

Sample Rejection Rate in Clinical Biochemistry Laboratory of a Tertiary Care Centre

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ABSTRACT

BACKGROUND: Recent publications have reported that up to 70 % of total laboratory errors occur in the pre analytical phase. Many times samples have to be rejected in laboratory without analysis. The common causes of rejection are; quantity not sufficient, hemolyzed samples, lipemic samples and samples in improper containers. **AIMS AND OBJECTIVES:** 1) To calculate the proportions of samples being rejected due to various pre analytical errors. 2) To enumerate the different reasons for rejection of samples. **MATERIALS AND METHOD:** This retrospective descriptive study was carried out on samples rejected over one year period from January 2015 to December 2015 in Clinical Biochemistry Laboratory of S.S.G. Hospital and Medical College Baroda, Gujarat. The source of data was Laboratory Information System (LIS) of our Clinical Biochemistry Laboratory. In our laboratory, tests requests, tests results and information of rejected samples are entered in LIS routinely. From this LIS data, the mean rejection rate was calculated. The types of rejection were categorized as: Insufficient volume of samples, Hemolyzed samples, Lipemic samples and samples in improper containers. **RESULTS:** A total 1,57,382 number of blood samples were received during the period of study (Jan-2015 to Dec-2015). Among these samples, 2315 blood samples were rejected. Total rejection rate was 1.47%. Most common cause for rejection was quantity not sufficient (78.83%) followed by hemolyzed samples (18.92%), lipemic samples (1.81%) and samples in improper container (0.43%). **CONCLUSION:** Among the patient samples included for one year period (Jan-2015 to Dec-2015) in our study, the maximum number of sample rejection was due to insufficient volume of sample received from different wards and OPDs. This is mainly due to lack of proper training of a person collecting the blood samples. Whenever a sample is rejected, a new sample has to be collected which increases turnaround time and thus affects patient care. The development of better blood collection procedures, training and interdepartmental communication can reduce these errors. Further studies should be performed after preventive and corrective actions to obtain a possible decrease in number of rejected samples.

Key words: Pre analytical errors, Sample rejection

INTRODUCTION

Collecting and analyzing data consistently are necessary tasks for assessing quality, monitoring standardized key processes, improving performance and patient safety in clinical laboratories. These influences 70% of medical diagnosis¹⁻². Laboratory testing, commonly known as total testing process, is generally subdivided as pre analytical, analytical and post analytical phases³⁻⁴. Pre analytical phase errors have been found at the majority of the total

Errors (46-68.2%) in laboratory and research medicine⁵. An understanding of the most critical steps in the total lab testing process is a prerequisite for setting up a plan for a corrective and preventive strategy aimed at minimizing lab errors and safeguarding the patients. Data on rejected samples due to various types of pre analytical errors is one of the laboratory medicine pre analytical quality indicators. There is a set of significant data including various types of errors such as the appropriateness of test order, patient wristband identification error, timing errors in sampling and preparation, hemolytic, lipemic blood samples and inappropriate transport, inadequate and inappropriate tubes portion of the sample^{2,7-10}. Poor communications among physicians, nurses and phlebotomists involved in the TTP or poorly designed

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processes are also counted as laboratory errors in pre analytical phase⁵. Pre analytical phase errors start to occur at the point of entry for laboratory test requests by clinicians. Rejection reasons of test requests generally include requests for wrong tests, missing input of tests, ordering a medically unnecessary tests, overordering, erroneous coding or unintelligible requests. In some conditions, test requests were rejected with the whole test panel, while only a few tests were selected to be rejected within the clinicians' request panel. Personal impact on specimen collection is important factor and the pre analytical error rate is 2 to 4 times higher for non-laboratory phlebotomists than laboratory staff⁹. Inappropriateness of the samples especially due to blood drawing errors generally occurs when the blood samples are drawn by nurses whose experiences and training are not sufficient for blood drawing in clinics comparing to the phlebotomists who are a group of more stable staff. Specimen rejection may have significant consequences for patients and their clinical management. Patients whose specimens are rejected are frequently subjected to repeated specimen collection, resulting in inconvenience, the discomfort of repeated phlebotomy or other collection procedures, and/or the potential need for blood transfusion due to excessive iatrogenic blood loss. Specimen rejection and the need for specimen recollection or correction also ultimately lead to a delay in specimen analysis and the availability of test results and may lead to abandonment of the test(s) requested. The prolonged turnaround time is clinically most significant for tests ordered with a stat testing priority, but similar delays may also impact routine and other nonstat tests. The reasons for rejection and their high-level rates might gather into certain tests due to the unique operating characteristics of the test groups during routine work. The aim of this study was to better explain the rates and reasons of rejected samples, regarding to the certain test groups in our laboratory. Their respective rates might

provide aid for the planning of the preventive and corrective operations in order to reduce the incidence of these errors.

MATERIAL AND METHOD

This retrospective descriptive study was carried out on samples rejected over one year period from January 2015 to December 2015 in Clinical Biochemistry Laboratory of S.S.G. Hospital and Medical College Baroda, Gujarat. The source of data was Laboratory Information System (LIS) of our Clinical Biochemistry Laboratory.

Sample collection tubes: Samples are drawn by routine venipuncture using the order of blood draw as suggested by the Clinical and Laboratory Standards Institute in OPD-8¹². The specimens were transferred to the laboratory by the trained staff for processing. At the time of sample receipt, technicians visually checked the samples with regard to volume, label, clot and simultaneously matched label with those on the accompanying requisition form and accepted accordingly. Any inappropriateness was recorded in laboratory information system. Laboratory personnel were asked to register rejections and its causes, in the problem notification log book if any pre analytical error. The data generated was reviewed on a weekly basis. The specimens were allowed to clot, centrifuged at 1500 x g for 10 minutes and then delivered to the analyzers.

METHOD

Monthly total data were obtained from laboratory information systems. The source of data was Laboratory Information System (LIS) of our Clinical Biochemistry Laboratory. In our laboratory, tests requests, tests results and information of rejected samples are entered in LIS routinely. Errors that occurred during pre-analytical phase have been identified as incomplete patients data on request form, quantity not sufficient (QNS), clotted sample, visible haemolysis after centrifugation, mismatch, wrong tube and others. The frequency of the main factors affecting the pre analytical quality of test results was calculated. Percentage

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calculations were obtained by 'number of rejected samples' / 'total number of received samples' formula for each laboratory test unit.

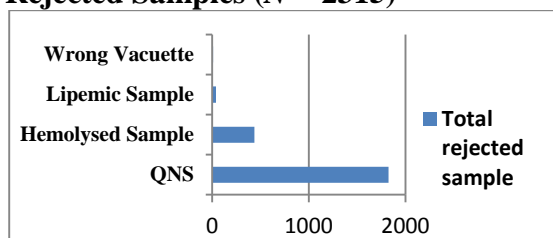
Types Of Inappropriateness: They were evaluated in four groups as follows: Insufficient volume of samples, Hemolyzed samples, Lipemic samples and samples in improper containers.

Rejection rates of blood drawing errors that were quantity not sufficient (78.83%) followed by hemolyzed samples (18.92%), lipemic samples (1.81%) and samples in improper container (0.43%) among all rejected samples in the study. Mishandling of samples cause hemolysis, clotting and insufficient volume of samples. These blood drawing errors were visually detected by technicians. If there were not any marked change in colour of the serum and no visible clot is seen sample (fluoride vacuette), samples are not rejected. Calculations of rejected samples for each test group were presented as number and percentages.

RESULTS

A total 1,57,382 blood samples were received during the period of study (Jan-2015 to Dec-2015). Among these samples, 2315 blood samples were rejected. Total rejection rate was 1.47%. The total number of samples and the rejection rates of each laboratory test unit are shown in Figure 1. Rejection rates of blood drawing errors that were quantity not sufficient (78.83%) followed by hemolyzed samples (18.92%), lipemic samples (1.81%) and samples in improper container (0.43%) among all rejected samples in the study.

Figure 1: Proportions of Rejections of Samples on Each Criterion of All Rejected Samples (N = 2315)



Percentages were calculated by 'number of rejected samples' / total number of received samples' of the laboratory for a 1 year period.

Table 1: Bars Represent Actual Laboratory Data for a 1 Year Period (Jan-2015 to Dec-2015)

Cause of Rejection	Total rejected sample(n)	Percentage (%)
Quantity Not Sufficient in vacuette	1825	78.83
Hemolyzed Sample	438	18.92
Lipemic Sample	42	1.81
Sample is collected in wrong vacuette	10	0.43

DISCUSSION

Among the patient specimens included for a one year period in our study, the maximum sample rejection was due to insufficient volume of specimen. The majority of the total testing process errors is caused by personal and system-based defects in the pre analytical phase. The development of procedures, training, interdepartmental communication, information technology, and robotics can reduce these errors³. Carraro *et al.* performed the study and revealed that the frequency of errors regarding order transmission and hemolysed samples in the pre analytical phase were high. They also concluded that patient misidentification including test requests without patient's name and failure to check the identity during drawing blood were frequently observed⁶. Since 2007, increasing use of automation systems for pre analytical phase also has helped to reduce errors. Because of the rejection of specimen has an effect on repeat behaviour, delay in reporting and finally, missed diagnosis and unnecessary costs, using available published guidelines for a variety of clinical situations and various diseases for screening, diagnosis and treatment to select appropriate tests with respect to the clinical question as a quality indicator is recommended. Defects in laboratory samples that result in sample rejection are a cause of inconvenience and discomfort to patients, lead to a delay in the availability of often critical laboratory results and increases turnaround time.

CONCLUSION

Efficient use of health information technology, good laboratory practices, provision of education, feedback, electronic decision- support systems and

reminders to clinicians and revisions in requisition forms can contribute to this process and then, will also provide opportunities for corrective actions. The efforts aimed to reduce the rates of rejected samples can provide to improve the quality of laboratory based health care processes. This study suggests keeping a record of the errors at all stages of the pre-analytical process and then devising corrective strategies among different department according to the common causes for rejections, for their prevention, which can gradually free a laboratory from such errors. In addition to documentation of rejected samples, the periodic training of healthcare personnel is an essential step in decreasing sample rejection ratios, improving quality of the total testing process in the clinical laboratory and promoting patient-centered health care service. However, this study has few methodological limitations. First of all, although the intensive regular trainings were provided to the nursing staff responsible to for drawing the samples and filling the requisition forms and laboratory technician at collection room scrutinizing each request and sample send with it, their motivation was not assessed. This factor is important as this can confound the results as although a person may be trained for the job, but to implement that training on continuous basis needs staff's motivation toward quality work. This can be assessed in future studies

Further studies should be performed after preventive and corrective actions for rejecting samples.

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