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Original Research Article

Pre-Analytical Error in Biochemistry Laboratory

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Abstract

An observational study was done for a period of 6 months from 1st January, 2023 to 30th June, 2023 in the clinical biochemistry laboratory at GCS Medical College, Hospital and Research Centre. The study delved into pre-analytical errors within clinical biochemistry laboratories, focusing on error types, their prevalence, and potential impact. The study aimed to identify and quantify errors occurring in the pre-analytical phase, spanning from sample collection to report generation. Among the recorded errors (n=50), the most frequent was insufficient sample volume, signifying a pressing concern. Another prevalent error was Tests Not Mentioned or Add-on Testing, accounting for 26% of all errors, potentially disrupting workflow. The research also highlighted additional errors, including hemolysis, clotted samples, contamination from infusion routes, and lipemic samples. The study underscored the significance of addressing these errors to ensure accurate and reliable test results, thereby enhancing patient care. Overall, it provided valuable insights into the landscape of pre-analytical errors in clinical biochemistry, emphasizing the need for improved procedures, enhanced training, and effective communication to enhance the quality and precision of laboratory testing and, ultimately, patient care.

Keywords: Pre-analytical errors, Clinical biochemistry, Sample collection, Insufficient sample volume, Tests Not Mentioned, Hemolysed sample, Error frequency, Observational study.

INTRODUCTION

In modern day medicine, clinicians tend to rely on laboratory findings to support and confirm their findings. About 60-70% of the critical decisions related to patient's diagnosis, recovery and discharge are based on the laboratory findings (Forsman, 1996). So, the laboratory results have to be reliable and accurate. But errors can still occur in the testing process.

The total testing process can be divided into 3 phases, namely, pre-analytical, analytical and post-analytical:

1. Pre-analytical Phase:
   - Test ordering
   - Patient identification
   - Sample collection.
   - Sample transportation and storage
   - Sample preparation for analysis

2. Analytical Phase:
   - Sample processing
   - Instrumentation
   - Analysis
   - Quality control.
   - Calibration and validation.

3. Post-analytical Phase:
   - Result interpretation
   - Result reporting.
   - Result delivery
   - Result verification
   - Result storage
   - Result communication

An error in the clinical laboratory refers to any deviation or mistake that occurs during the testing process, leading to inaccurate or unreliable results, or failure to achieve the intended outcome.

Any error in any of the phases can make a major impact on patient care. Plebani and Carraro observed in their paper that the great majority of errors result from problems in the preanalytical or post-analytical phases (Bonini *et al*., 2002). Although with the automation of laboratories the number of errors has significantly decreased, the pre-analytical phase still relies heavily on human involvement. The pre-analytical phase is still prone to human error. Pre-analytical errors account up to 70% of the total errors (Antonia *et al*., 2011).

In this article, we did a study on the pre-analytical errors at clinical biochemistry laboratory at a tertiary care hospital setting. The data was collected over a period of six months and includes both IPD and OPD samples.

MATERIALS AND METHOD

GCS Hospital is a tertiary care multi-speciality centre with 750 bed capacity. It is equipped with modern medical facilities and houses various departments, including general medicine, surgery, paediatrics, obstetrics and gynaecology, orthopaedics, ophthalmology, ENT, dermatology, and more. The hospital caters to both general patients and those seeking specialized medical care.

A prospective observational study was done on both OPD and IPD samples in Central Clinical Biochemistry Laboratory of GCS Hospital for a period of six months from 1st January, 2023 to 30th June, 2023.

Internal and external quality assurance has been maintained in the laboratory and documented thus, ruling out any error in analytical phase and assuming that errors mainly occur in the pre-analytical phase this study was conducted with the following objectives:

1. To observe the frequency of pre-analytical errors occurring in the biochemistry section of laboratory.
2. To study the types of pre-analytical errors.

The collection of samples is done by the phlebotomist in the OPD sample collection centre after billing of the patient is done and their registration number is allotted. Samples with the computerized test requisition form is sent to the central biochemistry laboratory. In the laboratory, the sample is first acknowledged by the technician and then sent for centrifugation. A similar procedure is followed with IPD sample collection except that the phlebotomist visits all the wards for sample collection.

The pre-analytical errors observed in the collected samples included the following:

- Incomplete Test Requisition Form
- Hemolysed Sample
- Insufficient Sample Volume
- Clotted Sample
- Sample Collected in Inappropriate Container
- Improper time of collection
- Improperly labelled sample
- Missing samples
- Improper Transport
- Delay in Sample Transport
- Contamination from Infusion Route
- Misidentification of patients
- Illegible handwriting
- Tests not mentioned
- Blood vacuette inversion
- Software problem
- Incomplete or Inaccurate order entry
- Communication errors

Ethics Committee Approval: Ethics committee approval was received for this study from the Institutional Ethics Committee of GCS Medical College, Hospital and Research Centre. (Approval Date: 25.02.2023, Approval Number: GCSMC/EC/Research Project/APPROVE/2023/542)

RESULTS AND DISCUSSION

Over a period of 6 months from 1st January, 2023 to 30th June, 2023, a total of 46729 samples were documented. Out of these, 50 samples were rejected due to pre-analytical errors. Details are mentioned in the below tables.

Table 1

Total Number of Samples	Number of Pre-Analytical Errors	% Rate of Sample Rejection
46729	50	0.106

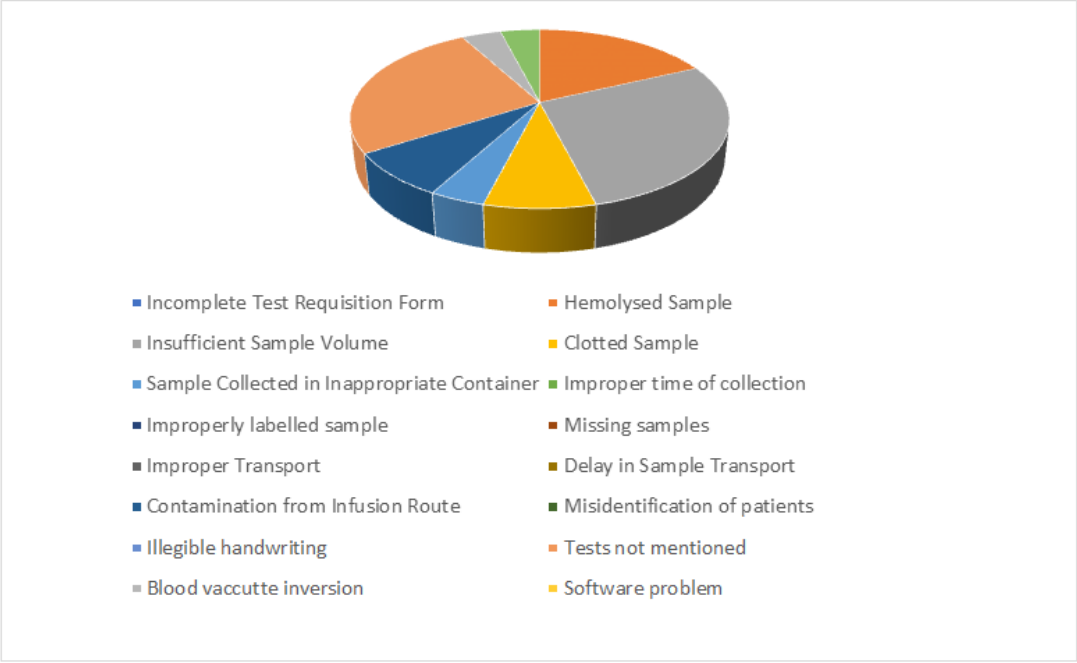
Table 2: Characterization of the Pre-Analytical Errors Observed

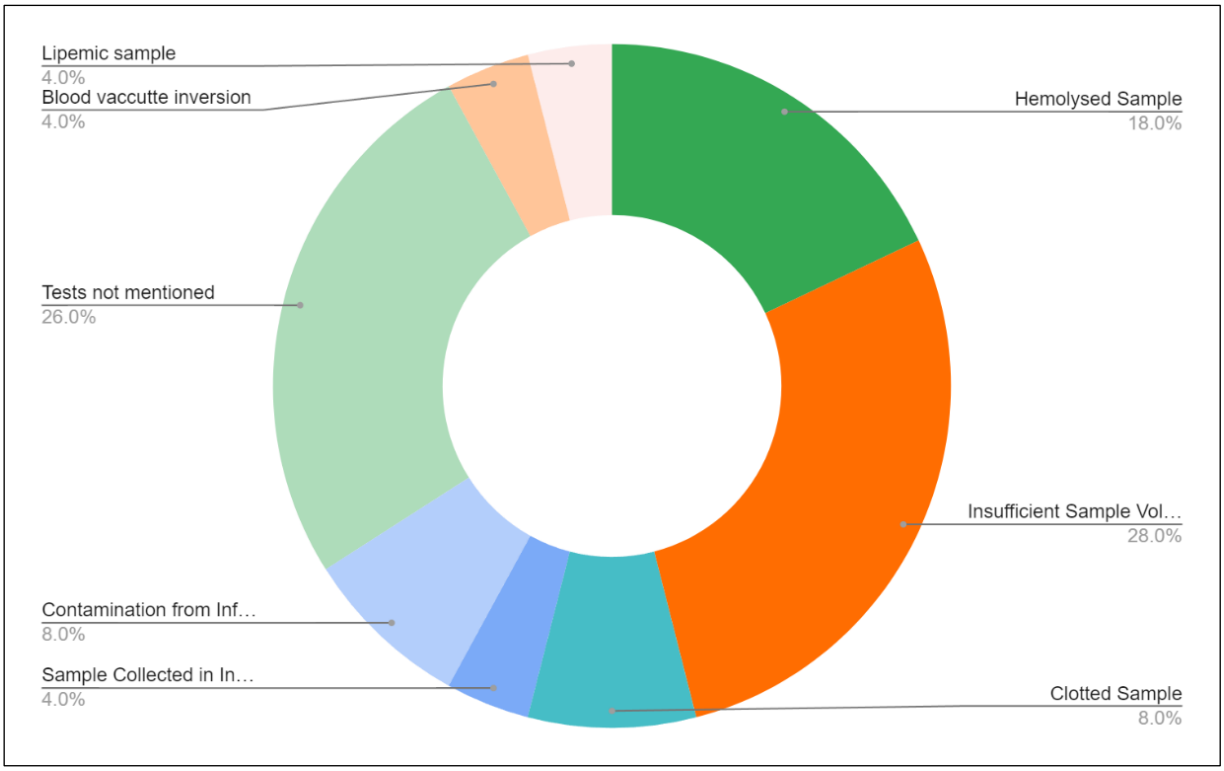
Sr. No	Error	Frequency
1	Incomplete Test Requisition Form	0
2	Hemolysed Sample	9
3	Insufficient Sample Volume	14
4	Clotted Sample	4
5	Sample Collected in Inappropriate Container	2
6	Improper time of collection	0

Sr. No	Error	Frequency
7	Improperly labelled sample	0
8	Missing samples	0
9	Improper Transport	0
10	Delay in Sample Transport	0
11	Contamination from Infusion Route	4
12	Misidentification of patients	0
13	Illegible handwriting	0
14	Tests not mentioned	13
15	Blood vacuette inversion	2
16	Software problem	0
18	Communication errors	0
19	Lipemic sample	2

Table 3: Percentage of Each Error in Accordance of Total Errors

Sr. No	Error	Percent of Error
1	Incomplete Test Requisition Form	0 %
2	Hemolysed Sample	18 %
3	Insufficient Sample Volume	28 %
4	Clotted Sample	8 %
5	Sample Collected in Inappropriate Container	4 %
6	Improper time of collection	0 %
7	Improperly labelled sample	0 %
8	Missing samples	0 %
9	Improper Transport	0 %
10	Delay in Sample Transport	0 %
11	Contamination from Infusion Route	0 %
12	Misidentification of patients	0 %
13	Illegible handwriting	0 %
14	Tests not mentioned	26 %
15	Blood vacuette inversion	4 %
16	Software problem	0 %
18	Communication errors	0 %
19	Lipemic sample	4 %





Upto 60% of pre-analytical errors are attributable to the sample, may it be insufficient volume, hemolysed sample or lipemic sample (Lippi *et al*., 2006).

Among the 50 errors recorded, the most common pre-analytical error was Insufficient sample volume. 14 samples were rejected due to insufficient volume, making it 28% of all the rejected samples. When the collected sample can't meet the need for the required amount for a given test then the error is classified as Insufficient sample volume. If the healthcare provider or phlebotomist doesn't collect enough blood or other specimen during the collection process, the resulting sample may not meet the required volume. Some patients, especially paediatric or elderly individuals, may have difficult veins for venipuncture, leading to a smaller amount of collected blood. Some tests require a certain amount of volume to perform the test, if the phlebotomist uses smaller syringes for collection there may not be enough blood for testing. If anticoagulant is required and used for the sample collection then its improper mixing would lead to clot formation, thereby reducing the volume.

Another major pre-analytical error observed was "Tests Not Mentioned", making up 26% of all the errors. It is otherwise known as Add-on Testing. It is the practice of adding other tests after blood sample collection is already done. This may be due to the healthcare provider not fully understanding the condition of patient initially but after a few tests are done they add more as the situation requires. Other causes may include any emergency situation or a critical case. The results of earlier test may give more insight regarding the patient's condition promptly requiring further testing. This add-on testing might give rise to other pre-analytical errors such as insufficient sample volume as initially only a few tests were mentioned and the blood was collected accordingly. Further they can also disturb the laboratory workflow leading to increased turnaround time, delayed transport or error in reports.

Other observed pre-analytical was hemolysed sample. This may be due to improper technique of blood collection as aggressive needle insertion or using a smaller needle can cause the cells to rupture. Using inadequate anticoagulant or having improper transportation of samples can also cause haemolysis of the collected blood. In a study by Jay *et al*., (2008), it was observed that the majority of hemolyzed samples (>95%) were due to mistakes resulting from incorrect sampling procedure or transportation (Hayden *et al*., 2008). Hemolysis not only affects test results but can also lead to unnecessary repeat testing, delayed diagnosis, and increased healthcare costs. Minimizing hemolysis through proper procedures and training is essential for delivering accurate and reliable laboratory results.

Clotted sample is another observed pre-analytical error. Using incorrect vacuette, improper mixing of blood with the anticoagulant, delayed centrifugation and improper transport are a few probable causes for this error. Educating the healthcare providers and phlebotomists, proper mixing and timely centrifugation can help to prevent this error.

Contamination from the infusion route is another pre-analytical error affecting laboratory test results. This error can occur when substances from an ongoing infusion, such as medication or intravenous fluids, inadvertently enter the blood sample collected for testing. Using the same limb or site for both infusion and blood collection as well as backflow from the intravenous line can cause this error. Proper site selection is therefore important for accurate testing.

A lipemic sample refers to a blood specimen that appears cloudy or milky due to an elevated concentration of lipids (fats) in the blood. This pre-analytical issue can affect the accuracy of laboratory test results, particularly tests that involve the measurement of analytes in the serum or plasma. The consumption of a fatty meal shortly before blood collection can lead to lipemic sample. Improper fasting before blood collection, inadequate mixing of the blood sample with additives, or excessive agitation during or after collection can cause lipemia. Therefore, it is necessary to ensure proper fasting and proper blood collection techniques are used to prevent error in test results.

All the pre-analytical errors ultimately lead to inconvenience to the patient as well as the laboratory. They tend to make the patient uncomfortable due to repeated blood collection as well as increased time for the results to be ready for evaluation. They increase the overall turn-around time for the laboratory. Therefore, it is absolutely necessary to train the technicians and phlebotomist to prevent these errors and ensure patient satisfaction.

CONCLUSION

Over the last few decades, with the introduction of computerized hospital management it has become a lot easier to keep track of all the samples collected and received. It has made the total testing process smoother than earlier. As a lot of the pre-analytical phase depends on manpower so proper training and education of the healthcare providers as well as phlebotomists is necessary to prevent errors.

Laboratory results play a critical role in modern day medical care. Many major decisions regarding the patients treatment or diagnosis are dependent on these test results. So, it is necessary to ensure that all the processes taking place are thorough and of highest quality. It is also important to check every step of the total testing process and continuously evaluate the results. Necessary steps should be taken every step of the way to minimize chances of errors and ensure patient safety.

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