

Original Article

The Frequency and Types of Pre-Analytical Errors in Hematology Laboratory for Two Large Academic Hospitals of Shiraz University of Medical Sciences

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ABSTRACT

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Introduction: The pre-analytical phase, the most critical phase in quality assurance, accounts for the largest portion of laboratory errors, underscoring the importance of accurate processing and minimizing these errors in the laboratory. Our study was designed to retrospectively examine the types and frequencies of pre-analytical errors in the hematology laboratories of two large academic hospitals.

Materials and Methods: We conducted a cross-sectional study in the hematology laboratories of two academic hospitals, collecting and analyzing data over a defined period. This research specifically focused on pre-analytical variables and encompassed both inpatient and outpatient departments.

Results: A total of 195161 samples were received in the hematology laboratory during this period. Overall, pre-analytical errors were found in 887 samples, which composed 0.45% of the total samples. The most common error in both mentioned hospitals was clotted complete blood count (655/195161, 0.33%). The wrong container for the erythrocyte sedimentation rate test has the lowest number of errors (3/195161, 0.001%).

Conclusions: Pre-analytical errors, despite their simplicity, continue to be repeated. The most important principle in preventing these types of errors seems to be sufficient knowledge and accuracy. It is essential to continually train and adhere to standards and principles to prevent errors during the pre-analytical stage and maintain control over this stage.



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Introduction

The diagnosis and treatment of most diseases are dependent on the laboratory test results obtained from the patient's sample. The laboratory's ability to provide reliable and accurate results directly impacts the optimal management of patients [1, 2]. Laboratory errors are categorized as pre-analytical, analytical, or post-analytical, depending on the stage at which they occur. The pre-analytic phase, as the first step, is crucial in laboratory processing, as errors can occur during specimen handling and identification. Rigorous control measures are essential in preventing errors. It is crucial to have a well-managed pre-analytical phase to ensure accurate and reliable laboratory results. The "pre-analytical" stage is the most crucial part of quality assurance, as it involves manual work and is highly susceptible to errors [3, 4]. Previous studies have shown that pre-analytical errors account for 62-70% of all laboratory errors [1, 5-7]. Pre-analytical errors can occur in various ways, including patient misidentification, contamination from infusion routes, hemolysis, sample clotting, inadequate sample collection, use of inappropriate containers, incorrect blood-to-anticoagulant ratios, and improper transport and storage conditions. These errors must be avoided to ensure accurate and reliable test results. This study aimed to survey pre-analytical procedures in the hematology laboratory of two central hospitals to identify sources of error and their relative frequencies. Such data

enables laboratories to take corrective measures.

Materials and Methods

This retrospective and cross-sectional study was conducted at two academic hospitals in Shiraz, Iran: Shahid Rajaei and Hafez Hospital. The data were collected through the laboratory error recording system at Shahid Rajaei Hospital from March 21, 2021, to November 26, 2022, and at Hafez Hospital from August 30, 2020, to July 15, 2022. During this period, the hematology laboratories in Shahid Rajaei and Hafez Hospitals received a total of 88,080 and 10,7081 samples, respectively. The available types of pre-analytical errors that can be analyzed are misidentification (incorrectly labeled vials or incorrectly filled forms), incorrect tube selection, clotted samples, incorrect volume (inadequate sample-to-anticoagulant ratio, i.e. blood was filled above or below the indicated mark on the tube), and hemolyzed samples. The types, total number, and relative frequency of errors were calculated separately.

Results

Our analysis indicates that the overall pre-analytical error rate in the hematology laboratories of the two hospitals studied is 0.45% (887 out of 195,161 samples). Among these errors, the most frequently occurring error is clotted complete blood count (CBC) samples, accounting for 73.84% (655 out of 887). Conversely, the least standard error observed in

the study is sample collection in the wrong tube, occurring in only 0.001% of cases (3 out of 887). Out of 88,080 blood samples submitted to the hematology laboratory at Shahid Rajaei Hospital, 345 were deemed unacceptable, reflecting a pre-analytical error rate of 0.39%. The most frequently encountered issue was clotted CBC samples, which accounted for 64.92% (224 out of 345) of the errors. In contrast, the least common mistake involved using the wrong tube for the erythrocyte sedimentation rate (ESR) test, occurring in just 3 cases (0.86%). Analysis of

data from Hafez Hospital revealed that 542 out of 107,081 received samples were deemed unsuitable for test performing, corresponding to a pre-analytical error rate of 0.51% in the hospital's hematology laboratory. The most frequently observed error was clotted CBC samples, accounting for 79.52% of cases (431 out of 542). In contrast, the least common error was an incorrect volume in the ESR tube, occurring in just 4 cases (0.73%). The collected data is summarized in Table 1.

Table1. Type and frequency of errors recorded in Shahid Rajaie and Hafez Hostpitals

	Total data (Rjaie+Hafez)			Rajaie			Hafez		
	No.	Total samples (%)	Total errors (%)	No.	Total samples (%)	Total errors (%)	No.	Total samples (%)	Total errors (%)
Total samples; Total errors (%)	195161; 887 (0.45)	-	-	88080; 345 (0.39)	-	-	107081; 542 (0.51)	-	-
Clotted CBC	655	0.33	73.84	224	0.25	64.92	431	0.40	79.52
incorrect volume CBC	31	0.01	3.49	3	0.003	0.86	28	0.02	5.16
Mislabeled CBC	55	0.02	6.20	36	0.04	10.43	19	0.01	3.50
Clotted ESR	132	0.06	14.88	72	0.08	20.86	60	0.05	11.07
incorrect volume, ESR	11	0.005	1.24	7	0.007	2.02	4	0.003	0.73
Wrong tube ESR	3	0.001	0.33	3	0.003	0.86	0	0	0

CBC= Complete blood count; ESR= Erythrocyte sedimentation rate

Table 2. Error of coagulation section in Shahid Rajae Hospital

	Numbers	Total samples (%)	Total errors (%)
Total samples; Total errors (%)	38505; 323 (0.83)	-	-
Clotted sample	248	0.64	76.78
Lysed sample	15	0.03	4.64
Mislabeled sample	7	0.01	2.16
Incorrect volume	51	0.13	15.78
Wrong tube	2	0.005	0.61

Discussion

Our study revealed that clotted samples had the highest error rate (88.72%) among pre-analytical errors, aligning with findings from previous research [8]. Given these findings, it seems that crucial aspects of blood sample-collecting procedures are often overlooked. The first is the phlebotomy procedure, which sometimes encounters difficulties, especially in patients with minor or difficult-to-identify veins. The second involves improper mixing of the sample with the anticoagulant in the tube or delays in transferring the sample from the syringe needle to the tube. The third is inadequate quality control supervision during the in-house preparation of anticoagulant tubes. Thus, utilizing the basic evacuated tube system may be beneficial in reducing this type of error, such as sample volume and delay in transfer. In this study, errors such as mislabeling, incorrect sample volume, and wrong containers occurred less frequently.

Although mislabeling had a low incidence in this study, its occurrence can pose significant risks. To enhance patient safety, it is advisable to adopt a barcode reader system to minimize labeling errors. According to the collected data, it is evident that Shahid Rajaee Hospital has been more efficient in recording errors since it has collected significant data on errors related to coagulation tests. On the other hand, data from the coagulation department at Hafez Hospital was not available, indicating that error registration in this hospital was likely negligent. A study by Kang et al. demonstrated that sample clotting and insufficient sample amounts

were the most frequent reasons for sample rejection in the hematology section [9]. Iqbal et al. found that the most frequent error in pre-analytical procedures at the hematology laboratory was insufficient samples (54.17%) while using an empty or damaged tube was the least common error (0.4%) [10]. In a study conducted from 2007 to 2011, Giménez-Marín et al. analyzed 751,441 samples and found an overall critical pre-analytical error rate of 0.047% in the general laboratory, with the highest rates observed in hemolyzed samples [11]. Pre-analytical errors in the coagulation section recorded by Salvagno et al. over two years show that the most common errors were samples not received in the laboratory following a doctor's order (49.3%), hemolysis (19.5%), clotting (14.2%), and incorrect sample volume (13.7%) [12]. In 2011, Chawla et al. found that 1.52% of all samples collected in the clinical chemistry laboratory were unsuitable for further processing, with the majority being due to hemolysis (0.74%) [13]. The pre-analytical stage is known as the most error-prone phase in laboratory quality assurance, primarily due to the considerable manual involvement of personnel. Various studies conducted globally reveal the diversity of these errors and their prevalence. Consequently, each laboratory must examine and analyze these errors in order to enhance performance and minimize the occurrence of mistakes. So, we decided to re-evaluate pre-analytical errors to determine whether their occurrence has declined. However, it appears that the same old mistakes

have persisted over time. While the overall error rate has decreased, despite years of emphasis on this issue, its significance remains inadequately addressed. Therefore, it is advisable to conduct regular practical and theoretical training sessions to ensure these principles are thoroughly ingrained in medical staff. Improving communication and awareness, and providing retraining to ward and laboratory staff can significantly enhance the quality of laboratory services and patient management. One strength of the present study is the large number of analyzed samples. This study specifically focused on the hematology laboratory. Regarding the retrospective nature of our study, incomplete data recording should be taken into consideration. More accurate data collection is promised by prospective studies.

Conclusions

Clinical laboratories often encounter difficulties with errors in the pre-analytical phase, an area particularly susceptible to uncertainties and

mistakes. It is essential to record the types and frequency of these errors in each laboratory and implement appropriate corrective measures to address them fully. Proper training for staff, ongoing monitoring, and adherence to strict standards play a vital role in minimizing and preventing such issues. Maintaining these practices enables laboratories to uphold quality standards and enhance patient care.

Ethical Considerations

This study was approved by the Ethics Committee of Shiraz University of Medical Sciences, Shiraz, Iran.

Funding

None.

Conflict of Interest

The authors declare that they have no conflict of interest.

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Not applicable.

Authors' Contribution

H.S and S.M: Contributed to data gathering and drafting the the manuscript, N.N and Gh.T: provided direction and guidance throughout the preparation of this manuscript, and MJ. Sh: critically reviewed, edited, and approved the final manuscript.

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