

Frequency of Specimen Rejection and Associated Factors at St. Paul's Hospital Millennium Medical College, Addis Ababa Ethiopia

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ABSTRACT

Background: Clinical laboratory diagnosis is an integral part of the clinical decision of health care service. While every phase is error prone, different literatures showed that more than 70% of errors in clinical laboratory occur in the pre analytical phase. The purpose of this study is to determine the frequency of specimen rejection and associated factors at St. Paul's Hospital Millennium Medical College, Addis Ababa, Ethiopia.

Methods: Cross sectional study was conducted. A total of 8063 specimens were collected from December 1, 2013 to March 30, 2014. The quality of all specimens submitted to laboratory during the data collection period was checked and inappropriate specimens were recorded in data collection format. The data was entered and analyzed using SPSS version 16.0 software. Chi square test was used to see associations and binary logistic regression was used to avoid confounding effect. P value less than 0.05 was taken as statistically significant.

Results: of the total 8063 specimens submitted to the laboratory, 116(1.4%) were rejected. The most frequent reason of rejection was hemolysis (27.6%), followed by clotting specimens (16.4%) and unlabelled specimens (16.4%). Significantly more rejected specimens occurred in Hematology (2.1%) and Serology (2.1%) departments. More than twice higher rejections were recorded for specimens collected by non-laboratory personnel (2.8%) compared to collection by laboratory personnel (1.2%)($P<0.001$). The proportion of specimens that were rejected in emergency department (ED) and inpatient service were twice more than the outpatient (1.1%) services ($P<0.001$). No

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Habtamu Molla
Tesfaw

statistically significant difference was noted in rejection rates between work shifts.

Conclusion: Quite high numbers of specimens were rejected during the study period, rejection rates being higher in those collected by non-laboratory personnel and those collected from in patient and ED. Thus, availing and adherence to standard operating procedures and targeted training for those who collect specimen is needed.

1. INTRODUCTION

Clinical laboratory diagnosis is a part of the whole clinical decision in health care service, so the laboratory diagnosis results strongly affect patient treatments and care. In the past, quality improvement of laboratory diagnosis focused mainly on analytical phase of laboratory process. Nowadays laboratory automation technologies and improvements in analytical quality, quality of pre analytical and post analytical phases of clinical laboratory testing should be targeted [15, 20].

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 [25-26].

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 [12].

Rejection of specimens has a lot of clinical consequences. Re-collecting of venous blood for a patient is uncomfortable, and there is a risk of complication like hematoma and iatrogenic anemia. Similarly, there is a risk in re-collecting urine and stool samples. For example, hard to get more urine and stool right away, and for patients who require catheterization, there is greater risk for infection [6, 9, 28].

In most areas, clinical laboratory has little control on collection of specimens for laboratory examinations. Non laboratory personnel like nurses, physicians and others who are involved in specimen collection for laboratory examination

should be aware of specimen collection and transport procedure which is very important for quality of laboratory results. Specimens which do not fulfill the required quality will be rejected as per the rejection criteria. However, the laboratory personnel must inform to the physician or nurse before rejecting any valuable specimens. Continuous communication between laboratory staff and other health care providers is necessary to maintain quality of laboratory results [4, 7, 19, 27].

Frequency
of Specimen
Rejection and
associated factors
at St. Paul Hospital
Millennium
Medical College,
Addis Ababa
Ethiopia

Literature is 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 laboratory errors occur in the pre analytical phase. Most of pre analytical phase variables are out of direct control of laboratory personnel, and it needs effective educational and preventive policies [29].

Pre analytical phase evaluation, particularly regarding sample rejection, is important to identify areas which need improvement. Rejections of samples due to factors out of the laboratory's control affect quality of patient care and 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 the laboratory to identify the areas where improvement is necessary to minimize specimen rejection.

2. METHODOLOGY

2.1 Study area and population

The study was conducted at St. Paul's 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 Evangelical church with the aim of serving the poor. A Millennium medical college was started in 2007. Now it serves as referral hospital for those people in Addis Ababa and referred from other places and as a teaching center for Medicine. The hospital has about 340 beds and serves an average of 700 patients daily including in its private wing. The laboratory gives service on average 300 patients daily including private wing. The reason for selection

Habtamu Molla
Tesfaw

of the study site was its accessibility, and the laboratory has implemented laboratory information system (LIS) and has to assess specimen quality and document reasons for rejection.

2.2 Study design and Sampling technique

Cross sectional descriptive study design was applied to determine the frequency of specimen rejection and associated factors at St. Pual's Hospital Millennium Medical College. All samples submitted to the laboratory of the Hospital for analysis during the data collection period were included. In this study a total of 8063 specimens were included by employing convenient sampling technique.

2.3 Procedure for Data collection

The data was collected by principal investigator, and laboratory personnel who are working at St. Paul Hospital Millennium Medical College laboratory. The laboratory records all specimens submitted to the laboratory that were unsatisfactory for the analysis during the study period. The specimen rejection register include the following variables: (A) specimen type (blood, urine, feces, etc), (B) requested laboratory service (hematology, chemistry, etc), (C) personnel type (laboratory or Nonlaboratory), (D) reason for rejection (hemolysis, insufficient volume, etc), (E) point of collection (inpatient, outpatient, etc), (F) work shift (day, evening or night) and (G) measures taken for rejected specimens.

2.4 Definitions of terms

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.

2.5 Statistical analysis

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. Binary logistic regression was used to avoid confounding effect. P values less than 0.05 was taken as statistically significant. All statistical tests were done by using SPSS version 16.0 software.

Frequency
of Specimen
Rejection and
associated factors
at St. Paul Hospital
Millennium
Medical College,
Addis Ababa
Ethiopia

2.6 Ethical considerations

Ethical clearance to conduct the study was obtained from Departmental Research Ethics and Review 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.

3. RESULTS

In this study a total of 8063 specimens submitted to the laboratory for different laboratory tests were analyzed. Figure 1 depicts the number (percent) of requested test types by the laboratory service to which the request was sent. Accordingly, the majority of requests were for Clinical chemistry tests

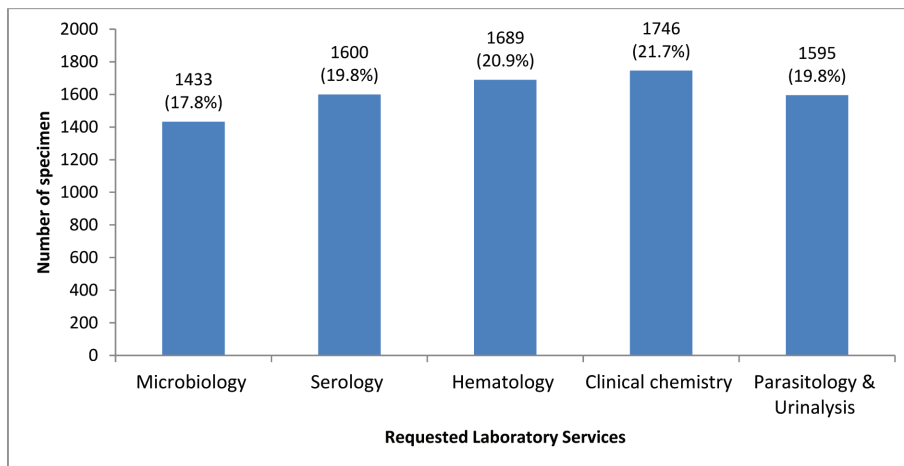


Figure 1: Distribution of Requested test types by department from December 2013 to March 2014 at St. Paul's Hospital Millennium Medical College, Addis Ababa, Ethiopia. Number and percentage of requested test type are shown on the bar graph.

Habtamu Molla
Tesfaw

(21.7%) followed by Hematology (20.9%), Serology (19.8%), Parasitology and Urinalysis (19.8%), and Microbiology (17.8%).

Of the total 8063 specimens, 1.4 % (n = 116) were rejected because of errors in the pre analytical phase of laboratory diagnosis. As shown in Table 1, overall, the most frequent reason for specimen rejection was hemolysis (27.6%) followed by clotting (16.4%), unlabelled specimens (16.4%), and insufficient specimens (14.7%).

Stratification of data by the type of requested laboratory service revealed that, of the total 116 specimens rejected, 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 (Figure 2).

After adjusting for the total numbers of specimens submitted to each department, the proportion of rejected specimens both in Hematology (2.1%) and Serology (2.1%) departments were higher than other departments, which was more than twice of rejected in Clinical Chemistry department (0.8%), and 7-fold higher than specimens rejected in Parasitology and Urinalysis department(0.3%)(Table 2).

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;

Table 1: Reasons for specimen rejection from December 2013 to March 2014 at St. Paul’s 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	14.6
Delay in time	8	6.9
Contaminated	6	5.2
Sample without request form	6	5.2
Others	9	7.7
Total	116	100

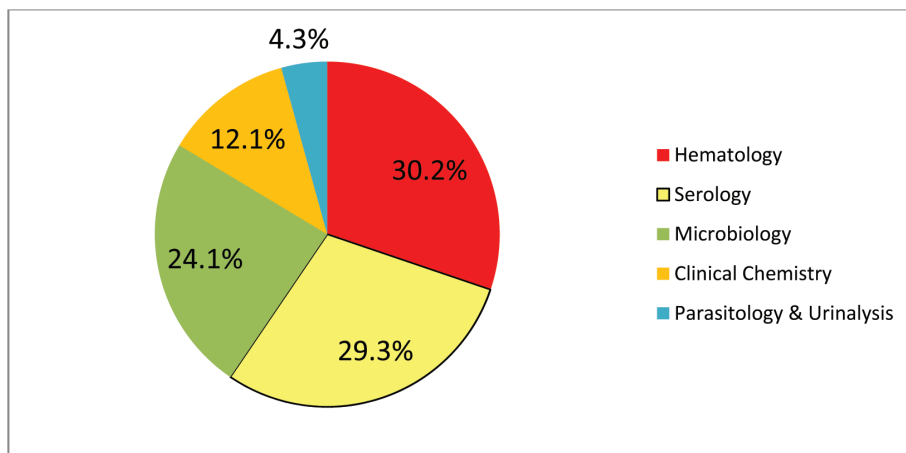


Figure 2: Distribution of rejected specimens (n=116) by laboratory service areas from December 2013 to March 2014 at St. Paul’s Hospital Millennium Medical College, Addis Ababa, Ethiopia

Table 2: Status of laboratory specimens by type of requested laboratory service from December 2013 to March 2014 at St. Paul’s Hospital Millennium Medical College, Addis Ababa, Ethiopia

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

*Pearson Chi-Square test (df = 4 and P<0.001)

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 (2.8%) were more than twice that of laboratory personnel (1.2%). As shown in Figure 3, of the total 8063 specimens, 1414 of them were collected by non-laboratory personnel.

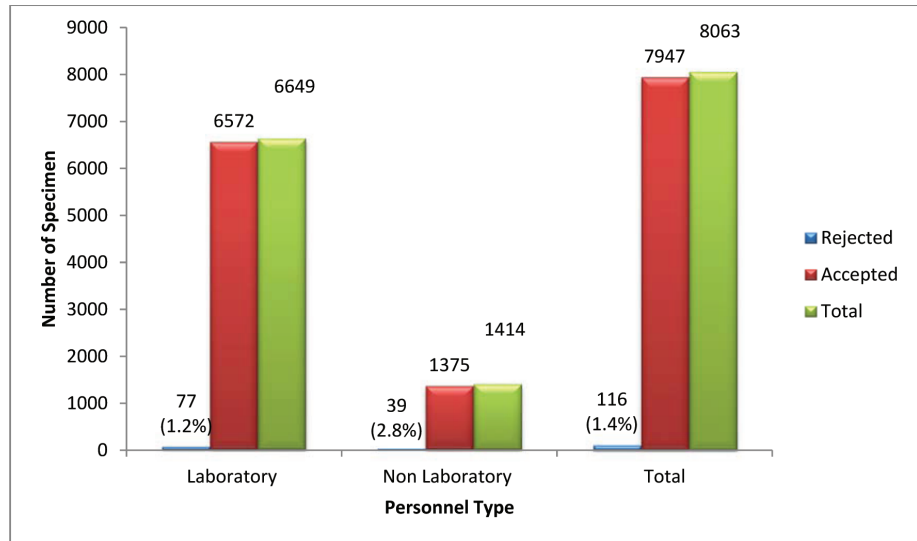


Figure 3: Status of laboratory specimen by type of personnel collecting the specimen from December 2013 to March 2014 at St. Paul’s Hospital Millennium Medical College, Addis Ababa, Ethiopia

Table 3: Reasons for specimen rejection by type of requested laboratory service from December 2013 to March 2014 at St. Paul’s Hospital Millennium Medical College, Addis Ababa, Ethiopia

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

(*Pearson Chi-Square test (df = 1 and P<0.001))

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 inpatients (2.9%) and emergency department (2.9%) were more than twice that of the outpatient services (1.1%). (Table 5)

Frequency
of Specimen
Rejection and
associated factors
at St. Paul Hospital
Millennium
Medical College,
Addis Ababa
Ethiopia

Table 4: 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%)

Table 5: 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	437 (97.1%)	1180 (97.1%)	6329 (98.9%)	1 (100%)	7947 (98.6%)
Rejected	13 (2.9%)	35 (2.9%)	68 (1.1%)	0	116 (1.4%)
Total	450(100%)	1215 (100%)	6397 (100%)	1 (100%)	8063 (100%)

*Pearson Chi-Square test (df = 3 and P<0.001)

Table 6: 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%)

Table 7: Influence of different factors on specimen status

Characteristics	Specimen status		COR(95% CI)	P value	AOR(95% CL)	P value
	% accepted	% rejected				
Work shift						
Day time	98.6	1.4	+			
Evening time	97.9	2.1	1.47(0.679–3.184)	0.329		
Night time	98.3	1.7	1.196(0.376–3.804)	0.762		
Personnel type						
Lab personnel	98.8	1.2	+			
Non lab personnel	97.2	2.8	2.421(1.640–3.574)	< .001	0.357(0.104–0.791)	0.004
Collection site						
Emergency department	97.1	2.9	2.769(1.518–5.052)	0.001	0.418(0.208–0.842)	0.015
Inpatient service	97.1	2.9	2.761(1.828–4.171)	< .001	0.388(0.148–1.021)	0.055
Outpatient service	98.9	1.1	+			

Requested lab test							Frequency of Specimen Rejection and associated factors at St. Paul Hospital Millennium Medical College, Addis Ababa Ethiopia
Microbiology	98.0	2.0	6.337(2.440–16.457	< .001	0.214(0.081–0.565)	0.002	
Serology	97.9	2.1	6.904(2.693–17.699	< .001	0.170(0.066–0.438)	< .001	
Hematology	97.9	2.1	6.729(2.630–17.219	< .001	0.171(0.066–0.438)	< .001	
Clinical chemistry	99.2	0.8	2.570(0.924–7.152)	0.071	0.442(0.158–1.235)	0.119	
Parasitology & urinalysis	99.7	0.3	+				

*COR indicates crude odd ratio, AOR adjusted odd ratio, CI confidence interval, and + indicates baseline

4. DISCUSSION

Of the 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 a retrospective study conducted at Prince Hamzah Hospital, Amman/Jordan over a six months period by [1] and a Study at G. B. Pant Hospital, New Delhi, India by [10] which were 1.5% and 1.52%, respectively [2,13, 33]. But this finding is much higher than the studies reported [20] and [3] which were 0.74% and 0.699%, respectively [3,6,18]. The difference may be due to the study design used, the sample size and the number of data collection sites. Moreover, in addition to the large sample size they used in their study which are in millions, technical capacity differences might also contribute since those studies are from the more affluent nations.

Again the observed overall specimen rejection rate of 1.4%, was nearly 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 [32]. This difference may be due to the difference in total health organizations included in the study, data collection methods and reporting mechanism difference, and the difference in defining laboratory errors. Our study uses data derived from one single medical laboratory only; whereas, the previous study was the result of a combination of a total of 703 different laboratories.

Almost 28% of the rejections were because of hemolysis, which occurred much more often than the second reasons, unlabelled specimens and clotted specimens. also reported that the main reason for rejection was hemolysis followed by specimens sent to the laboratory without request form and insufficient quantity [10]. 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.

Habtamu Molla
Tesfaw

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. The commonest reason for rejection of specimens for hematology was due to clotting (54.3% of the rejected specimens), a finding which is consistent with that of Abed R, 2013 [1].

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. But when the data is adjusted for the total number of collections, the rate of rejection was significantly lower than that collected by non laboratory personnel. This finding appears to substantiate the value of having trained and experienced laboratorians devoted to phlebotomy as a clinical skill. In this study, Nonlaboratory personnel (such as nurses, physician, medical students, and other personnel not accountable to the laboratory) produced disproportionately higher percentage of rejected specimens [10,34] corroborating our finding. This specimen rejection rate may benefit from directed educational efforts. Those specimen collectors outside the direct control of the laboratory need to be trained about following SOPs for specimen collection, handling and transportation. Communicating the specimen rejection criteria would also help to alert them. 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 conducive to efficient specimen collection than basing them elsewhere. Still there are 1.2% rejections of specimen collected by the laboratory staffs, which underscores the need for practical trainings for this group as well.

The reasons for rejection also varied somewhat by personnel type. The Non-laboratory 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 retraining.

Rejected sample proportion that were collected in the ED and in the inpatient services was higher compared with study by [32]. This difference may due to, habit of sample collection in ED and inpatient service, and the difference in sample collection mechanisms; for example, to save time and minimize patient discomfort, most medical staff at the ED and inpatient services collect a blood specimen through an intravenous catheter at the time of its insertion [14]. less training of Nonlaboratory staffs in sample collection compared to the trained laboratory professionals may be additional reason for the difference. The nature of the patients and the working condition in emergency department could also partly explain for the high rate of rejections in these two collection sites.

Frequency
of Specimen
Rejection and
associated factors
at St. Paul Hospital
Millennium
Medical College,
Addis Ababa
Ethiopia

In our findings about 87% of rejected specimens were repeated for diagnosis. Poor quality laboratory specimens cannot be processed by the laboratory. In such condition re-collection of specimens is necessary which increase turnaround time for laboratory investigations, which is positively correlated with the delay in diagnosis. About 90% to 96% of laboratory delays were due to pre analytical errors [14].

5. CONCLUSION

Our finding shows the rate of specimen rejection was 1.4% and the most frequent reasons were hemolysis, clotting and labelling problems of specimens. Significantly higher rejection rates were observed in samples sent for Hematology and Serology tests.

The study also shows high rate of rejection among 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.

COMPETING INTERESTS

We, authors declare that we have no competing interests.

AUTHORS' CONTRIBUTIONS

Habtamu M. has contributed to the conception of the study question, designed the study, collected the data, analyzed the data, interpreted the data and drafted the manuscript.

Tsegaye A. and Hassen F. are involved in conception and designed the study and interpretation of data. All the authors have read and approved the final version of this manuscript.

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Frequency
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