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BURDEN AND PATTERN OF PRE-ANALYTICAL ERRORS IN CLINICAL BIOCHEMISTRY AT A TERTIARY CARE LABORATORY IN NORTHEAST INDIA

Biochemistry

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ABSTRACT

Background: The pre-analytical phase is the most error-prone component of laboratory testing and significantly influences the reliability of biochemical results. Identifying the burden and pattern of such errors is essential for improving laboratory quality and patient safety, particularly in resource-limited tertiary care settings. Objective of our study was to determine the frequency, types, and sources of pre-analytical errors in clinical biochemistry samples received at a tertiary care laboratory in Northeast India. **Materials And Methods:** A hospital-based observational cross-sectional study was carried out in the Department of Biochemistry at Agartala Government Medical College and Govind Ballabh Pant Hospital, Agartala, Tripura, from June 2025 to January 2026. All blood samples received from outpatient and inpatient departments during the study period were evaluated. Each sample and its accompanying request form were screened for pre-analytical errors, and the frequency and types of errors recorded in the Laboratory Information System were analyzed. **Results:** 6.81% samples exhibited pre-analytical errors, with haemolysis constituting the most frequent error, followed by insufficient sample volume and incomplete clinical information on request forms. Errors were more common in indoor patient samples, particularly from high-dependency and paediatric units. Several errors were attributable to collection technique, transport delays, and inadequate documentation. **Conclusion:** Pre-analytical errors continue to represent a significant burden in clinical biochemistry laboratories. Regular staff training, standardized collection protocols, improved documentation, and efficient sample transport systems are essential to minimize these errors and enhance diagnostic accuracy.

KEYWORDS

Preanalytical error, haemolysis, glycolysis, interference, automation.

INTRODUCTION:

Laboratory Medicine plays a crucial role in contemporary diagnosis and patient management; therefore, it is essential that laboratory results are accurate and reliable, as patient care directly depends on them. Clinical laboratory testing is broadly divided into three phases: pre-analytical, analytical, and post-analytical. The pre-analytical phase encompasses all procedures from the time a test is requested by the clinician until the specimen is properly collected, handled, and prepared for analysis.[1] It includes the processes of test ordering by the physician, completion of request forms, sample collection, transportation of the specimen to the laboratory, and final preparation of the sample for analysis. The analytical phase involves the actual testing of the specimen and generation of results, whereas the post-analytical phase pertains to the reporting and communication of laboratory results to the physician for appropriate patient management.[1]

Errors occurring at any phase of the testing process can significantly affect accurate diagnosis and adversely impact patient health. With increasing automation in laboratory analysis, errors particularly those arising during the analytical phase, have markedly decreased. However, nearly 70% of total errors across the entire diagnostic process continue to occur during the pre-analytical phase.[1] Various studies have documented this high burden of pre-analytical errors, with different researchers reporting that they account for approximately 77.1%, 81%, and a wide range of 31.6% to 75% of total errors in the diagnostic testing process.[2,3,4]

Errors may arise at any step of the pre-analytical phase and therefore require careful evaluation at this stage. However, some of these errors are occasionally identified during the analytical or post-analytical phases, such as in cases of samples contaminated by infusion fluids or glycolysed specimens. Although analytical errors have substantially declined, the large proportion of pre-analytical errors continues to significantly influence the overall error rate and, consequently, the accuracy of laboratory test results. This study was aimed to identify and quantify the various errors occurring during the pre-analytical phase and to determine their frequency, with the objective of implementing corrective measures to minimize these errors and ensure the reliability of laboratory results.

MATERIALS AND METHODS:

A hospital based observational cross-sectional study was conducted in the Department of Biochemistry, Agartala Government Medical College & Govind Ballabh Pant Hospital, Agartala, Tripura from June, 2025 to January, 2026. The study population comprised all blood samples received from the Outpatient Departments (OPD) and Inpatient Departments (IPD) of AGMC & GBP Hospital by the Biochemistry Service Laboratory during the study period. All blood samples and their accompanying laboratory request forms were screened for pre-analytical errors, and the daily occurrences and types of these errors recorded in the Laboratory Information System (LIS) were analyzed. The minimum sample size was calculated using the standard formula for prevalence studies. Based on a 95% confidence level (Z = 1.96), an expected prevalence of pre-analytical errors of 5.2% from a previous study,[5] and an allowable error of 5% of the prevalence, the required sample size was estimated. After adding 10% to account for attrition and incomplete data, the final minimum sample size was determined to be 31,000 blood samples. The study was conducted after obtaining approval from Institutional Ethics Committee (IEC) of Agartala Govt. Medical College.

Laboratory request forms for both IPD and OPD samples were screened for the following details:

1. Patient information – name, age, sex, hospital UHID number;
2. Clinical information; and
3. Sample information – nature of the sample and the date & time of collection.

All OPD and IPD samples were screened for the following pre-analytical variables:

- Wrong or absent identification number on sample containers and missing samples;
- Haemolysed samples;
- Insufficient sample volume; and
- Samples collected in inappropriate containers.

RESULTS:

A total of 31,000 samples were received during the study period, of which 11,680 were OPD samples and 19,320 were indoor samples. Among the 11,680 OPD laboratory request forms screened, 11,104 were incomplete, with only 576 forms containing all the required information. Similarly, of the 19,320 IPD laboratory request forms screened, 18,812 were incomplete, and only 508 forms were found to

be complete. Table 1 summarizes the different parameters that were missing from the laboratory request forms along with their respective percentages.

Table 1: Frequency Of Missing Information In Laboratory Request Forms

Absence of necessary information in laboratory request forms	No. of IPD laboratory request forms (19320)	Percentage
Patient Information		
Name of the patient	0	0
Age	876	4.53%
Sex	1116	5.77%
Hospital UHID No.	2145	11.1%
Clinical information	16412	84.94%
Sample Information		
Nature of sample	12634	65.39%
Date & Time of sample collection	17062	88.31%
Absence of necessary information on laboratory request forms	**No. of OPD laboratory request forms (11680)**	**Percentage**
Patient Information		
Name of the patient	0	0
Age	348	2.97%
Sex	471	4.03%
Hospital UHID No.	104	0.89%
Clinical information	9108	77.97%
Sample Information		
Nature of sample	5367	45.95%
Date & Time of sample collection	7164	61.33%

Pre-analytical errors were identified in 1719 indoor samples (8.89%) and 392 OPD samples (3.35%). The overall error percentage is presented in Table 2, while the distribution and percentage of various types of pre-analytical errors are detailed in Table 3.

Table 2: Total Pre-analytical Errors & Their Percentage

Data collection period (June, 2025 to January, 2026)	No. of samples	No. of tests	Number of pre-analytical errors	Percentage of pre-analytical errors
IPD	19320	384500	1719	8.89%
OPD	11680	175380	392	3.35%
Total	31000	559880	2111	6.81%

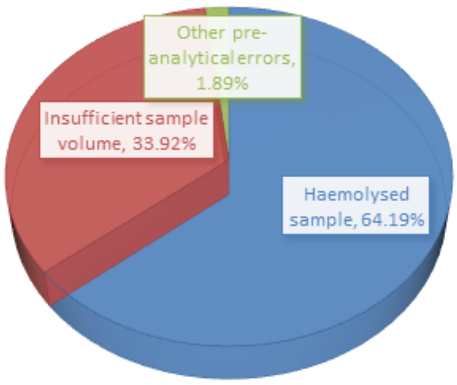
Table 3: Distribution Of Types Of Pre-analytical Errors Across Different Stages Of Sample Collection And Transport

Total samples	IPD (19320)		OPD (11680)	
Pre-analytical Error	**Number**	**%**	**Number**	**%**
Sample collected in inappropriate container	8	0.04%	0	0%
Delay in sample transport	4	0.02%	2	0.01%
Wrong numbering of sample	6	0.03%	2	0.01%
Sample not received	11	0.05%	0	0%
Haemolysed sample	1104	5.71%	251	2.15%
Insufficient volume of sample	579	2.99%	137	1.17%
Contamination from infusion route	7	0.03%	0	0%
Total Errors	1719	8.89%	392	3.35%

Haemolysed samples constituted the most frequently observed pre-analytical error in both OPD and IPD samples. Haemolysis was detected in 5.71% of IPD samples and 2.15% of OPD samples. Inadequate sample volume was the second most common error, observed in 2.99% of IPD samples and 1.17% of OPD samples.

A total of 2,111 pre-analytical errors were identified during the study period. Haemolysed samples constituted the most common error, with 1,355 such samples received over the eight months study period, accounting for 64.19% of all errors. The second most frequently encountered error was insufficient sample volume, which comprised 33.92% of the total errors. Other errors collectively contributed 1.89%, including samples collected in inappropriate containers (0.37%), delays in sample transport (0.28%), incorrect sample numbering (0.37%), samples not received (0.52%), and contamination from the infusion route (0.33%).

FIG 1: DISTRIBUTUION OF PRE-ANALYTICAL ERRORS



DISCUSSION:

Over the past four decades, laboratory errors have declined markedly, largely due to technological advancements such as automation, which have substantially reduced analytical inaccuracies. Currently, most laboratory errors occur during the pre-analytical phase. The impact of these errors on patient care is considerable, as clinical laboratory data influence nearly 60–70% of medical decisions. Therefore, laboratory personnel must ensure accurate and timely reporting of test results.

In this study, evaluation of laboratory request forms accompanying indoor samples revealed that 97.37% lacked complete patient and sample information, while only 2.63% contained all the required details. This deficiency may be attributed to the heavy patient workload and inadequate awareness among medical staffs regarding the importance of complete documentation for accurate sample processing and timely report dispatch.

The patient's name was documented on all request forms; however, age was missing in 3.95%, sex in 5.12%, hospital UHID number in 7.25%, and clinical information in 82.32% of the forms. Recording a patient's age and sex on laboratory request forms is essential for accurate interpretation of test results, as reference ranges vary across different age groups and between sexes. Furthermore, patient-specific details such as age, gender, physiological states (e.g., pregnancy or menopause), current medications, and suspected diagnosis are crucial for proper evaluation of results and for preventing unnecessary repeat testing when discrepant findings cannot be interpreted due to insufficient clinical information.

Clinical details were absent in 82.32% of the requisition forms. Inclusion of a brief clinical note with the sample facilitates accurate interpretation and reporting of results. A comparable study by Nutt et al.[6] found that diagnostic information was missing in 19.1% of request forms, and even when a diagnosis was provided (80.9%), over one-third (37.3%) were recorded in abbreviated form, potentially limiting their clinical usefulness. The absence of clear clinical details is particularly important because many biochemical parameters show physiological variation that can influence interpretation. Several hormones are secreted in a pulsatile pattern and exhibit circadian rhythms, complicating assessment of their serum concentrations. For instance, serum TSH demonstrates marked diurnal variation, peaking between 0200 and 0400 hours and reaching a nadir between 1800 and 2200 hours, with fluctuations approaching 50%. Similarly, plasma insulin levels are higher in the morning, and therefore a glucose tolerance test performed later in the day may yield comparatively higher glucose values. These observations highlight the need for adequate clinical information and appropriate timing of sample collection to ensure accurate interpretation of laboratory results.

The proportion of glycolysed samples was 0.24%. Glycolysis was suspected when the measured glucose value fell below the reportable range (<20 mg/dL). Inquiry revealed that, in many instances, there was a delay of 4-6 hours between sample collection and receipt in the laboratory, and occasionally samples arrived only on the following day. These delays were likely attributable to patients' inability to pay for the test immediately or the absence of an attendant to transport the specimen to the collection centre. According to guidelines issued by

the National Committee for Clinical Laboratory Standards (NCCLS) H5-A3 (1994), blood samples should ideally be transported within a maximum of two hours at a temperature between 10 °C and 22 °C.[1]

In samples where a significant delay occurs between collection and serum separation, several parameters, including potassium (K), can be affected. During glycolysis, an intracellular shift of K takes place, leading to falsely low potassium levels. However, this effect is biphasic—once the glucose supply is depleted, K begins to leak out of the cells, resulting in an increased potassium concentration.[7]

Most pre-analytical errors arise during the sampling stage, with as many as 60% of these errors directly attributable to issues related to the sample itself.[8] A retrospective analysis (2001–2005) of data from the Spanish Society of Clinical Chemistry (SECQ) Quality Assessment Program for the pre-analytical phase identified "sample not received" as the most frequent error, followed by haemolysed samples.[9]

In the present study, screening of both OPD and IPD samples revealed an overall error rate of 6.81%, with IPD samples showing higher rate (8.89%) compared to OPD samples (3.35%). Haemolysis was the most frequently observed error in both the groups. Overall, 4.37% of samples were found to be haemolysed and were consequently rejected. The incidence of haemolysis was greater in IPD samples (5.71%) than in OPD samples (2.15%).

In a study by Jay W, more than 95% of haemolysed samples were attributed to in-vitro causes, primarily resulting from improper sampling techniques or faulty transport conditions.[10] In the OPD, standardized blood collection procedures are generally followed by trained technicians; however, the involvement of technician trainees in sample collection may have contributed to the increased rate of haemolysis observed among OPD patients. In contrast, in indoor wards, lapses in proper collection and transport procedures likely contributed to the higher proportion of haemolysed samples. A comparable study conducted at Karwar Institute of Medical Sciences and Hospital reported pre-analytical errors in 1.9% of indoor samples, with haemolysis accounting for 1.1% of these errors. The error rate was slightly lower in OPD samples (1.2%), with haemolysis observed in only 0.2% of cases.[11] External quality assessment programs for the pre-analytical phase conducted by the College of American Pathologists (CAP) have also identified haemolysed samples as the most frequently encountered error (Jones et al., 1997).[12]

The second most frequent pre-analytical error observed in the present study was insufficient sample volume, accounting for 0.91% of cases. This error was predominantly seen in IPD samples (2.99%). Most of these originated from the NICU (Neonatal intensive care unit) and paediatric wards, likely reflecting the inherent challenges associated with blood collection in paediatric patients. Similar findings have been reported by Lippi G et al, who noted that insufficient specimen quantity and quality together accounted for more than 60% of pre-analytical errors.[8]

Eight (08) samples submitted for routine biochemistry testing were received in EDTA vials, which are unsuitable for such analyses, as serum or heparinised plasma is the recommended specimen for autoanalyzer processing. In addition, seven (07) indoor samples were suspected to be contaminated from the infusion route, as they appeared to have been collected through intravenous lines. This suspicion arose during report evaluation. In all instances, repeat samples were obtained and reanalyzed, and the subsequent results confirmed the initial concerns.

Sample interferences were detected across multiple stages of the testing process: during the pre-analytical phase through visual identification of haemolysis, lipemia, hyperviscosity, and icterus; during the analytical phase through instrument-based quantification of haemolysis, turbidity, and bilirubin; and in the post-analytical phase through the recognition of aberrant or unexpected test results.

Most activities within the pre-analytical phase of clinical laboratory testing are performed manually, making this stage particularly vulnerable to human error. A heavy workload, coupled with insufficient training and limited awareness of proper procedures, often contributes to a higher frequency of errors during this phase. A clear understanding of the sequence of events involved in the pre-analytical process is therefore essential, as it facilitates identification of error sources, aids in root-cause analysis, and supports the implementation of appropriate corrective and preventive measures.

For IPD patients:
Step 1: The physician orders the required investigations.
Step 2: The laboratory request form is completed.
Corrective measure: Greater awareness should be promoted among doctors and nursing staffs regarding the importance of documenting complete patient details, clinical information, and relevant sample particulars on the request form, as this information is essential for accurate laboratory interpretation and reporting.

Step 3: Sample Collection
Corrective Measures:
(a) Samples should be collected only by trained phlebotomists.
(b) Regular continuing education programs should be conducted for phlebotomists, medical staffs, and students on proper blood collection techniques, appropriate sample volume, and correct mixing with anticoagulants.

Step 4: Sample Handover for Payment and Transport
Currently, samples are handed over to the patient's attendant for payment and transport to the collection centre.

Corrective Measures:
(a) Payment for investigations should ideally be completed prior to sample collection to avoid delays.
(b) Specimens should be transported by designated laboratory personnel to maintain sample integrity and accountability.

Step 5: Sample Receipt and Numbering at Collection Centre
Corrective Measure:
Establishing floor-wise collection centres may help distribute workload efficiently and reduce congestion at a single point.

Step 6: Transport of Sample from Collection Centre to Laboratory
Samples should be transferred promptly to the laboratory under appropriate handling conditions to prevent deterioration.

For OPD Patients:
Step 1: Test Requisition by Physician
The treating physician orders the required laboratory investigations.

Corrective Measure:
Physicians should ensure that adequate clinical details, provisional diagnosis, and relevant patient information accompany the test request to aid proper interpretation of results.

Step 2: Payment For Investigations
The patient completes the payment process prior to further laboratory procedures.

Corrective Measure:
A streamlined billing system should be maintained to minimize waiting time and prevent delays in sample collection.

Step 3: Generation of Computerized Laboratory Request Form
The laboratory request form is generated electronically following payment.

Corrective Measure:
Where feasible, physicians should directly enter or verify clinical information in the requisition system to ensure completeness and accuracy of patient and test details.

Step 4: Sample Collection
The specimen is collected at the designated phlebotomy area.
Corrective Measures:
(a) Samples should be collected by trained personnel following standard phlebotomy protocols.
(b) Proper identification of the patient and correct labelling of specimens must be ensured at the time of collection.

Step 5: Transport of Sample to Laboratory
Collected samples are transported to the laboratory for processing.
Corrective Measures:
(a) Samples should be transported promptly using designated carriers.
(b) Appropriate handling conditions, including temperature control

where required, must be maintained to preserve specimen integrity.

CONCLUSION:

Laboratory medicine is integral to modern clinical decision-making, and the reliability of patient management often depends on the accuracy of laboratory reports. This study highlights that the majority of testing errors occur in the pre-analytical phase, where manual processes, heavy workload, and inadequate awareness contribute significantly to sample quality issues. Haemolysis emerged as a major cause of sample rejection, indicating that targeted interventions in phlebotomy practices, sample handling, and transport logistics can substantially enhance laboratory efficiency. Continuous monitoring of pre-analytical indicators, staff training, and adherence to standardized protocols are essential to minimize preventable errors. Equally important is effective coordination between laboratory personnel and clinical departments to ensure complete patient information and proper sample collection practices. Strengthening these areas will not only reduce error rates but also improve diagnostic accuracy, turnaround time, and overall patient care outcomes.

REFERENCES:

1) LLopis MA, Alvarez V, Martínez-Brú C, Gómez R, Barba N, Ibarz M, et al. Quality assurance in the preanalytical phase. Applications and experiences of quality control. 2011 Apr 26:704.
2) Binita G, Bhawna S, Ranjna C, Venkatesan M. Evaluation of errors in a clinical laboratory, a one-year experience. Clin Chem Lab Med 2010; 48:63-6.
3) Szecsi PB, Odum L. Error tracking in a clinical biochemistry laboratory. Clin Chem Lab Med 2009; 47:1253-7.
4) Bononi P, Plebani M, Ceriotti F, Rubboli F. Errors in Laboratory Medicine. Clinical Chemistry 2002; 48:691-692.
5) Begum F. A study of pre-analytical errors in a hospital based clinical biochemistry laboratory and formulation of measures for correction. Age. 2014; 758:6-18.
6) Nutt L, Annalise EZ, Rajiv TE. Incomplete lab request forms: the extent and impact on critical results at a tertiary hospital in South Africa. Ann Clin Biochem.2008; 45:463-466.
7) Young DS, Bermes EW. (2001). Specimen collection and other preanalytical variables. In: Burtis CA, Ashwood ER. (ed). Tietz Fundamentals of Clinical Chemistry. Elsevier, India:41-56.
8) Lippi G, Bassi A, Brocco G, Montagnana M, Salvagno GL, Guidi GC. Preanalytical Error tracking in a laboratory Medicine Department: results of a 1year experience. Clin Chem. 2006; 52:1442-3.
9) Alsina M, Alvarez V, Barba N, Bullich S, Cortés M, Escoda I, et al. Preanalytical quality control program–an overview of results (2001–2005 summary). Clinical Chemistry & Laboratory Medicine. 2008 Jun 1;46(6).
10) Jay W, Provasek D. Characterization and Mathematical Correction of hemolysis interference in selected Hitachi 717 assays. Clin Chem. 1993; 39:1804-1810.
11) Chawla R, Goswami B. Identification of the types of Preanalytical Errors in the clinical Chemistry Laboratory: 1 Year study at GB Pant Hospital. Lab Medicine 2010; 41:89-92.
12) Jones BA, Calam RR, Howanitz PJ. Chemistry specimen acceptability. A College of American Pathologists Q-Probes Study of 453 Laboratories. Arch Pathol Lab Med.1997; 121:19-26.