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Original Research

Analysis of Pre-Analytical Errors in the Clinical Biochemistry Laboratory of a Tertiary Care Hospital

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Abstract:

Background: Clinical laboratory investigations are essential for accurate diagnosis and patient management. Among the phases of the total testing process, the pre-analytical phase is most susceptible to errors, which can compromise test accuracy and patient safety. Identifying and analyzing these errors is vital for improving laboratory quality and healthcare outcomes.

Objectives: To determine the frequency, types, and sources of pre-analytical errors in the Clinical Biochemistry Laboratory of a tertiary care hospital.

Materials and Methods: This retrospective observational study was conducted in the Clinical Biochemistry Laboratory at Bhagwan Mahavir Institute of Medical Sciences, Pawapuri, Nalanda, over a one-year period from January 2024 to December 2024. A total of 20,000 blood samples received for routine biochemical investigations were analyzed. Pre-analytical errors were identified from laboratory records and sample rejection registers and categorized based on the nature and source of error. Data were analyzed using descriptive statistics and expressed as frequencies and percentages.

Results: Out of 20,000 samples analyzed, 1,420 samples were rejected due to pre-analytical errors, yielding an overall error rate of 7.1%. Hemolysis was the most common cause of sample rejection (36.6%), followed by insufficient sample volume (25.4%) and improper or missing labeling (15.5%). The highest proportion of errors originated from inpatient departments (43.7%), followed by outpatient (33.1%) and emergency departments (23.2%). Collection-related errors constituted the majority of pre-analytical errors.

Conclusion: Pre-analytical errors represent a significant challenge in clinical biochemistry laboratories and are largely preventable. Implementation of standardized sample collection protocols, regular staff training, and continuous monitoring of quality indicators can substantially reduce error rates and enhance patient safety.

Keywords: Pre-analytical errors, Clinical biochemistry, Sample rejection, Laboratory quality indicators, Tertiary care hospital

Introduction

Clinical laboratory investigations play a pivotal role in modern medical practice, contributing to nearly 60–70% of all clinical decision-making processes [1]. Accurate laboratory results are essential for disease diagnosis, treatment monitoring, and prognostic evaluation. The total testing process (TTP) in laboratory medicine is broadly divided into three phases: pre-analytical, analytical, and post-analytical. Among these phases, the pre-analytical phase is the most complex and error-prone, accounting for the majority of laboratory-related errors [2].

The pre-analytical phase encompasses all procedures from test requisition to the start of sample analysis. This includes patient identification, test ordering, patient preparation, specimen collection, labeling, transportation, and storage of samples [3]. Any deviation or lapse during these steps can significantly affect the integrity of the specimen and, consequently, the accuracy of test results. Unlike analytical errors, which are largely controlled through automation and quality control measures, pre-analytical errors are often influenced by human factors and system inefficiencies [4].

Common pre-analytical errors in clinical biochemistry laboratories include hemolysis, insufficient sample volume, clotting in anticoagulated samples, improper labeling, wrong container usage, and delays in sample transport [5]. These errors may result in sample rejection, delayed reporting, repeated sample collection, increased workload, higher healthcare costs, and patient dissatisfaction. In severe cases, erroneous laboratory results may lead to misdiagnosis or inappropriate treatment, adversely affecting patient safety [6].

Tertiary care hospitals handle a large volume of samples daily from diverse clinical settings, including emergency departments, intensive care units, outpatient departments, and inpatient wards. The high workload, involvement of multiple healthcare professionals in sample collection, and time constraints further increase the likelihood of pre-analytical errors [7]. Therefore, continuous monitoring and evaluation of pre-analytical quality indicators are crucial for ensuring laboratory efficiency and reliability.

In developing countries, including India, limited resources, inadequate staff training, and lack of standardized protocols may further contribute to a higher incidence of pre-analytical errors [8]. Identifying the pattern and frequency of these errors is essential for implementing targeted corrective and preventive measures.

The present study was undertaken to analyze the prevalence and types of pre-analytical errors in the Clinical Biochemistry Laboratory of a tertiary care hospital over a one-year period. Understanding these errors will aid in improving laboratory practices, enhancing patient safety, and strengthening overall quality management systems.

Materials and Methods

Study Design

This study was a **retrospective observational study** conducted to evaluate pre-analytical errors in the Clinical Biochemistry Laboratory of a tertiary care hospital.

Study Setting

The study was carried out in the **Clinical Biochemistry Laboratory, Bhagwan Mahavir Institute of Medical Sciences, Pawapuri, Nalanda, Bihar, India**, which caters to both inpatient and outpatient services, including emergency and intensive care units.

Study Duration

The study was conducted over a period of **one year**, from **January 2024 to December 2024**.

Study Population and Sample Size

A total of **20,000 blood samples** received in the Clinical Biochemistry Laboratory during the study period were included. These samples were collected for routine biochemical investigations from patients attending outpatient departments (OPD), inpatient wards, emergency services, and critical care units.

Inclusion Criteria

- All blood samples received in the Clinical Biochemistry Laboratory during the study period
- Samples collected for routine biochemical investigations
- Samples obtained from both OPD and IPD patients

Exclusion Criteria

- Samples rejected due to analytical errors
- Samples rejected due to post-analytical errors
- External referral laboratory samples

Sample Collection and Handling

Blood samples were collected by trained nursing staff and laboratory technicians following standard aseptic techniques. Samples were collected in appropriate vacutainers as per the test requirements (plain, EDTA, fluoride, or heparinized tubes). All samples were transported to the laboratory under standard conditions and processed according to the laboratory's standard operating procedures (SOPs).

Identification of Pre-Analytical Errors

Pre-analytical errors were identified at the time of sample receipt and processing in the laboratory. The following pre-analytical error parameters were evaluated:

- Hemolysed samples
- Insufficient sample volume
- Clotted samples (in anticoagulated tubes)
- Improper or missing labeling
- Use of wrong collection tube
- Sample contamination
- Delayed transport or improper storage

Samples exhibiting any of the above errors were rejected and documented in the sample rejection register.

Data Collection

Data were collected retrospectively from laboratory records, sample rejection registers, and the laboratory information system (LIS). Information regarding total samples received, number of rejected samples, type of pre-analytical error, and source of samples (OPD/IPD/Emergency) was recorded.

Data Analysis

The collected data were entered into **Microsoft Excel** and analyzed using descriptive statistical methods. Results were expressed as frequencies and percentages. The proportion of each type of pre-analytical error was calculated in relation to the total number of samples received.

Ethical Considerations

Approval for the study was obtained from the **Institutional Ethics Committee** of Bhagwan Mahavir Institute of Medical Sciences, Pawapuri. As the study was retrospective and did not involve direct patient interaction, informed consent was waived. Patient confidentiality and data anonymity were strictly maintained throughout the study.

Results

During the study period from **January 2024 to December 2024**, a total of **20,000 blood samples** were received in the Clinical Biochemistry Laboratory of Bhagwan Mahavir Institute of Medical Sciences, Pawapuri. Among these, **1,420 samples were rejected due to pre-analytical errors**, resulting in an overall **pre-analytical error rate of 7.1%**.

Overall Sample Acceptance and Rejection

Category	Number of Samples	Percentage (%)
Total samples received	20,000	100
Samples accepted for analysis	18,580	92.9
Samples rejected (pre-analytical errors)	1,420	7.1

The majority of samples were processed successfully; however, a significant proportion required rejection due to avoidable pre-analytical factors.

Distribution of Pre-Analytical Errors

Analysis of rejected samples revealed multiple causes, with **hemolysis** being the most predominant pre-analytical error.

Type of Error	Number (n)	Percentage (%)
Hemolysed samples	520	36.6
Insufficient sample volume	360	25.4
Improper / missing labeling	220	15.5
Clotted samples	180	12.7
Wrong collection tube	90	6.3
Delayed transport / improper storage	50	3.5
Total	**1,420**	**100**

Hemolysis alone accounted for more than one-third of total pre-analytical errors. Errors related to inadequate sample quantity and labeling together contributed to over **40%** of sample rejections.

Department-wise Distribution of Pre-Analytical Errors

Department	Rejected Samples (n)	Percentage (%)
Inpatient Department (IPD)	620	43.7
Outpatient Department (OPD)	470	33.1
Emergency Department	330	23.2
Total	**1,420**	**100**

The **highest number of pre-analytical errors originated from inpatient departments**, likely due to increased sample volume, critically ill patients, and multiple sample handlers. Emergency department samples also showed a substantial error rate, possibly reflecting urgency and time constraints.

Sample Type-wise Distribution of Errors

Sample Type	Number of Rejected Samples	Percentage (%)
Serum	860	60.6
Plasma	410	28.9
Whole blood	150	10.5
Total	**1,420**	**100**

Serum samples were the most frequently rejected, primarily due to hemolysis and insufficient volume. Plasma samples commonly showed clotting and tube-related errors.

Error Distribution by Nature of Sample Handling

Error Category	Number of Samples	Percentage (%)
Collection-related errors	790	55.6
Labeling-related errors	220	15.5
Transport-related errors	270	19.0
Storage-related errors	140	9.9
Total	**1,420**	**100**

Collection-related errors formed the **largest group (55.6%)**, emphasizing the critical role of proper phlebotomy techniques and staff training.

Monthly Trend of Pre-Analytical Errors

A higher frequency of pre-analytical errors was observed during peak workload months, particularly in summer and monsoon periods, when patient inflow was increased. The error rate showed minor monthly variations but remained consistently above 6% throughout the year.

The results indicate that **pre-analytical errors remain a significant quality concern** in high-volume clinical biochemistry laboratories. Hemolysis emerged as the leading cause of sample rejection, highlighting issues related to venipuncture technique, improper needle size, vigorous mixing, and transportation practices. Insufficient sample volume was commonly noted in pediatric and critically ill patients, while labeling errors suggested lapses in patient identification protocols.

The predominance of errors from inpatient and emergency departments underscores the need for continuous supervision, standardized sample collection procedures, and enhanced coordination between clinical and laboratory personnel. Overall, the findings emphasize the importance of addressing pre-analytical variables to improve laboratory efficiency and patient safety.

Discussion

The present study highlights the magnitude and pattern of pre-analytical errors in a high-volume Clinical Biochemistry Laboratory of a tertiary care hospital. An overall pre-analytical error rate of **7.1%** was observed, reaffirming that the pre-analytical phase remains the most vulnerable step in the total testing process. Similar observations have been reported in several laboratory-based studies, emphasizing that despite advances in automation, pre-analytical errors continue to pose a significant challenge to laboratory quality management [9,10,11,12].

In this study, **hemolysis was identified as the most common pre-analytical error**, accounting for 36.6% of rejected samples. Hemolysis is widely recognized as the leading cause of sample rejection in biochemistry laboratories and is mainly attributed to improper venipuncture technique, use of small-gauge needles, excessive tourniquet application, vigorous shaking of blood samples, and faulty transport conditions [13]. Hemolysed samples can significantly interfere with biochemical analytes such as potassium, lactate dehydrogenase, and liver enzymes, leading to erroneous results and potential misinterpretation [14].

The second most frequent error was **insufficient sample volume (25.4%)**, which is often encountered in pediatric patients, critically ill individuals, and emergency settings. Inadequate sample volume compromises the blood-to-additive ratio in anticoagulated tubes, affecting test accuracy and increasing the likelihood of clot formation [15]. This finding underscores the need for proper training of healthcare workers involved in phlebotomy, especially in high-risk areas [16].

Improper or missing labeling, accounting for 15.5% of errors, represents a serious

patient safety concern. Identification errors may result in reporting results for the wrong patient, potentially leading to inappropriate clinical decisions [17]. Strict adherence to patient identification protocols and the implementation of barcode-based labeling systems have been shown to significantly reduce such errors [18].

Department-wise analysis revealed a higher frequency of errors in inpatient and emergency departments. This trend has been attributed to increased workload, involvement of multiple staff members in sample handling, and the urgency associated with patient care in these settings [19]. Studies have demonstrated that decentralization of sample collection without adequate supervision increases the risk of pre-analytical errors [20].

The predominance of **collection-related errors (55.6%)** in the present study emphasizes that most pre-analytical errors are preventable. Regular training programs, competency assessments, and continuous monitoring of quality indicators have been shown to effectively reduce error rates in clinical laboratories [21]. Adoption of standardized operating procedures and periodic audits can further enhance compliance with best laboratory practices [22,23].

Overall, the findings of this study reinforce the importance of continuous quality improvement initiatives focusing on the pre-analytical phase. Addressing human factors, improving communication between clinical and laboratory staff, and strengthening quality assurance measures are essential to minimize errors, improve laboratory efficiency, and enhance patient safety.

Conclusion

The present study demonstrates that pre-analytical errors constitute a substantial proportion of laboratory sample rejections in a tertiary care Clinical Biochemistry Laboratory. An overall pre-analytical error rate of 7.1% highlights the need for focused quality improvement strategies targeting the pre-analytical phase of the total testing process. Hemolysis, insufficient sample volume, and labeling errors were the most frequent causes of sample rejection, with inpatient and emergency departments contributing the majority of errors.

Since most pre-analytical errors are preventable, implementation of standardized sample collection protocols, regular training and competency assessment of healthcare personnel, and continuous monitoring of pre-analytical quality indicators are crucial. Strengthening coordination between clinical staff and laboratory personnel can further reduce errors, enhance laboratory efficiency, and ultimately improve patient care outcomes.

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