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Retrospective Analysis of Preanalytical Errors in the Clinical Biochemistry Laboratory of a Tertiary Care Teaching Hospital

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Abstract

Background: The Preanalytical errors are still a primary cause of laboratory quality failure. The Preanalytical phase is the most error prone part, spanning from clinicians request to sample receipt in the laboratory, accounting for about 46-68% of all laboratory errors.

Objectives: To retrospectively analyze the frequency, type and ward-wise distribution of pre-analytical errors in the clinical biochemistry laboratory of a tertiary care teaching hospital for a period of 6-months from January to June 2026.

Materials and Methods: This retrospective record-based observational study analyzed data from S.V.R. R.G.G.H, Tirupathi Central Biochemistry Laboratory's sample rejection/error log and sample receipt register. All samples with documented pre-analytical errors during the study period were included. Epi info version 7.2.1 was used for data analysis; categorical variables were presented as frequencies and percentages, associations between variables were evaluated by Chi-square test considering p value < 0.05 as statistically significant.

Results: Of the 91,885 samples received during the study period, 2,389 samples were identified with documented pre-analytical errors, yielding an overall error rate of 2.60%. 71.2% of all the errors were due to Insufficient sample volume (25.3%), improper labeling (24.0%) and hemolyzed samples (21.9%). Ward-wise, the pediatric ward had the highest proportion of errors (18.0%), followed by Adult ICU and Medicine (each 13.0%). The association between error type and source location was statistically significant ($p<0.001$); standardized residual analysis confirmed that insufficient - volume errors in NICU/ pediatric wards, labeling errors in Medicine, and hemolysis in Adult ICU were the largest individual contributors to this association.

Conclusion: Pre-analytical errors affected 2.60% of all samples processed over the six-month study period, with insufficient sample volume, mislabeling, and hemolysis together accounting for nearly three-quarters of all documented errors. The concentration of volume-related errors in pediatric and neonatal/pediatric intensive care settings, and of labeling errors in emergency and general wards, indicates targeted, location-specific corrective interventions, rather than a uniform, institution-wide approach to yield the greatest improvement in pre-analytical quality and enhance patient safety.

Keywords: Pre-Analytical Errors, Sample Rejection, Clinical Biochemistry Laboratory, Patient Safety, Quality Improvement.

Introduction

The clinical biochemistry laboratory occupies a central position in patient diagnosis, management, and monitoring, with a large proportion of clinical decisions in a tertiary care hospital being influenced directly or indirectly by laboratory results. The total testing process (TTP), often described as the “brain-to-brain loop,” comprises three broad phases: the pre-analytical phase, the analytical phase, and the post-analytical phase[1].

The pre-analytical phase begins with the clinician's decision to order a test and extends through patient preparation, sample collection, labeling, transport, and receipt of the sample in the laboratory, ending only when the sample is placed on the analyzer. This phase is performed largely outside the direct control of laboratory personnel (by clinicians, nursing staff, phlebotomists, and transport personnel) and is widely recognized as the most error-prone segment of the total testing process, reportedly accounting for 46–68% of all laboratory errors[,2,3].

Common pre-analytical errors include improper patient identification, incorrect or missing test requisition details, use of a wrong anticoagulant or collection tube, inadequate or excessive sample volume, hemolyzed or lipemic samples, clotted samples, inappropriate sample-to-anticoagulant ratio, delayed or improper transport, and samples received without proper labeling or requisition forms. Such errors can lead to spurious results, unnecessary repeat sampling, patient in convenience, diagnostic delay, increased healthcare cost and if undetected, potential harm through inappropriate clinical decisions[4].

Despite their clinical significance, pre-analytical errors remain under-reported and under-studied compared with analytical errors, partly because they occur before the sample reaches the analyzer and are therefore easy to overlook unless a dedicated quality-monitoring system is in place. Systematic, periodic audit of pre-analytical errors is recommended by accreditation bodies such as the National Accreditation Board for Testing and Calibration Laboratories (NABL) and ISO 15189 as a

quality indicator for laboratory performance improvement[4,5].

In a tertiary care teaching hospital with a high daily sample load, multiple sample-collection points (wards, outpatient departments, intensive care units, and emergency services), and involvement of relatively inexperienced collecting staff, the pre-analytical phase is particularly vulnerable to error[6,7]. This study was undertaken to generate baseline data that could guide targeted corrective and preventive action as part of continuous laboratory quality improvement.

Aim and Objectives

The aim of this study was to retrospectively analyse the pattern, frequency and distribution of pre-analytical errors encountered in the Clinical Biochemistry Laboratory of a tertiary care teaching hospital between January and June 2026. The specific objectives were: (1) to determine the overall frequency of samples affected by pre-analytical errors among total samples received; (2) to categorize and quantify the major types of pre-analytical errors identified; and (3) to describe the distribution of these errors according to source location and where data permitted, time/shift of collection.

Materials and Methods

Study Design and Setting

This was a retrospective, record-based observational study conducted at the Central Biochemistry Laboratory, Sri Venkateswara Ramnarayan Ruia Government General Hospital (SVRR GGH), attached to Sri Venkateswara Medical College, Tirupathi, Andhra Pradesh.

Study Period

Data were retrieved from clinical Biochemistry laboratory records for the period of six months from January to June 2026.

Study Population

A total of 91,885 samples received in the Clinical Biochemistry Laboratory for biochemical investigations during the study period, as documented in the laboratory sample-receipt register and the sample-rejection/error log.

Inclusion Criteria

- All samples and their accompanying requisition forms received during the study period for which pre-analytical error records were available/documented.
- Samples from inpatients, outpatients, intensive care units, and the emergency department routed to the Clinical Biochemistry Laboratory.

Exclusion Criteria

- Samples with incomplete or illegible error-log documentation precluding categorization of the error type.
- Samples pertaining to analytical or post-analytical errors e.g., instrument malfunction, transcription error not related to the pre-analytical phase.
- Duplicate entries for the same sample event in the register.

Data Source and Collection Procedure

Following approval from the Institutional Scientific Committee and Ethics Committee, data were retrieved from existing sample rejection/error log register and the sample receipt register with accompanying requisition forms with no direct patient contact or intervention. Data were extracted using a pre-designed, structured data-collection proforma capturing date and time of sample receipt, source ward/department, sample/test type, type of pre-analytical error identified, and action taken (sample recollected, processed with caveat, or rejected). No patient-identifiable information was recorded.

Sample Size

As this was a retrospective, total-enumeration audit of laboratory records, no separate sample-size calculation was performed. All samples and pre-analytical error entries logged during the study period were included.

Statistical Analysis

Data were analyzed using Epi Info version 7.2.1; Categorical variables were summarized as frequencies and percentages. The overall pre-analytical error rate was expressed as a proportion and additionally as errors per 1,000 samples for benchmarking against published quality-indicator standards[5]. Association between error type and source location was assessed using the Chi-square test, with $p<0.05$ considered statistically significant. Standardized residuals were calculated for each cell of the error-type × ward cross-tabulation to identify which specific ward–error combinations contributed most to the overall Chi-square statistic, and post-hoc odds ratios (with 95% reasoning based on 2×2 collapsed tables) were computed for the three dominant error–location associations. Trends across error categories were depicted using a Pareto chart, a ward-wise bar diagram, and a heat map of error type by ward.

Ethical Considerations

The study was approved by the Institutional Scientific Committee and the Institutional Ethics Committee of Sri Venkateswara Medical College, Tirupathi As this was a retrospective, record-based audit using anonymized/ coded data with no direct patient contact, no intervention, and no alteration of patient management, a waiver of individual informed consent was granted, in accordance with the ICMR National Ethical Guidelines for Biomedical and Health Research for secondary use of existing records[10]. Patient confidentiality was maintained throughout; no personally identifiable information was recorded, stored, or reported.

Results

During the six-month study period, a total of 91,885 samples were received across all institutional sample-collection points. Of these, 2,389 pre-analytical errors were identified corresponding to an overall preanalytical error rate of 2.60%

Distribution by error category

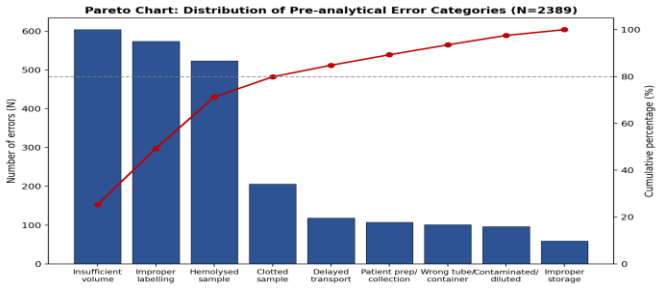
Analysis of pre-analytical errors as shown in table 1, revealed that Insufficient sample volume (quantity not sufficient, QNS) was the predominant error category (25.3%), followed by improper labelling (24.0%) and hemolyzed samples (21.9%). Together, these three categories accounted for 71.2% of all documented events, consistent with a Pareto-type distribution (Figure 1). In contrast, improper storage was the least frequent error category (2.5%).

Table 1: Distribution of Pre-analytical Errors by Cate gory (N = 2389)

Sn.	Type of Pre-analytical Error	N	Percentage (%)
1	Insufficient sample volume (QNS)	604	25.3
2	Improper labeling (unlabeled/ mislabeled)	574	24.0
3	Hemolyzed sample	524	21.9
4	Clotted sample	206	8.6
5	Delayed transport	118	4.9
6	Patient preparation/collection error	107	4.5
7	Wrong tube/ container (anticoagulant mismatch)	101	4.2
8	Contaminated/diluted	96	4.0

	sample		
9	Improper storage	59	2.5
	Total	2389	100.0

Figure 1: Pareto chart showing the distribution and cumulative percentage of pre-analytical error categories (N = 2389).



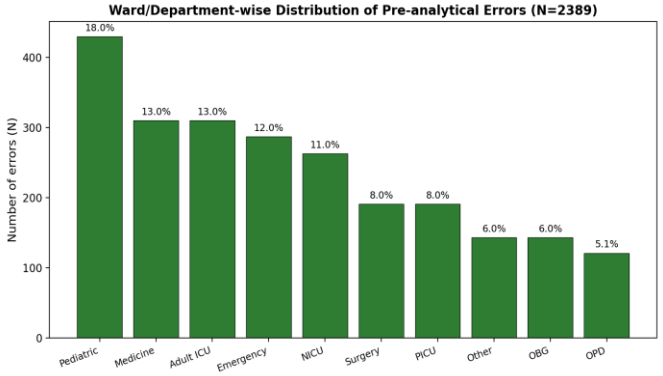
Distribution by ward/department

The pre-analytical errors were most frequently observed in the pediatric ward (18.0%), followed by Adult ICU and Medicine wards (each 13.0%), the Emergency department (12.0%), and NICU (11.0%). PICU and Surgery (each 8.0%), whereas OBG and other specialty wards (each 6.0%), and the OPD the fewest (5.1%). Details of ward's share of the total error burden are presented in Table 2 and Figure 2.

Table 2: Ward/Department-wise Distribution of Pre-analytical Errors (N = 2389)

Source Ward / Department	N (Errors)	Percentage (%)
Pediatric	430	18.0
Adult ICU	310	13.0
Medicine	310	13.0
Emergency	287	12.0
NICU	263	11.0
PICU	191	8.0
Surgery	191	8.0
OBG	143	6.0
Other	143	6.0
OPD	121	5.1
Total	2389	100.0

Figure 2: Ward/department-wise distribution of pre-analytical errors (N = 2389), ranked in descending order of frequency.



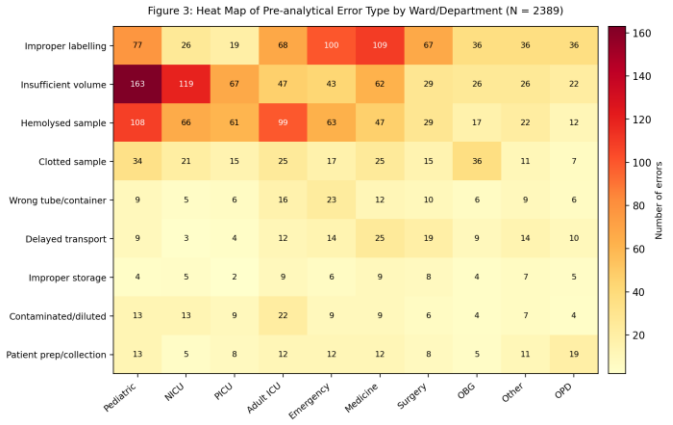
Association between error type and source location

The distribution of pre-analytical error types differed across hospital wards. Insufficient sample volume was the most common error in pediatric (37.9%), NICU (45.2%), and PICU (35.1%). Hemolyzed sample was the leading error in Adult ICU (31.9%). In contrast, improper labelling was the frequently reported error in Emergency (34.8%), Medicine (35.2%), Surgery (35.1%), OBG (25.2%), other specialty wards (25.2%), and OPD (29.8%). A Chi-square test demonstrated a statistically significant ($\chi^2 = 445.6$, df = 72, $p < 0.001$) association between error type and source location. Table-3 presents the detailed cross tabulation, while figure-3 provides a heat map that visually highlights the concentration and distribution of specific error types across hospital wards.

Table 3: Tabulation of pre-analytical error type by source location (Ward/Department)

Error type	Pediatric	NICU	PICU	Adult ICU	Emergency	Medicine	Surgery	OBG	Other	OPD	Total
Improper labelling	77	26	19	68	100	109	67	36	36	36	574
Insufficient volume	163	119	67	47	43	62	29	26	26	22	604
Hemolyzed sample	108	66	61	99	63	47	29	17	22	12	524
Clotted sample	34	21	15	25	17	25	15	36	11	7	206
Wrong tube/container	9	5	6	16	23	12	10	6	9	6	102
Delayed transport	9	3	4	12	14	25	19	9	14	10	119
Improper storage	4	5	2	9	6	9	8	4	7	5	59
Contaminated/diluted	13	13	9	22	9	9	6	4	7	4	96
Patient preparation / collection	13	5	8	12	12	12	8	5	11	19	105
Total	430	263	191	310	287	310	191	143	143	121	2389

Figure 3: Heat map of pre-analytical error type by ward/department (N = 2389)



Strength of statistical association - standardized residuals and odds ratios

To identify which specific ward–error combinations contributed most to the overall Chi-square statistic, standardized residuals [(observed − expected)/ √ expected] were calculated for each cell of Table 3. The largest positive residuals were observed for clotted samples in OBG (observed 36 vs. expected 12.3; standardized residual +6.7), insufficient volume in NICU (observed 119 vs. expected 66.5; +6.4), patient preparation /collection errors in OPD (observed 19 vs. expected 5.3; +5.9), insufficient volume in pediatric ward (observed 163 vs. expected 108.7; +5.2), improper labelling in Medicine (observed 109 vs. expected 74.5; +4.0), and hemolyzed samples in Adult ICU (observed 99 vs. expected 68.0; +3.8); improper labelling showed a large negative residual in NICU and PICU (−4.7 and −4.0 respectively), indicating a marked deficit relative to the pattern expected if errors were distributed uniformly. These cell-level residuals, rather than the omnibus Chi-square value alone, are what should guide ward-specific corrective priorities.

Post-hoc odds ratios computed from collapsed 2×2 tables reinforced these findings: the odds of an error being classified as insufficient sample volume were approximately 3.2 times higher in pediatric, NICU, and PICU settings combined than in all other locations; the odds of an error being classified as improper labelling were approximately 2.5 times higher in the high-throughput areas (Emergency, Medicine, Surgery, OBG, other specialty wards, and OPD) than elsewhere; and the odds of an error being classified as hemolysis were approximately 1.8 times higher in Adult ICU than in all other locations combined..

Discussion

This study demonstrates the magnitude and pattern of pre-analytical errors in a high-volume clinical biochemistry laboratory of a tertiary care hospital.

During the six-month study, 91,885 samples were processed and 2,389 pre - analytical errors were identified, giving an overall error rate of 2.60%. Three error types insufficient sample volume (25.3%), improper labelling (24.0%), and hemolysis (21.9%) accounted for over 70% of all errors, indicating that targeted interventions addressing these priority areas could substantially improve laboratory quality.

The distribution of errors varied significantly across clinical areas. Insufficient volume was concentrated in pediatric, NICU, and PICU settings (standardized residuals of +5.2 and +6.4 in NICU and pediatrics respectively), accounting for 35-45% of errors there consistent with the technical difficulty of pediatric and neonatal venipuncture, given small vein caliber, low circulating blood volume, frequent collection by relatively junior staff without a dedicated pediatric phlebotomy team, and curtailed repeat attempts in distressed children. Because this is primarily a technique and patient-factor-driven error rather than a documentation failure, it is unlikely to respond to administrative fixes and instead requires focused phlebotomy training and pediatric-specific micro-collection devices. Improper labeling, by contrast, predominated in high-throughput areas Emergency, Medicine, Surgery, OBG, and OPD where the odds of a labelling error were roughly 2.5 times those elsewhere, reflecting multiple concurrent requisitions, shift changes, and, in Emergency particularly, competing time-critical priorities; this points toward a process-level fix, principally reinforcing two-identifier bedside labelling before the collector leaves the patient. Hemolysis was the leading category in Adult ICU, where the odds of a hemolyzed sample were roughly 1.8 times those elsewhere, consistent with reliance on indwelling arterial or venous lines, which are prone to hemolysis from turbulent flow, residual flush solution, or vigorous aspiration through narrow-bore catheters, compounded by more forceful venipuncture in patients with fragile or previously cannulated veins pointing to a technique-level fix specific to line-draw practice (adequate discard volume, gentle aspiration, prompt processing).

These findings are consistent with previous reports that have repeatedly identified hemolysis, inadequate volume, and clotting as the leading contributors to pre-analytical error across diverse hospital settings, and that similarly link volume- and hemolysis-related errors to difficult venous access and line-based sampling in critically ill and pediatric patients, and labelling errors to high patient volume and time pressure in high-throughput areas[6,7,8,9].

Comparison with other Indian centers shows considerable variation in reported error rates, largely reflecting differences in denominator definition and which categories are counted, rejection rates range from 0.054% in a very large Dehradun series to 2.32%, 3.45%, and 3.75% in tertiary/secondary teaching hospitals in western Uttar Pradesh, Chhattisgarh, and Gujarat respectively, with hemolysis and insufficient volume recurring as leading causes, and one Gujarat audit specifically noting, as here, that insufficient volume was particularly difficult to minimize in pediatric patients[11,12,13,14].

An emergency department focused Indian audit likewise identified pre-analytical causes as the dominant source

of laboratory error in high-throughput settings, echoing the labelling error pattern seen in Emergency here[15].

Despite this variation in absolute rates driven largely by local counting conventions these regional data support hemolysis, insufficient volume, and labeling/ identify cation failures as the recurring leading categories of pre-analytical error across Indian hospital settings.

The statistically significant association between error type and source location ($\chi^2 = 445.6$, df = 72, $p < 0.0\ 01$) confirms that pre-analytical error is not a uniform, institution-wide phenomenon but is shaped by the specific clinical, technical, and workflow conditions of each collection site. Standardized residual analysis localized this association to a small number of wards–error cells principally insufficient volume in NICU and pediatrics, labelling in Medicine, and hemolysis in Adult ICU with post-hoc odds ratios of approximately 3.2, 2.5, and 1.8-fold respectively, reinforcing that pre-analytical quality improvement should be tailored to local risk profiles rather than applied as a single, generic intervention[5,9].

These findings support targeted, location - specific interventions: focused pediatric phlebotomy training and appropriately sized collection devices in pediatric, neonatal, and pediatric intensive-care settings; review of line-draw technique in Adult ICU; and reinforced two-identifier bedside labeling in high-throughput areas such as Emergency, Medicine, Surgery, and OPD.

Institution-wide, the concentration of errors in three categories supports a Pareto-based quality-improvement cycle prioritizing insufficient volume, labeling, and hemolysis, with structured feedback to the highest - contributing wards (pediatrics, Adult ICU, Medicine, and Emergency)[4,5]. This audit has already informed such feedback, with findings shared with nursing and phlebotomy staff in these wards as baseline data, and the ward-level breakdown in Tables 2 and 3 proposed as the basis for prioritizing retraining resources rather than distributing them uniformly.

Sustaining any gains will require embedding this monitoring into a continuous Plan–Do–Study–Act cycle: defining the priority error–ward combinations identified here, implementing the corresponding interventions, re-auditing the same error log at a fixed interval (e.g., three to six months) using identical categories and denominators, and scaling up interventions that demonstrably reduce the targeted error rate.

Conclusion

In this six-month retrospective analysis of 2389 documented Preanalytical error events, insufficient sample volume, improper labeling and hemolysis accounted for 71.2%. Error patterns varied significantly by source location: volume-related errors predominated in pediatric and intensive-care settings, hemolysis in Adult ICU, and labeling errors in high-throughput wards and the emergency department, an association confirmed both by Chi-square testing and by cell-level standardized residuals and odds ratios.

These findings indicate that pre-analytical quality-improvement efforts at this institution are likely to be most effective if targeted specifically at these three error categories, through focused phlebotomy training, reinforced bedside labelling protocols, and review of line-draw technique. Routine monitoring of pre - analytical quality indicators with periodic audit, structured as a continuous Plan–Do–Study–Act improvement cycle and supported by ward- and month-level sample denominators, should become an integral component of laboratory quality management in tertiary care hospitals.

Strengths: The study is strengthened by its large sample size, complete six-month audit, and use of total sample numbers to calculate a bench markable error rate

Limitations: As it is a retrospective single-centre design, possible under-reporting, lack of ward-specific denominators, and inability to capture unrecorded errors limit generalize bility.

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