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Original Research Article

Pre-analytical errors in clinical chemistry laboratory of a tertiary care hospital

Priyanka Prasad[1]*, Rakesh Kumar[2], Rekha Kumari[3]

[1]Department of Biochemistry, [2]Department of Pediatrics, Nalanda Medical College & Hospital, Patna, Bihar, India
[3]Department of Biochemistry, Indira Gandhi Institute of Medical Sciences, Patna, Bihar, India

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***Correspondence:**
Dr. Rakesh Kumar,
E-mail: drrakes512@gmail.com

ABSTRACT

Background: Pre-analytical errors account for up to 70% of all mistakes made in laboratory diagnostics, most of which arise from problems in patient preparation, sample collection, transportation, and preparation for analysis and storage. Pre-analytical errors influence the total error thus hindering TQM in laboratory, consequently decreasing the accuracy and reliability of the results generated. This study was conducted with the aim to determine nature and frequency of the occurrence of pre-analytical errors.
Methods: This prospective analytical study was designed to evaluate the pre-analytical errors observed in a total of 13,892 out-patient and inpatient samples. Samples received for routine clinical chemistry analysis were screened for pre-analytical errors. Samples received for other investigations were excluded. We recorded all nonconformities and errors occurring over a 3-month period and corrective measures were suggested to minimise them. Laboratory personnel were asked to register rejections, and pre-analytical causes for rejection of ward as well as out-patient samples collected in the laboratory. Types of inappropriateness were evaluated as follows: hemolyzed, blood collection in wrong tubes, clotted blood, inappropriate timing of collection, improperly labelled samples, insufficient volume of specimen and lipemic samples.
Results: A total of 13,892 samples from the outpatient department and in-house patients were received by our clinical biochemistry laboratory during the period from April 2019 to June 2019. Out of these 404 samples were found unsuitable for further processing. This accounted for 2.9% of all samples collected in the laboratory and pre-analytical errors were responsible for these samples to be rejected over a period of 3 months. Rejections arose as a result of the following reasons: 0.92% were rejected due to hemolysis; 0.58% were blood collected in wrong tubes; 0.55% were clotted blood; 0.26% had inappropriate timing of collection; 0.24% were mislabeled samples; 0.20% had insufficient sample quantity and 0.14% were lipemic samples.
Conclusions: Of all the samples received in the lab, the overall percentage of rejection is 2.9%. Substantial number of samples undergo repeated testing because of rejection owing to pre-analytical errors. The efforts should be aimed to reduce the rates of rejected samples can provide to improve the quality of laboratory based health care processes.

Keywords: Clinical Chemistry Laboratory, Hemolysis, Pre-analytical errors, Rejected Samples

INTRODUCTION

Quality control refers to the technical procedures employed in quality assurance program. These include control of pre-analytical variables, analytical variables and monitoring the quality of analysis. TQM (total quality management) is essential for generating accurate and reliable reports from the laboratory.[1] The process of

sample testing in a clinical chemistry laboratory is done in three phases: Pre-analytical, analytical and post-analytical. Accuracy in the analytical phase and post-analytical phase has largely been considered for reporting from laboratory.[2]

On the contrary, importance of determining errors in the pre-analytical phase has not largely been stressed upon. Errors during collection and transport of biological specimens, errors in processing of the samples and in patient's data entry may occur. It has been reported that the errors in the pre-analytical phase may occur to the extent of 60% . Pre-analytical errors influence the total error thus hindering TQM in laboratory, consequently decreasing the accuracy and reliability of the results generated.[3]

This study was conducted with the aim to determine nature and frequency of the occurrence of pre-analytical errors. These errors was identified and corrective measures was suggested to minimize them. The objectives formulated for present study was: 1. to perform categorization of pre-analytical errors; 2. to determine the frequency of occurrence of these errors; 3. to determine the percentage occurrence of these errors; and 4. to take corrective measures to prevent the occurrence of such errors in future.

METHODS

This study was a prospective analytical study, performed in the Clinical Biochemistry Laboratory of Indira Gandhi Institute of Medical Sciences, Patna with the capacity of 500 beds comprising of various super speciality departments. The lab provides routine test, specialized profiles and hormonal analysis in biochemistry. The present study was conducted over a period of 3 months between April 2019 to June 2019 after obtaining approval from the Institutional Ethical Committee . A total of 13,892 samples were received in clinical biochemistry laboratory, of which 7,421 were from OPD and 6,471were from IPD.

Blood samples collected in vacutainers during this period were included in the study. Samples received for routine clinical chemistry analysis were screened for pre-analytical errors. Samples received for other investigations were excluded. Blood collection for outpatient department (OPD) was centralized (central blood collection center) for different sections of central laboratory which cater the samples to various sections such as hematology, clinical pathology, biochemistry, and microbiology and whereas blood samples from inpatients' department (IPD) were collected by staff nurses. The samples from IPD and OPD (central blood collection center) were delivered to the clinical biochemistry laboratory by paramedical staff and laboratory support staff, respectively. The biochemical investigations were done for repeat samples as well as rejected samples to analyse derangements if any. Laboratory regularly runs internal quality controls and takes part in external quality assurance programmes. These samples were analyzed for following preanalytical variables:

- Hemolysis (was identified on observation and confirmed by potassium determination).
- Clotted blood (was observed on naked eye and confirmed by inverting the collection tubes).
- Improper blood collection tubes (was identified by colour coded caps of vacutainers).
- Improper time of collection
- Insufficient volume (volume of the sample was checked in relation to the number and the type of tests ordered).
- Improperly labelled samples
- Lipemia

All the samples along with the requisition forms was analyzed. Frequency and types of pre-analytical errors (collection and handling variables) in clinical chemistry samples were categorized. Sample rejection data with the pre-analytical variable responsible was noted down in a logbook. The data was collected and summarized on monthly basis. Their relative frequencies when compared with the total specimens were also calculated and presented as percentage.

RESULTS

13,892 samples (7,421 OPD & 6,471 IPD) were analysed, it was seen that 404 samples (2.9%) were rejected due to some unfavourable pre analytical variable. Out of total 404 samples being rejected, the cause of abandoning tests in 129 samples was hemolysis, followed by blood collection in wrong tubes as being the second most frequent cause of rejection of samples as seen in 81 samples. Clotted blood was seen as the cause of rejection in 77 samples. Inappropriate timing of collection of samples resulted in the rejection of 36 samples. Mislabelling or misidentification was seen as a preanalytical error in 33 samples. Due to insufficient sample volume total of 28 samples were redemanded for investigations to be performed. Lipemia was considered as the preanalytical variable responsible for rejection of 20 samples (Table 1).

The majority of the rejected samples were hemolyzed (31.93%) and collection of blood samples in wrong tube was seen in 20.04% of the samples. Clotted blood in 19.05% samples and incorrect timing of collection of samples was seen in 8.91% of the total samples.

Mislabeling of the samples by the laboratory personnel was seen as a cause of rejection of 8.16% of the samples. Obtaining wrong volume accounted for faulty results in 6.9 % of the samples due to which they were rejected 4.95% lipemic (milky) samples were rejected being an interfering factor in analysis.

Table 1: Frequency and nature of occurrence of pre-analytical errors in 404 rejected samples.

Pre-analytical Variable	No. of Rejected Samples	Frequency of preanalytical error in rejected samples	Frequency of preanalytical error in total samples
Hemolysis	129	31.93%	0.92%
Wrong tube	81	20.04%	0.58%
Clotted blood	77	19.05%	0.55%
Wrong timing	36	8.91%	0.26%
Mislabeled samples	33	8.16%	0.24%
Wrong volume	28	6.9%	0.20%
Lipemia	20	4.95%	0.14%

DISCUSSION

Advances in science and technology have led to many path-breaking innovations that have transformed laboratory diagnostics from manual, cumbersome testing methods to fully automated science, ensuring accuracy and speed. This decrease in errors has largely been seen in the analytical phase and consequently pre-analytical phase is the one in which most of the errors are expected to occur now. Plebani M et al studied on "Errors in laboratory medicine" and suggested that recent surveys on errors in laboratory medicine conclude that in the delivery of laboratory testing, mistakes occur more frequently before and after the test has been performed. Most errors are due to pre-analytical factors (46-68.2% of total errors), while a high error rate (18.5-47% of total errors) has also been found in the post-analytical phase.[4]

Lippi G et al studied on "Preanalytical variability: the dark side of the moon in laboratory testing" and suggested that Errors occurring within the extra-analytical phases are still the prevailing source of concern.[5,6] Nigam PK studied on "Preanalytical Errors: some common errors in blood specimen collection for routine investigations in hospital patients" and concluded that the preanalytical phase is the major source of error in lab tests . Since the blood collection is the first step, any error in this step will jeopardize the whole test results, no matter how accurately these are analysed in the laboratory.[7]

Hemolysis accounted for the majority of rejections in our study. These findings were similar to the study done by Ashakiran S et al, 2011. Lack of staff training engaged in phlebotomy is an impediment for expediting sample collection and transport.[8] Hemolysis of samples occurs when blood is forced through a fine needle, shaking the tubes vigorously, and centrifuging the sample specimens before clotting is complete.[9] Red top vacutainers without any anticoagulant should not be shaken after the sample has been collected, and vacutainers for plasma should be gently inverted a few times so the anticoagulant mixes with the blood. Freezing and thawing of blood specimens may cause massive hemolysis. Collecting the blood in proper vacutainers which are easily identifiable by colour coding would also ensure avoidance of wrong results due to incorrect volume of the sample reaching the laboratory.[10,11]

Misidentification in terms of errors in recording name, sex, sample number, tests recommended and even double entry was recorded for the blood samples. Lipemic samples were identified as the least common factor responsible in our study.

CONCLUSION

Pre-analytical phase is a lesser identified area for the occurrence of errors in a Clinical Chemistry Laboratory which can account to a large extent for the generation of faculty reports from the laboratory. Advances in automation should be used for proper sample collection and transport. Frequency, type and percentage occurrence of these errors must be identified in each laboratory so that corrective measures may be taken to overcome these errors.

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