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ORIGINAL RESEARCH

Identification of preanalytical errors in clinical biochemistry Laboratory in a pediatric tertiary care centre: A Prospective Analytical Study

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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. The frequencies of PAE and sample rejection rates in pediatric clinics are not yet fully understood compared to PAE in adult departments. Such pre-analytical errors (PAE) can affect children's safety due to delayed clinical decision-making support or discomfort related to repeat blood sampling. This study was conducted with the aim to determine nature and frequency of the occurrence of pre-analytical errorsin pediatric patients.

Material and Methods: This prospective analytical study was designed to evaluate the pre-analytical errors observed in a total of 2971 out-patient and inpatient samples received from pediatric patients. 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 minimize 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: hemolysed, blood collection in wrong tubes, clotted blood, inappropriate timing of collection, improperly labeled samples, insufficient volume of specimen and old samples.

Results: A total of 2971 samples from the outpatient pediatric department and in-house pediatric patients were received by our clinical biochemistry laboratory during the period from March 2022 to May 2022. Out of these 95 samples were found unsuitable for further processing. This accounted for 3.2% 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: 1.02% were rejected due to hemolysis; 0.67% were blood collected in wrong tubes; 0.61% were clotted blood; 0.29% had inappropriate timing of collection; 0.26%were mislabeled samples; 0.21% had insufficient sample quantity and 0.14% were old samples.

Conclusions: Of all the pediatric samples received in the lab, the overall percentage of rejection is 3.2%. Substantial number of samples undergoes repeated testing because of rejection owing to pre-analytical errors in pediatric patients. The efforts should be

aimed to reduce the rates of rejected samples can provide to improve the quality of laboratory based health care processes in pediatrics.

Key Words: Pre-analytical errors, Clinical Chemistry Laboratory, Haemolysis , Rejected Samples.

INTRODUCTION

Quality control refers to the technical procedures employed in quality assurance program. The TTP (total testing process) starts and ends with the patient, and can sub divided into three distinctive phases: the pre-analytical step, the analytical step and the post-analytical step These include control of pre-analytical variables, analytical variables and monitoring the quality ofanalysis.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)]

Most blood test errors occur in the pre-analytical phase. The frequencies of PAE and sample rejection rates in pediatric clinics are not yet fully understood compared to PAE in adult departments. Such pre-analytical errors (PAE) can affect children's safety due to delayed clinical decision-making support or discomfort related to repeat blood sampling. This study was conducted with the aim to determine nature and frequency of the occurrence of pre-analytical errors in pediatric patients. This error was identified and a corrective measure 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.

MATERIAL AND METHODS

This study was a prospective analytical study, performed in the Clinical Biochemistry Laboratory of Nalanda Medical College & Hospital, Patna with the capacity of 500 beds comprising of various super specialty 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 March 2022 to May 2022 after obtaining approvals from the Institutional Ethical Committee. A total of 2971samples were received in clinical biochemistry laboratory, of which 1627were from pediatric OPD and 1344 were from pediatric IPD.

Blood samples collected in vacationers during this period were included in the study. Pediatric samples received for routine clinical chemistry analysis were screened for pre-analytical errors. Samples received for other investigations were excluded. Blood collection for pediatric 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 pediatric 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 analysederangements if any. Laboratory regularly runs internal quality controls and takes part in external quality assurance programmes. These samples were analyzed for following preanalytical variables:

- Haemolysis (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 color 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
- Old samples

All the pediatric samples along with the requisition forms were 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 log book. 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.

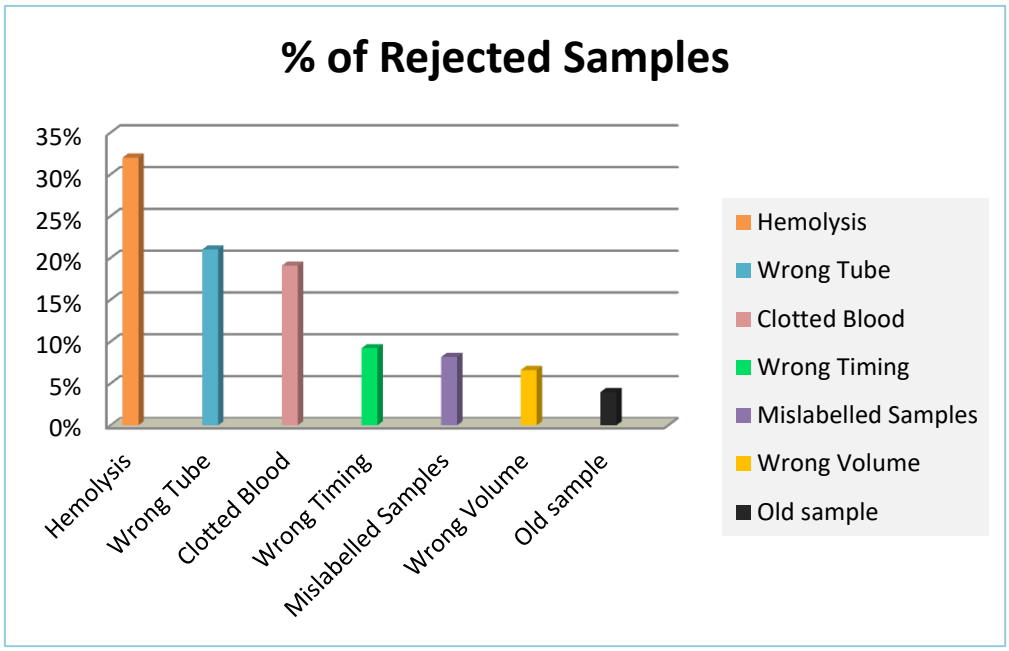
RESULTS

2971 pediatric samples (1627 OPD & 1344 IPD) were analyzed, it was seen that 95 samples (3.2%) were rejected due to some unfavorable pre analytical variable. Out of total 95 samples being rejected, the cause of abandoning tests in 30samples was hemolysis, followed by blood collection in wrong tubes as being the second most frequent cause of rejection of samples as seen in 20 samples. Clotted blood was seen as the cause of rejection in 18 samples. Inappropriate timing of collection of samples resulted in the rejection of 9 samples. Mislabeling or misidentification was seen as a preanalytical error in 8 samples. Due to insufficient sample volume total of 6 samples were redemanded for investigations to be performed. Old sample was considered as the preanalytical variable responsible for rejection of 4 samples. (Table 1 and Figure 1).

Table 1: Frequency and nature of occurrence of preanalytical errors in 95 rejected samples

Pre-analytical Variable	No. of Rejected Samples	Frequency of preanalytical error in rejected samples	Frequency of preanalytical error in total samples
Hemolysis	30	32%	1.02%
Wrong Tube	20	21%	0.67%
Clotted Blood	18	19.07%	0.61%
Wrong Timing	9	9.2%	0.29%
Mislabeled Samples	8	8.16%	0.26%
Wrong Volume	6	6.6%	0.21%
Old samples	4	3.97%	0.14%

Figure 1: Frequency of occurrence of pre-analytical errors



The majority of the rejected samples were hemolyzed (32%) and collection of blood samples in wrong tube was seen in 21% of the samples. Clotted blood in 19.07% samples and incorrect timing of collection of samples was seen in 9.2% 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 6.6 % of the samples due to which they were rejected 3.97% old samples was rejected being a interfering factor in analysis.

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 thatthe 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 analyzed 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.[(8-10)]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.[11-13] 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.[14,15]

Misidentification in terms of errors in recording name, sex, sample number, tests recommended and even double entry was recorded for the blood samples. Old 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. Future studies should focus on interventions targeted at decreasing the frequency of PAE in pediatrics hospital care. The next step of future research should focus on evaluate the interventions involving multiple educational activities for reducing the costs of PAE and also increasing patient safety in pediatrics hospital care.

FUNDING

Self

CONFLICT OF INTEREST

None declared

ETHICAL APPROVAL

Taken by Institutional Ethics Committee.

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