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Original Research Article

Prevalence and Pattern of Pre-Analytical Errors in a Clinical Biochemistry Laboratory: A Cross-Sectional Study

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Abstract:

Background: Errors in the total testing process are being increasingly recognized as an important cause of preventable patient harm, and pre-analytical phase has the highest percentage of these events. Contemporary data on the prevalence and spectrum of pre-analytical error in routine biochemistry laboratories, especially in low- and middle-income settings, are still sparse.

Methods: This observational single centre cross-sectional study was conducted in the laboratory of clinical biochemistry at Department of Biochemistry, Government P.D.U. Medical College, Churu, Rajasthan, India, from May 2024 to December 2024. Every serum and plasma sample admitted to routine and urgent chemistry analyses was screened on arrival in line with International Federation of Clinical Chemistry (IFCC) quality indicators as sample identification, request form, collection, transporting, or specimen quality-related errors. The frequencies of pre-analytical errors were computed as the percentage of samples with 1 or more error. Chi-square test and multivariate logistic regression were used to compare patient location (outpatient, inpatient, and intensive care) and request priority (routine vs emergency).

Results: Out of 45,126 samples, 810 contained at least one error of pre-analysis meaning a total prevalence of error of 1.8. The most commonly occurring problems were quality problems of the specimen (52.1%), hemolysis (28.5%), lack of volume in the sample (21.0%), and anticoagulation clotting of the sample (18.6%). The deficiencies of request forms shared 26.5 percent consisting of mostly non-completely clinical detail as well as physician signature and patient / sample identification errors constituted 8.3 percent. Error rates on pre-analytical were considerably much greater among inpatient and outpatient samples (2.2% vs 1.3% $p<0.001$) and between emergency and routine requests (2.5% vs 1.6% $p<0.001$). Inpatient origin and emergency status realized their status as independent predictors of error, after adjustment.

Conclusion: This medium level biochemistry laboratory had close to 1 out of 55 samples with at least one pre-analytical error, with hemolysis and inadequate volume being the most common. Centralization of errors in emergency and inpatient samples indicates that a specific intervention, such as standardized training on phlebotomy, improved communication with clinical areas, and ongoing monitoring with harmonized quality indicators will be necessary.

Keywords: Pre-Analytical Errors; Clinical Biochemistry; Quality Indicators; Hemolysis; Specimen Rejection; Patient Safety.

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Introduction

A significant share of clinical decisions has been supported by laboratory diagnostics, and the overall testing procedure has become a primary target of patient safety efforts [1,2]. In the past, the focus was almost entirely on the quality of analysis, where imprecision of assays and biasness were of major concern. Nevertheless, the experience of the last twenty years shows that the majority of the detectable laboratory errors are committed at the pre-analytical phases of the testing process, i.e., 46-70% of all laboratory errors happen at this stage of the process. Most of these steps, before analyzing, include test order and patient preparation to collection of specimen labeling, handling, transport, and processing, and are often performed manually, at multiple sites of care and by staff not directly overseen by the lab. Depending on the consequence can be rejection of the specimen used, repeating the process of phlebotomy, spurious or misleading tests that can lead to mistaken clinical

judgment. To reconcile this, professional organizations like the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) and the European Federation of Clinical Chemistry and Laboratory Medicine (EFLM) have been championing standardized monitoring of the pre-analytical stage with standardized quality indicators (QIs).[5,8,9] Harmonized QIs allow laboratories to measure the rate of errors, standardize performance and focus corrective efforts in a systematic and evidence-based way.

A number of studies in various environments have defined the pattern and the burden of pre-analytical errors within the clinical laboratories. The overall error rates have been found to range widely, 0.1 - 2.5% of samples to 7-10% of samples, across reports based on the varying definitions, methods of finding cases, and organisation of the laboratory, plus across inter-laboratories[6,7,10,13]. An Indian tertiary-care lab, whose IFCC-conforming QIs were based, reported that request form and specimen quality errors were dominant [7]. Later multicenter studies and systematic reviews substantiate the fact that hemolysis, inadequate volume, improper container and lack of identification are consistent motifs in healthcare systems [8,11,14,15].

However, little data is available in most areas, and specific interest in contemporary areas of the challenges of pre-analytical flaws is that the targeted intervention might be tailored, resources allocated optimally, and success or failure compared over time. It is based on this that the current study attempted to establish the commonness and trend of pre-analytical errors in the clinical biochemistry laboratory at Department of Biochemistry, Government P.D.U. Medical College, Churu, Rajasthan, India, from May 2024 to December 2024.

We aimed to (i) measure the rate of overall and category pre-analytical errors, (ii) to compare the rate of error in the various areas of patient care and the priority of requests, (iii) to identify independent predictors of pre-analytical error with the aim of guiding specific quality-improvement plans using a set of harmonized QIs which are consistent with IFCC/EFLM advice.

Materials and Methods

Study design and setting: This was a cross-sectional observational study conducted in the clinical biochemistry laboratory at Department of Biochemistry, Government P.D.U. Medical College, Churu, and Rajasthan, India. The laboratory performs routine and specialized chemistry assays for both inpatients and outpatients.

Study period and samples: The study was carried out over eight consecutive months (from May 2024 to December 2024). All serum and plasma samples received during this period for routine or emergency biochemistry investigations (electrolytes, liver and renal function tests, lipid profile, glucose, cardiac biomarkers, and others) were eligible. Arterial blood gas samples and point-of-care tests were excluded.

Participants and inclusion/exclusion criteria: Each specimen constituted a sampling unit. Samples were included if they were accompanied by a laboratory requisition originating from hospital outpatient clinics, inpatient wards, intensive care units (ICUs), or the emergency department. Samples received from external laboratories, research projects, or lacking essential request information (patient name or hospital number) were excluded from detailed analysis and recorded separately.

Definition and classification of pre-analytical errors: Pre-analytical errors were defined as any deviation from the laboratory's standard operating procedures occurring before the analytical phase and detected at the time of sample reception or pre-analysis processing. Using IFCC/EFLM-recommended QIs, errors were classified into the following categories:

1. **Patient and sample identification:** missing or mismatched identifiers, unlabeled or duplicate-labeled tubes.
2. **Request form non-conformities:** incomplete demographics, missing clinical information, absent physician signature, illegible orders.
3. **Collection-related errors:** wrong container, incorrect anticoagulant, wrong sample type, inappropriate fill volume.
4. **Transport and handling errors:** delays beyond defined time limits, improper storage temperature, visible leakage.
5. **Specimen quality issues:** hemolysis, clotting in anticoagulated samples, lipemia, gross contamination, or insufficient sample volume for requested tests.

Each sample could have more than one recorded error type; however, for prevalence estimates, a specimen was counted once if ≥1 error was identified.

Data collection: Trained laboratory technologists screened all incoming samples at reception and during centrifugation for predefined non-conformities, documenting them in a standardized pre-analytical error log integrated with the laboratory information system. For each sample with an error, patient location (outpatient, inpatient ward, ICU, emergency), request priority (routine vs emergency), time of receipt (day/evening/night shift), and error category were recorded. Where necessary, photographs of hemolysed or clotted

samples were stored for internal quality-improvement discussions.

Ethical considerations: The study protocol was reviewed and approved by the Institutional Ethics Committee. As only routine laboratory data were used and no additional patient contact was involved, the requirement for informed consent was waived. Data were anonymized prior to analysis.

Statistical analysis: Data were exported from the laboratory information system into a statistical software package. The prevalence of pre-analytical errors was calculated as the number of samples with ≥1 error divided by the total number of samples received, expressed as a percentage with 95% confidence intervals (CIs). Category-specific error rates were expressed as the number of samples with that particular error per 1,000 samples received. Comparisons of error prevalence by patient location (outpatient, inpatient, ICU, emergency), request type (routine vs emergency), and time of day were performed using chi-square tests for proportions. A multivariable logistic regression model was constructed with the presence of any pre-analytical error as the dependent variable and patient location, request priority, and time of day as independent variables, adjusting for age and sex where available. Odds ratios (ORs) with 95% CIs were reported. A p-value <0.05 was considered statistically significant.

All analyses were conducted in accordance with current recommendations on monitoring pre-analytical performance using quality indicators.

Results

Overall prevalence of pre-analytical errors: During the eight-month study period, a total of 45,126 biochemistry samples were received and screened. Of these, 810 samples had at least one documented pre-analytical error, corresponding to an overall prevalence of 1.8% (95% CI, 1.7–2.0). Among error-positive specimens, 71.4% had a single error, 21.0% had two errors, and 7.6% had three or more concurrent non-conformities. Error prevalence differed significantly by patient location and request type. Inpatient samples (including ICUs) exhibited higher error rates than outpatient samples, and emergency requests had more errors than routine requests. Time-of-day analysis suggested a modest increase during evening and night shifts compared with daytime.

Table 1: Distribution of samples and pre-analytical errors by patient location

Patient location	Total samples (n)	Samples with ≥1 error (n)	Error prevalence (%)
Outpatient	18,420	235	1.3
Inpatient wards	17,860	385	2.2
ICU	5,312	117	2.2
Emergency	3,534	73	2.1
Total	**45,126**	**810**	**1.8**

Outpatient samples had the least prevalence of pre-analytical errors, almost 70 percent of which were inpatient and ICU samples.

It is a trend that probably indicates the increased acuity, complicated workflow, and higher frequency of emergency blood transfusions in hospitalized patients.

The rate of error was also high in the samples of emergency department and this is in line with the pressure in time and the high turnover rates in this environment. These results are in line with previous reports that inpatient and emergency services are the most contributors to pre-analytical issues and indicate that measures to be implemented to address this high-risk group of clinical areas should focus on inpatient and emergency services.

Spectrum of pre-analytical errors: Specimen quality issues constituted the largest proportion of errors (52.1%), followed by request form non-conformities (26.5%), collection-related errors (13.1%), transport/handling issues (7.0%), and identification errors (8.3%). Hemolysis and insufficient volume were the dominant specimen-related problems.

Table 2: Frequency of specific pre-analytical error types

Error category / type	Error-positive samples (n)	Rate per 1,000 samples
Specimen quality issues		
Hemolyzed sample	231	5.1
Insufficient volume	170	3.8
Clotted anticoagulated sample	151	3.3
Gross lipemia / contamination	70	1.6
Request form non-conformities		
Incomplete clinical details	132	2.9
Missing physician signature/identifier	57	1.3
Illegible / ambiguous test request	26	0.6
Collection-related errors		
Wrong / inappropriate container	54	1.2
Wrong sample type	33	0.7
Transport and handling errors		
Delayed transport beyond allowed time	48	1.1
Improper storage temperature / leakage	9	0.2
Identification errors		
Unlabeled or partially labeled tube	28	0.6
Mismatched tube and request identifiers	39	0.9

Most of the issues with the quality of the specimen were attributed to hematysis, inadequate volume and clotting, which matched the trends reported in multi-centre surveys and systematic reviews.

The issue of request forms especially incompleteness of clinical information was also widespread and could lead to poor test selection and interpretation. Errors in identification were comparatively common albeit in the clinical aspect as to be of serious misdiagnosis. The distribution observed underlines the necessity of specific measures that are to be taken to enhance phlebotomy practice, request form designing, and identification of patients/specimens procedures.

Pre-analytical errors by request priority and time of day: Emergency requests comprised 12.6% of total samples but 15.6% of error-positive specimens.

Error prevalence for emergency requests was 2.5% compared with 1.6% for routine samples ($p<0.001$). Error rates were 1.6%, 2.0%, and 2.1% for day (08:00–16:00), evening (16:01–22:00), and night (22:01–07:59) shifts, respectively.

Table 3: Pre-analytical error prevalence by request priority and time of day

Variable	Category	Total samples (n)	Samples with ≥1 error (n)	Error prevalence (%)
Request priority	Routine	39,437	621	1.6
	Emergency	5,689	143	2.5
Time of receipt	Day	26,780	422	1.6
	Evening	11,532	228	2.0
	Night	6,814	160	2.1

In emergency samples the pre-analytical error rates were much higher than in routine samples probably because of the pressured schedules, having to sample unstable patients, and not optimal adherence to phlebotomy procedures in emergency departments.

There is a small yet significant growing number of errors in the evening and night shifts which may indicate the effect of staffing, experience, and fatigue.

Like patterns in time have been reported in other workplaces, highlighting that workflow and workforce organization is part of pre-analytical quality, rather than simple technical processes..

Multivariable analysis of predictors: In logistic regression, inpatient location (OR 1.54; 95% CI 1.31–1.81), ICU (OR 1.61; 95% CI 1.27–2.03), and emergency status (OR 1.43; 95% CI 1.19–1.71) were independently associated with the presence of any pre-analytical error, after adjustment for age, sex, and time of day. Night-shift receipt remained borderline significant (OR 1.18; 95% CI 1.00–1.39).

Table 4: Independent predictors of pre-analytical errors (logistic regression)

Predictor	Adjusted OR	95% CI	p-value
Inpatient vs outpatient	1.54	1.31–1.81	<0.001
ICU vs outpatient	1.61	1.27–2.03	<0.001
Emergency vs routine	1.43	1.19–1.71	<0.001
Evening vs day shift	1.16	0.99–1.36	0.067
Night vs day shift	1.18	1.00–1.39	0.048
Age (per 10-year increase)	1.02	0.99–1.05	0.18
Male vs female	1.05	0.93–1.18	0.43

A sample originating in inpatient wards, ICUs, and emergency services was far more prone to error during pre-analysis, notwithstanding the fact that such samples had been controlled on demographic factors and the time of day. This supports the idea of organizational and environmental conditions, including urgency, workload and staff staffing diversity, having a significant material impact on pre-analytical quality. The borderline effect of night-shift sampling also implies that staffing trends and supervision can have to be reconsidered as one of the quality-improvement efforts.

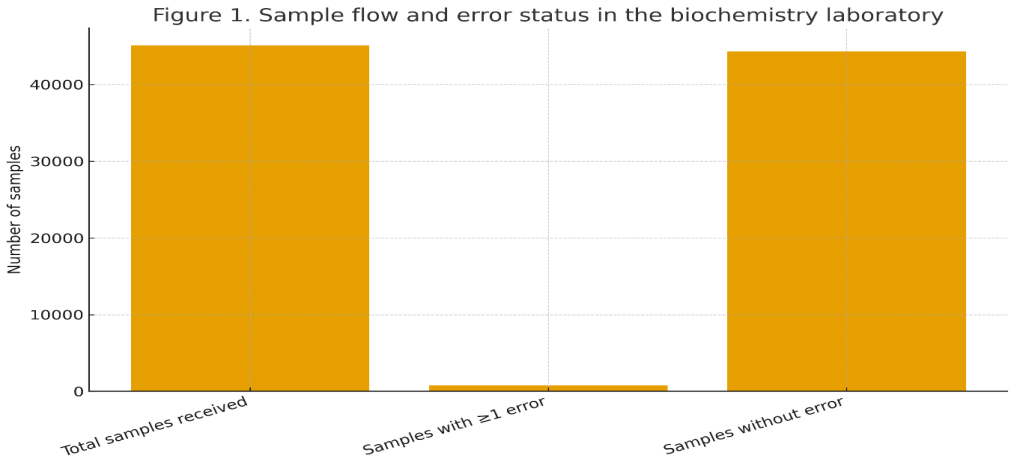

Figure 1: Flow Diagram of Sample Inclusion and Outcomes

The flow chart provides a pictorial overview of how the entire sample of biochemistry samples would get to the analysis and finally to the sub sample of samples that will be reported to have pre-analytical errors.

An illustration of the contribution of each error category relative to the other gives a direct insight of which point in the pre-analytical sequence most non-conformities occur.

These types of visual tools are useful in reporting findings to clinicians and hospital management and in prioritization of interventions around the most lucrative outcomes, like specimen quality and promptness of request forms.

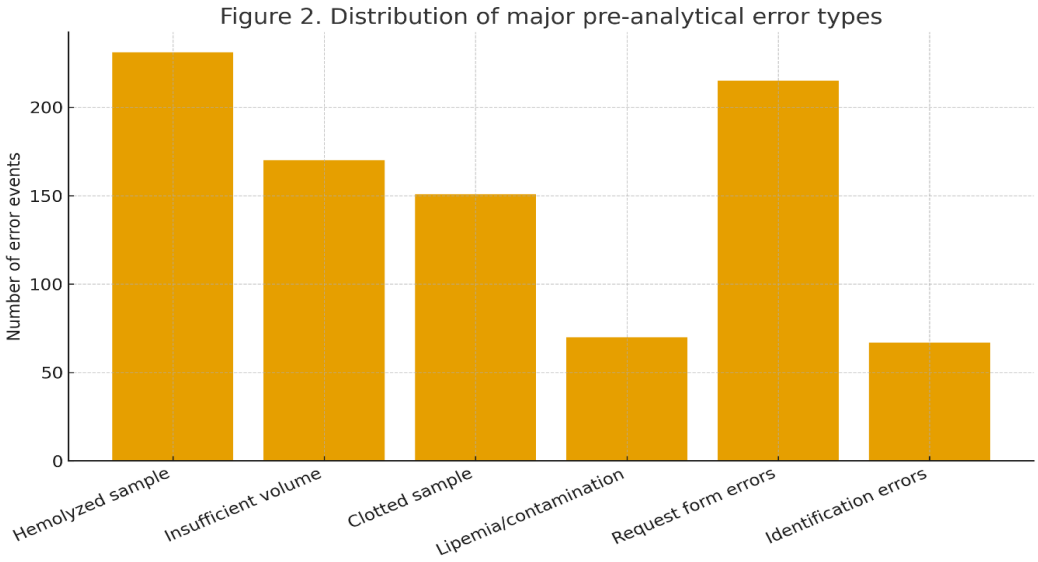

Figure 2: Distribution of Major Pre-Analytical Error Types

As the bar chart shows, a few recurring issues, such as hemolysis, not enough volume, clotting dominate the error space, but, in the context of patient-safety, identification errors are significant, even though they are less common. The cluster of the types of errors indicates that a special set of measures (standardized phlebotomy education, obvious minimum volume policies, and powerful labeling/checks measures) might lead to significant improvements. The source proportions also allow easy tracking of change following quality-improvement efforts and benchmarking against published data using the visual focus on proportions.

Discussion

In this cross-sectional audit of over 45,000 biochemistry samples, we found an overall pre-analytical error prevalence of 1.8%, with specimen quality problems—particularly hemolysis, insufficient volume, and clotting—accounting for more than half of all events. Error rates were significantly higher among inpatient, ICU, and emergency samples, and these settings remained independent predictors of pre-analytical errors in multivariable analysis. These findings underscore the continuing vulnerability of the pre-analytical phase, even in laboratories where analytical processes are highly automated and quality-controlled.[1–4]

Our overall error prevalence falls within the lower range of published estimates but is comparable to several recent reports that used structured QIs and systematic logging.[6,7,10–12,14] Najat reported pre-analytical error rates between 0.4% and 7.0% in Sulaimani laboratories, with improper handling and hemolysis as key issues.[6] Mehndiratta et al., using IFCC-aligned QIs in an Indian tertiary-care setting, found frequent request form deficiencies and specimen quality problems, similar to our pattern.[7] A recent multicenter study on pre-analytical performance and a systematic review of laboratory errors likewise identified hemolysis, inadequate volume, and mislabeled samples as recurrent issues across diverse health systems.[8,11,14,15]

Our observation that inpatients and emergency samples had significantly higher error rates is consistent with earlier studies showing increased error burden in hospitalized populations.[3,6,11,13] Plebani and colleagues highlighted that procedures conducted outside the direct supervision of laboratory staff—such as test ordering, patient preparation, and phlebotomy on wards and emergency units—are particularly prone to non-standard practices and communication gaps.[3,9] Recent prospective analyses and quality-indicator-based evaluations have similarly shown that high-acuity areas contribute disproportionately to pre-analytical non-conformities.[11–13,16] The association we observed with evening and night shifts extends these findings by suggesting that staffing patterns, workload, and supervision may be modifiable drivers of error. The predominance of hemolysis and insufficient volume in our cohort aligns with multiple investigations in clinical chemistry and emergency laboratories.[2,6,10–12,14] Hemolysis can lead to spurious elevations of potassium, lactate dehydrogenase, and other analytes, potentially triggering unnecessary or harmful interventions.[2,10] Insufficient sample volume may necessitate repeat phlebotomy, causing patient discomfort, delaying diagnosis, and increasing costs. Systematic reviews and recent multinational surveys indicate that addressing these seemingly “basic” problems through standardized phlebotomy training, use of closed blood-collection systems, and clear minimum volume requirements

can yield meaningful improvements in both quality and efficiency.[4,8,11,14,15]

Our findings also reinforce the value of using harmonized QIs to monitor pre-analytical performance. The IFCC and EFLM working groups have developed consensus sets of indicators to capture critical steps such as patient identification, sample collection, transport, and specimen acceptance criteria.[5,8,9] Adoption of such indicators enables laboratories not only to quantify internal performance but also to benchmark across institutions and over time. Studies evaluating QI-based programs have demonstrated reductions in key error rates and highlighted residual problem areas, particularly in extra-laboratory processes.[5,7,8,12]

From a clinical perspective, the implications of our study are two-fold. First, even an apparently "modest" error prevalence of 1.8% translates into substantial absolute numbers in a high-volume laboratory, with potential downstream impact on clinical decisions. Second, the concentration of errors in specific settings and categories suggests that targeted interventions—rather than diffuse, generic training—are likely to be most effective. Potential strategies include structured competency-based training for ward and emergency phlebotomy staff, standardized request forms integrated into electronic order entry, clear rejection and recollection criteria, and ongoing feedback to clinical units using QI dashboards.[4,5,8,11,14]

Our study has limitations. It was conducted in a single institution and may not fully represent other laboratory configurations or healthcare systems. Detection of errors relied on visual inspection and systematic logging at the laboratory reception; some upstream "pre-pre-analytical" errors (such as inappropriate test selection or poor patient preparation) may have been missed.[2,3,9] We did not systematically assess the direct clinical or economic impact of individual errors, which is an important dimension increasingly explored in contemporary literature.[8,14] Finally, although we aligned our categories with IFCC/EFLM QIs, minor differences in definitions may limit direct comparison with some published series.

Despite these constraints, the study provides robust, locally relevant estimates of pre-analytical error prevalence and identifies clear priority areas for quality improvement. Future work should couple sustained QI monitoring with intervention bundles targeting high-risk settings, and extend evaluation to clinical outcomes and cost-effectiveness. [8,11,14,15]

Conclusion

This cross-sectional audit has identified that pre-analytical errors still constitute a significant proportionality of avoidable non-conformities in a high throughput clinical biochemistry lab with an overall rate of 1.8. The error profile is dominated by specimen quality issues, especially hemolysis, inadequate volume, and clotting, among others, with inpatient, ICU, and emergency samples being underrepresented in the sample. These results, which corroborate evidence in the international base point to the necessity of combining the perspective of the pre-analytical phase as a collective responsibility of the laboratory-clinical interface. One of the measures that allow reducing the number of errors, improving patient safety, and optimizing resource use is the use of harmonized quality indicators, phlebotomy training and supervision, and periodic feedback to clinical areas.

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