ORIGINAL ARTICLE

Pre-analytical Laboratory Errors in the Department of Chemical Pathology at a Tertiary Care Hospital

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ABSTRACT

Objective: To determine the frequency and types of pre-analytical laboratory errors in the Department of Chemical Pathology at a tertiary care hospital in Pakistan.

Study Design: Prospective cross-sectional study.

Place and Duration of Study: This study was conducted at the Department of Chemical Pathology & Endocrinology, Fauji Foundation Hospital, Rawalpindi, from December 1, 2023, to March 1, 2024.

Materials and Methods: Following approval of the study protocol by the Institutional Review Board (IRB), data on laboratory requests (n=68,899) was assessed through the Laboratory Information System (LIS) in the Department of Chemical Pathology and Endocrinology. The study assessed all laboratory requests received during the study period to determine the prevalence of errors. Samples received from the Inpatient Department (IPD) and Outpatient Department (OPD) were examined physically and cross-checked for any specimen-related discrepancy against the records in the LIS.

Results: Of the total requests (n=68,899), 34,422 (49.96%) were received in the morning, 23,729 (34.44%) in the evening, and 10,748 (15.60%) at night. The overall incidence of pre-analytical errors was 5.53% (n=3,808). The most frequent errors were hemolyzed samples (52.65%) and lipemic samples (36.97%). Other errors included insufficient specimen quantity (6.80%), labeling errors (2.02%), and inadequate patient information (1.58%). From the total 68,899 requests, 41,340 were received from wards (IPD) and 27,559 from the OPD. The error rate was significantly higher in the IPD (6.75%, n=2,790) compared to the OPD (3.69%, n=1,018) ($p < 0.001$). A statistically significant difference was also observed in error frequencies between morning and evening sample requests ($p \leq 0.05$).

Conclusion: This study highlights the burden of pre-analytical errors in clinical chemistry samples and underscores the need for improved specimen collection and handling practices. Continuous training and strict adherence to protocols are essential to minimize these errors.

Key Words: *Clinical Chemistry, Laboratory Errors, Lipemic Samples, Pre-Analytical Error, Sample Requests.*

Introduction

Patient safety and medical diagnoses are significantly influenced by laboratory results, with studies showing that 60% to 70% of diagnostic decisions are affected by laboratory tests. [1] Clinical chemistry laboratory testing consists of three phases: pre-analytical, analytical, and post-analytical, together referred to as the Total Testing Process (TTP). Within this TTP, many errors occur outside the analytical phase: pre-analytical errors account for approximately 48–60%, while analytical errors comprise less than 10%, and post-analytical errors account for 19–47% of total laboratory errors.[2] The term pre-analytical factors was first introduced by Statland and Winkel in 1977. [3] It covers critical steps such as patient preparation and identification, specimen collection, transportation, centrifugation, and pre-analysis handling (such as dilution) in certain cases. Specimen collection errors include using inappropriate containers, inadequate sample volume, or improper labeling. Delayed or inappropriate transportation and inadequate centrifugation can lead to sample rejection, compromised analyte stability, and erroneous

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results. [4,5] Test requisition errors or incomplete patient information can also lead to misinterpretation of laboratory results.

The analytical phase involves the analysis of specimens followed by the verification and validation of test results. In clinical chemistry, this phase is frequently highly automated, reducing but not eliminating errors. The post-analytical phase includes the interpretation of results by laboratory consultants and the communication of these results to clinicians electronically or in printed format. [6]

Laboratory investigations are vital for clinical diagnosis and treatment decision-making. Since a significant portion of critical clinical decisions are based on laboratory results, errors in the testing process can have serious consequences, including the cost of repeat analysis, delayed diagnosis, and potentially worse patient outcomes. [7]

The importance of accurate and reliable laboratory outcomes for medical diagnosis and patient care is frequently underscored. [8] The laboratory staff must adhere to written policies for sample acceptance and rejection; non-adherence increases preventable pre-analytical errors. [1] The absence of adequate clinical information for routine laboratory tests leads to increased workload (e.g., through follow-up queries and repeated sampling) and healthcare costs. [9,10] The sample collection stage is a critical step in the testing process. This step is primarily manual and thus highly susceptible to human error. Effective quality management interventions are required to lessen errors and guarantee high-quality results. [10] The pre-analytical errors include test requisition mistakes, improper patient identification and preparation, untimely specimen collection, transportation delays, and processing faults that endanger sample integrity and accuracy. The importance of strict adherence to protocols in the pre-analytical phase is repeatedly emphasized. [6,11]

In Pakistan, variability in phlebotomy training and awareness may contribute to inaccuracies in specimen collection. Although general studies on laboratory errors have been conducted, there is limited focused research on pre-analytical errors within the specific environment of Pakistan's tertiary care hospitals, especially regarding error specificity and the impact on diagnostic accuracy and patient outcomes.

The aim of this study was to determine the frequency of pre-analytical errors in the Department of Chemical Pathology at a tertiary care hospital in Pakistan and to find improvement in diagnostic accuracy, patient care, and healthcare outcomes by identifying areas for improvement in laboratory processes.

Materials and Methods

This was a prospective cross-sectional study conducted at the Department of Chemical Pathology & Endocrinology, Fauji Foundation Hospital, Rawalpindi. A total of 68,899 laboratory requests were included. The study duration was three months, from December 1, 2023, to March 1, 2024.

Sample collection for routine and special chemistry tests was performed by phlebotomists in the Pathology lab for outpatients, while nursing staff and house officers collected samples from inpatient departments (IPD). Tests were allocated an ID number from the wards or OPD as per hospital protocol upon receipt in the Chemical Pathology Section. This study was conducted after approval from the Institutional Review Board (IRB) (Ref No. 618/RC/FFH/RWP).

The study assessed all laboratory requests (n=68,899) received during the study period to determine the prevalence of errors. Improper requests with incorrect or missing IDs, insufficient specimen volume, improper collection tubes, and hemolyzed, clotted, or lipemic specimens were categorized as errors. Laboratory requests with samples collected following standard operating procedures (SOPs) without pre-analytical errors were included in the total count to calculate error prevalence. A non-probability consecutive sampling technique was used. Statistical analysis was performed using SPSS Version 25. Chi-square test was applied to compare the proportions of pre-analytical errors between the outpatient and inpatient departments, as the outcome variables were categorical. A p-value of ≤ 0.05 was considered statistically significant.

Results

The overall incidence of pre-analytical errors was 5.53% (n=3,808). Of the total requests (n=68,899), 34,422 (49.96%) were received in the morning, 23,729 (34.44%) in the evening, and 10,748 (15.60%) at night. A statistically significant difference was

observed between morning and evening sample errors ($p < 0.05$), while no statistical difference was found between morning and night requests.

The majority of pre-analytical errors were due to hemolysis, accounting for 2,004 (52.65%) of total errors, followed by lipemic samples at 1,408 (36.97%). Inadequate sample volume comprised 259 (6.80%), labeling errors 77 (2.02%), and inadequate patient information 60 (1.58%) (Figure 1).

Comparison of Departments: Out of 68,899 lab requests, 41,340 were received from wards (IPD) and 27,559 were received from the OPD. Although the absolute number of errors was higher in the IPD (2,790 errors) compared to the OPD (1,018 errors), the error rate was also significantly higher in the IPD.

- **IPD Error Rate:** 6.75% (2,790 / 41,340 total sample requests)
- **OPD Error Rate:** 3.69% (1,018 / 27,559 total sample requests)

Chi-square test for independence was conducted to compare the incidence of pre-analytical errors which showed a significant association between the outpatient and inpatient departments ($p < 0.001$), confirming that the frequency of errors in the inpatient department was significantly higher than in the outpatient department (Figure 2).

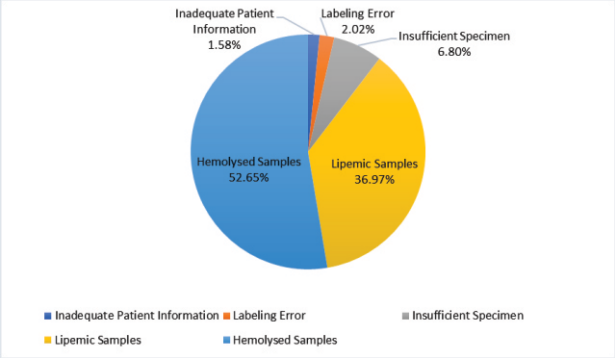

Figure 1: Distribution of Pre-analytical Error Types

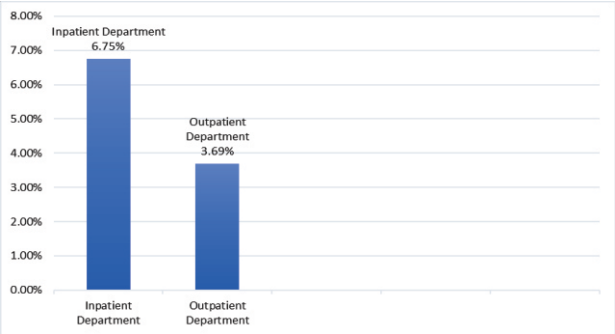

Figure 2: Comparison of Pre-analytical Error Rates

Discussion

Errors in laboratory sampling can significantly compromise result accuracy and adversely affect patient diagnosis and treatment. Systematic recognition and documentation of such errors are essential to improve the quality of laboratory medicine. [12] In the present study, the most frequent pre-analytical error was hemolysis. Comparable results were reported in a study at the Multan Institute of Kidney Diseases, where pre-analytical errors accounted for 0.67%, with hemolysis (41.6%) being the most frequent discrepancy. [13] The lower incidence observed in that study may reflect differences in case mix, workload, error definitions, or specimen handling protocols.

Another study conducted at CMH Kohat by Haroon Z et al. [14] found that pre-analytical errors accounted for 77% of all laboratory errors, primarily due to inadequate sampling methods. Our findings suggest that pre-analytical errors can be minimized by addressing factors such as mislabeling, insufficient volume, and transportation delays. Having skilled laboratory technicians and dedicated phlebotomy staff is essential for effectively minimizing these errors.

Hemolysis was also a major contributor in studies conducted in Doha, Qatar (24%) [15] and Jaipur, Rajasthan [16]. Hemolysis may occur due to traumatic venipuncture, use of small-gauge needles, vigorous tube mixing, or premature centrifugation. [13] Hemolysis interferes with laboratory results by releasing intracellular analytes (e.g., potassium, LDH, AST) and interfering with spectrophotometric measurements due to free hemoglobin. [17]

In a retrospective study conducted at the same hospital approximately eleven years ago, 41% of samples exhibited discrepancies, compared to the current study's rate of 5.53%.[18] This reduction suggests improvements in laboratory protocols over the decade. However, both studies found that the majority of errors originated from inpatient wards. This underscores the continuing need for targeted education for their staff regarding appropriate sampling techniques, proper container selection, and correct timing. Another cross-sectional questionnaire-based study conducted in a tertiary care setting stressed the importance of proper specimen collection, storage, and dispatch to assess

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the knowledge of junior doctors and nurses. The study showed that neither doctors nor nurses had enough knowledge about specimen collection and there was no statistically significant difference between their level of knowledge (p value = 0.435). [19]

The current study revealed a higher incidence rate of pre-analytical errors in samples received from the Inpatient Department (6.75%) compared with the Outpatient Department (3.69%). This higher error rate in the IPD may reflect differences in staffing, workload, patient acuity, and transport complexity in inpatient settings. Alcantara JC et al. [20] observed similar findings, noting that inpatient settings remain particularly vulnerable to pre-analytical errors.

Our study revealed a statistically significant difference in errors between morning and evening shifts. The higher error frequency in evening samples may be related to reduced supervision, increased workload, or staffing patterns; however, this was not formally evaluated in this study. Night shifts showed fewer errors, likely due to a lower volume of samples.

Conclusion

The pre-analytical errors identified in this study are primarily associated with sample collection and processing. This underscores the necessity for continuous and expanded educational initiatives that emphasize specimen quality issues and provide hospital staff with training in sample collection techniques. The data obtained from this research can be utilized to develop new strategies aimed at reducing pre-analytical errors. Reduction of the overall error rate can be achieved through regular training sessions, integrating suitable technologies, and routinely tracking quality indicators (QIs).

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CONFLICT OF INTEREST

Authors declared no conflicts of Interest.

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DATA SHARING STATEMENT

The data that support the findings of this study are available from the corresponding author upon request.

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