

RETROSPECTIVE EVALUATION OF PRE-ANALYTICAL ERRORS IN CLINICAL BIOCHEMISTRY LABORATORY AT A TERTIARY CARE CENTRE IN RAJSAMAND, RAJASTHAN.

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Abstract

Background: This study was carried out to identify the causes of pre-analytical errors in the clinical biochemistry laboratory and their percentage occurrence so as to formulate the strategy for necessary corrective and preventive actions.

Methods: A retrospective quantitative study was conducted in the department of biochemistry to identify the different causes of pre-analytical errors in the outpatient and inpatient samples. The sample rejection register and test requisition forms for the period of May 2018 to April 2019 were analysed and the percentage occurrence of the different types of errors was calculated.

Results: Data analysis revealed that the occurrence of different errors was as follows: hemolysis (46.43%), sample not received (28.32%), insufficient quantity (8.16%), improper collection technique (7.14%), delayed transport (5.87%), wrong container (1.79%), sample clotted (1.28%), lipemic sample (0.77%) and sample exchanged during separation in lab (0.26%).

Conclusion: The decline in the errors during the analytical phase of sample processing has shifted the focus towards reducing errors occurring in the pre-analytical phase. This is necessary to ensure patient safety.

Keywords: Pre-analytical errors, Biochemistry, hemolysis.

Introduction

The immense advances in the field of diagnostics have uplifted the role of clinical laboratory in patient diagnosis, care and management. It is the responsibility of the lab to provide valid and reliable results of investigations requested, so as to ensure delivery of efficient and safe health care to the patients. Acquisition of this goal is dependent on a well-structured framework for Quality Management System (QMS) in a lab. The entire procedure of processing a sample in a clinical biochemistry laboratory can be divided into three phases: pre-analytical, analytical and post-analytical. Pre-analytical phase begins even before the collection of samples till the samples is put up for analysis.

The breakthrough developments in science and technology and implementation of automation in a clinical laboratory have led to a drastic decline in the error rates in analytical phase of sample testing. Regardless, the pre-analytical

phase is still considered as a prominent obstacle in providing optimum quality of test results. Pre-analytical errors have shown to account for upto 68.2 % of the errors reported in a laboratory^{1,2}. The pre analytical phase of sample testing comprises of various related process like correct patient identification, appropriate selection of sample collection vials, proper transport of samples and preparation of samples in the laboratory via centrifugation, aliquoting, and proper storage of samples for add on or repeat testing. Each of these steps are vulnerable which can introduce potential errors and affect test results. Thus, errors can be introduced at the site of sample collection, during its transport to the laboratory or in the laboratory itself^{3,4}.

With this mindset, the study was undertaken to analyze the pre-analytical errors in the clinical biochemistry laboratory so that necessary corrective and preventive actions could be initiated to improve laboratory performance.

Objectives:

To identify the different causes of pre-analytical errors and inadequacies and to determine the frequency of their occurrence for samples received from outpatient and inpatient departments in the clinical biochemistry laboratory.

Methods:

This was a retrospective quantitative study conducted in the Clinical Biochemistry Laboratory of a tertiary care teaching institute providing services under various super speciality departments like nephrology, urosurgery, oncosurgery, medical oncology, neurosurgery, in addition to all the other departments. The laboratory is well equipped with fully automated analysersto perform various routine biochemical investigations, special investigations like iron profiles, cardiac markers as well as hormonal analysis and tumour markers. The laboratory receives samples in the form of coagulated or anticoagulated blood specimen as well as urine and various body fluids like pleural, pericardial, cerebrospinal and synovial fluids for biochemical investigation. Permission of the Institutional Ethics Committee was taken before the initiation of the study.

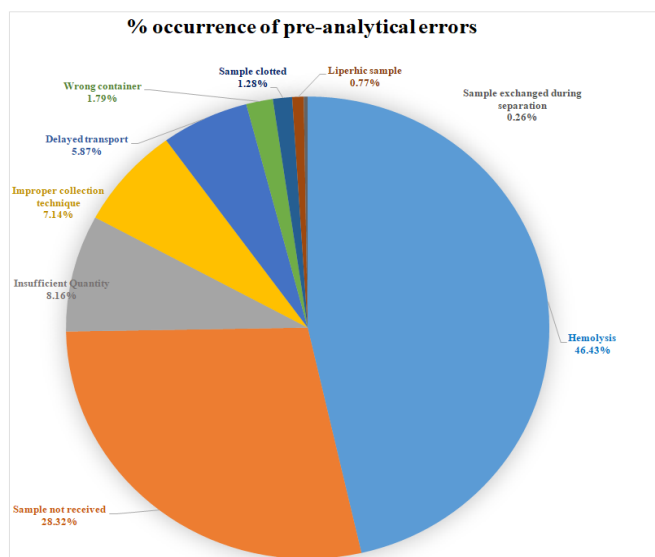
The records for all the outpatient and inpatient samples, including blood and body fluids, receivedfor analysis in clinical biochemistry laboratory during the period from May 2018 to April 2019 were considered for the study. Errors recorded in the sample rejection register and the test requisition forms (TRF) from the period of May 2018 to April 2019 wereanalysedfor the reasons of sample rejection and the frequency of each type. Pre analytical variables/ errors considered for evaluation included: inappropriate sample collection tubes, insufficient quantity of samples, hemolysis, wrong labelling of specimen, lipaemic samples, clotted blood, wrong timing of sample collection, wrong sample sent for analysis, possible delay in sample transport, incorrect sampling techniqueand any other cause for sample rejection. All the test requisition forms received during the same period were also scrutinized for completeness of essential information in them. The statistical analysis was performed using Microsoft Office Excel 2019. The sum of all errors was calculated and the result for relative frequencies of each category was presented as percentage of total errors.

Results:

Data analysis revealed that total percentage occurrence of pre-analytical errors for all outpatient and inpatient samples received by the laboratory was 1.41%, of which outpatient samples contributed to only 0.1% and inpatient samples contributed 1.31% of errors.

Table 1: Nature of Pre-analytical error and percentage occurrence.

Pre-analytical Errors	% of total samples received	% of all pre-analytical errors
Hemolysis	0.66	46.43
Sample Not Received	0.40	28.32
Insufficient Quantity	0.10	8.16
Improper collection technique	0.09	7.14
Delayed transport	0.08	5.87
Wrong container	0.03	1.79
Sample Clotted	0.02	1.28
Lipemic sample	0.01	0.77
Sample exchanged during separation in lab	0.004	0.26

**Figure 1:** Percentage occurrence of pre-analytical errors

The analysis of percentage occurrence of different pre-analytical errors revealed that hemolysis accounted for 46.43% of the sample rejections. Of the entire hemolysed specimen, 80.22% were those in plain vials and 19.78% were anticoagulated specimen. Also, out of all the hemolysed samples, 34.62% came from the different Intensive Care Units (MICU, SICU, PICU, NICU). Sample not receivedwith the test requisition form accounted for 28.32% of the pre-analytical errors.

8.16% of pre-analytical error was due to insufficient specimen volume to carry out the requested investigation. 43.75% of such samples were received from the paediatric ward and NICU. 7.14% of the pre-analytical errors were because of improper collection technique. This could have been due to sample contamination during collection, which was determined by correlating the results obtained from first sample and the results of repeat fresh sample requested. Most of these samples gave erroneous results for serum electrolytes where values of serum sodium and chloride were beyond the reportable range or not

correlating with the patient's previous results, suggesting possible contamination during sample collection. In some samples the values of serum potassium were also very high which could not be reported and request for fresh sample was made. There were some instances where random blood sugar levels were erroneously high or serum calcium levels were very low with the patient having no clinical signs or symptoms suggesting hypocalcaemia. 42.86% of such rejected samples were received from the ICUs.

Delay in sample transport accounted for 5.87% of the rejections. All of these samples were those received in fluoride vials for blood sugar estimations. The results received with these samples were very low and not reportable. There is a possibility that these samples were collected and remained standing for a long time before being sent to lab for analysis. Wrong container, sample clotted, lipemic sample, sample exchanged during separation in lab were responsible for 1.79%, 1.28%, 0.77%, 0.26% of pre-analytical errors respectively.

The test requisition forms were also scrutinised to check for availability of a brief clinical history or clinical diagnosis on them. Only 0.14% of OPD requisition forms and 18.25% of the IPD requisition forms mentioned a brief clinical history of clinical diagnosis of the patient.

Discussion:

The importance of generation of accurate, valid and reliable laboratory results in patient management cannot be emphasized enough on. With the advances in automation, errors in the analytical phase of sample processing have reduced significantly helping to achieve greater accuracy of laboratory results. However, the emphasis now is on procedures necessary to achieve optimum quality control during the pre-analytical and post-analytical phases so as to provide efficient laboratory services¹.

The percentage occurrence of pre-analytical errors in this study was found to be 1.41%. Various studies have reported rejection rates between 0.65% to 1.38%^{5,6}. Our study found that the percentage occurrence of error in OPD samples was only 0.1% whereas IPD samples accounted for 1.31% of the total pre-analytical errors. The reason for this could be better trained phlebotomists at the collection area, and less variation in individuals involved in collection as opposed to the IPD samples which are collected in the various sites within hospital by different individuals. Also, the collection center is located just outside the laboratory working area, so the transit time for samples is also considerably reduced and the samples are picked from the collection center by the laboratory staff themselves.

The major cause of preanalytical error in our study was hemolyzed sample (46.43%) with 34.62% of hemolyzed

samples being received from the various intensive care units. Tiwari et al in their study also found that hemolysis was responsible for 51.1% of pre-analytical errors⁷. Hemolysis can occur due to faulty collection techniques, vigorous shaking of the tubes, centrifuging the samples before clot formation or forcing the blood into the tubes via small needles. Analysis of hemolysed specimen can yield erroneous results for analytes like lactate dehydrogenase (LDH), potassium, aspartate transaminase (AST) because of which the samples have to be rejected and thus increasing the turnaround time and causing delay in report generation⁸. Regular training of all the staff involved in sample collection especially those in intensive care units, oncology units and pediatric units will help to minimize this type of error. The next most common cause of pre-analytical error was sample not received with the test requisition form. The reason for this could be that sample itself was not collected from the patient or the samples were lost during the process of transport to laboratory. Insufficient sample volume accounted for 8.16% of pre-analytical errors in our study with a major contribution from pediatric and NICU specimen. This could be the result of difficult sampling in children, patient noncompliance and difficulty to localize veins in pediatric age group⁷. Regular training and competency assessment of staff or phlebotomists at such places, as well knowledge of the sample volume required for the tests can help to reduce the errors due to hemolysis and insufficient volume⁹. Tiwari et al reported insufficient sample volume to account for 2.6% of the total errors whereas Atay et al in their study found that insufficient sample volume was responsible for a rejection rate of 34%^{5,7}.

In our study improper collection techniques were found to cause 7.14% of pre-analytical errors. These lead to spurious results of serum electrolytes with abnormally elevated values of sodium, potassium and chloride. Elevated potassium concentrations could be because of prolonged duration of tourniquet application, fist clenching or lysis of white blood cells, or leakage from platelets during clot formation^{9,10}. Shortening the time for coagulation and rapid separation of cells might be the reason for the spuriously elevated chloride values obtained from some samples¹⁰. Delayed transport was responsible for 5.87% of the pre-analytical errors. Wrong container, sample clotted, lipemic sample, sample exchanged during separation in lab were responsible for 1.79%, 1.28%, 0.77%, 0.26% of pre-analytical errors respectively. Sonmez et al in their study observed rejection rates of 0.53% due to clotting of specimen whereas Tiwari et al found rejection rates of 42.6% due to clotted samples^{7,11}.

The investigators would also like to reiterate the importance of providing complete patient related information on the test requisition forms. At times without any clinical history or diagnosis, the test results are

withheld till a confirmation is received from the treating physician or in the case of OPD, till the patient is available to obtain a clinical history. This causes unnecessary delay in the reporting of test results leading to inconvenience to the OPD patients and also delay in management of the IPD patients. Avoiding such delays becomes of utmost importance especially in patients whose results are in the critical alert range⁴. Incompleteness of the requisition forms has also been reported by previous studies and this can also greatly add to the errors in a laboratory^{3,6}.

The findings of our study indicate that errors occurring during the pre-analytical phase of laboratory testing significantly affect the quality of results generated. Directing quality control activities to curtail the pre-analytical errors will help the laboratories to go a long way in providing efficient and safe patient care. This will also help to reduce the burden on the economy by avoiding worthless expenses involved in repeat testing.

Conclusion:

Recognition of the errors in a laboratory testing process as possible modulators in causing potential adverse outcome for patients is a need of the hour in ensuring patient safety. With the implementation of well-structured quality management system, advances in science and technology the laboratory can help provide not only accurate results but also aid in providing most favorable patient care and management.

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