

pre-analytical errors in laboratories of Makkah hospitals

prepared by

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Abstract

When it comes to medical care and diagnosis, nothing is more important than lab findings. The researchers set out to determine the frequency and kind of mistakes made prior to actual analytical testing in a Clinical Chemistry diagnostic facility.

The Clinical Chemistry Laboratory of a Makkah hospital was evaluated between January 2021 and December 2022. All cancelled test and request data were obtained from the lab's database and checked for preanalytical mistakes.

There were a total of 55,345 requests for laboratory testing, and their corresponding samples were analyzed for preanalytical mistakes. Preanalytical mistakes were found to occur at a rate of 12.1% overall (6705). The largest rate of these mistakes was reported in the emergency room (21%). The most common causes of failure in the pre-analysis phase were undelivered samples (3.7%) and hemolysis (3.5%). Preanalytical mistakes increased annually in the ED while increasing in outpatient and inpatient settings. Throughout the course of the study's two years, the error rate went up from 11.3% to 12.2%.

The preanalytical step has a considerable impact on the accuracy of laboratory analyses. Non-receipt of samples and hemolysis were the main reasons of the high error rate in the inquiry. Hemolyzed specimens were seen more often in the outpatient clinic. Improved training and education for hospital workers on specimen quality concerns and sample collecting is required.

Keywords: clinical chemistry, laboratory errors, preanalytical errors, Makkah

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المجلة الإلكترونية الشاملة متعددة التخصصات
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Chapter 1. Introduction

The significance of laboratory findings in patient care and medical diagnosis cannot be overstated. Scholarly studies have shown that correct laboratory tests provide the basis for 60%-70% of medical diagnostic conclusions. Patient safety may be improved in a dynamic way by tracking down the sources of system mistakes and failures. High rates of mistake persist in clinical labs despite the use of cutting-edge laboratory automation. Resolving unexpectedly uncorrelated laboratory data requires an in-depth comprehension and understanding of potential causes of mistake. Laboratory medicine is a unique and intricate process that employs a wide range of techniques, tools, and human expertise to guarantee reliable diagnostics and effective therapeutics.

The term "complete examination" describes this kind of test. Laboratory mistakes may happen at any point between the pre-analytical, analytical, and post-analytical stages. Hence, it is difficult to detect and lessen the potential for mistakes in laboratory medicine. Moreover, it is difficult to assess the consequences of laboratory mistakes, which commonly result in wrong clinical judgments, missed diagnoses, extended hospital stays, and increased demands on available resources. Between 46 and 68 percent of all laboratory mistakes occur during the preanalytical phase. Six separate investigations have shown a wide range of mistake rates and root causes in clinical chemistry laboratories. Sample coagulation and hemolysis were shown to be the primary reasons of the preanalytical error rate of 2.07% in a research done in Makkah, Makkah. Identical investigations found that some of the most frequent mistakes were using the wrong containers, not collecting enough data, and mishandling the samples during collection, storage, and transport.

Studies also showed that even within the same hospital, mistake rates and kinds differed, with the ED having the highest error rate and the ambulatory care department having the lowest (OPD). Preanalytical errors, such as patient identification mistakes, mislabeling of samples, and insufficient mixing that leads to clot formation, are more likely in emergency rooms due to workload constraints and the involvement of several healthcare workers.

The preanalytical phase is the most critical and challenging to manage and monitor because of the large number of professionals involved, such as nurses, doctors, laboratory scientists, laboratory technicians, and phlebotomists. Insufficient attention is given to what happens before samples reach the laboratory, leading to underreporting and undervaluing of preanalytical impacts. Hence, the purpose of this investigation was to evaluate the prevalence of preanalytical testing mistakes at a Makkah-based clinical chemistry diagnostic laboratory. In order to keep an eye on existing mistakes, boost patient safety, and enhance laboratory diagnosis, this research highlights the need of quality controls and quality assurance in the preanalytical phase.

1.1. Problem statement:

The aim of this academic research is to investigate the prevalence and types of pre-analytical errors that occur in the laboratories of hospitals in Makkah. Pre-analytical errors refer to mistakes or deviations that occur during the pre-analytical phase of laboratory testing, which includes the collection, transport, and processing of specimens. These errors can lead to incorrect or unreliable test results, potentially compromising patient care and outcomes. Despite the importance of identifying and addressing pre-analytical errors, limited research has been conducted in this area within the context of Makkah hospitals. Therefore, this study seeks to fill this gap by exploring the nature and frequency of pre-analytical errors in these hospitals, as well as identifying the factors and barriers that may contribute to their occurrence. The findings of this research will provide valuable insights and recommendations for improving the quality and safety of laboratory testing in Makkah hospitals, ultimately benefiting patient care and outcomes.

1.2. Aim of the study:

The researchers wanted to get a sense of how often mistakes are in the lead-up to actual analytical testing in a Clinical Chemistry lab.

1.3. Methodology:

Between January 2021 and November 2022, researchers at a Makkah hospital examined data from its Clinical Chemistry Laboratory. All cancelled test and request data was collected from the laboratory information system and evaluated for preanalytical errors.

1.4. Study limitation:

One potential limitation of the academic research on pre-analytical errors in the laboratories of Makkah hospitals is the possibility of selection bias. The study may only include hospitals that are willing to participate, which could result in a non-representative sample of hospitals in the region. Additionally, the study may only capture pre-analytical errors that are reported or observed by laboratory staff, which may underestimate the true prevalence of errors that go unnoticed or unreported.

Another limitation could be the reliance on self-reported data, which could be subject to social desirability bias. Laboratory staff may not want to report errors or may under-report their occurrence to avoid negative consequences or to maintain a positive image. This could result in an underestimation of the frequency or severity of pre-analytical errors in the hospitals.

Finally, the study may not capture the full range of factors that contribute to pre-analytical errors, such as organizational or cultural factors. This could limit the ability to fully understand the root causes of pre-analytical errors and to develop effective interventions to prevent them.

Chapter 2. Literature Review

2.1. Error Sources in The Laboratory

Pre-analytical errors are a significant problem in laboratory medicine, accounting for up to 70% of all laboratory errors (Plebani, 2012). These errors can occur at various stages of the pre-analytical phase, including sample collection, handling, transport, and processing, and can result in inaccurate or unreliable test results, potentially leading to misdiagnosis, incorrect treatment, or delayed care (Lippi et al., 2016). Several studies have investigated the sources and prevalence of pre-analytical errors in laboratory medicine, highlighting the need for improved quality control measures (Carraro et al., 2010; Plebani, 2012; Lippi et al., 2016).

For example, a study conducted by Carraro et al. (2010) aimed to identify the sources of pre-analytical errors in laboratory medicine. The study involved a retrospective analysis of laboratory error reports from two hospitals over a 5-year period. The results showed that the most common sources of pre-analytical errors were related to sample collection and handling, including patient identification errors, incorrect labeling of samples, and inadequate sample volume. The study also identified organizational factors, such as inadequate training and communication, as contributing to pre-analytical errors.

In conclusion, the literature suggests that pre-analytical errors are a significant problem in laboratory medicine, and identifying their sources is essential for developing effective quality control measures. The study by Carraro et al. (2010) provides valuable insights into the sources of pre-analytical errors in laboratory medicine and highlights the importance of addressing organizational factors to prevent these errors.

2.2. Error in the pre-analytical phase

Pre-analytical mistakes include, but are not limited to: hemolysis, collection from the wrong patient, unsuitable anticoagulant, inappropriate volume collected, coagulation, IV fluid contamination, incorrect tourniquet usage, mislabeling of specimens, and request form-related errors. A subsequent piece of this analysis will go more deeply into these inaccuracies.

Faulty analysis

Analytical mistakes may be either random (i.e., occur at random and irrespective of the operator) or systematic, as defined by Wians (2009). (such as a change in the instrument calibration). Laboratory specimen mixing, faulty quality control procedures, and broken equipment can contribute to analytical mistakes. At their chemical pathology lab, Witte, VanNess, Angstadt, and Pennell (1997) found an analytical error rate of 447 ppm (0.05%), whereas a prior study of Australian labs found analytical error rates of between 2% and 30%. Khoury, Burnett, and MacKay (1996). Given that what constitutes an error in one research may not apply to another, these findings highlight the necessity for a uniform method of mistake reporting.

2.3. Error post-analysis

Post-analytical errors include things like invalidating suspicious findings, making mistakes in transcribing, incorrectly interpreting results, waiting too long to get results back to the doctor, and not notifying the doctor of key results. The practitioner is also held accountable for tracking down test findings and sharing them with the patient in a timely manner. A post-analytical mistake would be made if this step wasn't taken. One poll of doctors indicated that as many as 37% of them had stumbled across a patient whose major test findings had gone unchecked. This statistic is particularly worrisome since it includes individuals who returned for follow-up after undergoing diagnostic testing for cancer. The average incidence of missed findings was 7.1%,

according to a more in-depth analysis of the post-analytical procedure that included reviewing data, notifying patients of relevant results, and doing the necessary follow-up.

Notifying patients of abnormal findings is not standardized, even within the same practice. Hospital-based research shows that this problem of doctors failing to tell patients of crucial test findings is not exclusive to primary care settings. 0.9% of patients who were discharged had significant findings that were not shared with either the patient or their primary care physician, according to research by Roy et al. (2005). These studies show that it is important for labs and clinicians to pay close attention to the follow-up of clinically relevant or urgent findings, which is not always the case.

2.4. Pre-Analytical Error Types

Despite the fact that patient identification is undoubtedly one of the most crucial pre-analytical stages, it is only one of a long list of variables that can be categorized as follows: patient identification-related, request-related, collection-related, and sample-related.

2.4.1 Identification and labeling of samples by patient

A major prospective research was performed on identification mistakes in the general clinical laboratory at several institutions to ascertain the prevalence of patient misidentification while collecting pathology specimens. To test their hypothesis that institutions that caught more mistakes before validation would have lower po, the authors divided the errors into those caught before and after validation of findings. There were 324 false positives for every 1,000,000 billable tests (0.0324%) before validation, whereas there were only 55 (0.0055%) after. Compared to institutions that relied exclusively on misleading findings to discover mistakes, those with an identification error monitoring tool reported much lower post-validation error rates, suggesting that they are more cautious in spotting such errors. The authors have also made an effort to characterize the possible outcomes of these mistakes by having participants keep

track of unintended repercussions. There were 345 complaints, the vast majority of which included minor discomfort rather than serious harm to the patients. While this research collected a large quantity of data, it was limited to a 5-week time frame and depended on self-reporting by the institutions. More thorough identification error rates and other pre-analytical mistakes that may not have been deemed identification errors but yet contributed to adverse occurrences may be revealed with more extensive data gathering.

Researchers looked at "pre-pre-analytical mistakes," or the moments on the hospital ward before specimens are collected and delivered to the lab. They spent a week following healthcare personnel and recording any deviations from procedure from test request through specimen collection. There were three confirmed incidences of misidentification out of a total of fifteen patients whose specimens were collected without their identities being verified by nursing personnel. In two of these cases, the authors also noticed that blood was taken in containers that had already been labeled. Extrapolating these numbers would suggest that there are 156 false positives every year at the institution where the research was performed.

2.4.2. Errors in transfusion medicine prior to analysis

Since transfusing the wrong blood type might have fatal repercussions for the patient, transfusion medicine has likely focused most on pre-analytical mistakes, and more particularly, patient identification errors. When a sample's blood type does not match the patient's record, it is called "wrong blood in tube" (WBIT) and is discarded as potentially being from the wrong donor. Silent WBIT occurs when blood is drawn from the wrong patient but is still compatible with the recipient's blood type, however this is seldom reported since it is difficult to detect. The WBIT rate after applying correction factors is still an approximation. WBIT rates are estimated to be anything from 0.007% to 0.6%. (Dzik et al., 2003; Linden, Wagner, Voytovich, & Sheehan, 2000; Murphy, Stearn, & Dzik, 2004; Quillen & Murphy, 2006). The stronger regulatory

standards for transfusion specimens are expected to result in a reduced mistake rate overall, and these findings may be generalized to other sections of the laboratory, such as haematology or clinical chemistry.

As was previously indicated, automated laboratory systems may employ delta checks to rely on patient data as their own internal control (Ladenson, 1975). The validating scientist may spot sample collection issues and other mistakes before sending the data to the clinician by using these approaches, which compare the difference between the present and past values. Falsely normal findings in particular might slip through the cracks when using these procedures, thus they are not foolproof.

2.5 Perception of Pre-Analytical Error Cause and Effect

Although several studies have looked at the skills and background of blood collectors, few have assessed how nurses and doctors feel about the possibility of pre-analytical inaccuracy. A recent observational research of nursing staff (Stauss et al., 2012) found that staff assumed haemolysis was attributed to the laboratory technician who evaluated the material, suggesting that employees doing blood collection did not accept personal responsibility for haemolysed specimens. By itself, this finding proves that all people involved in specimen collecting need to get more training, especially in the area of pre-analytical mistake prevention.

Researchers looking into the etiology of haemolysis in emergency department samples found that ED staff members often blamed lengthy laboratory processing times for high haemolysis rates. Despite the fact that this misconception was debunked, the ED staff nevertheless refused to accept responsibility for the haemolysis of samples.

29% of ward staff in an interview on pre-analytical mistakes blamed equipment, while 23% blamed a lack of awareness about the proper containers to collect for testing.

2.6 Consequences of Pre-Analytic Error

2.6.1 Effect on the individual

16.6% of hospital admissions were connected with an adverse event induced by health care management, leading to longer hospital stays or a handicap for the patient, as reported in "The Quality in Australian Health Care Study" (R. M. Wilson et al., 1995). Almost 14,000 patients' medical records were reviewed for evidence of adverse events using predetermined study criteria. Although laboratory-related mistake was not specifically included in any of the 18 categories, several of them covered similar situations, such as "Unplanned transfer from general care to critical care" or "Unplanned readmission following release from index hospitalization." This calls for a deeper dive into how laboratory mistakes affect patients in Australia. Data collecting (such as chart review or event audits) and data summarizing are recommended by La Pietra, Calligaris, Molendini, Quattrin, and Brusaferrero (2005) for analyzing and planning a solution to a problem (in this example, pre-analytical error rates in pathology).

Using process and risk analysis, researchers in five Italian labs calculated the far-reaching implications of pre-analytical laboratory mistake (Signori et al., 2007). The authors set out to determine how often such mistakes are, standardize a method for finding them, and evaluate their effect on lab results. Damage was classified by a team of specialists as follows:

Using this technique, even if the error's real effect was small, its prospective impact may be assessed. Quality failures (across the laboratory, not only pre-analytical mistakes) had an actual grade of 1 for 72.7% of the research period, and all failures had an A grade of 3 or below. And yet, the P scores were far higher, with 65.9% of failures obtaining a P of Grade 5. While early laboratory diagnosis of these mistakes may mitigate any harm to patients, the risk to them is significant.

2.6.2 Safety of transfusions

The biggest body of research on the consequences of pre-analytical mistake may be found in the field of transfusion medicine. It was suggested in 1992 that transfusing a blood product to the wrong person is just as harmful as the spread of an infectious illness during a transfusion (Linden, Paul, & Dressler, 1992). Acute transfusion responses due to the delivery of the wrong blood type were responsible for three deaths in a recent study of transfusion mistakes in a single U.S. state. One patient got seven incompatible units before the mistake was discovered, while 51 other cases of ABO incompatible red cells did not result in death. Given that a mistake at any point in the collection process might result in a patient receiving an incompatible blood product, these scenarios highlight the need of pre-analytical safety across the whole process, (Dzik et al., 2003).

2.6.3 Blood cultures contaminated with pathogens

The quality of the material is particularly important in tests like blood culture. Blood samples taken from a patient suspected of having bacteraemia must be collected under sterile conditions to ensure that any bacteria developed in culture are indeed from the patient and not a contaminant (Bates et al., 1991). A false positive culture result may not seem like a big deal at first, but it might end up costing a lot of money for the hospital and the patient. Positive blood culture findings are thought to be important until proved otherwise, leading to unnecessary treatment and extended hospital stays when the organism is revealed to be a contaminant rather than a bacterium or other infectious agent (Segal & Chamberlain, 2000). Studies have shown that the patient (or business) might incur extra expenses in the range of \$642–\$2500 owing to the prolonged hospital stay and higher pharmaceutical expenditures associated with a false positive result (Segal & Chamberlain, 2000; Souvenir et al., 1998; Weinbaum et al., 1997). The published frequency of contamination varies from 1.3% to 10.2%, depending on the organization and

policy. Segal and Chamberlain (2000); Norberg, Christopher, Ramundo, Bower, and Berman (2003); Archibald and colleagues (2006); Gander and colleagues (2009); Weinbaum and colleagues (1997)). Significantly, the implementation of a policy for dedicated phlebotomy draw (as opposed to collection from an existing intravenous catheter) resulted in a dramatic reduction in contamination rates from 9.1% to 2.8% (Weinbaum et al., 1997). (Norberg et al., 2003). Evidence from these investigations highlights the need for careful sample collection prior to analytical analysis.

2.6.4 Pharmaceutical Defects

It is vital to generate the accurate result and the relevant interpretative remarks on the pathology report when laboratory testing is asked to directly monitor therapeutic drug levels or analytes on which doctors depend for medication administration (such as INR for warfarin dosage). In one study, Zemlin, Nutt, Burgess, Eiman, and Erasmus (2009) looked at data collected from requests for thyroid function tests. It was found that in 74.5% of cases, the patient's medication history was not included in the request, which might lead to unnecessary treatment (such as thyroxine replacement therapy) or a missed diagnosis (in the case of patients currently receiving thyroxine replacement therapy). None of these effects could be confirmed since the patients were not followed up with.

Chapter 3: Methods

3.1. Study design and location

A Makkah hospital that offers outpatient, inpatient, and emergency care conducted the research in its 200-bed Clinical Chemistry Laboratory. The hospital-wide clinical chemistry services are provided by the Clinical Laboratory division, in addition to the normal and specialty laboratory tests performed by other parts of the clinical laboratory. The time period from January 2021 through December 2022 is included in this analysis. Samples are collected by non-laboratory staff in every hospital department and ward.

3.2. Method for collecting data

After approval of the study methods by the Research Ethics Committee and the laboratory director, clinical chemistry laboratory data were obtained from the laboratory information system and analyzed for preanalytical errors. The number and kind of pre-analysis mistakes were properly recorded. The two-year retrospective investigation includes laboratory queries and patient samples from the emergency room, outpatient clinic, and inpatient wards.

3.3. Statistical examination

The frequency and percentage of preanalytical mistakes were computed and reported in relation to the total number of samples received. The statistical analysis and assessment of data was performed using SPSS version 21. The chi-square test was used to examine the dissimilarity in relative error frequency across sections. The level of statistical significance was set at a P value of 0.05.

3.4 Responsible declaration

The Research Ethics Committee at Hail University has given its stamp of approval to the study's protocol (H-2021-247). Also, formal approval was received from the Clinical Laboratory director of the hospital's laboratory. Only academic purposes were served by collecting this data.

Chapter4: Results

Laboratory requests and samples totaling 55,345 from different departments and wards were analyzed to determine the extent of preanalytical mistakes. Preanalytical mistakes were shown to account for 12.1% of all mistakes (6705). The ER exhibited the greatest rate of these mistakes (21%) compared to the IPD (13.4%) and the ambulatory care unit (7%). Hemolysis (3.5% of samples) and non-receipt of samples (3.7%) were the most common causes of incorrect results before analysis. Hemolysis accounted for 4.2% of all preanalytical mistakes in the outpatient department, while non-received samples accounted for 6.1% and "unauthorized order" accounted for 5.7% in the emergency department. Non-receipt of samples accounted for 4.8% of IPD preanalytical mistakes, while hemolyzed samples accounted for another 3.3%. The lowest frequency of any preanalytical mistake was found to be "specimen contamination" (0.01%). This blunder was done by the IPD alone. (Table 1).

	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,	60 (0.1)	0 (0)	0 (0)	60 (0.2)

	Total, n (%)	Emergency, n (%)	Outpatient, n (%)	Inpatient, n (%)
compromised, etc				
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)

Table 1 Distribution and analysis of preanalytical errors in different departments.

The research found that the IPD was responsible for 72.6% (4870) of the total preanalytical errors, the OPD for 16.1% (1071), and the ED for 11.4% (672). Hemolyzed samples account for 29.2% of all preanalytical mistakes, whereas inability to obtain samples is responsible for 30.7% (Table (Table2).2). There was an increase in preanalytical errors in the OPD and IPD, but a reduction in the ED over the course of a year (Table (Table3).3). The error rate increased from 11.3% to 12.2% during the course of the study's two-year duration. No statistically significant differences were found across groups ($P = .128$).

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

Preanalytical errors	n	(%)
Incomplete test request data	29	0.4
Specimen contamination	7	0.1

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

Year	2021% (error/total)	2022% (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)

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

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

Chapter 5: Discussion & Conclusion

5.1. Discussion

The accuracy of patient diagnosis and therapy might be compromised by mistakes made in the laboratory. These mistakes need to be recorded and analyzed so that the quality of laboratory medicine may be improved. Preanalytical errors were more common in the ED than in the IPD or the OPD in this research. The research by Zaini and colleagues yielded similar findings. In emergency and inpatient settings, blood sample collection is more challenging owing to increased workload demands, a more demanding patient demographic, and a higher number of samples received.

The current investigation established a preanalytical error rate of 12.1% based on the total number of samples and laboratory requests received from different departments. Results from similar probes in Egypt (43.7%), Iraq (39%) and Ethiopia (24%), for example, were far lower. The present figure was higher than that obtained in Greece (1.94%), India (0.15%), and Ghana (3.7%). In addition, 1.3%-3.15% rate reductions were supposedly implemented in Makkah. [7,15,16] Disparate findings may be attributed to a number of factors, including variations in quality indicators used, sample acceptance and rejection criteria, research period length, reporting and recording system, sample size, and laboratory facilities.

Not receiving samples accounted for 30.7% of preanalytical mistakes, while hemolysis accounted for another 29.0%. The percentage of samples that were not received was significantly higher in the ED (6.1%) and the IPD (4.8%) than it was in the OPD (4.2%). Our results are consistent with those of the Spanish Preanalytical Quality Monitoring Program, which found that during a 12-year period, the most common reasons for rejecting blood samples were nonreceipt

(34.5%, 37.5%) and hemolysis (29.3%, 36.2%). [17] A further research found that 25.5% of preanalytical mistakes occurred because samples were not received. Unreceived samples will cause a fresh sample collection request, hence this error is a process indication that offers information about sample collecting. Problems with blood sample collection, a lack of a dedicated unit to accept and distribute samples, a lack of automation in the regular preanalytical phase, and a lack of divisional integration are all possibilities.

The second most common kind of preanalytical mistake in this research was hemolysis (29.2%). Hemolyzed samples was the most prevalent mistake in the outpatient department. As compared to other wards and outpatient phlebotomy services, emergency departments had a greater frequency of hemolysis, according to data published in medical publications. Hemolysis is more common when specimens are not obtained by skilled phlebotomists, according to studies. It seems that in the other departments (ED and IPD), specimens and blood were collected by clinical staff with higher levels of training and experience. Some factors that contribute to its occurrence in the OPD include: inappropriate sample handling and storage; increasing workload pressure; inconsistent monitoring; and insufficient assistance. Hemolysis is the leading cause of rejected and inappropriate clinical laboratory samples, accounting for 40-70 percent of all such cases. While a reduced incidence was seen in this investigation, hemolysis is still the most common source of preanalytical mistakes. Lactate dehydrogenase, creatine kinase, MB isoenzyme of creatine kinase, potassium, conjugated bilirubin, alanine aminotransferase, aspartate aminotransferase, and iron are the most sensitive clinical chemistry tests to hemolysis.

Unauthorized order rates in ED were shockingly high. This mistake occurs when a member of staff with limited or no access to computerized laboratory requests makes one. This blunder occurred in ED nearly entirely (5.07% of the time). The prevalence of this blunder in the emergency room shows that clinical personnel did not get sufficient training on these criteria and policies. Nevertheless, studies conducted over the course of two years showed that this

inaccuracy significantly decreased from 40.1% to 17.2%. Increased staff experience, improved communication with the laboratory, and better indoctrination of new hospital personnel to the test requisition system all contributed to the drop. Non-received samples, insufficient sample amount, damaged, released, compromised, etc. specimens, duplicate test requests, labeling mistakes, and incomplete test request data have all reduced during the previous two years. Nevertheless, there was an increase in hemolysis, mistakes in transporting specimens, improper collecting methods, and misplaced barcodes (Figure (Figure1)1). Inadequate sample collecting techniques and transport may also contribute to hemolysis. It was also noted that unqualified hospital staff were responsible for transporting laboratory specimens. Potential contributors to these mistakes include inexperienced phlebotomists and staff, inadequate sample collection, poor training and instruction, and an overburdening of resources. An observational research done across 12 European nations by the European Federation of Clinical Chemistry and Laboratory Medicine found an unsatisfactory lack of adherence to the Clinical and Laboratory Standards Institute's H3-A6 standards for phlebotomy.

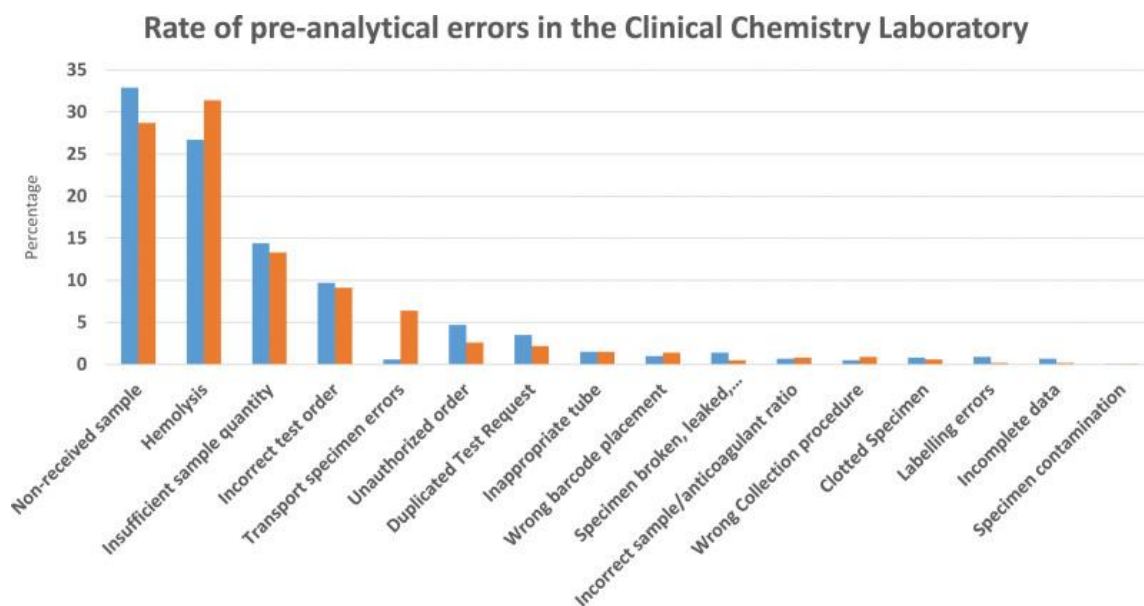


Figure 1 Preatalytical errors in the Clinical Chemistry Laboratory.

There is a significant probability of laboratory mistakes during the preanalytical phase due to factors including patient variables, specimen collecting variables, and specimen management variables. Others are beyond of our hands, but understanding them is essential for finding solutions and making sense of them (eg, cold agglutinins in winter seasons). The first step in improving the quality of the preanalytical phase is to identify potential mistakes and to determine whether errors constitute a danger to the patient's outcome. This study's findings showing a rising incidence of preanalytical mistakes, especially in OPD and IPD, call into question the adequacy of present preanalytical processes, and raise the question of whether or not they should be adjusted to lower the error risk. In addition, the occurrence of laboratory mistakes should be tracked and examined on a regular basis in order to identify areas of weakness and trends.

The current study's results offer a critical and important data set that might be utilized to systematically assist quality management of the laboratory testing process, ultimately improving diagnostic quality for both patients and healthcare providers. Managers, quality officers, and other administrative officials will be more likely to participate in quality monitoring systems and welcome criticism as a result. Internal or external quality monitoring systems may be mandated by managers. This might also lead to an increased emphasis on audit trails as a means of obtaining documenting proof in advance of making decisions, introducing rules, or otherwise upgrading tactics or processes. Our results come at a pivotal moment and may convince authorities to follow suit or work together with other regional labs to standardize recording and monitoring procedures. This affords us the chance to hone our analysis, establish its veracity, and create a brand-new approach to tracking and evaluating lab quality.

5.2. Conclusion

Laboratory findings and patient safety are both jeopardized by preanalytical mistakes. If anything goes wrong at this stage, the patient's proper diagnosis and care might be jeopardized. The high incidence of inaccuracy in this experiment was caused by two main factors: samples that were never received, and hemolysis. Hemolyzed samples were found to be more common in the outpatient department. Hospital staff should participate in continuing educational programs that highlight specimen quality concerns and sample collection training since these mistakes occur during the collection and processing of samples. The results of this research may also be utilized to develop novel methods and techniques for reducing preanalytical mistakes. A systematic quality evaluation tool for monitoring the preanalytical phase and evaluating laboratory or hospital performance may be aided and guided by the findings of this research. The authors contacted the lab, which has now put in place quality control procedures.

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