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Navigating Preanalytical Vulnerabilities in Hematology Labs: Preventive Strategies for Quality Control and Assurance

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Abstract

Context

Clinical laboratories are critical to patient care, with accurate diagnostics essential for effective management. The preanalytical phase is particularly prone to errors, accounting for up to 70% of lab mistakes. These can distort results, increase costs, and compromise patient safety.

Quality indicators (QIs) help monitor and minimize such errors, especially in hematology testing. This study focuses on assessing preanalytical QIs and proposes strategies—including staff training and workflow audits—to improve laboratory accuracy and overall performance.

Aim: *To evaluate preanalytical quality indicators (QIs) in hematology laboratory settings and implement targeted strategies—such as staff training and workflow audits—to enhance diagnostic accuracy and overall laboratory performance.*

Study Protocol: *All samples received by the Hematology Laboratory of the Maternity and Pediatric Hospital in Hail were retrospectively reviewed for preanalytical issues using predefined QIs. Blood samples (n-10000) were analyzed from January 2023 to December 2023.*

Results: *Of 10,000 hematology samples assessed in 2023, 9.3% showed preanalytical errors—predominantly clotted specimens (502) and unreceived samples (3.5%). While quality indicators largely reflected moderate to low performance against benchmarks, sigma analysis affirmed acceptable levels in key processes. Notably, error rates declined from 11.6% to 6.5% over the year, highlighting the impact of continuous quality improvement measures.*

Conclusion: *Minimizing preanalytical errors is essential for accurate hematology reporting. Standardized protocols, staff training, sample tracking, and continuous audits strengthen quality assurance and promote diagnostic reliability. Embedding these safeguards into routine workflows ensures consistent clinical value and patient safety.*

Keywords: *Preanalytical phase, Quality Indicators, Patient care, Errors, Diagnostic Accuracy*

INTRODUCTION

Expanded and Refined Introduction: Safeguarding Diagnostic Integrity in Hematology Laboratories

Clinical laboratories are central to delivering high-quality healthcare, as accurate and timely diagnostics underpin critical patient management decisions. Excellence in coagulation and hematology testing requires a comprehensive quality framework that spans every phase of the testing process. Despite the inevitability of occasional lapses, systematic and ongoing performance evaluation remains indispensable for identifying vulnerabilities and driving continuous improvement in laboratory medicine.

Among the testing phases, the preanalytical segment stands out as the most susceptible to errors due to its multifaceted nature and extensive human involvement. These errors—occurring before actual sample analysis—can significantly compromise diagnostic accuracy and treatment outcomes. Recognized as the most error-prone stage, the preanalytical phase accounts for nearly 70% of laboratory mistakes, compared to 7–13% in the analytical phase and 20–50% in the postanalytical phase [(1), (2)]. As highlighted by Plebani, a narrow focus on analytical precision while neglecting preanalytical flaws poses a serious threat to patient safety and diagnostic reliability.

To systematically address these concerns, **Quality Indicators (QIs)** have emerged as pivotal tools. They offer quantifiable, objective metrics to assess various components of healthcare delivery, including laboratory services [(1), (2)]. In laboratory diagnostics—upon which nearly 80% of clinical decisions are based—QIs enable benchmarking, error surveillance, and targeted interventions aimed at enhancing testing integrity and clinical impact.

Furthermore, the cost implications of unchecked preanalytical errors are substantial. They increase resource utilization, delay patient care, and erode trust in diagnostic services [(2)]. Thus, the implementation of standardized QIs to monitor preanalytical and postanalytical phases is not merely an operational enhancement but a strategic imperative.
This study seeks to define and assess preanalytical QIs specific to hematology testing within a clinical laboratory context. It emphasizes not only the quantification of error trends and performance gaps but also the need for sustainable interventions. By integrating analytical insights with targeted training for laboratory personnel, the research aims to foster an environment of diagnostic excellence and reinforce the commitment to patient safety [(3)].

METHODS:
Over a span of one year, all samples received by the Hematology Laboratory of the Maternity and Pediatric Hospital in Hail were retrospectively reviewed for preanalytical issues using predefined QIs. Blood samples (N-10000), out of which 930 were analyzed since 9.3% showed preanalytical errors predominantly clotted specimens (502) and unreceived samples (3.5%) that were collected from January 2023 to December 2023.
The clinical laboratory at our hospital plays a pivotal role in providing a wide range of routine and specialized tests across various departments, including hematology. Specimen collection for patients admitted to the hospital, those visiting as outpatients, and those arriving through the emergency department is managed by non-laboratory personnel.
Upon obtaining formal approval and establishing protocols with laboratory management, we conducted a thorough retrospective analysis. Using our comprehensive laboratory information system, we meticulously reviewed data from all hematology tests conducted during this timeframe, encompassing critical parameters. Our primary focus was on identifying preanalytical errors, which include misidentification of specimens, incorrect labeling or handling of samples, insufficient specimen volumes, issues related to transportation and storage conditions, sample contamination, visual detection of hemolysis, and instances of clotting.
To evaluate and quantify these preanalytical errors, we applied a set of Quality Indicators (QIs) annually, utilizing the Model of Quality Indicators (MQI) established by the International Federation of Clinical Chemistry and Laboratory Medicine Working Group on Laboratory Errors and Patient Safety (IFCC WG-LEPS). Priority was given to Level 1 QIs, which are crucial for assessing the performance of key processes in the preanalytical phase. (6)The results of these assessments were categorized into performance levels based on the latest analytical quality specifications (QSs) defined by IFCC WG-LEPS:

- High: Reflecting optimal performance
- Medium: Indicating common performance
- Low: Signifying unsatisfactory performance

Statistical analysis:
assess process capability, and inferential tests such as the Chi-square and Mann–Whitney U to evaluate variability over time. Preventive measures such as staff retraining, standardized phlebotomy protocols, barcode-based sample tracking, and preanalytical checklists were implemented and their impact assessed through comparative error rate analysis. This methodology enabled a comprehensive understanding of systemic weaknesses and facilitated the evaluation of targeted interventions for improved laboratory quality assurance.

RESULTS:
Established quality specifications revealed that most preanalytical QIs were categorized as demonstrating moderate to low performance levels. However, sigma-based analysis indicated acceptable performance across critical processes.
The study also observed a decrease in preanalytical error rates from 11.6% initially to 6.5% over time, underscoring ongoing efforts to improve laboratory practices. Despite these improvements, challenges persist in specimen collection procedures that affect sample quality. Utilizing QIs in the preanalytical phase provides a

valuable framework for enhancing clinical laboratory performance. Continuous monitoring and management of QI data are imperative to uphold satisfactory performance standards and elevate overall quality in the preanalytical phase of laboratory testing.

Preanalytical Variables	Number of Samples N
1 Inappropriate tube	*161 (12%)*
2 Clotted sample	*400 (43%)*
3 Insufficient sample	*239 (20%)*
4 Hemolyzed sample	*37 (4%)*
5 Diluted sample	*18 (2%)*
6 Excessive sample	*9 (1%)*
7 Labeling error	*48(5%)*
8 Delay in sample transfer to lab	*18 (2%)*
9 Empty tube/damaged tube	*0 (0%)*
Total	*930 (100%)*

Table 1- Distribution of Preanalytical Sample Errors in Hematology Workflow (n = 930)

Among 930 recorded preanalytical errors, clotted samples were most common (43%), followed by insufficient volume (20%) and inappropriate tube use (12%). Labeling mistakes (5%), hemolysis (4%), dilution and delayed transfers (each 2%), and excess volume (1%) were less frequent. No errors were due to empty or damaged tubes. This underscores the need for tighter control over sample collection and handling protocols.

Specimen Type	***Total Samples***	***Errors Identified***	***Error Rate (%)***
EDTA Anticoagulated Blood	6,000	620	10.3%
Citrated Plasma	2,000	190	9.5%
Heparinized Samples	1,200	82	6.8%
Capillary Samples	800	38	4.8%
Total	**10,000**	**930**	**9.3%**

Table 2: Error Distribution by Specimen Type
Among 10,000 samples analyzed across four specimen types, the overall error rate was 9.3%. EDTA-anticoagulated blood showed the highest error rate at 10.3%, contributing 620 of 930 total errors. Citrated plasma followed with

a 9.5% error rate, while heparinized samples and capillary specimens had lower rates at 6.8% and 4.8%, respectively. These findings highlight specimen type–specific vulnerabilities in preanalytical processing, with EDTA samples requiring focused quality improvement efforts to reduce diagnostic inaccuracies.

Intervention Phase	*Samples Analyzed*	*Clotted Specimens*	*Error Rate (%)*
Pre-Intervention	5,000	295	5.9%
Post-Training Phase	3,000	75	2.5%
SOP Revision Phase	2,000	30	1.5%
Total	**10,000**	**400**	**3.3**% (avg)

Table 3: Effect of Interventions on Clotted Specimen Rates

Across 10,000 analyzed samples, the overall clotted specimen error rate decreased significantly following targeted interventions. During the pre-intervention phase, the error rate was 5.9% (295 clotted samples out of 5,000). This reduced to 2.5% (75/3,000) after staff training and further declined to 1.5% (30/2,000) following standard operating procedure (SOP) revisions. These findings underscore the effectiveness of structured training and protocol refinement in minimizing clotted specimen errors and improving preanalytical quality control.

DISCUSSION:

In our study there is an initial preanalytical error rate of 11.6%, which decreased to 6.5% over time, underscoring ongoing improvement efforts. This rate represents the proportion of samples exhibiting preanalytical errors. In comparison, Mankar et al[12] and Nordin et al.[13] emphasize the broader impact, stating that preanalytical errors constitute a significant majority of all laboratory errors, ranging from 46%–70%. Plebani [4]also aligns with this, noting that preanalytical errors account for up to 70% of all mistakes in laboratory diagnostics.

Narang et al [14] reported a much lower total preanalytical error rate of 0.38% from their specific study of 471,006 samples. They consider this low, but acknowledge that such errors are avoidable. This notable difference in reported percentages (e.g., 6.5% vs. 0.38%) could be due to variations in methodologies, types of errors included, or how the percentages are calculated (e.g., percentage of total samples vs. percentage of total laboratory errors).

Our study identified **clotted samples (43%)** as the most common preanalytical error, followed by **insufficient volume (20%)** and **inappropriate tube use (12%)**. This aligns with **Narang et al [14]** who also found **clotted samples (0.28%)** to be the main reason for rejecting samples in their study. They also noted insufficient quantity as a significant error (0.06%). **Mankar et al.'s** [12] comprehensive review, drawing data from multiple studies, also highlights **clotted samples (0.816%)** and **insufficient sample (0.476%)** as high-frequency errors, along with hemolyzed samples (0.146%).

Mankar et al[12] systematically examined various sources, including specimen collection, transportation, and handling, citing issues like incorrect patient identification, improper tube selection, and insufficient sample volume. They also differentiated between errors occurring **outside the laboratory** (e.g., incorrect test requests, patient misidentification, inappropriate containers/labeling, insufficient sample collection/transportation) and **within the laboratory** (e.g., sorting, pour-off, labeling errors).

Nordin et a[13] provided an extensive breakdown of contributing factors, categorizing them into:

- **Inappropriate test requests** (pre-preanalytical phase), including unnecessary or un-ordered tests.
- **Patient preparation lapses**, such as inadequate fasting, cigarette smoking, alcohol consumption, chewing gum, and drug interference.
- **Sample collection errors**, including patient misidentification (16% of phlebotomy errors) and improper labeling (56% of phlebotomy errors), patient position, diurnal variation, phlebotomy techniques (e.g., excessive fist clenching, prolonged tourniquet leading to pseudohyperkalemia), and incorrect order of draw.
- **Improper sample handling, transportation, and storage**, which affect analyte stability due to time and temperature. Narang et al [14] specifically attributed clotted samples to improper mixing and inadequate

EDTA, and insufficient quantity errors to pediatric patients and untrained personnel. Also, **Plebani [4]** highlighted that while the pre-analytical phase is error-prone, most errors actually occur in the **'pre-pre-analytical phase'**, which involves initial procedures performed by healthcare personnel *outside* the direct control of the clinical laboratory.

Our study also showed evidence of the effectiveness of interventions: **staff training reduced clotted specimen rates from 5.9% to 2.5%**, and **Standard Operating Procedure (SOP) revisions further declined the rate to 1.5%**, showing improved preanalytical quality control. **Mankar et al [12] also** advocated for **quality management systems** (utilization of SOPs, timely employee education, routine audits), **staff education and training**, **advancements in technology and automation**.

Narang et al [14] concluded that preanalytical errors can be overcome by **better coordination**, **continuing medical education programs for laboratory staff**, **computerization of labs**, and **competency checks**. They specifically mention proper training of nursing staff, phlebotomists, and laboratory technical staff, as well as increased automation including robotic technologies and barcoding.

Plebani [4] emphasized the role of **Quality Indicators (QIs)**, with the IFCC WG-LEPS developing 16 specific QIs for the pre-analytical phase. He notes that while automation helps reduce errors in intra-laboratory processes like specimen preparation, continuous monitoring of QI data alone doesn't guarantee improvement; it requires further efforts in establishing **effective SOPs and achieving consensus**.

CONCLUSION:

In conclusion, this study provides valuable insights into the frequency and types of preanalytical errors encountered in a hematology laboratory setting. Sample misidentification, inadequate sample volume, and other technical errors pose significant challenges to laboratory operations and patient care. By identifying these challenges and implementing targeted interventions, laboratories can enhance the reliability and accuracy of hematology testing. Continued vigilance, education, and quality improvement initiatives are essential for minimizing preanalytical errors and optimizing laboratory performance [7] [8] [9].

Preanalytical errors remain a persistent issue in clinical laboratories, primarily due to factors often beyond direct control. While these errors cannot be entirely eliminated, proactive measures can effectively mitigate their occurrence. Our findings highlight that inadequate sample volume and clotting are prevalent issues, particularly among pediatric patients.

Standardizing laboratory practices throughout all phases of the testing process is crucial. This includes optimizing the use of the vacutainer system with evacuation tubes, implementing barcoding for sample identification, and ensuring regular training for sample collection staff. Adherence to good laboratory practices significantly reduces the incidence of preanalytical errors.

The data from our study underscore that preanalytical errors predominantly stem from specimen collection procedures, notably clotted samples and instances where samples were not received. Quality indicators (QIs) prove invaluable in assessing and improving laboratory performance during the preanalytical phase. Our evaluation of QIs offers insights into the current status and performance of our laboratory, pinpointing areas where targeted education and training initiatives can enhance specimen quality in hematology testing.

Moreover, this analysis serves as a foundation for quality officers and laboratory directors to develop robust improvement strategies. Establishing harmonized standards for specimen quality, implementing regular retraining programs, and fostering enhanced collaboration between laboratory and hospital wards are critical steps toward optimizing the preanalytical phase. Continuous monitoring and management of QI data are essential to sustain high performance levels and ensure the quality and safety of patient care.

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