

# Analysis of preanalytical errors in a clinical chemistry laboratory

## A 2-year study

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### Abstract

Patient safety and medical diagnosis of patients are mainly influenced by laboratory results. The present study aimed to evaluate the errors in the preanalytical phase of testing in a Clinical Chemistry diagnostic laboratory.

A review was conducted at the Clinical Chemistry Laboratory of a hospital in Saudi Arabia from January 2019 to December 2020. Using the laboratory information system, the data of all canceled tests and requests were retrieved and evaluated for preanalytical errors.

A total of 55,345 laboratory test requests and samples from different departments were evaluated for preanalytical errors. An overall rate of 12.1% (6705) was determined as preanalytical errors. The occurrence of these errors was found to be highest in the emergency department (21%). The leading preanalytical errors were nonreceived samples (3.7%) and hemolysis (3.5%). The annual preanalytical errors revealed an increasing rate in outpatient and inpatient departments, while a decreasing rate was observed in the emergency department. An increased rate of errors was also noted for the 2-year study period from 11.3% to 12.9%.

The preanalytical phase has a significant impact on the quality of laboratory results. The rate of error in the study was high and the leading causes were nonreceived samples and hemolysis. An increased occurrence of hemolyzed samples in the outpatient department was noted. Enhanced educational efforts emphasizing specimen quality issues and training in sample collection among hospital staff must be carried out.

**Abbreviations:** ED = emergency department, IPD = inpatient department, OPD = outpatient department.

**Keywords:** clinical chemistry, laboratory errors, preanalytical errors, Saudi Arabia

## 1. Introduction

Patient safety and the medical diagnosis of patients are mainly influenced by laboratory results. Literature studies have revealed that 60% to 70% of medical diagnostic decisions are made based on accurate laboratory tests.<sup>[1]</sup> Identifying errors and failures in the system and the causes of these is a dynamic way of ensuring patient safety. Substantial error rates consistently occur in clinical laboratories, even with advanced automation in diagnostic laboratories.<sup>[2]</sup> Understanding and awareness of the sources of errors are crucial for resolving unexpected laboratory results that are not correlated with clinical information.<sup>[3]</sup>

A distinct and intricate process within laboratory medicine includes laboratory procedures, instruments, technology, and

human skills intended to warrant accurate, precise, and appropriate diagnosis and treatment decisions. This is known as the total testing process.<sup>[4]</sup> Laboratory errors are not limited to the analytical phase but can arise in any of the 3 distinct phases: preanalytical phase, analytical phase, and postanalytical phase. Thus, identifying and reducing errors and the risk of errors in laboratory medicine is challenging. Furthermore, assessing the impact of laboratory errors is difficult and often leads to inaccurate clinical decisions, delayed diagnoses, prolonged hospitalization, and increased demand for resources.<sup>[5]</sup> The major source of errors in laboratories occurs in the preanalytical phase, with over 46% to 68%.<sup>[6]</sup>

Studies of laboratory errors in clinical chemistry revealed different rates and causes. In a study conducted in Makkah, Saudi Arabia, a rate of 2.07% preanalytical errors was reported, of

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which hemolysis and clotted sample were the leading causes.<sup>[7]</sup> Similar studies also found that inappropriate sample containers, insufficient sample volume, specimen handling, storage, and transportation were among the common errors.<sup>[8]</sup> In addition, studies revealed that different departments showed different rates and types of errors even within the same institution; highest errors in the emergency department (ED) and lowest in the outpatient department (OPD).<sup>[9]</sup> In EDs, urgent and accurate test results are crucial, but due to workload pressures and various health care professionals involved, it increases the likelihood for preanalytical errors, including patient identification errors or mislabeling and inadequate mixing causing clotted samples.<sup>[10]</sup>

The participation of various professionals, such as nursing, physicians, laboratory scientist, laboratory technicians, and phlebotomists, makes the preanalytical phase the most essential and challenging to regulate and monitor.<sup>[5]</sup> Underreported and undervalued influence of preanalytical is due to inadequate attention on what occurs to samples before reaching the laboratory.<sup>[11]</sup> Hence, the present study aimed to evaluate the errors in the preanalytical phase of testing in a clinical chemistry diagnostic laboratory in Saudi Arabia. This study underscores the need for quality controls and quality assurance in the preanalytical phase to monitor existing errors to improve patient safety and laboratory diagnosis.

## 2. Methods

### 2.1. Study design and setting

The study was conducted at the Clinical Chemistry Laboratory of a hospital in Saudi Arabia, a 200-bed capacity with inpatient, outpatient, and emergency services. The department of Clinical Laboratory provides clinical chemistry services throughout the hospital apart from the routine and special laboratory tests from other sections of the clinical laboratory. The data in this study cover the period from January 2019 to December 2020. Specimen collections are done by nonlaboratory personnel in all the hospital departments or wards.

### 2.2. Data collection procedure

Using the laboratory information system, the data of all unacceptable, rejected specimens and canceled tests in the clinical chemistry laboratory was retrieved and analyzed for preanalytical errors following the approval of the study protocol by

the Research Ethics Committee and permission from laboratory director. Preanalytical errors were carefully determined and recorded. Laboratory requests and patient samples from the emergency, outpatient, and inpatient departments that were received from the 2-year retrospective analysis period were included in the study.

### 2.3. Statistical analysis

The frequency of preanalytical errors was determined and the rate of errors was calculated and expressed as frequencies and percentages as compared to the total samples received. Assessment of data and all statistical analyses were done using SPSS version 21. The difference between relative frequencies of errors observed in the different departments was tested using the chi-square test. A *P* value of  $\leq .05$  was considered statistically significant.

### 2.4. Ethical statement

Approval of the study protocol was obtained from the University of Hail, Research Ethics Committee (H-2021-247). Written permission was also granted by the hospital laboratory director of the Clinical Laboratory. The data were utilized only for research purposes.

## 3. Results

A total of 55,345 laboratory requests and samples from different departments and wards were evaluated for preanalytical errors. An overall rate of 12.1% (6705) was determined as preanalytical errors. The occurrence of these errors was found to be highest in the ED (21%) as compared to the inpatient department (IPD; 13.4%) and the outpatient department (7%). The overall leading preanalytical errors were nonreceived sample (3.7%) and hemolysis (3.5%). Notably, in the OPD, the single most common preanalytical error was hemolysis (4.2%), whereas 6.1% of the preanalytical errors in the ED were due to nonreceived samples and 5.7% of the preanalytical errors were due to "unauthorized order." For the IPD, 4.8% of the preanalytical errors were nonreceived samples and 3.3% of the preanalytical were hemolyzed samples. The least among the preanalytical errors from all the departments was "specimen contamination" (0.01%) that occurred in the IPD only (Table 1).

**Table 1**

**Distribution and analysis of preanalytical errors in different departments.**

	Total, n (%)	Emergency, n (%)	Outpatient, n (%)	Inpatient, n (%)
Number of requests	55,345	3635 (6.6)	15,313 (27.6)	36,397 (65.8)
Preanalytical errors	6705 (12.1)	764 (21)	1071 (7.0)	4870 (13.4)
Nonreceived sample	2056 (3.7)	222 (6.1)	104 (0.7)	1730 (4.8)
Hemolysis	1956 (3.5)	127 (3.5)	645 (4.2)	1184 (3.3)
Insufficient sample quantity	926 (1.7)	38 (1)	65 (0.4)	823 (2.3)
Incorrect test order	631 (1.1)	89 (2.4)	103 (0.7)	439 (1.2)
Transport specimen errors	245 (0.4)	15 (0.4)	0 (0)	230 (0.6)
Unauthorized order	241 (0.4)	208 (5.7)	22 (0.1)	11 (0.03)
Duplicated test request	189 (0.3)	10 (0.3)	96 (0.6)	83 (0.2)
Inappropriate tube	103 (0.2)	17 (0.5)	3 (0.02)	83 (0.2)
Wrong barcode placement	81 (0.1)	7 (0.2)	2 (0.01)	72 (0.02)
Specimen broken, leaked, compromised, etc	60 (0.1)	0 (0)	0 (0)	60 (0.2)
Incorrect sample/anticoagulant ratio	50 (0.09)	7 (0.2)	2 (0.01)	41 (0.1)
Wrong collection procedure	49 (0.09)	13 (0.4)	4 (0.03)	32 (0.09)
Clotted specimen	46 (0.08)	1 (0.03)	12 (0.08)	33 (0.09)
Labeling errors	36 (0.07)	1 (0.03)	13 (0.08)	22 (0.06)
Incomplete data	29 (0.05)	9 (0.3)	0 (0)	20 (0.05)
Specimen contamination	7 (0.01)	0 (0)	0 (0)	7 (0.02)

Of the 6705 preanalytical errors found in the study, 72.6% (4870) were mainly from the IPD, whereas 16% (1071) were from the OPD and 11.4% (672) from ED. Non-received samples account for 30.7% of the preanalytical errors, whereas 29.2% were hemolyzed samples (Table 2). Analysis of the annual preanalytical errors revealed an increasing rate in the OPD and IPD, whereas a decreasing rate was observed in the ED (Table 3). An increased rate of errors was also noted for the 2-year study period from 11.3% to 12.9%. Statistically, no significant difference exists between the different departments ( $P = .128$ ).

#### 4. Discussion

Laboratory errors can negatively impact the quality of laboratory results and have adverse consequences on diagnosis and patient care. Recognition and documentation of these errors are crucial phases in enhancing the quality of laboratory medicine.<sup>[11]</sup> The rates of preanalytical error in the present study revealed that ED exceeded those from IPD and OPD. A similar finding was reported in the study by Zaini et al.<sup>[7]</sup> Emergency and inpatient departments represent a large number of samples received, high workload pressures, more challenging group, and more difficulty in collecting blood samples.

The present study determined a rate of 12.1% of preanalytical errors from the total samples and laboratory requests received from the different departments. The result was much lower than those in similar studies conducted in Egypt (43.7%),<sup>[12]</sup> Iraq (39%),<sup>[6]</sup> and Ethiopia (24%).<sup>[13]</sup> In contrast, the present finding was higher than the studies conducted in Tunisia (7.7%), Ghana (3.7%), Greece (1.94%), and India (0.15%).<sup>[14]</sup> Lower rates were also reported in Saudi Arabia ranging from 1.3% to 3.15%.<sup>[7,15,16]</sup> Variation of the quality indicators used, sample acceptance and rejection criteria, length of the study periods, reporting and recording system, sample

size, and laboratory facilities are factors that contribute to the disparity of results.

The majority of preanalytical errors in the study include nonreceived samples (30.7%) and hemolysis (29.2%). Notably, nonreceived samples were the most prevalent in ED (6.1%) and IPD (4.8%), while hemolysis (4.2%) was predominantly observed in OPD. Consistent with our findings, the Spanish Preanalytical Quality Monitoring Program found that nonreceived samples (34.5%, 37.5%) and hemolysis (29.3%, 36.2%) are the most frequent cause of serum sample rejections for the span of 12 years.<sup>[17]</sup> In another study, nonreceived samples (25.5%) were reported as the major preanalytical errors.<sup>[18]</sup> This error is a process indicator that provides data on sample collection since nonreceived samples will prompt a new request for sample collection.<sup>[18]</sup> Difficulties in blood sample collection, absence of assigned unit to receive and distribute samples, low automation in the routine preanalytical phase, and the low level of integration in a laboratory's divisions are the possible sources of these errors.<sup>[19,20]</sup>

Another leading preanalytical error in this present study was hemolysis (29.2%). Noticeably, hemolyzed sample was the most common error in the OPD. In contrast, literature studies provide excellent evidence that EDs have a higher incidence of hemolysis than other wards or outpatient phlebotomy services.<sup>[21,22]</sup> Moreover, studies suggest that hemolysis rates are higher when specimens are not collected by professional phlebotomists.<sup>[22]</sup> Based on this, it appears that specimen or blood collections from the other departments (ED and IPD) were done by more trained and experienced clinical staff. Furthermore, incorrect handling and storage of samples, increase workload pressure, inconsistent monitoring, and inadequate support in the OPD are factors that contribute to its high occurrence. Hemolysis accounts for 40% to 70% of all rejected and unsuitable samples in clinical laboratories.<sup>[23]</sup> Though this present study recorded a lower rate, hemolysis is still considered a major source of preanalytical errors. Frequent clinical chemistry tests that are most sensitive to hemolysis include lactate dehydrogenase, creatine kinase, MB isoenzyme of creatine kinase, potassium, conjugated bilirubin, alanine aminotransferase, aspartate aminotransferase, and iron.<sup>[24]</sup>

Interestingly, unauthorized order was remarkably high in ED. This type of error refers to a laboratory request entered electronically by staff that is otherwise not allowed or has limited access to test requisitions. This error was almost exclusively seen in ED with a 5.07% occurrence rate. The high rate of this error implies that ED clinical staff were not fully oriented to this criteria or policy. However, analysis showed a significant decline in this error over the 2 years from 40.1% to 17.2%. There was no focus on this error or data, but the decline can be credited to appropriate communication with the laboratory department, increase experience of staff, and proper orientation of test requisition system to new hospital staff. Furthermore, a decline was also observed over the 2 years in the following: nonreceived samples, insufficient sample quantity, specimen broken, leaked, compromised, etc, duplicated test requests, labeling errors, and incomplete test request data. On the contrary, an increase was noted in hemolysis, transport specimen errors, wrong collection procedure, and wrong barcode placement (Figure 1). These errors are associated with each other, such that wrong collection procedures and incorrect sample transport can potentially lead to sample hemolysis. Moreover, it was noted that transportations of laboratory specimen were done by untrained hospital staff. Inexperienced phlebotomist/staff, insufficient training and education on sample collection and quality, and heavy workload are other factors that could contribute to these errors. An observational study conducted in 12 European countries by the European Federation of Clinical Chemistry and Laboratory Medicine reported unacceptably low compliance of phlebotomy procedures following the Clinical and Laboratory Standards Institute H3-A6 guidelines.<sup>[25]</sup>

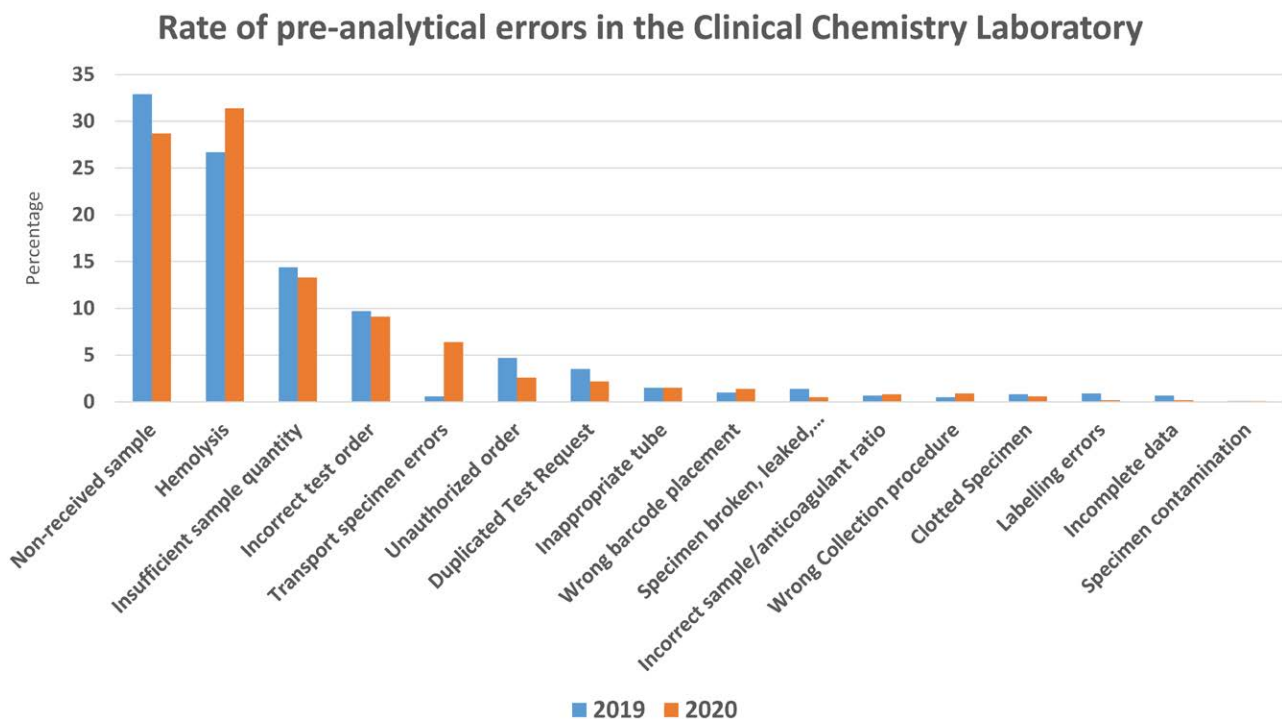
**Table 2**  
Distribution and percentage of errors in the preanalytical phase (total (N) = 6705).

Preanalytical errors	n	(%)
Nonreceived sample	2056	30.7
Hemolysis	1956	29.2
Insufficient sample quantity	926	13.8
Incorrect test order	631	9.4
Transport specimen errors	245	3.7
Unauthorized order	241	3.6
Duplicated test request	189	2.8
Inappropriate tube	103	1.5
Wrong barcode placement	81	1.2
Specimen broken, leaked, compromised, etc	60	0.9
Incorrect sample/anticoagulant ratio	50	0.7
Wrong collection procedure	49	0.7
Clotted Specimen	46	0.7
Labeling errors	36	0.5
Incomplete test request data	29	0.4
Specimen contamination	7	0.1

**Table 3**  
Overall errors in the preanalytical phase in different departments.

Year	2019 % (error/total)	2020 % (error/total)	Total % (error/total)
ER	23.2 (334/1440)	19.6 (430/2195)	21 (764/3635)
OPD	6.4 (496/7781)	7.6 (575/7532)	7 (1071/15,313)
IPD	12.4 (2316/18,622)	14.4 (2554/17,775)	13.4 (4870/36,397)

ER = emergency department; IPD = inpatient department; OPD = outpatient department.



**Figure 1.** Preanalytical errors in the Clinical Chemistry Laboratory.

The large ratio of laboratory errors in the preanalytical phase stems from the spectrum of variables, including patient variables, specimen collection variables, and specimen handling variables. Some are predictable, whereas others are beyond control and must be understood in order to resolve and interpret appropriately (eg, cold agglutinins in winter seasons).<sup>[26,27]</sup> The foremost step in enhancing the quality of the preanalytical phase is to define potential errors and evaluate which errors pose a danger for the outcome of the patient. The increasing rate of preanalytical errors in this study and more specifically in OPD and IPD suggests the need to review the existing preanalytical procedures and explore if procedures should be changed to reduce the risk of errors. Moreover, continual monitoring and analysis of the frequency of laboratory errors should be regularly done to determine improvements and patterns that may exist.

The findings of the present study provide a critical and valuable source of information that could systematically support quality management of the laboratory testing process to promote diagnostic excellence in the laboratory and patient care settings. This will encourage managers, quality officers, and administrative leaders to participate or engage in quality monitoring systems and become more open to scrutiny and challenge. Managers may be driven toward the adoption of internal or external quality monitoring systems. Further, this may result in a focus on audit trails that provide documentary evidence before making decisions and policies, and implementing or improving strategies or practices. Our findings are timely and may stimulate leaders to emulate or conduct collaboratively with all other laboratories in the region to achieve uniformity and a standardized recording and monitoring system. While the study has presented facts or data that can potentially direct and support the quality teams in this institution, this provides an opportunity to further refine and validate our analysis and conceptualize a new approach to monitoring and evaluating laboratory quality performance.

## 5. Conclusion

Preanalytical errors have a significant impact on the quality of laboratory results and patient safety. Errors in this phase pose

serious consequences and potentially compromise the correct diagnosis and management of patients. The rate of error in the study was high and the leading causes were nonreceived samples and hemolysis. An increased occurrence of hemolyzed samples in the OPD was noted. These errors are associated with sample collection and handling; thus, suggesting that enhanced and continuing educational efforts emphasizing specimen quality issues and training in sample collection among hospital staff must be carried out. Likewise, data from this study can serve as guides in defining new approaches and strategies in decreasing the errors in the preanalytical phase. This study can direct and support the quality teams in this institution to establish quality improvement plans, incorporate corrective measures, and develop a systematic quality assessment tool to monitor the preanalytical phase and evaluate the laboratory or hospital performance. The authors have communicated with the laboratory, and quality measures and interventions were initiated.

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