion of rejected specimens stratified by point of collection, type of test requested and personnel type in St. Paul hospital millennium medical college, Addis Ababa, Ethiopia.

4. MATERIALS AND METHODS

4.1.Study area and population

The study was conducted at St. Paul Hospital Millennium Medical College from December 1, 2013 to March 30, 2014. St. Paul Hospital is found in Addis Ababa, capital city of Ethiopia. It is teaching and referral Hospital located western part of Addis Ababa, Gulelle sub-city, Woreda 9, House No 461. The hospital is built by Emperor Haileselassie in 1969 with the help of the German Evangelican church aimed to serve the poor. A Millennium medical college was started in 2007. Now it provides service as referral hospital for those people in Addis Ababa and referred from other places and teaching center for Medicine. The Hospital serves an average of 700 Patients daily including private wing. The Hospital has 340 beds. The laboratory gives service on average 300 patients daily including private wing. Many patients referred from different parts of the country. The hospital provides different services for those referred patients. The reason for selection of the study site was its accessibility, and this laboratory has implemented laboratory information system (LIS) and has to assess specimen quality and document reasons for rejection.

4.2.Study design

Cross sectional descriptive study design was applied to determine the frequency of specimen rejection and associated factors at St. Paul Hospital Millennium Medical College.

4.3.Study period

The study was conducted for ten months, of which from December 2013 to March 2014 was a data collection period.

4.4.Study variables

Dependent variable: frequency of specimen rejection.

Independent variables: Reasons for specimen rejection, Personnel type, Point of collection and Work shift.

4.5.Sampling technique and sample size

All samples submitted to the laboratory of St. Paul Hospital Millennium Medical College for analysis during the data collection period were included. In this study a total of 8063 specimens were included. The sampling technique was convenient sampling technique.

4.6. Data collection

The data was collected by principal investigator, and laboratory personals who are working at St. Paul Hospital Millennium Medical College laboratory. The laboratory was record all specimens submitted to the laboratory that was unsatisfactory for the analysis during the study period. The specimen rejected register include the following variables: (1) specimen type (blood, urine, feces, etc), (2) requested laboratory service (hematology, chemistry, etc), (3) personnel type (laboratory or Nonlaboratory), (4) reason for rejection (hemolysis, insufficient volume, etc), (5) point of collection (inpatient, outpatient, etc), (6) work shift (day, evening or night) and (7) measures taken for rejected specimens. (Annex)

4.7.Data quality control

The data collection tool was pre tested for 5 days at St. Paul Hospital Millennium Medical College laboratory. During data collection the collected data was checked for completeness, clarity and consistency by the PI on daily bases. Data was computerized using double data entry to minimize transcription errors.

4.8.Data analysis and interpretation

The overall rate of specimen rejection was calculated by the number of rejected specimens per total specimens. The rejected specimens were analyzed by reasons for rejection, as well as the effect of collection personnel, work shift and point of collection.

The percent of rejected specimens were summarized separately by point of collection, personnel type and requested laboratory service. A Pearson's chi square test was used to test the association between specimen rejection and factors of interest All statistical tests was done by using SPSS version 16.0 software. P values less than 0.05 were considered statistically significant.

4.9. Ethical considerations

Ethical clearance to conduct the study was obtained from the Research Ethics Committee at the School of Medical Laboratory Technology, Addis Ababa University. Permission was also obtained from St. Paul Hospital Millennium Medical College where the study was conducted.

4.10. Research dissemination

The findings of the study will be forwarded to the department of medical laboratory science, college of health science, school of allied health science, Addis Ababa University. I intend to present the findings to St. Paul Hospital Millennium Medical College staffs and Managers, with the hope that it will encourage the responsible individual to reflect on the issue of specimen rejection and decide on quality of specimens. I also propose to submit the study for publication in various Medical Journals.

4.11. Operational definitions

Rejected specimen - specimens that do not fulfill specimen acceptance criteria of the test(s) requested

Point of collection - the sites where the specimens are collected i.e., inside the health facility (emergency, inpatient or outpatient service) or outside the health facility

Work shift – working hours in the health facility classified as day, evening and night.

5. RESULTS

In this study a total of 8063 specimens submitted to the laboratory for different laboratory tests were analyzed, of which 1.4 % (n = 116) were rejected because of errors in the pre analytical phase of laboratory diagnosis. Overall, the most frequent reason for specimen rejection was a hemolyzed specimen followed by clotted specimens and unlabelled specimens.

Table 1: the reasons for specimen rejection by percentage from December 2013 to March 2014 at St. Paul hospital millennium medical college, Addis Ababa, Ethiopia

Reasons for specimen rejection	Number of specimens rejected	Percentage (%)
Hemolyzed	32	27.6
Unlabelled	19	16.4
Clotted	19	16.4
Low quantity	17	14.7
Delay in time	8	6.9
Contaminated	6	5.2
Sample without request form	6	5.2
Others	9	7.8
Total	116	100

Stratification of data by the type of requested laboratory service revealed that the proportions of rejected specimens were the highest in the Hematology department (30.2%) followed by Serology department (29.3%). The rejection was 24.1%, 12.1% and 4.3% in Microbiology, Clinical Chemistry, and in Parasitology and Urinalysis department, respectively. After adjusting for the total numbers of specimens submitted to each department, the proportion of rejected specimens both in Hematology and Serology departments were higher than other departments, which was more than twice of rejected in Clinical Chemistry department, and 7-

fold higher than specimens rejected in Parasitology and Urinalysis department ($P < .001$) (Table 2).

Table 2: the status of laboratory specimens by type of requested laboratory service from December 2013 to March 2014 at St. Paul hospital millennium medical college, Addis Ababa, Ethiopia

Specimen status	Requested laboratory services					Total
	Microbiology	Serology	Hematology	Clinical chemistry	Parasitology and urinalysis	
Accepted	1405(98.0%)	1566(97.9%)	1654(97.9%)	1732(99.2%)	1590(99.7%)	7947(98.6%)
Rejected	28(2.0%)	34(2.1%)	35(2.1%)	14(0.8%)	5(0.3%)	116(1.4%)
Total	1433(100%)	1600(100%)	1689(100%)	1746(100%)	1595(100%)	8063(100%)

Further evaluation of data showed that 54.3% (n = 19) of the rejected specimens in Hematology department were because of specimens clotted, 22.8% (n = 8) because of insufficient quantity of specimens, and the remaining 22.8% (n = 8) were rejected because of other mentioned reasons (Table 3).

Of the total specimens that were rejected in Serology department, 73.5% (n =25) were rejected because of hemolysis, 8.8% (n = 3) because of low quantity, 8.8% (n = 3) because of labelling problems, and the remaining 8.8% (n=3) because of other mentioned and unspecified problems (Table 3).

Of the specimens rejected in the microbiology department, 28.6% (n = 8) because of unspecified problems (inappropriate specimen was the major one particularly sputum

specimens), 25% (n = 7) were rejected because of unlabelled specimens, and the remaining 46.4% (n = 13) were rejected because of other mentioned reasons. (Table 3)

Of the specimens rejected in Clinical Chemistry department, 35.7 %(n=5) were rejected because of hemolysis, 35.7 %(n=5) because of labelling problems, and remaining 28.6% (n=4) were due to other reasons (Table 3). Finally, of the specimens rejected in Parasitology and Urinalysis department, 60% (n=3) were rejected because of insufficient quantity of specimens and 40% (n=2) were because of specimens contaminated (Table 3).

Table 3: the reasons for specimen rejection by type of requested laboratory service from December 2013 to March 2014 at St. Paul hospital millennium medical college, Addis Ababa, Ethiopia

Reasons for specimen rejection	**Requested laboratory service**					**Total**
	Microbiology	**Serology**	**Hematology**	**Clinical chemistry**	**Parasitology and urinalysis**	
Unlabelled	7(25%)	3(8.9%)	4(11.4%)	5(35.7%)	0(0%)	19(16.4%)
Delay in time	3(10.7%)	1(2.9%)	2(5.7%)	2(14.3%)	0(0%)	8(6.9%)
Contaminated	4(14.3%)	0(0%)	0(0%)	0(0%)	2(40%)	6(5.2%)
Hemolyzed	0 (0%)	25(73.5%)	2(5.7%)	5(35.7%)	0(0%)	32(27.6%)
Clotted	0 (0%)	0(0%)	19(54.3%)	0(0%)	0(0%)	19(16.4%)
Sample without request form	5(17.8%)	1(2.9%)	0(0%)	0(0%)	0(0%)	6(5.2%)
Low quantity	1(3.6%)	3(8.9%)	8(22.9%)	2(14.3%)	3(60%)	17(14.7%)
Others	8(28.6%)	1(2.9%)	0(0%)	0(0%)	0(%)	9(7.8%)
Total	28(100%)	34(100%)	35(100%)	14(100%)	5(100%)	116(100%)

Evaluation of data by the type of personnel who has collected the specimen showed that the proportions of rejected specimens were higher for laboratory personnel (66.4%) than non laboratory personnel (33.6%). This is because; the majority of laboratory specimens were collected by laboratory personnel. However, after adjusting for the total number of specimens collected by each personnel, the proportion of rejected specimens from non laboratory personnel were more than twice that of laboratory personnel ($P < .001$) (Table 4). Further evaluation of data showed that 28.2% (n = 11) of the rejected specimens collected by non laboratory personnel were rejected because of labelling problems, 17.9% (n = 7) because of delay in time, 12.8% (n = 5) because of hemolysis, 12.8%(n=5) because of specimens were contaminated and the remaining 28.3% (n = 11) were rejected because of other mentioned and unspecified reasons (Table 5). Of the rejected specimens that were collected by laboratory personnel, 35.1% (n =27) were rejected because of hemolysis, 20.8% (n = 16) because specimens were clotted, 16.8% (n = 13) because of low quantity of specimens and the remaining 27.3% (n=21) were rejected because of the other mentioned and unspecified problems (Table 5).

Table 4: the status of laboratory specimen by type of personnel collected the specimen from December 2013 to March 2014 at St. Paul hospital millennium medical college, Addis Ababa, Ethiopia

Specimen status	**Type of personnel**		**Total, No (%)**
	Laboratory personnel	**Nonlaboratory personnel**	
Accepted, No (%)	6572 (98.8%)	1375 (97.2%)	7947 (98.6%)
Rejected, No (%)	77 (1.2%)	39 (2.8%)	116 (1.4%)
Total, No (%)	6649 (100.0%)	1414 (100.0%)	8063 (100.0%)

Table 5: the reasons for specimen rejection by type of personnel collected the specimen from December 2013 to March 2014 at St. Paul hospital millennium medical college, Addis Ababa, Ethiopia

Reasons for specimen rejection	Type of personnel		Total
	Laboratory personnel	Non laboratory personnel	
Unlabelled	8 (10.4%)	11(28.2%)	19 (16.4%)
Delay in time	1 (1.3%)	7(17.9%)	8 (6.9%)
Contaminated	1(1.3%)	5(12.8%)	6 (5.2%)
Hemolyzed	27(35.1%)	5(12.8%)	32 (27.6%)
Clotted	16(20.8%)	3(7.7%)	19 (16.4%)
Sample without request form	3(3.9%)	3(7.7%)	6 (5.2%)
Low quantity	13(16.8%)	4(10.2%)	17 (14.7%)
Others	8(10.4%)	1(2.7%)	9 (7.8%)
Total	**77(100.0%)**	**39(100.0%)**	**116 (100%)**

Stratification of data by the site of service revealed that the proportions of rejected specimens were the highest in the outpatient services (58.6%) followed by inpatient service and emergency department with 30.2% and 11.2%, respectively. However, after adjusting for the total number of specimens submitted by each site, the proportion of rejected specimens from both inpatient and emergency department were more than twice that of the outpatient services ($P < .001$) (Table 6).

Further evaluation of data showed that 46.1% (n = 6) of the rejected specimens from the ED were because of hemolysis, 23.1% (n = 3) because of unlabelled specimens, 15.4% (n = 2) because of low quantity of specimens and the remaining 15.4% (n = 2) were rejected because of samples without request form and clotted specimens (Table 7).

Of the rejected specimens that were collected in the inpatient services, 28.6% (n =10) were rejected because of labelling problems, 20.0% (n = 7) because of delay in time, 14.3% (n = 5) because of contamination, 11.4% (n=4) because of low quantity and the remaining 25.7% (n = 9) were rejected because of the other mentioned problems (Table 7).

Finally, of the specimens collected in the outpatient services, 33.8% (n = 23) were rejected because of hemolysis, 22% (n = 15) because of specimens were clotted, 16.2% (n = 11) because of low quantity, and the remaining 28% (n = 19) because of the other mentioned problems and unspecified reasons (Table 7).

Table 6: the status of specimen by point of specimen collection from December 2013 to March 2014 at St. Paul hospital millennium medical college, Addis Ababa, Ethiopia

Specimen status	**Specimen collection sites**				**Total, No (%)**
	Emergency department	**Inpatient service**	**Outpatient service**	**Outside the institution**	
Accepted, No (%)	437 (97.1%)	1180 (97.1%)	6329 (98.9%)	1 (100.0%)	7947 (98.6%)
Rejected, No (%)	13 (2.9%)	35 (2.9%)	68 (1.1%)	0 (0.0%)	116 (1.4%)
Total, No (%)	450 (100.0%)	1215 (100.0%)	6397 (100.0%)	1 (100.0%)	8063 (100.0%)

Table 7: the reasons for specimen rejection by point of specimen collection from December 2013 to March 2014 at St. Paul hospital millennium medical college, Addis Ababa, Ethiopia

Reasons for specimen rejection	Site of specimen collection			Total
	Emergency department	Inpatient service	Outpatient service	
Unlabelled	3(23.1%)	10 (28.6%)	6 (8.8%)	19 (16.4%)
Delay in time	0(0.0%)	7 (20.0%)	1 (1.5%)	8 (6.9%)
Contaminated	0(0.0%)	5 (14.3%)	1 (1.5%)	6 (5.2%)
Hemolyzed	6(46.1%)	3 (8.6%)	23 (33.8%)	32 (27.6%)
Clotted	1(7.7%)	3 (8.6%)	15 (22.0%)	19 (16.4%)
Sample without request form	1(7.7%)	2 (5.7%)	3 (4.4%)	6 (5.2%)
Low quantity	2(15.4%)	4 (11.4%)	11 (16.2%)	17 (14.7%)
Others	0(0.0%)	1 (2.8%)	8 (11.8%)	9 (7.8%)
Total	13 (100.0%)	35 (100%)	68 (100%)	116 (100%)

We assessed the proportion of rejection by the work shifts of the laboratory personnel. About 91.4% of rejections occurred during the day shift. Laboratory personnel working during the evening and midnight shift accounted for 6% and 2.6% of rejected specimens, respectively. Proportion of rejected specimens was then adjusted for the total number of specimens that were submitted to the laboratory during each shift. The proportion of rejections was the

highest for the evening shift (2.1%), followed by the midnight shift (1.7%) and day shift (1.4%), respectively ($P = 0.6$).

We also assessed the proportion of rejection by the type of specimens submitted to the laboratory for different diagnosis. About 77.6% of rejections occurred on blood specimens that were submitted to different laboratory departments. Urine, sputum, feces and other unspecified specimens accounted for 11.2%, 6.9%, 0.9% and 3.4% of rejected specimens, respectively. Proportion of rejected specimens was then adjusted for the total number of specimen's type that was submitted to the laboratory. The proportion of rejections was highest for blood specimens (1.8%), followed by other unspecified specimens (1.5%), sputum specimens (1.3%), urine specimens (1.2%) and feces specimens (0.1%), respectively ($P = 0.007$).

6. DISCUSSION

We conducted a cross-sectional study with the primary objective of determining the frequency of specimen rejection and associated factors of specimens submitted for different laboratory tests. Identification and documentation of a problem is a first step in the multistep process of reducing errors and improving the quality of health care.

Of 8063 specimens submitted to the laboratory for different laboratory tests during the study period, 1.4% was rejected. The rate of rejection was almost similar with Retrospective study conducted at Prince Hamzah Hospital, Amman/Jordan over a six months period by Abed R and A Study at G. B. Pant Hospital, New Delhi, India by Chawla R et al which were1.5% and 1.52%, respectively(30, 32). But this finding is much higher than the studies reported by Lippi G et al and Alsina MJ et al which were 0.74% and 0.699% respectively(22, 23). The difference may be due to the study design used, the sample size and the number of data collection sites.

In this study, the overall specimen rejection rate was 1.4%, which was almost twice as high as the median rate (0.45%) that was reported by the College of American Pathologists Q-Probe study of 703 laboratories in 1999 (19). This difference may be due to the variations in the number of institutions involved in each study, the method of data collection and reporting, and the definition of errors. Our finding is derived from practitioners, policies, and procedures used in one single medical laboratory only; whereas, the previous study was the result of cooperation of a total of 703 different laboratories. The heterogeneity in the definition of errors has been reported as one of the difficulties in assessing the true rates of errors in the preanalytic phase of laboratory diagnosis (37).

Almost 28% of the rejections were because of hemolysis, which occurred much more often than the second reasons, unlabelled specimens and clotted specimens. Chawla R et al also

reported that the main reason for rejection was hemolysis followed by without request form and insufficient quantity (32). Because of the predominance of hemolysis, the laboratory may benefit from review of blood collection procedures to identify problems, such as inappropriate drawing of specimen and transferring the specimen to collection tubes.

When the rejection percentages stratified by requested laboratory services, there was a greater rate of rejection occurred on specimens submitted for Hematology and Serology departments than other laboratory departments.

Although the data showed that laboratory personnel collected more than three quarter of all specimens, they collected a little more than half of the rejected specimens. This finding appears to substantiate the value of the training and experience laboratorians devoted to phlebotomy as a clinical skill. In this study, Nonlaboratory personnel (i.e. nurses, physician, medical students, and other personnel not accountable to the laboratory) produced disproportionately higher percentage of rejected specimens. Findings from the Q-Probe study yielded a significant increase in the probability of rejection if the specimen was collected by Nonlaboratory personnel (19). Our finding also showed that from the collected specimens there were higher amount of specimens rejected by Nonlaboratory personnel. This Specimen rejection rate may benefit from directed educational efforts. Otherwise, it appears that focusing specimen collection skills in specially trained phlebotomy teams is relatively efficient. This outcome showed that basing specimen collection in the laboratory is more conductive to efficient specimen collection than basing them elsewhere.

The reasons for rejection also varied somewhat by personnel type. The Nonlaboratory personnel category had a lower percentage hemolysis than laboratory personnel; however, Nonlaboratory personnel had a greater percentage of rejection because they were unlabelled and delayed in time (28.2% and 17.9%, respectively). Laboratory personnel had a lower

percentage of delay in time and contaminated specimens than Nonlaboratory personnel, and a greater percentage of specimens rejected because they were hemolyzed and clotted. Laboratory personnel may be more conscious of the importance of blood specimen collection procedures (or receive more effective feedback in this matter) than their clinical colleagues. Any personnel category can be associated with a higher than expected rate of rejection should be targeted by the laboratory for additional training and subsequent training.

Our finding showed that the proportions of rejected specimens that were collected in the ED and in the inpatient services was higher compared with previous findings by Stark et al (19). This difference may be attribute to, our finding to a combination of several factors such as the practice of specimen collection in the ED and the inpatient services, the higher complexity of the examination performed, and the number of physicians involved with the care of a patient (38). Also, it is common for the medical staff at the ED and inpatient services to collect a blood specimen through an intravenous catheter at the time of its insertion to minimize the patient's discomfort and to save clinical time (39). In addition, the lesser proficiency and training of Nonlaboratory staffs in phlebotomy relative to the trained laboratory phlebotomist may be another reason for the higher specimen rejections in ED and inpatient services.

In our findings about 87% of rejected specimens were repeated for diagnosis. When the quality of a blood specimen is poor, it cannot be processed by the laboratory. This leads to a second request for specimens and therefore to an increased turnaround time for the laboratory, which is positively correlated with the delay in diagnosis. About 90% to 96% of the diagnostic delays have been attributed to problems associated with errors in preanalytic phase of laboratory medicine (40).

7. LIMITATIONS OF THE STUDY

The limitation of our study is that the pre-analytical variables like patient preparation, patient drug intake, diet, and timing of sampling and application of tourniquet have not been included as this is a hospital based laboratory where samples are received from ED and inpatient services. In our study specimens collected at the weekends are not included because these specimens not recorded within the laboratory.

8. CONCLUSION AND RECOMMENDATIONS

Our finding shows the rate of specimen rejection was 1.4% and the most frequent reasons are hemolysis, clotting and labelling problems of specimens in the preanalytic phase. The study also shows particularly with respect to specimen collections performed outside the laboratory walls by Nonlaboratory personnel who are not under the direct control of the laboratory; moreover, the finding shows that the rates of specimen rejection are higher for inpatients and ED than outpatients, owing to the performance of outpatient procedures by personnel under direct laboratory control.

Therefore, the main take-home message is the need to prepare and adopt standard operating procedures for specimen collection. Such standard operating procedures should be developed by use of a consensus process that includes both the laboratory and the wards. This approach should also be used to improve on appropriateness in test requesting, procedures for safely performing patient identification and preparation, aspects that are beyond the scope of the present study.

The appropriate training and education required for specimen collection should be developed collaboratively between the ward and the clinical laboratory, thus enabling all involved to understand the important and complementary roles each plays.

Technological tools, information technology in particular, play a key role in assuring traceability and higher safety in all the preanalytic steps, but the active and cooperative involvement of human resources is mandatory to reduce errors.

To conclude, we would like to state that we as laboratorians need to adopt a holistic approach toward laboratory diagnosis and function in concert with the Nonlaboratory personnel to provide effective services to the patients. Adoption of quality control in all the phases and not

merely the analytical processes, and regular appraisal and audits are necessary to safeguard patient interests and deliver our services to society.

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ANNEXS

ANNEX I: CONSENT FORM

Code number _____

Name of the Health facility _____

I have been informed about the study which is aimed at assessing the frequency of specimen rejection and associated factors of specimens submitted for different tests to the laboratory of St. Paul Hospital Millennium Medical College, in Addis Ababa, Ethiopia. For this study true and direct information is needed to fill the questionnaire and a document observation will be performed. The aims of the study were explained to me.

It is therefore with full understanding of the situation that I gave the informed consent voluntarily to the researcher to use the information gathered within the laboratory regarding specimens. In addition, I have had the opportunity to ask questions about it and received clarification. I have also been informed that the benefit of the laboratory is to identify factors affecting specimen quality and hence design appropriate intervention strategies so as to improve the quality of the laboratory service.

Laboratory head Signature _____

Name of data collector _____ Signature_____ Date _____

Please direct any questions or problems you may encounter during this study to:

Name: Habtamu Molla

Mobile: +251-91-07-22-375

Email: habtamumolla8@gmail.co

ANNEX II: DATA COLLECTION CHECKLIST FORMAT

Patient ID_____

1. Type of specimen collected
    a. Blood
    b. Urine
    c. Feces
    d. CSF
    e. Sputum
    f. Others
2. The personnel responsible for collection
    a. Laboratory personnel
    b. Nonlaboratory personnel
3. The site where the specimen collected
    a. Emergency department
    b. Inpatient service
    c. Outpatient service
    d. Referred
4. The requested laboratory service
    a. Microbiology
    b. Serology
    c. Hematology
    d. Clinical chemistry
    e. Parasitology and urinalysis
5. Time of specimen collection work shift
    a. Day shift

b. Evening shift

c. Midnight shift

6. Status of the specimen

   a. Accepted for analysis

   b. Rejected

7. If rejected, what is the reason for rejection

   a. Unlabelled

   b. Sample lost

   c. Delay in time

   d. Contaminated

   e. Hemolyzed

   f. Clotted

   g. Incorrect transportation

   h. Sample without request form

   i. Low quantity

   j. Others (specify)_____

8. What corrective actions or measurements taken on rejected specimens?

   _____

ANNEX III: DECLARATION

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

Name: Habtamu Molla

Signature: _____

Place: _____

Date of submission: _____

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

Name: _____ _____

Signature: _____ _____

Place: _____ _____

Date: _____ _____