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Original Research Article

A study of pre-analytical errors in the clinical biochemistry laboratory at Victoria hospital, BMCRI, Bangalore

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ABSTRACT

Objective: To categorize and calculate the percentage error of pre-analytical variables in the clinical biochemistry laboratory.

Methodology: Prospective observational study conducted for two months with documenting the frequency and type of pre-analytical errors occurring in venous samples.

Result: The total errors recorded were 1.31%. Insufficient volume followed by haemolysis amounted to a major proportion of errors.

Conclusion: Continuous pre-analytical phase evaluation and taking corrective measures to make this phase error-free, have to be done.

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1. Introduction

The laboratory medicine plays a pivotal role in the promotive, curative and preventive aspects of a nation's health delivery system. For reliable laboratory service; it is necessary to execute standard practices at all levels to guarantee the best possible care for the patients. Clinical laboratory testing process comprises of three broad phases: Pre-analytical, Analytical & Post Analytical. Out of the three phases, the pre-analytical phase is accountable for up to two-thirds of the errors. This study was conducted to enumerate the different errors taking place in the pre-analytical phase and their frequency so that corrective measures can be taken to remove them.

2. Methodology

A prospective observational study was conducted in the clinical Biochemistry laboratory at Victoria Hospital attached to Bangalore Medical College & Research

Institute, without direct interaction with the patients for 2 months from 1st May 2019 to 30th June 2019. Venous blood samples and their lab request forms received for routine clinical chemistry analysis were screened for pre-analytical errors by visual inspection.

Types of inappropriateness were evaluated as follows:

1. Hemolysed samples,
2. Insufficient sample volume,
3. Improperly labeled samples (wrong vial/wrong slip),
4. Clotted samples, &
5. Lipemic samples

When any of the above-mentioned error occurs, entries are made in problem notification log book. The data generated was reviewed daily.

3. Result

The total number of samples received in 2 months was 12880.

Of this, Outpatient samples were 9192 and Inpatient samples were 3688.

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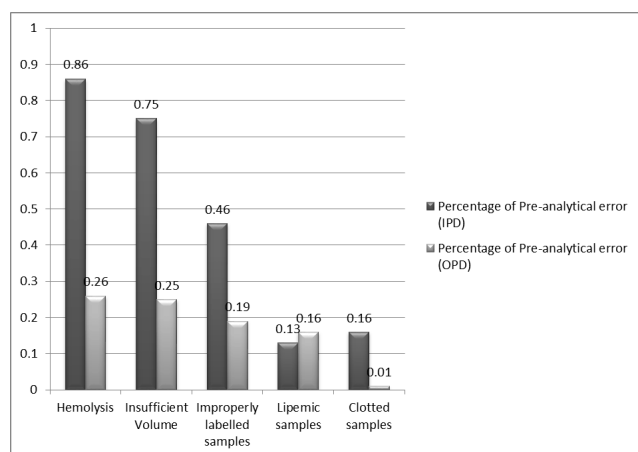
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Table 1:

S No.	Pre-analytical error	Frequency in Inpatient samples	Frequency in Outpatient samples	Total Frequency
1	Hemolysis	32(0.86%)	24(0.26%)	56(0.43%)
2	Insufficient Volume	28(0.75%)	23(0.25%)	51(0.39%)
3	Improperly labeled samples	17(0.46%)	18(0.19%)	35(0.27%)
4	Lipemic samples	5(0.13%)	15(0.16%)	20(0.15%)
5	Clotted samples	6(0.16%)	1(0.010%)	7(0.05%)
	TOTAL	88	81	169

The distribution of different types of errors observed is given in the Table 1.

Total errors detected were 169. Hemolysis constituted the majority of errors accounting for 0.43% of the total number of samples received. The next commonly encountered error was of insufficient sample volume, which constituted 0.39% of errors. Other pre-analytical errors observed includes sample with insufficient information (0.27%), lipemic samples(0.15%) and clotted samples(0.05%).

**Fig. 1:**

4. Discussion

Clinical laboratory testing plays a crucial role in the diagnosis, prevention of disease, treatment, and monitoring of patients. Hence for better patient care, the performance of high-quality analysis is also critical.¹ Patient preparation, sample collection, sample transportation, sample preparation, and sample storage (until the analysis), are the pre-analytical steps, which are the major error sources in laboratory diagnostics.² Laboratory professionals mainly focused on analytical errors and mistakes in the past. However, the recent concentration is more on the pre-analytical and post-analytical steps due to the increased frequency of the errors.³

The term pre-analytical phase was coined by Statland and Winkel in 1977 and then influence and inference factors were included in the terminology of laboratory medicine.⁴ Since the pre-analytical phase step is mainly performed by

the staff working outside the laboratory, it is difficult to manage and evaluate quality in this phase.⁵

Hemolysis constituted the most frequent pre-analytical error in our study. Most causes of in vitro hemolysis are related to specimen collection. Hemolysis of samples occurs when blood is forced through a fine needle, shaking the tubes vigorously, and centrifuging the sample specimen before clotting is complete.⁶ In vitro hemolysis during specimen collection can cause inaccurate laboratory test results by contaminating the surrounding plasma with the contents of hemolyzed red blood cells. For example, the concentration of potassium inside red blood cells is much higher than in the plasma and so an elevated potassium level is usually found in biochemistry tests of hemolyzed blood. Experience and proper technique are key for any phlebotomist, nurse or doctor to prevent hemolysis.⁷

Blood collection tubes contain specific quantities and types of additives. They are designed to collect a predetermined quantity of blood in order to achieve a defined concentration of additive in the blood sample, that is, a correct blood to additive ratio. An incorrect blood to additive ratio can lead to inaccurate test results and flawed patient management.⁸ The main reasons behind error due to insufficient sample volume are difficult sampling as in patients with chronic, debilitating diseases, pediatric patients and patients having thin veins. The practice of skilful phlebotomy techniques can reduce such errors to a minimum.⁹

A common cause of clotted EDTA samples is improper mixing of sample tubes after collection. This is often an avoidable event, overcome by inverting the tube 8-10 times immediately after collection to mix the blood thoroughly with the EDTA. These should be gentle inversions, avoiding rigorous shaking. When this is done correctly, the coagulation cascade is blocked, eliminating the possibility of clot formation and these samples then remain stable (suitable for analysis) for up to 24 hours. It is also observed that when syringes are used to collect blood samples into EDTA tubes, they are sometimes over-filled, leaving too little or no air-space that will enable proper mixing during inversions. Inappropriate 'order of draw', prolonged venepuncture episodes and mixing-up of sample tube caps (when they are taken off for syringe blood collection method) are also common factors that we have observed to contribute to these events.¹⁰

Also, mislabeled, unlabeled, or incompletely labeled specimens present potential serious harm to patients. Labeling errors can lead to possible serious misinterpretation of test results when specimens with similar identifying information enter an environment where thousands of specimens are handled each day and results must be accurately associated with the patient among the many.

5. Conclusion

In order to produce results that provide monitoring and diagnostic value, it is essential that the in-vivo state of our patient remains represented in the blood sample, as at the time of collection from the body. Practitioners tasked with collecting blood samples must be appropriately trained, competent and always follow their local standard operating procedures with respect to venipuncture. Immediate and adequate mixing of the blood sample and the EDTA is critical to avoid the formation of clots.

Proper specimen collection, handling, labeling and transport are essential for accurate laboratory results. Automation and technology can affect significant change in minimizing these types of errors, but staff training and open communication provide equally important opportunities for quality improvement. Consistent staff training and competency evaluation also play a major part in reducing pre-analytical errors.

6. Source of Funding

None.

7. Conflict of Interest

The authors declare no conflict of interest.

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