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PRE-ANALYTICAL ERRORS IN CLINICAL BIOCHEMISTRY: FREQUENCY, PATTERNS, AND COMPARISON BETWEEN INPATIENT AND OUTPATIENT SAMPLES AT A TERTIARY CARE HOSPITAL, GUJARAT

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ABSTRACT

Background: Pre-analytical errors can compromise the accuracy and reliability of clinical biochemistry results and may lead to repeat sampling, increased workload, and delays in patient management. This study was conducted to evaluate the frequency and distribution of hemolyzed samples, lipemic samples, insufficient sample volume, and samples not received in a tertiary care hospital and to compare their occurrence between inpatient and outpatient settings.

Materials and Methods: A retrospective observational study was conducted in the Department of Biochemistry of a tertiary care hospital. A total of 18,250 clinical biochemistry samples received during the study period were evaluated for pre-analytical errors. Hemolysis, lipemia, insufficient sample volume, and samples not received were documented using predefined criteria. Data were analyzed using descriptive statistics and Chi-square test, with $p<0.05$ considered statistically significant.

Results: Among 18,250 clinical biochemistry samples, 9,969 (54.62%) were received from IPD and 8,281 (45.38%) from OPD. Overall, 747 (4.09%) samples had pre-analytical errors. Hemolyzed samples were the most common error, accounting for 337 (45.11%), followed by lipemic samples 163 (21.82%), insufficient sample volume 163 (21.82%), and samples not received 84 (11.24%). The frequency of any pre-analytical error was significantly higher in IPD (502/9,969; 5.04%) than OPD (245/8,281; 2.96%; $\chi^2=49.71$, $p<0.001$). Hemolysis (2.27% vs. 1.34%), lipemia (1.09% vs. 0.65%), insufficient sample volume (1.09% vs. 0.65%), and samples not received (0.58% vs. 0.31%) were also significantly higher in IPD than OPD ($p<0.05$ for all).

Conclusion: Pre-analytical errors affected a measurable proportion of clinical biochemistry samples, with hemolysis being the predominant error. Standardized specimen collection, handling, transportation, staff training, and regular quality monitoring are important for reducing preventable pre-analytical errors.

Keywords: Clinical biochemistry, Hemolysis, Insufficient sample, Lipemia, Pre-analytical errors, Specimen quality.

INTRODUCTION

Clinical laboratory investigations are integral to diagnosis, treatment decisions, and monitoring of patients, making the reliability of laboratory results an essential component of patient safety. The total testing process comprises pre-analytical, analytical, and post-analytical phases, with a substantial proportion of laboratory errors occurring before analysis. Recent evidence emphasizes that inappropriate patient preparation, specimen collection, handling, transportation, and sample quality are major contributors to pre-analytical errors.[1–3]

In clinical biochemistry, hemolysis, lipemia, and inadequate sample volume are important causes of specimen rejection and may compromise the accuracy and interpretation of biochemical results. Hemolysis can produce clinically significant interference in several analytes, while lipemia may cause analytical interference through sample turbidity and other mechanisms.[4–6] Studies evaluating hemolysis, icterus, and lipemia have demonstrated that these interferences can vary according to the analyte and analytical method.[7] Insufficient sample volume may result in inability to perform requested investigations, leading to repeat sampling and increased laboratory workload.[2,3] Indian studies have demonstrated considerable variation in the frequency and pattern of pre-analytical errors across healthcare settings. Recent tertiary-care studies have identified hemolysis and insufficient sample volume among the prominent causes of sample rejection, with errors occurring more frequently among inpatient samples in some settings.[8–10] Earlier Indian evidence has similarly reported hemolysis, insufficient samples, and lipemia among commonly observed pre-analytical problems.[11] Studies from other healthcare settings have also reported non-received samples and hemolysis as important contributors to pre-analytical errors.[12]

However, the magnitude and distribution of these errors are influenced by local patient populations, sample collection practices, and laboratory workflows. Therefore, systematic assessment of pre-analytical errors is important for identifying local problem areas and strengthening laboratory quality indicators. The present study was undertaken to evaluate the frequency and distribution of hemolyzed samples, lipemic samples, insufficient sample volume, and samples not received in a tertiary-care hospital, and to compare their occurrence between inpatient and outpatient settings.

MATERIALS AND METHODS

A retrospective observational study was conducted in the Department of Biochemistry at a tertiary care hospital. All blood samples received in the Clinical Biochemistry/Clinical Chemistry Laboratory during the study period were evaluated. The study included 18,250 blood samples received from inpatient (IPD) and outpatient (OPD) departments for routine biochemical investigations, covering all age groups. Samples received according to the standard sample collection protocol were included in the study. Samples with incomplete patient details or missing requisition information, as well as those that had already been processed or partially analyzed before detection of the error, were excluded. On receipt in the laboratory, samples were visually inspected before analysis for pre-analytical errors. Hemolysis was identified by pink or red discoloration of the serum/plasma, while lipemia was identified by a visibly milky appearance. Insufficient sample volume was defined as a sample containing less than 50% of the required vacutainer volume. Samples not received by the laboratory were also documented. A structured data collection sheet was used to record age, sex, MRD/laboratory identification number, source of sample (IPD/OPD), department, date and time of collection, sample type, tube type, adequacy of sample volume, hemolysis, lipemia, and relevant remarks. Data were entered into Microsoft Excel and subsequently analyzed using Epi Info/SPSS. Frequencies and percentages were calculated. The Chi-square test was used to compare the distribution of pre-analytical errors between IPD and OPD samples. A p-value <0.05 was considered statistically significant. Ethical approval was obtained from the Institutional Ethics Committee before commencement of the study. Patient confidentiality was maintained throughout data collection, analysis, and reporting, and no personally identifiable information was disclosed.

RESULTS

[Figure 1] shows that the majority of clinical biochemistry samples were received from inpatient departments (IPD), accounting for 54.62% of the total 18,250 samples, while 45.38% were received from outpatient departments (OPD). Thus, IPD samples constituted a slightly higher proportion of the overall samples processed during the study period. Figure 2 depicts the distribution of observed pre-analytical errors among the 747 affected clinical biochemistry samples. Hemolyzed samples were the most frequent error, accounting for 45.11%, followed by lipemic samples and insufficient sample volume, each contributing 21.82%. Samples not received accounted for the remaining 11.24% of the observed errors.



Figure 1: Distribution of Clinical Biochemistry Samples According to Source

Table 1: Distribution of Pre-Analytical Errors According to Sample Source

Type of Error	IPD n (%)	OPD n (%)	Total n (%)
Hemolyzed sample	226 (45.0%)	111 (45.3%)	337 (45.1%)
Lipemic sample	109 (21.7%)	54 (22.0%)	163 (21.8%)
Insufficient sample volume	109 (21.7%)	54 (22.0%)	163 (21.8%)
Sample not received	58 (11.6%)	26 (10.6%)	84 (11.2%)
Total	502 (100%)	245 (100%)	747 (100%)

[Table 1] shows that hemolyzed samples were the most common pre-analytical error in both IPD and OPD samples, accounting for 226 (45.0%) and 111 (45.3%), respectively. Lipemic samples accounted for 109 (21.7%) of errors in IPD and 54 (22.0%) in OPD, while insufficient sample volume showed a similar distribution, with 109 (21.7%) in IPD and 54 (22.0%) in OPD. Samples not received constituted 58 (11.6%) of IPD and 26 (10.6%) of OPD errors. Overall, hemolysis was the predominant pre-analytical error, accounting for 337 (45.1%) of the 747 observed errors, followed by lipemic samples and insufficient sample volume, each contributing 163 (21.8%). [Table 1]

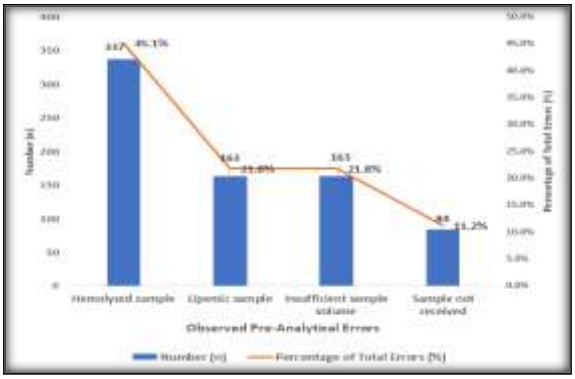


Figure 2: Distribution of Observed Pre-Analytical Errors Among Clinical Biochemistry Samples

Table 2: Frequency of Pre-Analytical Errors According to Patient Setting

Patient Setting	Total Samples	Samples with Pre-Analytical Error	Error Frequency (%)
IPD	9,969	502	5.04
OPD	8,281	245	2.96
Total	18,250	747	4.09

[Table 2] demonstrates that pre-analytical errors were more frequently observed among IPD samples than OPD samples. Among 9,969 IPD samples, 502 (5.04%) had pre-analytical errors, whereas 245 (2.96%) of 8,281 OPD samples showed errors. Overall, 747 (4.09%) pre-analytical errors were identified among 18,250 clinical biochemistry samples. Thus, the frequency of observed pre-analytical errors in IPD samples was approximately higher than that observed in OPD samples. [Table 2]

Table 3: Comparison of Selected Pre-Analytical Errors Between IPD and OPD

Error	IPD n/N (%)	OPD n/N (%)	χ^2	p
Hemolysis	226/9,969 (2.27%)	111/8,281 (1.34%)	21.43	<0.001
Lipemia	109/9,969 (1.09%)	54/8,281 (0.65%)	9.95	0.0016
Insufficient volume	109/9,969 (1.09%)	54/8,281 (0.65%)	9.95	0.0016
Sample not received	58/9,969 (0.58%)	26/8,281 (0.31%)	7.08	0.0078
Any pre-analytical error	502/9,969 (5.04%)	245/8,281 (2.96%)	49.71	<0.001

*Percentages are calculated using the total number of samples received in the respective setting as the denominator (IPD = 9,969; OPD = 8,281).

The [Table 3] demonstrates a higher frequency of all evaluated pre-analytical errors among IPD samples compared with OPD samples. Hemolysis was observed in 226 of 9,969 IPD samples (2.27%) compared with 111 of 8,281 OPD samples (1.34%), and this difference was statistically significant (χ^2 = 21.43, $p < 0.001$). Lipemia was detected in 109 IPD samples (1.09%) and 54 OPD samples (0.65%), showing a statistically significant difference (χ^2 = 9.95, p = 0.0016). Similarly, insufficient sample volume was reported in 109 IPD samples (1.09%) and 54 OPD samples (0.65%), with the difference being statistically significant (χ^2 = 9.95, p = 0.0016).

Sample-not-received was documented in 58 IPD samples (0.58%) compared with 26 OPD samples (0.31%), which was also statistically significant (χ^2 = 7.08, p = 0.0078). Overall, at least one pre-analytical error was identified in 502 IPD samples (5.04%) and 245 OPD samples (2.96%), with a highly significant difference between the two groups (χ^2 = 49.71, p < 0.001). Thus, the findings indicate that pre-analytical errors were significantly more frequent among IPD samples than OPD samples, with hemolysis being the most frequent individual error. [Table 3]

DISCUSSION

The present study evaluated pre-analytical errors in 18,250 clinical biochemistry samples received during the study period and identified 747 affected samples, giving an overall pre-analytical error frequency of 4.09%. The findings demonstrate that errors occurring before analysis remain an important component of laboratory quality control, particularly those related to specimen collection, handling, and receipt.

Our study shows that IPD samples constituted 54.62% of all samples, whereas OPD samples accounted for 45.38%. The slightly higher contribution of IPD samples may reflect the greater frequency of laboratory investigations performed among hospitalized patients and the repeated monitoring required during inpatient care. A higher contribution of inpatient samples to pre-analytical errors has also been reported in other clinical laboratory studies. Alcantara et al. observed that 72.6% of pre-analytical errors originated from IPD samples compared with 16.0% from OPD samples, although their study also included emergency department samples and a broader range of error categories.[12] Similarly, Balasundararaj et al. reported that rejected samples were predominantly from IPD, with haemolysis being the leading cause of rejection.[8]

Our study demonstrates that hemolysis was the predominant pre-analytical error, accounting for 45.11% of all observed errors. Lipemic samples and insufficient sample volume each accounted for 21.82%, while samples not received constituted 11.24%. When expressed in relation to all 18,250 samples, these correspond to approximately 1.85% hemolyzed, 0.89% lipemic, 0.89% insufficient-volume, and 0.46% samples not received. The predominance of hemolysis is consistent with several studies from India and other settings. Balasundararaj et al. reported haemolysis in 53.6% of rejected samples, while Hamid et al. identified hemolysis as the major category of pre-analytical error in their clinical biochemistry laboratory.[8,13] Kotasthane et al. reported hemolyzed samples in 9.05% of their total pre-analytical errors and observed that they were more common among IPD samples.[14] Differences in reported proportions may be related to differences in sample rejection criteria, laboratory workflow, study duration, and the range of pre-analytical errors included.

The high proportion of hemolyzed samples in the present study may reflect difficulties during venipuncture, inappropriate collection techniques, prolonged tourniquet application, vigorous mixing, or improper handling and transportation of specimens. Hemolysis can release intracellular constituents and may interfere with several biochemical measurements, potentially affecting the reliability of laboratory results. Ho et al. demonstrated that hemolysis, icterus, and lipemia can produce assay-specific interference and therefore require appropriate laboratory detection and management.[4]

The finding that lipemia accounted for 21.82% of observed errors is also important. Lipemic specimens may interfere with biochemical assays through physical and analytical mechanisms. ArulVijayaVani et al. evaluated the effect of lipemia on routine biochemical investigations and demonstrated that the magnitude of interference varies according to the analyte and degree of lipemia.[5] Soh et al. similarly highlighted the need for appropriate approaches to identify and manage lipemic interference in clinical chemistry testing.[6] Kotasthane et al. reported lipemic samples in 5.28% of their total errors, with a greater occurrence in IPD samples.[14] The higher proportion observed in the present study may reflect differences in patient characteristics and the operational criteria used for identifying visibly lipemic specimens.

Distribution of error types was broadly similar between IPD and OPD samples. Hemolysis accounted for 45.0% of IPD errors and 45.3% of OPD errors. Lipemia represented 21.7% and 22.0%, respectively, while insufficient sample volume showed the same proportion in both settings. Samples not received constituted 11.6% of IPD errors and 10.6% of OPD errors. Thus, although the overall number of errors was greater in IPD, the relative pattern of major error categories was similar in the two settings. This indicates that specimen-quality problems are not restricted to a particular patient setting and may occur at multiple points in the pre-analytical process.

Our study demonstrates a higher frequency of pre-analytical errors among IPD samples. Errors were identified in 5.04% of IPD samples compared with 2.96% of OPD samples, while the overall frequency was 4.09%. A similar pattern has been reported by Alcantara et al., who documented pre-analytical error rates of 13.4% in IPD and 7.0% in OPD samples.[12] Balasundararaj et al. also reported that rejected samples were more frequent among IPD samples.[8] Hamid et al. reported overall error frequencies of 0.93% and 0.76% during two study periods and demonstrated a reduction following reinforcement training of laboratory personnel.[13] The variation between these studies and the present study emphasizes that pre-analytical error rates

depend on institutional procedures, definitions of error, sample rejection practices, workload, and staff training. The relatively higher error frequency among IPD samples may be associated with the complexity of inpatient care, frequent blood sampling, greater workload, and collection of specimens by different categories of healthcare personnel. Alcantara et al. similarly discussed workload, staff experience, specimen collection, and transportation as factors associated with pre-analytical errors.[12] Therefore, continuous monitoring and periodic competency-based training in phlebotomy and specimen handling may be useful quality-improvement measures.

Our study further demonstrates a significantly higher frequency of each assessed pre-analytical error among IPD samples compared with OPD samples. Hemolysis was observed in 226/9,969 (2.27%) IPD samples compared with 111/8,281 (1.34%) OPD samples, showing a statistically significant difference (χ^2=21.43, p<0.001). Similarly, lipemia was identified in 109/9,969 (1.09%) IPD samples and 54/8,281 (0.65%) OPD samples (χ^2=9.95, p=0.0016). Insufficient sample volume also occurred significantly more frequently in IPD (1.09%) than OPD (0.65%) samples (χ^2=9.95, p=0.0016). Samples not received were reported in 0.58% of IPD and 0.31% of OPD samples, with the difference being statistically significant (χ^2=7.08, p=0.0078). Overall, any pre-analytical error was significantly more frequent in IPD (502/9,969; 5.04%) than OPD (245/8,281; 2.96%) samples (χ^2=49.71, p<0.001). A similar study conducted by Kotasthane et al. reported a significantly higher overall pre-analytical error frequency in IPD samples (3.68%) compared with OPD samples (0.87%). Hemolyzed and lipemic samples were also more frequently observed among IPD specimens in their study.[14]

Alcantara et al. similarly reported higher overall pre-analytical error rates in IPD (13.4%) than OPD (7.0%) samples in a clinical chemistry laboratory.[12] The significantly higher frequency of hemolysis, lipemia, insufficient sample volume, and non-received samples in IPD in the present study suggests that inpatient specimen collection and handling may require greater attention. This may be related to repeated blood sampling, difficult venous access, collection by different healthcare personnel, and greater clinical complexity among hospitalized patients.

Overall, the significant differences across all assessed error categories emphasize the need for standardized phlebotomy practices, adequate sample collection, proper specimen handling, and regular training of personnel involved in inpatient sample collection.

CONCLUSION

Pre-analytical errors remain an important quality concern in clinical biochemistry laboratories. In the present study, 747 (4.09%) errors were identified among 18,250 samples, with hemolysis being the most common error (45.11%). Pre-analytical errors were significantly more frequent in IPD (5.04%) than in OPD samples (2.96%). All assessed error categories, including hemolysis, lipemia, insufficient sample volume, and samples not received, were significantly higher among IPD samples.

These findings highlight the need for standardized specimen collection, proper handling, and regular training of healthcare personnel, particularly in inpatient settings, to reduce pre-analytical errors and improve the quality and reliability of laboratory results.

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