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RESEARCH ARTICLE
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"STUDY OF PRE-ANALYTICAL ERRORS IN CLINICAL BIOCHEMISTRY LABORATORY"

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Abstract

Background: Pre-analytical errors are a major concern in clinical biochemistry, accounting for approximately 60-70% of total laboratory errors. These errors occur during the pre-examination phase, from test ordering to sample analysis.

Objectives: To enumerate & analyze the frequency of pre-analytical errors in Clinical Biochemistry laboratory and to assess the impact hemolysis on blood glucose levels.

Materials and Methods: Results: The data reveals variations in the prevalence of pre-analytical errors across different departments. Among the departments analyzed, the highest proportion of errors is observed in the Inpatient Department, constituting 50.36% of the total errors identified. Following closely, the Critical Care Medicine department accounts for 43.13% of the errors, indicating a significant occurrence of pre-analytical errors in critical care settings. In contrast, lower frequencies of errors are noted in the Emergency Department (3.61%) and the Outpatient Department (2.89%). These findings suggest that pre-analytical errors are more predominant in inpatient and critical care settings compared to outpatient and emergency settings. Understanding the department-wise distribution of errors can aid in targeted interventions and quality improvement initiatives tailored to specific clinical areas, thereby enhancing the overall quality and reliability of laboratory testing service.

Conclusion: The research findings underscore the critical importance of pre-analytical factors in influencing laboratory testing outcomes. Analysis of pre-analytical errors revealed a range of error types, with hemolysis being the most prevalent, followed by inadequate sample volume, inappropriate tube usage, labelling errors, and clot formation in serum samples. These findings highlight the need for vigilant adherence to standardized protocols and quality control measures to mitigate errors and ensure accurate laboratory results.

Keywords: FBS, Aspartate aminotransferase, Alanine transaminases, Triglycerides

Introduction

Diverging from several aspects within the healthcare system presently contending with issues surrounding patient quality outcomes, laboratories have consistently taken a pioneering stance in the dedicated pursuit of quality within their analytical processes. This proactive approach is defined by an unwavering dedication to rigorous standards and continuous improvement efforts, all directed toward ensuring the precision, accuracy, and reliability of laboratory testing procedures. [1]

The principles and application of quality assessment programs are ingrained in the field of laboratory diagnostics. Competent laboratory services form a fundamental cornerstone of modern healthcare systems, contributing approximately 70% to the procedures of medical diagnoses and treatments.[2] Contemporary medical practice is predominantly rooted in evidence-based methodologies, emphasizing the reliance on accurate laboratory reports for the efficient and timely management of patients.[3] Laboratory testing, a pivotal component of this paradigm is intricately divided into three distinct phases: **Laboratory testing mainly involves three phases:** Pre-analytical phase, Analytical phase and Post-analytical phase. **Pre-analytical Phase:** The pre-analytical phase spans the entire journey of a patient's specimen from collection to its arrival in the laboratory. Numerous variables, including specimen handling, transportation, and processing, can influence the integrity of the sample and, consequently, the precision of laboratory results. These pre-analytical errors pose a substantial challenge, as they have the potential to introduce biases, affect assay precision, and compromise the clinical utility of laboratory tests.[4-5] This research embarks on an exploration of the often-overlooked realm of pre-analytical errors within the Clinical Biochemistry Laboratory, seeking to unravel the intricacies, implications, and potential interventions associated with this critical phase. The necessity for laboratories to uphold accountability and accuracy in their reports is crucial for ensuring accurate disease diagnosis and appropriate treatment, thereby safeguarding patients from erroneous diagnoses and treatments. This imperative arises from the reliance on precise laboratory reports for disease identification, emphasizing the need for meticulousness and precision in reporting to prevent patient harm due to misdiagnosis or improper treatment.[6] Steps by Laboratories that can minimize Pre-analytical errors: Laboratories can implement various measures to minimize pre-analytical errors, acknowledging that best practices represent optimal approaches rather than paths to perfection. These strategies aim to significantly reduce the occurrence of errors in the pre-analytical phase.[7-8] Recommended approaches: Phlebotomy Education: Mandate ongoing continuing education for all staff to ensure they stay abreast of recent developments in pre-analytical error reduction. Healthcare professionals should possess knowledge of the impact of pre-analytical errors on specimen quality and undergo annual competency assessments. Utilization of Appropriate Technology: Employ technologies such as barcodes, radiofrequency identification, and wristbands to mitigate errors in patient identification, thereby enhancing accuracy. Monitoring Quality Indicators in the Laboratory: Maintain a comprehensive record of observed pre-analytical errors in laboratories. Formulate and implement corrective strategies to progressively reduce the occurrence of such errors. Monitoring serum indices and lab errors aids in assessing the quality of the blood collection process and evaluating the effectiveness of implemented measures. Quality indicators (QIs) play a pivotal role in continuous improvement activities and risk reduction in clinical practice, particularly during the pre-analytical stage. However, it is crucial to recognize that the collection and monitoring of QI data alone do not automatically result in quality improvement. Even when investigating procedures performed outside the laboratory walls by healthcare operators, focused efforts are essential for translating QI data into meaningful quality enhancement [9-10]. The objectives of the present study were to enumerate & analyze the rate of pre-analytical errors in Clinical biochemistry laboratory, to find out the frequency of pre-analytical errors in the Clinical Biochemistry Laboratory and to correlate pre-analytical errors with derangement in the results by repeat sample analysis.

Materials and Methods

Source of data and study design: It is a Prospective observational study. conducted at central laboratory, National Institute of Medical Science & Research Hospital in Jaipur, Rajasthan. Collaboration was established with all Clinical Departments.

Study Participants: Complete Enumeration from IPD & OPD samples of National Institute of Medical Science & Research Hospital, Jaipur, Rajasthan.
Inclusion Criteria: Samples received for routine clinical chemistry analysis were screened for pre-analytical errors in patients aged between 1 – 70 years of both genders**.**
Exclusion Criteria: the following patients were excluded from the study.

- Patients unwilling to participate,
- Individuals less than 1 year of age,
- Samples received for other test, other than routine clinical biochemistry,
- Urine samples.

Sample Size Determination:
We included a total sample during the study period of a complete enumeration at the National Institute of Medical Science & Research Hospital, Jaipur, Rajasthan.

Data Collection:
Data Source: Direct observation and documentation of the sample collection process. This data was meticulously categorized under distinct quality indicators for further analysis.
Variables:

- Demographic information (age, gender, etc.).
- Sample type (blood).
- Test requested.
- Details of sample transport.
- Identification and labeling details.

Identification of Pre-analytical Errors:

- **Real-time Monitoring:** A system for real-time monitoring of the sample collection process was implemented.
- **Criteria for Identification:** Established guidelines and protocols were followed for identifying pre-analytical errors.

Quality Control Measures:

- Regular checks and audits were conducted to ensure data accuracy and reliability.
- Calibration of equipment and validation of test methods were performed as per standard operating procedures.

Sample collection: Direct observation and documentation of the sample collection process. This data was meticulously categorized under distinct quality indicators for further analysis.

Results

Table 1: Distribution of pre analytical errors in clinical biochemistry laboratory

Pre-Analytical Errors	n = 415	In %
Clot in Serum	13	3.13%
Hemolysed	140	33.73%
Inadequate amount	45	10.84%
Inappropriate tube	36	8.67%
Labelling errors	36	8.67%
Lipemic sample	24	5.78%
Sample from IV running area	17	4.10%
Software errors	11	2.65%
Transport Specimen	29	6.99%
TRF is missing	1	0.24%
Wrong barcode	32	7.71%
Wrong time for collection	31	7.47%

Figure 1: Distribution of pre analytical errors in clinical biochemistry laboratory

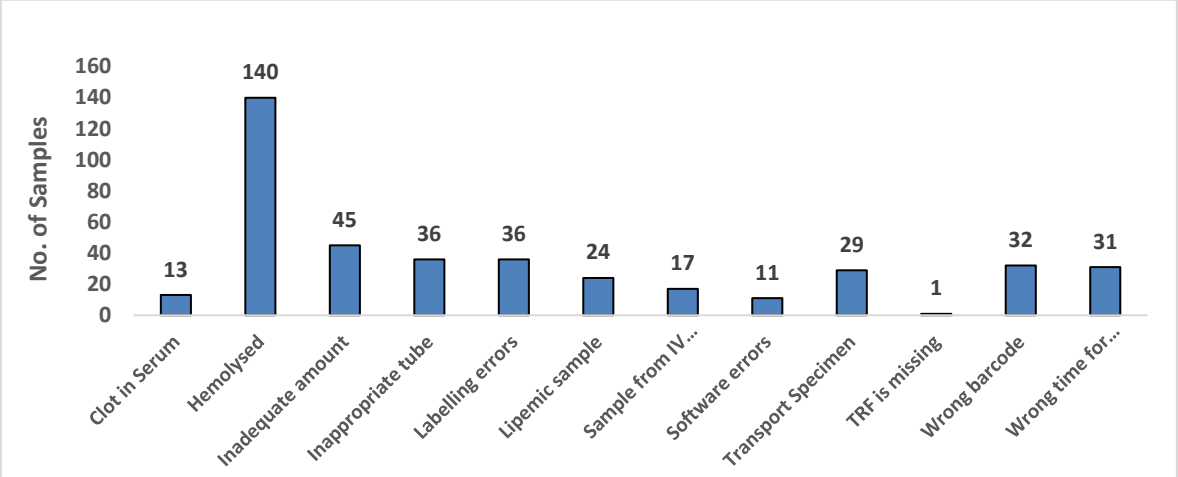

Table 1 and figure 1 presents the distribution of pre-analytical errors observed in the clinical biochemistry laboratory, based on a sample size of 415 cases.

The data indicates a range of pre-analytical errors, with varying frequencies observed across different error types. The most prevalent error type is hemolysis, accounting for 33.73% of the total errors identified. Following hemolysis, inadequate sample volume is the next most common error, representing 10.84% of the total errors. Other notable error types include inappropriate tube usage (8.67%), labelling errors (8.67%), and clot formation in serumsamples (3.13%). These findings underscore the significance of pre-analytical factors in influencing laboratory testing outcomes. Addressing and mitigating these errors are crucial for maintaining the integrity and accuracy of laboratory results, thereby ensuring quality patient care.

Table 2: Department wise distribution of prevalence rate of pre-analytical errors in clinical biochemistry laboratory

Department	**Total No. of Samples**	**Pre-Analytical Errors**	**In %**
Emergency Department	2948	15	0.51%
Out Patient Department	19656	12	0.06%
In Patient Department	38921	209	0.54%
Critical Care Medicine	18067	179	0.99%
Total	**79592**	**415**	**0.52%**

Figure 2: Department wise distribution of prevalence rate of pre-analytical errors in clinical biochemistry laboratory

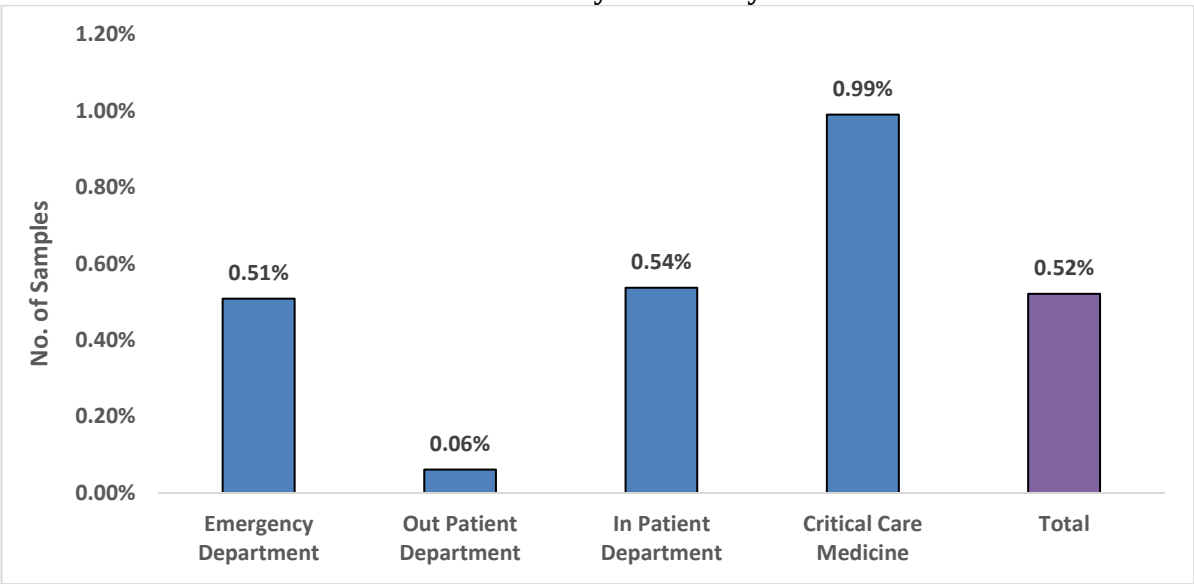

Table 2 and figure 2 presents the department-wise distribution of the prevalence rate of pre-analytical errors in the clinical biochemistry laboratory, based on the total number of samples processed and the corresponding number of pre-analytical errors identified, with a total sample size of 79,592.

The data reveals that pre-analytical errors occur across all departments, albeit at varying rates. Among the departments analyzed, the Critical Care Medicine department exhibits the highest prevalence rate of pre-analytical errors, accounting for 0.99% of the total samples processed. This indicates a relatively higher frequency of pre-analytical errors in critical care settings compared to other departments.

In comparison, the Emergency Department and the Inpatient Department demonstrate similar prevalence rates of pre-analytical errors, with both departments experiencing errors in approximately 0.51% of the samples processed. The Outpatient Department shows the lowest prevalence rate of pre-analytical errors at 0.06%.

Overall, the aggregated prevalence rate of pre-analytical errors across all departments is calculated to be 0.52%.

These findings underscore the importance of department-specific analysis in identifying areas of improvement and implementing targeted interventions to mitigate pre-analytical errors, thereby enhancing the quality and reliability of laboratory testing services.

Table 3: Month wise frequency distribution of pre analytical error samples

Months	No. of samples received	No. of Pre analytical error samples	In %
Sep-23	12948	43	0.33%
Oct-23	14807	82	0.55%
Nov-23	12489	61	0.49%
Dec-23	13367	91	0.68%
Jan-24	14295	79	0.55%
Feb-24	11686	59	0.50%
Total	**79592**	**415**	**0.52%**

Figure 3: Month wise frequency distribution of pre analytical error samples

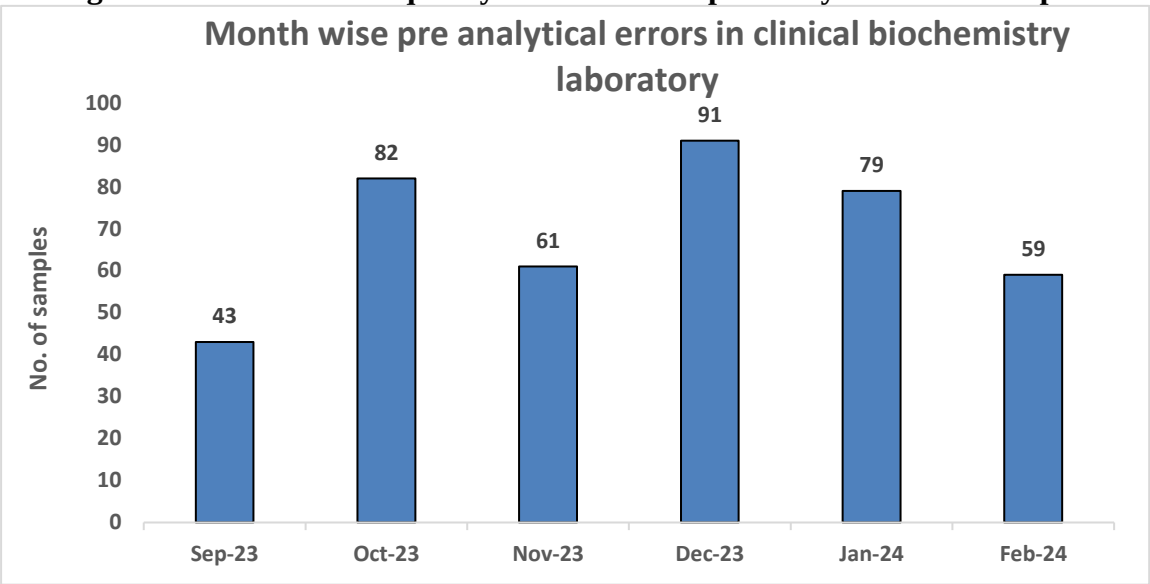

Table 3 and figure 3 illustrates the month-wise frequency distribution of pre-analytical errors in the clinical biochemistry laboratory over a period spanning from September 2023 to February 2024. The table includes the number of samples received during each month, along with the corresponding number of pre-analytical error samples identified, presented both in absolute numbers and percentages.

The data indicates fluctuations in the occurrence of pre-analytical errors across the six-month duration. In September 2023, the laboratory received 12,948 samples, with 43 samples (0.33%) exhibiting pre-analytical errors. The frequency of errors slightly increases in October 2023, with 82 error samples identified out of 14,807 samples received, accounting for 0.55% of the total.

November 2023 and January 2024 show similar trends, with error rates of 0.49% and 0.55%, respectively. December 2023 stands out with the highest error rate among the months analyzed, where 91 error samples are detected out of 13,367 samples received, representing 0.68% of the total.

February 2024 witnesses a slight decline in error frequency compared to the preceding months, with 59 error samples identified out of 11,686 samples received, constituting 0.50% of the total.

Overall, the aggregated prevalence rate of pre-analytical errors across all months is calculated to be 0.52%, with variations observed in error rates from month to month. These fluctuations may reflect changes in laboratory procedures, workload, or other operational factors during the specified time frame.

The month-wise analysis provided in this table offers valuable insights into temporal trends in pre-analytical error occurrence, facilitating targeted interventions and quality improvement initiatives to address specific challenges identified during each period.

Table 4: Descriptive statistics of blood glucose parameters of hemolysed and actual samples received in clinical biochemistry laboratory

Variables		Minimum	Maximum	Median (IQR)	Mean ± SD
Random Blood Sugar (mg/dL)	**Hemolysed**	78	164	126 (116-144)	126.9 ± 23.5
	Actual	121	197	162 (144-175)	158.8 ± 22.6
Fasting Blood Sugar (mg/dL)	**Hemolysed**	71	121	92 (85.25-99.75)	93 ± 12.9
	Actual	83	131	103 (97.5-114)	104.7 ± 12.6
Post Prandial Blood Sugar (mg/dL)	**Hemolysed**	123	173	136 (128.5-145.75)	138.8 ± 14.5
	Actual	134	182	148 (145.25-159.5)	153.2 ± 12.87

Table 4 presents the descriptive statistics of blood glucose parameters for both hemolysed and actual samples received in the clinical biochemistry laboratory. The table includes variables such as Random Blood Sugar, Fasting blood Sugar, and Post Prandial blood Sugar, with their respective minimum, maximum, median (interquartile range - IQR), and mean values ± standard deviation (SD).

Regarding Random Blood Sugar levels, hemolysed samples show a range from 78 mg/dL to 164 mg/dL, with a median of 126 mg/dL and a mean of 126.9 ± 23.5 mg/dL. Actual samples, on the other hand, have a wider range of 121 mg/dL to 197 mg/dL, a median of 162 mg/dL, and a mean of 158.8 ± 22.6 mg/dL.

For Fasting Sugar levels, hemolysed samples range from 71 mg/dL to 121 mg/dL, with a median of 92 mg/dL and a mean of 93 ± 12.9 mg/dL. Actual samples exhibit a wider range of 83 mg/dL to 131 mg/dL, a median of 103 mg/dL, and a mean of 104.7 ± 12.6 mg/dL.

Lastly, in terms of Post Prandial Sugar levels, hemolysed samples range from 123 mg/dL to 173 mg/dL, with a median of 136 mg/dL and a mean of 138.8 ± 14.5 mg/dL. Actual samples have a range of 134 mg/dL to 182 mg/dL, a median of 148 mg/dL, and a mean of 153.2 ± 12.87 mg/dL.

Overall, the descriptive statistics reveal differences in blood glucose parameters between hemolysed and actual samples, with actual samples generally exhibiting higher values across all parameters compared to hemolysed samples. These findings underscore the importance of ensuring sample integrity to obtain accurate blood glucose measurements in clinical practice.

Table 5: Comparing blood glucose parameters between hemolysed and actual sample by using paired t-test

Variables	Hemolysed	Actual	Mean Difference (Δ)	Paired t-test	P-Value
Random Blood Sugar (mg/dL)	126.9 ± 23.5	158.8 ±22.6	31.902	-23.34	0.00001
Fasting Sugar (mg/dL)	93 ± 12.9	104.7 ± 12.6	11.714	-16.77	0.00001
Post Prandial Sugar (mg/dL)	138.8 ± 14.5	153.2±12. 87	14.429	-11.56	0.00001

Table 5 presents the comparison of blood glucose parameters between hemolysed and actual samples using paired t-tests. The variables analyzed include HbA1c, Random Blood Sugar, Fasting blood Sugar, and Post Prandial blood Sugar, with their respective mean values and standard deviations for both hemolysed and actual samples, along with the mean difference (Δ), paired t-test values, p-values, and significance levels.

Similarly, for Random Blood Sugar, Fasting Sugar, and Post Prandial Sugar levels, hemolysed samples show lower mean values compared to actual samples, with mean differences of 31.902 mg/dL, 11.714 mg/dL, and 14.429 mg/dL, respectively. The paired t-test values are -23.34, -16.77, and -11.56, with p-values of 0.00001 for all parameters, signifying statistical significance.

Overall, the paired t-tests demonstrate significant differences in blood glucose parameters between hemolysed and actual samples, emphasizing the importance of ensuring sample integrity for accurate glucose level measurements in clinical settings.

5. Discussion

According to the International Organization for Standardization, laboratory errors encompass the "failure of planned action to be completed as intended, or the use of an incorrect plan to achieve an aim, occurring at any part of the laboratory cycle, from ordering examinations to reporting results and appropriately interpreting and reacting to them" (**Medical Laboratories, 2010**). As clinicians heavily rely on laboratory results for making critical decisions, it is imperative to minimize laboratory errors. With advancements in technology, analytical errors have decreased significantly, with the majority of errors now attributed to the pre-analytical phase (**Dereen Najat et al., 2017**). The impact of laboratory

errors on patient care cannot be understated. Inaccurate or delayed test results can lead to misdiagnosis, inappropriate treatment decisions, and compromised patient safety. Therefore, it is imperative for laboratories to continuously evaluate their processes, identify areas of weakness, and implement measures to enhance quality assurance and quality control practices. Our aim in the present study is to study pre-analytical errors in Clinical Biochemistry and objectives are to enumerate & analyse the rate of pre-analytical errors in Clinical biochemistry laboratory, to find out the frequency of pre-analytical errors in the Clinical Biochemistry Laboratory and to correlate pre-analytical errors with derangement in the results by repeat sample analysis.

6. CONCLUSION

Our study underscores the importance of continuous quality improvement initiatives in clinical biochemistry laboratories. By emphasizing the significance of pre-analytical factors and their impact on laboratory testing outcomes, the research advocates for rigorous adherence to standardized protocols and ongoing education and training to enhance the reliability and accuracy of laboratory results. Through collaborative efforts between laboratory personnel, clinicians, and healthcare administrators, the goals of quality assurance and patient safety can be effectively realized in clinical biochemistry practice. Despite the absence of direct comparative studies for validation, the unique findings of this thesis contribute to the existing body of knowledge in clinical biochemistry. By addressing gaps in understanding and offering practical insights, the research promotes evidence-based approaches to optimize laboratory practice and improve patient care outcomes.

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