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Strengthening Quality in The Pre-Analytical Phase of Laboratory Medicine: The Role of Quality Indicators

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ABSTRACT

Laboratory medicine has undergone substantial advancements over the past decades, particularly in the analytical phase, with the integration of automation, quality control, and advanced diagnostic technologies. However, the pre-analytical phase remains a critical area prone to errors, contributing to nearly 70% of total laboratory mistakes. Errors occurring before a sample reaches the laboratory, termed the 'pre-analytical phase', are often overlooked despite their significant impact on patient safety and diagnostic accuracy.

Quality indicators (QIs) are essential for monitoring and improving the pre-analytical phase of laboratory testing, ensuring accuracy and efficiency. The International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) has developed specific QIs to standardize and enhance this phase, reducing errors in sample collection, transport, and processing. Implementing these indicators in clinical practice helps laboratories track performance, identify weaknesses, and optimize workflows. By focusing on the QIs, from their lab, one can improve patient safety, diagnostic reliability, and overall laboratory efficiency. Standardized QIs contribute to better healthcare outcomes and reinforce the importance of quality control in laboratory medicine. This article focusses on the Qis followed in the Central Laboratory with analysis of these QIs, root cause analysis (RCA) and corrective and preventive actions (CAPA) of the non-conformities.

1. INTRODUCTION

Errors can occur at any stage of the laboratory testing process, potentially leading to delays in diagnosis and management, which in turn may cause patient distress. Among these, pre analytical errors—those occurring before the actual analysis of specimens—are particularly significant, as they can substantially compromise the accuracy and reliability of test results. This study focuses on assessing the prevalence and nature of pre analytical errors in the hematology laboratory of a tertiary care hospital and proposes effective strategies to mitigate them.

The total testing process (TTP) in laboratory medicine is traditionally divided into three distinct phases: pre-analytical, analytical, and post-analytical. Of these, the pre-analytical phase is considered the most error-prone, accounting for approximately 60–70% of all laboratory errors. [1,2] These errors typically arise before the sample reaches the laboratory and may involve issues related to patient identification, test requisition, specimen collection, labeling, handling, transportation, and preparation. Despite significant technological advancements and improvements in analytical procedures and information systems—which have considerably reduced errors in the analytical phase—pre-analytical mistakes remain a persistent challenge that jeopardizes both diagnostic accuracy and patient safety. [3,4]

In response to these challenges, laboratories worldwide have increasingly adopted structured quality indicators (QIs) to monitor, evaluate, and manage performance within this critical segment of the TTP. [5,6] By closely tracking these indicators, laboratories can identify areas of vulnerability and implement targeted interventions to minimize errors.

The pre-analytical phase encompasses several essential procedures, including specimen collection, labeling, handling, transportation, and storage. Errors during any of these steps can negatively impact the reliability of hematological diagnoses and delay clinical decision-making. Therefore, it is crucial to recognize the importance of this phase and to implement proactive measures to reduce errors, thereby improving diagnostic accuracy, laboratory efficiency, and ultimately, patient care outcomes.

Effective strategies for minimizing pre-analytical errors include comprehensive staff training, standardization of procedures, utilization of appropriate collection and transport equipment, implementation of robust quality control protocols, and the integration of automation technologies. Addressing these key areas can help reduce turnaround times, enhance patient safety, and improve the overall quality of laboratory services.

This article presents a focused study of pre-analytical QIs tracked over a defined period in the central laboratory of tertiary care academic institute, with a comprehensive overview of errors recorded and the CAPA taken to mitigate their recurrence

2. MATERIALS AND METHODS

A prospective observational study was conducted over a one and half year period in the central laboratory of a tertiary care hospital.

Four key pre-analytical quality indicators were selected based on their clinical relevance, frequency, and potential impact on patient care:

1. Syntax errors during patient registration
2. Number of venipuncture failures
3. Number of sample rejections
4. Number of times urgent samples reached late for testing

Data for each indicator were collected monthly and analyzed to identify trends and areas requiring improvement. CAPAs were formulated based on root cause analysis (RCA) of each incident.

3. RESULTS

The monthly data collected over one and half year (November 2023 to April 2025) months are summarized in Table 1.

Table No. 1 Monthly analysis of pre-analytical failures with RCA and CAPA for continuous laboratory quality improvement

Failure Type	Month-wise Data (18 Months)	Root Cause(s) Identified	Corrective and Preventive Actions (CAPA)	Remark on Spike (if any)
Syntax Errors	3, 2, 1, 2, 2, 3, 2, 3, 2, 3, 2, 3, 2, 0, 2, 3, 2, 0	Incomplete/incorrect test requisition forms; unfamiliarity with form fields; human oversight.	Refresher training on form filling; LIS validation checks; monthly audits.	No major spike noted.
Venipuncture Failures	1, 3, 2, 2, 3, 2, 2, 5, 2, 3, 2, 3, 2, 3, 2, 3, 2, 1	Inadequate technique; difficult veins; poor patient prep; insufficient experience; occasional rush during peak OPD.	Skill enhancement workshops; competency checks; regular pre-procedure patient briefing; supervision reinforcement.	Spike of 5 in August likely due to heavy patient load post monsoon fever outbreaks and junior staff handling.
Sample Rejections	2, 3, 2, 3, 2, 2, 3, 8, 2, 4, 2, 3, 2, 3, 3, 1, 2, 3	Wrong container; improper labeling; insufficient volume; hemolysis during collection; hurried sampling during peak hours.	Re-emphasis on SOP adherence; rejection criteria display in phlebotomy area; stricter supervision; targeted error analysis.	Spike of 8 in August due to sudden increase in samples needing urgent dispatch, leading to haste and errors.
Delayed Urgent Samples	1, 0, 0, 2, 3, 2, 3, 2, 0, 1, 1, 0, 3, 0, 2, 3, 0, 3	Miscommunication about priority; staff shortage; lack of dedicated urgent	Introduced priority tagging; dedicated staff for urgent samples; reinforced	No unusual spike, though minor rise in May-August due to seasonal

		sample runners.	shift-wise communication handovers.	outbreak workload.

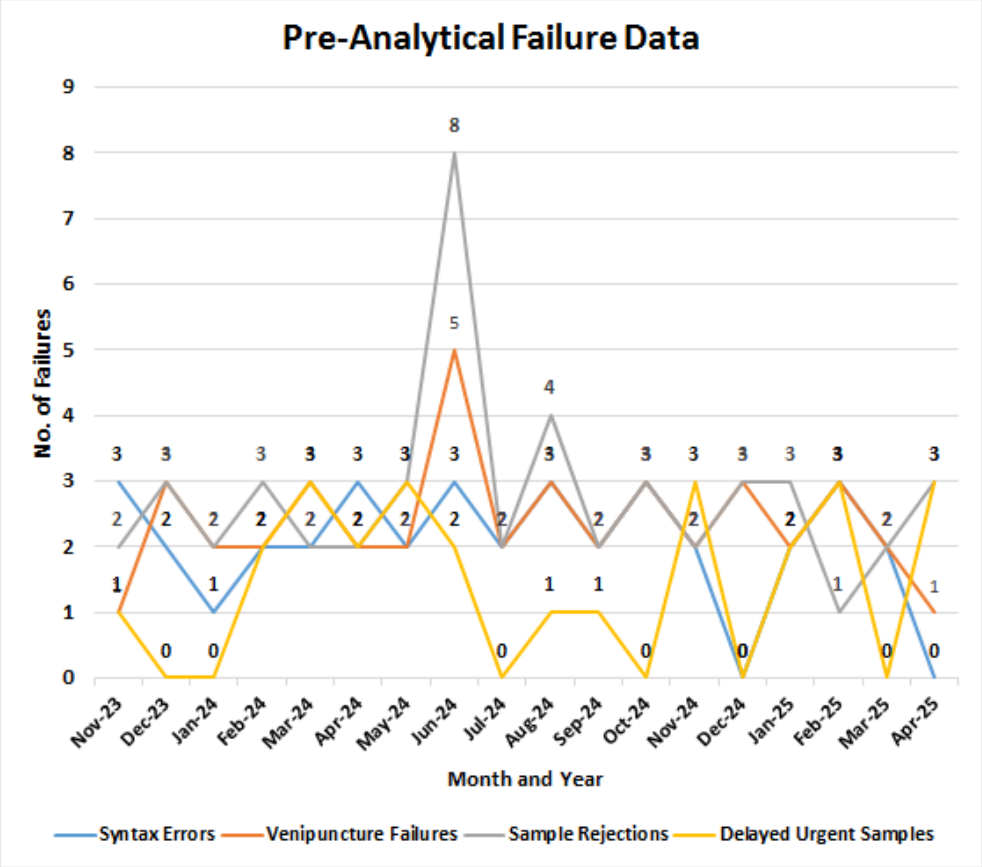

Figure No. 1 Pre-Analytical Failure Data Showing data of preanalytical failures

This graph displays monthly pre-analytical failures from November 2023 to April 2025. The four categories tracked include **Syntax Errors (blue line)**, **Venipuncture Failures (orange line)**, **Sample Rejections (gray line)**, and **Delayed Urgent Samples (yellow line)**, with the number of incidents plotted against each month.

4. DISCUSSION

Pre-analytical errors (PAEs) remain a persistent and significant concern in hematology laboratories, accounting for a considerable proportion of total laboratory errors despite continuous advances in automation, analytical techniques, and quality control measures. [7,8] In the present study conducted over a one-year period in a tertiary care hospital, the overall incidence of PAEs was 0.38%, with clotted samples being the most frequent error category, followed by insufficient sample quantity, wrong sample type, and labeling issues.

These findings are in agreement with previous reports that also identify clotted and insufficient samples as predominant pre-analytical issues in hematology laboratories. [9,10]

At Kalyan Singh Government Medical College, Bulandshahr, a similar pattern was observed over an 18-month internal audit. Syntax errors due to incomplete requisition forms, venipuncture failures arising from technique lapses and peak-hour rush, and sample rejections from improper labeling and insufficient volume were recurrently encountered. [9,10] Notably, spikes in PAEs coincided with seasonal outbreaks, underscoring the impact of increased workload and operational strain on pre-analytical performance. These observations further reinforce the need for continuous monitoring and proactive error management, particularly during high-demand periods. [11]

Recent multicentric studies in India and abroad echo these trends. A study at Jawaharlal Nehru Medical College, Aligarh, India, reported a PAE rate of 1.24% over one year, with insufficient samples, hemolyzed samples, and clotted specimens as the most common errors. Pediatric samples exhibited a notably higher error rate compared to adult samples, highlighting the

inherent challenges of pediatric phlebotomy and the critical need for specialized training, equipment, and child-specific protocols. [12] Similarly, a large-scale retrospective analysis from Ondokuz Mayıs University Health Practice and Research Center, encompassing over 7.7 million biochemistry laboratory requests, found that 74.8% of rejected samples were due to pre-analytical errors, with insufficient and clotted samples leading. Inpatient departments showed higher rejection rates than outpatient settings, possibly attributed to the severity of patient conditions, higher procedural complexity, and staff workload pressures. [13]

The clinical implications of these errors are considerable. PAEs can result in diagnostic delays, repeated venipunctures, increased workload, patient discomfort, and avoidable financial costs. In hematology laboratories, clotted samples are particularly problematic as they can lead to complete invalidation of test results, requiring repeat sampling. This underlines the need for rigorous adherence to phlebotomy protocols, proper sample mixing, and prompt handling of anticoagulated specimens. Regular hands-on training sessions, competency assessments, and protocol reinforcement for phlebotomists and nursing staff are essential to address these issues effectively. [14,15]

Emerging evidence underscores the value of integrating automation and digital technologies in mitigating PAEs. A 2022 literature review emphasized that barcode specimen labeling, computerized provider order entry (CPOE), and specimen tracking systems significantly reduce pre-analytical issues by minimizing manual transcription errors, enhancing traceability, and improving workflow efficiency. Similarly, cloud-based sample tracking platforms have demonstrated success in reducing container mismatch, underfilling, and collection-related errors while providing real-time oversight and operational analytics. While our laboratory predominantly utilized manual processes during the study period, adopting these technologies could further improve pre-analytical quality assurance. [16]

Moreover, a recent scoping review published in 2025 highlighted the promising role of artificial intelligence (AI) and machine learning (ML) in laboratory medicine. AI applications offer the potential to detect recurring error patterns, predict high-risk scenarios, and recommend corrective actions based on historical data and real-time analytics. However, the review also noted the necessity for further validation of these tools in practical, real-world laboratory environments, alongside addressing regulatory, privacy, and data security challenges associated with their implementation.

In conclusion, our study reinforces that PAEs continue to be a frequent and impactful source of laboratory errors in hematology settings. Systematic audits, root cause analyses, and corrective interventions—such as periodic training programs, strict adherence to standard operating procedures (SOPs), and robust quality monitoring—are critical to reducing their occurrence. Additionally, future studies should explore the practical benefits of incorporating digital health technologies, automated tracking, and AI-based systems in hematology laboratories to enhance patient safety and diagnostic efficiency. [17]

Path Forward: Enhancing Pre-Analytical Quality

To optimize the impact of QIs in the pre-analytical phase, a multi-pronged strategy is essential:

Standardized SOPs: Establish clear, standardized operating procedures for all pre-analytical activities, including those performed outside the laboratory.

Staff Training: Regular training and competency assessment programs for non-laboratory personnel involved in specimen collection and handling.

Audit and Feedback: Periodic audits of QI data followed by feedback sessions with clinical teams to address recurring issues.

Information Systems Integration: Utilize electronic test ordering and barcoded sample labeling to reduce identification errors.

Collaborative Governance: Formulate joint quality committees comprising laboratory and clinical staff to foster shared responsibility for pre-analytical quality.

5. CONCLUSION

Pre-analytical errors remain a significant and persistent challenge in laboratory medicine, directly affecting diagnostic accuracy and patient safety. Addressing these issues demands a comprehensive, multifaceted strategy encompassing staff education, stringent process standardization, and the adoption of advanced technologies. The continuous identification, monitoring, and analysis of quality indicators in this phase are vital to sustaining high standards of laboratory service. Initiatives like those by the IFCC WG-LEPS have laid important groundwork in defining relevant quality indicators, though their widespread implementation continues to face obstacles. By fostering interdepartmental collaboration, prioritizing continuous training, and reinforcing a culture of quality and patient-centered care, healthcare systems can meaningfully reduce pre-analytical errors and enhance the overall reliability of laboratory diagnostics.

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