

## ORIGINAL ARTICLE

## Frequency of pre-analytical errors in chemical pathology section of tertiary care hospital.

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**ABSTRACT... Objective:** To determine the frequency of Pre-Analytical Errors in the Chemical Pathology Section of Tertiary Care Hospital. **Study Design:** Descriptive study. **Setting:** Central Diagnostic Laboratory (CDL), KEMU/, Mayo Hospital, Lahore. **Period:** May 2022 to May 2024. **Methods:** The pre-analytical errors were noted out of 135,000 samples sent to Chemical pathology section both from indoor and outdoor. All the collected data was analysed by SPSS version 23. The frequency and percentage of errors were calculated. **Results:** A total of 12,852 (9.52%) laboratory errors including pre-analytical, analytical and post-analytical errors were observed. Out of the total errors, 8919 (69.4%), 1607 (12.5%), 2326 (18.1%) were pre-analytical errors, analytical and post-analytical errors, respectively. Haemolysis, unlabelled vial, quality not sufficient (QNS), EDTA, IV contamination, wrong vial, illegible hand writing, empty vial, spillage was 69, 20.4, 4.1, 2.6, 2.3 1.1, 0.3, 0.2, 0.1% respectively. **Conclusion:** The pre-analytical errors were the most common followed by post-analytical and analytical errors. The pre-analytical errors were more common in IPD samples than samples received from OPD and haemolysis was the most common pre-analytical error.

**Key words:** Laboratory Errors, Pre-analytical Errors, Post-analytical Errors and Analytical Errors.

**Article Citation:** John KM, Simran M, Dar R. Frequency of pre-analytical errors in chemical pathology section of tertiary care hospital. Professional Med J 2026; 33(03):538-543. <https://doi.org/10.29309/TPMJ/2026.33.03.10152>

### INTRODUCTION

Clinical laboratories are an essential component of the hospital setting, as almost 70% of clinical decisions are based on the laboratory results. Laboratory testing contributes to the right and timely diagnosis, thus consequently impacting the correct treatment, term of hospital stay, prognosis, and the overall well-being of patient.<sup>1-3</sup>

Laboratory work is generally divided into three phases, i.e., pre-analytical, analytical and post-analytical phase. The pre-analytical phase includes all steps from requesting a test by clinician to processing of the sample, these steps involve collection of the specimen, transportation, entry at laboratory's reception and preparation of sample for processing. The analytical phase includes analysis of sample and validation of results. The post-analytical phase involves incorporation of data in the laboratory information system (LIS), endorsement from the lab manager, posting the reports and interpretation of laboratory reports by the clinician.<sup>1,3-5</sup>

All three of these testing phases are vulnerable to errors. According to International Organization for Standardization (ISO), a laboratory error is stated as "any flaw from ordering tests to reporting results and appropriate interpretation."<sup>6,7</sup> These errors can compromise the entire quality management system of the laboratory leading to increased utilization for resources, inappropriate clinical decisions, delayed diagnoses or extended hospital stays. Among three phases of laboratory testing, the pre-analytical phase is the most error-prone stage of the total testing process. The errors in analytical phase are greatly reduced due to induction of internal and external quality control programs and automation of the analytical work. The errors in post-analytical phase are also reduced due to direct integration of analytical results to laboratory information system (LIS), reducing transcriptional mistakes.<sup>1-4,7,8</sup>

Around 70% of the total laboratory errors occur in the pre-analytical phase.<sup>3,6</sup> This high frequency is largely due to the involvement of many non-laboratory professionals in this phase and lack of

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**Article received on:**

24/10/2025

**Accepted for publication:**

30/12/2025



their proper training. The pre-analytical errors include two types of variables: patient-related and sample-related. Patient-related variables include improper patient preparation, misidentification, workout, stress, age, sex, postural effects, drug intake and menstruation. Sample related variables include poor sample collection technique, mishandling, transport and storage issues, haemolysis, clotting, lipemia, icterus, insufficient quantity, inappropriate vial/preservative.<sup>4,9,10</sup>

The poor understanding of these potential errors, inadequate training of phlebotomy and poor sample transportation practices are responsible for these problems. The regular monitoring of pre-analytical errors in laboratory is essential to improve overall quality and reliability of the laboratory.<sup>6,11</sup>

In this context, this study was conducted to evaluate frequency of pre-analytical errors in the chemical pathology section of a tertiary health care hospital.

## METHODS

This descriptive study, approved by the Institutional Review Board (No. 73/RC/KEMU), was conducted in Central Diagnostic Laboratory (CDL), KEMU/, Mayo Hospital, Lahore. A random selection of 135000 samples sent to the Chemical pathology section from May 2022 to May 2024 was made to include in this study. The pre-analytical errors such as quantity not sufficient (QNS), samples in wrong vial, unlabelled samples, haemolysis, EDTA contamination and IV contamination were noted at various levels of sample handling. Immediately, after receiving the sample in laboratory, the sample vial was matched with the requisition number and department from where it was requested. The samples from indoor patient department were marked as IPD while those from the outdoor patient department were marked as OPD.

The samples were then assessed for the adequacy, after matching patient details. Vials having sample volume inadequate for requested tests were marked as quantity not sufficient (QNS). Mislabeled and unlabelled vials were also detected during checking samples against test requirements. If the corresponding details did not match the request form it was marked as mislabelled and those samples

having no label on them or missing request form were considered unlabelled vials. Similarly, empty vials were identified using the same way. The samples were centrifuged at 3000 rpm for 3 to 5 minutes to separate serum and were checked qualitatively by visual inspection method. The degree of discoloration helped us in marking degree of haemolysis such as 1+ (light pink serum, mild haemolysis), 2+ (red tinge serum, moderate haemolysis), 3+ (dark red serum, marked haemolysis), and 4+ (deep red serum, gross haemolysis). The samples were run on Beckman Coulter Chemistry auto-analyzer for analysis. Samples showing spuriously high potassium and low calcium were considered for EDTA contamination. IV contamination was considered if the serum was clear or diluted and after running it on the analyser, their biochemical profile was unexpectedly disturbed. Samples suspected of EDTA or IV contamination were redrawn with special care and reanalysed for obtaining accurate results. Those samples which then showed the change in results after redrawing the sample were labelled as EDTA or IV contaminated.

Mislabeled and unlabelled samples were rejected for the analysis while sample marked as QNS were run for tests from STAT test panel and remaining tests were requested with a repeat sample.

+1 haemolysed sample was considered for analysis but a cautionary note was mentioned for the haemolysis sensitive electrolytes such as potassium, iron, CK, LDH and AST. +2 haemolysis was considered as rejection for haemolysis sensitive analytes while samples were still analysed for relatively stable parameters such as cholesterol, urea and glucose. +3 and +4 haemolysed samples were rejected for all type of analysis and were requested again with repeat sample request. All the collected data was transferred on data file lists and analysed by SPSS 23. The frequency and percentage of all pre analytical errors were calculated.

## RESULTS

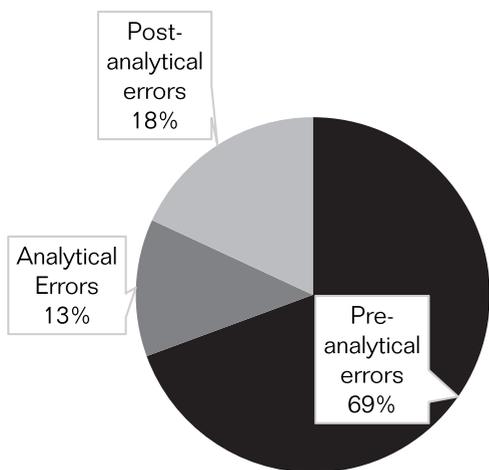
A random selection of a total of 135,000 samples was made in Chemical pathology section from 1<sup>st</sup> May 2022 to 31<sup>st</sup> May 2024. Out of these 135000, 92500 samples were from indoor patient department (IPD) while 42500 samples were from the outdoor

patient department (OPD).

A total of 12,852 (9.52%) laboratory errors including pre-analytical, analytical and post-analytical errors were observed. Out of these total errors, 8919(69.4%), 1607(12.5%), 2326(18.1%) were pre-analytical errors, analytical and post-analytical errors respectively.

**FIGURE-1**

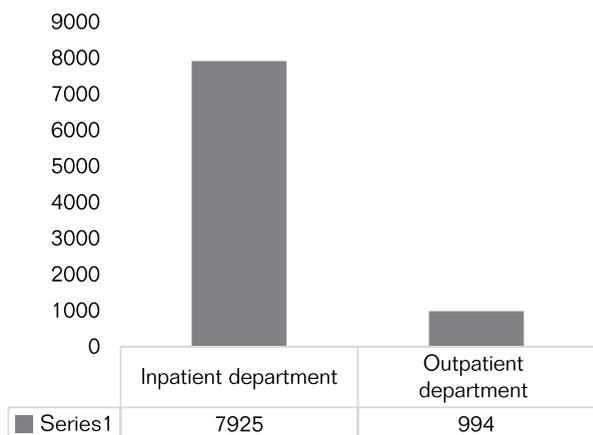
**Frequency of various laboratory Errors**



Of the total 8919 pre-analytical errors, 7925(88.9%) were detected in the IPD samples while 994(11.1%) were detected in the OPD samples as depicted in Figure-2.

**FIGURE-2**

**Comparison of frequency of pre-analytical errors between IPD and OPD**



The commonly encountered pre-analytical errors in are shown in Table-I.

**TABLE-I**

**Frequency of pre-analytical errors.**

Sr. No.	Types of Pre-Analytical errors	IPD (n= 7925)	OPD (n= 994)	Frequency	Percentage
1	Heamolyzed sample	5706	437	6143	68.9
2	Unlabelled vial	1425	394	1819	20.4
3	Quantity not sufficient (QNS)	271	97	368	4.1
4	EDTA contamination	180	53	233	2.6
5	IV Contamination	202	-	202	2.3
6	Wrong vial	96	-	69	1.1
7	Illegible hand writing	16	10	26	0.3
8	Empty vial	20	-	20	0.2
9	Spillage	9	3	12	0.1

**DISCUSSION**

Laboratory diagnostics have been transformed from manual to complex testing methods, to fully automated systems, but all the three phases i.e. pre-analytical, analytical and post-analytical of laboratory are still vulnerable to errors. Developing a strategy to understand the errors, note them down, evaluate methods to identify and prevent them is considered as the first step to the patient safety.<sup>1</sup>

In this background this study was carried out in Clinical chemistry section of the KEMU / Mayo Hospital. A total of 135,000 samples were collectively added in our study from the IPD and OPD of the hospital, in a six month period. Out of these, 12,852(9.52%) total errors including pre-analytical, analytical and post-analytical errors were detected. There has been varied information on error rate within whole laboratory testing procedure (0.1%-9.3%).<sup>12</sup> Comparing our study with other studies done in tertiary hospital laboratories gave varied results, with 1.48% errors in a study by Alavi et al., while 15.3% in other study by Teshome et al.,<sup>5,13</sup>

The pre-analytical, analytical and post-analytical

errors in our study were 8919 (69.4%), 1607 (12.5%) and 2326 (18.1%) respectively. The findings of our study are comparable to other studies that showed that majority of laboratory errors occur in the pre-analytical phase (61.9 - 68.2%), followed post-analytical (18.5 - 23.1%) and analytical (13.3 - 15%) phase of the total testing process (TTP).<sup>14-16</sup>

The errors were mostly encountered in pre-analytical phase followed by post-analytical and analytical phase. The findings of our study are in accordance with the study by Sadiq et al.<sup>7</sup>. The results are also comparable to previous studies showing most of the errors in the pre-analytical phase.<sup>2,3,6</sup>

The commonly encountered pre-analytical errors in our study were haemolysis, unlabelled vial, quality not sufficient (QNS), EDTA contamination, IV contamination, wrong vial, illegible handwriting, empty vial and spillage. Hemolysis was the most common pre-analytical error followed by unlabelled vials and quantity not sufficient (QNS).<sup>7,13,17,18</sup> In vitro haemolysis remains the leading cause of unsuitable specimens for both outpatient and inpatient samples. The possible causes of haemolysis are improper phlebotomy technique, including the clenching of fists by patients during sampling, forcing blood through a fine needle, vigorous shaking of tubes after collection and during transportation, high speed centrifuge and freezing and thawing of the samples. Haemolysis leads to falsely elevated potassium, aspartate amino transferase (AST), lactate dehydrogenase (LDH).<sup>16,19-21</sup>

Unlabelled vial (20.4%) was the second common error found in our study. The findings are comparable to study by Alavi et al.,<sup>5</sup> Different studies concluded varied results for this error. The results of our study are contrary to study by Bhutani et al., and Dikmen et al., in which unlabelled vial was not a common error.<sup>18,22</sup> According to the Centres for Disease Control and Prevention (CDC) guidelines, a specimen should be labelled with patient name, patient ID number etc. in the presence of the patient, before or after phlebotomy.<sup>16</sup>

QNS (4.1%) was the third common error found in our study. The findings are relatively closer to study by Alavi et al., in which 8.8% of the total pre-analytical

errors were found to be of insufficient volume. The findings are not in accordance with the studies by Bhutani et al., Zaini et al., and Dikmen et al., in which QNS was the frequent.<sup>5,18,22,23</sup> The main reason for this error is the ignorance of phlebotomist, difficult sampling in paediatric, debilitated and chemotherapy patients and those with difficult veins localization.<sup>19</sup>

EDTA contamination was found to be 2.3% of pre-analytical errors. EDTA contamination happened when order of draw is not obeyed, i.e., Lavender top tube is filled before golden top vial. The findings are in agreement with the study by Sharratt, and Gilbert's. This study didn't reproduce the findings of White et al., due to far smaller sample size of the study. EDTA contaminated were determined according to the following criteria: hyperkalaemia (> 6.0 mmol/L), hypocalcaemia (ionized calcium < 0.70 mmol/L), normal renal functions and LDH.<sup>24,25</sup> Although sequence of sample draw is recommended, still it remains one of the commonest mistake.<sup>16,26</sup> This error can be reduced by training and awareness as was seen in another study.<sup>27</sup>

Another commonly found pre-analytical error in the IPD samples was the sample contamination by IV line (2.2%). The results are similar to study by Dikmen et al. According to a study done by Plebani and Carro in 1997 and then 2007, 20.6% errors were due to direct sample collection from IV lines in 1997 and 1.9% in 2007 that shows that error rate can be grossly decreased by great focus on the phlebotomy techniques.<sup>14,15,22</sup> This error was detected as diluted sample after centrifugation or during result verification, when all results are extremely low except electrolytes.

The sample in wrong vacutainer was relatively less frequent error (1.1%) in our study. The results are similar to the study by Bhutani et al.<sup>18</sup> The training on use and interference of different vacutainers additives on different analytes can help to reduce this error.<sup>16</sup>

Illegible handwriting was found to be 0.3% on the test request forms. According to a research by Chhillar et al., it was found to be the major error making 89.29% found in all of the requisition forms. The major reason is the casual attitude of

the phlebotomist. It results in waste of time and resources. This can be reduced by computerised requisition of tests.<sup>17,28</sup>

The empty vials were found to be 0.2% of the total pre-analytical errors in our study. The findings are comparable to study by Goswami et al., but not in agreement with studies by Plebani et al., The empty vials were mainly received from In Patient Department. The main reason of this error may be due to inattentiveness of the nurses/ young doctors. It may also occur when during transportation, the sample is lost by the ward boys and instead of going through the proper channels of informing the staff, they replace it with an empty vial.<sup>15,17</sup>

The spillage of sample due to test tubes breakage during centrifugation or the samples spilled while transportation were found to be 0.1% of the total pre-analytical errors. This result was similar to the study by Teshome et al., (13). Kale et al., found 0.4% tube breakage errors in centrifuge, while Goswami et al., found 0.6% breakage errors out of the total errors seen in laboratory which was different than our study.<sup>17,29</sup>

The pre-analytical errors in our study were more in the indoor samples (89%) as compared to the outdoor samples (11%). The findings are similar to studies by Ian et al., and Sadiq et al., The reason underlying this trend is that in OPDs the sample is drawn by trained phlebotomists with SOPs. On the other hand, the sampling in IPD is performed by nursing students or the trainee doctors who are not directly under laboratory's control. Moreover, the phlebotomy of OPD patients is relatively easy than admitted patients.<sup>7,11</sup>

## CONCLUSION

On the basis of findings of our study, we concluded that pre-analytical errors were the most common followed by post analytical and analytical errors. Pre-analytical errors were 69.4 percent of all the errors The pre-analytical errors were more common in IPD samples than samples received from OPD. Haemolysis was the most common pre-analytical error followed by unlabelled vials and QNS constituting 68.9%, 20.4% and 4.1% respectively. High pre-analytical are attributed due to involvement

on many non-laboratory professionals in this phase. The very high percentage of pre-analytical errors in a tertiary care hospital demands training of phlebotomy staff particularly the staff in IPD section.

## ACKNOWLEDGMENT

The authors acknowledge the valuable support of Mr. Aslam Hayat and Mr. Muhammad Irtza Tanveer for their dedicated assistance in the successful completion of this research project.

## CONFLICT OF INTEREST

The authors declare no conflict of interest.

## SOURCE OF FUNDING

This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

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## AUTHORSHIP AND CONTRIBUTION DECLARATION

1	<b>Kainaat Mahzaib John:</b> Conceptualization of study, write up.
2	<b>Maliha Simran:</b> Data collection, literature search.
3	<b>Rehma Dar:</b> Proof reading.