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Original Article

Rates and Reasons of Laboratory Sample Rejection due to Pre-analytical Errors in Clinical Settings

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Abstract

Background: Laboratory analysis errors in procedure or interpretation may be seen during the process of completing physician test orders. They may also result in rejection of the requests due to some applicability reasons. Hence, this study was carried out to determine the rate and reasons for such rejections in clinical settings.

Methods: This cross-sectional comparative study was performed on 104 008 laboratory tests in a one-year period in terms of the percentage and type of errors that occurred in Shahid Bahonar Hospital in Kerman, Iran, in 2018. The types of studied errors included hemolysis, sample clotting, insufficient sample size, and mistakes in labels or absence of labels on the sample.

Results: In this study, 104 008 laboratory tests were performed, with 2299 (2.21%) sample rejections, 456 (32.31%) complete blood count (CBC) sample clotting; 417 (29.38 %) hemolysis; and 150 (17.47 %) inadequate sample volume as the majority of errors. There was no statistically significant relationship between pre-analysis errors and clinical aspects ($P=0.124$).

Conclusion: According to the results, it may be concluded that considering the high prevalence of laboratory errors in comparison with the majority of other studies, continuous training courses and determination of the causes of these errors are crucial to attaining better function and basic knowledge.

Keywords: Etiologies, Laboratory tests, Medical errors

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Introduction

Medical errors are significant challenges affecting health systems all over the world. In addition to causing high mortality rates by putting the patients' health in danger, this unsolvable but preventable aspect of the medical profession imposes great costs on health systems worldwide.[1,2] Two approaches have been implemented in medical error management. The first is the person-centered approach, which sees individuals as the guilty party. The second is the system-focused approach, which identifies the causes of errors through systematic analysis and investigation of mental causes, and provides appropriate solutions based on the types of errors in order to improve patient safety. These errors could be organizational, procedural, or individual errors. Applying a system-focused approach to medical errors not only improves patient safety and the effectiveness of clinical services and reduces complications and mortality caused by errors, but also has a significant effect on improving management efficiency and reducing costs. Preventing errors reduces the hospitalization period, medication use, medical interventions due to complications, and treatment and hospitalization costs.[3] While most health care centers are still struggling with patient safety, diagnostic laboratories have always been pioneers in achieving this goal, and the concepts of quality assessment have long been considered in clinical laboratories.[4] These concepts include accreditation, certification, quality monitoring, patient rights, standard operating processes, and quality standards of healthcare.[5] Accurate laboratory results play an important role in diagnosing and following the treatment process for patients if provided in a timely manner. Today, improving quality is the main goal of all organizations, associations, and medical groups.[4,5] Reputable scientific organizations and pathology and laboratory associations have grappled with this issue for many years and have developed and implemented various plans to identify and reduce errors.[3] These plans include implementing internal and external quality control programs, providing materials and resources to standardize methods, using accreditation systems, ISO, introducing appropriate systems for electronic registration of health information, and supporting programs which identify and reduce errors.[4] In general, laboratory activities are divided into three phases: pre-analytical, analytical, and post-analytical. All of these phases must be improved in order to reduce errors and improve laboratory quality. Most of the laboratory errors occur in the pre-analytical phase.[6-10] The pre-analytical phase includes patient assessment, requesting the test, completing the request, identifying the patient, collecting the sample, transferring the sample, and receiving the sample in the laboratory. According to a report by Bonini et al,[11] pre-analytical errors account for 31.6% to 75% of laboratory errors. Although research shows that most complications are related to the pre- and post-analytical phases, there are limited measures taken

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and studies conducted in this regard.[12-29] In addition to researchers' lack of interest, this problem can also occur due to scientific problems in reporting and finding sources of error in these phases. Therefore, the present study was conducted for the first time in Kerman, Iran, aiming to investigate pre-analytical errors, which lead to doctors' complaints about the accuracy and delay in test results in clinical wards.

Materials and Methods

Research Design

This observational and cross-sectional study was conducted on 104 008 laboratory tests performed for hospitalized patients in Shahid Bahonar hospital, affiliated to Kerman University of Medical Sciences, in 2018. Sampling was performed by census; all the tests performed for the hospitalized patients in different wards of Shahid Bahonar hospital were reviewed, and all types of errors in the pre-analytical stage of laboratory tests were considered, unless the doctor or the laboratory supervisor did not accept it. The types of errors are usually wrong codes, requests without sample delivery or samples without request, not prepared for the test, delays in sending the samples, mistakes in transporting the samples, lacking label with two identifiers, distorted or incomplete labels, wrong labels, wrong anticoagulant or tube, anticoagulant disproportion, inadequate sample size, hemolysis, errors in taking samples, and clotting samples as complete blood count (CBC), prothrombin time (PT) and partial thromboplastin time (PTT), arterial blood gases (ABG), blood culture. The error assessment steps are described in the following.

Procedure

An electronic application form collecting the patient's complete information was completed for patients who needed clinical examination. After transferring the samples to the ward, the receptionist evaluated them in terms of the criteria for accepting or rejecting the samples. All cases of errors were recorded by two trained technicians in special documents in terms of the type of sample, the clinical ward, and the name of the patient and were also reported to the clinical ward nurse by phone call under the supervision of laboratory doctor and supervisor. The informed nurse's name was also recorded in the documents. Because the patient's safety is endangered, by re-sampling, the laboratory supervisor monitors the samples before rejecting them. Before the analysis, the preparation of the samples, including centrifuge and sorting of samples for different sections, was done in the technical sections of the laboratory. Samples with errors affecting this phase such as hemolytic, icteric, and lipemic samples were investigated and, after the approval of the laboratory doctor, were recorded in the patient's electronic test result in case there was a need to repeat sampling. The laboratory errors were investigated in terms of sample type, ward type, and error type.

Statistical Analysis

All the information including sample type, the detected errors, and the type of the ward were recorded in the information forms of the present study. Finally, the required data were analyzed using SPSS 20 after collection, and the results were presented using descriptive statistics, percentages, tables, and graphs. The chi-square test was used for statistical comparisons, and the significance level was set at 0.05.

Results

In the present study, 2299 (2.21%) pre-analytical errors were observed in 104 008 laboratory tests. These errors included 709 cases (30.83%) in the biochemical samples out of the total of 35 000 samples sent to this section of the laboratory, 818 cases (35.58%) in the hematology samples, 54 cases (2.34%) in the microbiological samples, and 718 cases (31.23%) in sample request and sending of samples (Table 1).

The frequency of the pre-analytical errors is presented Table 2. The most common errors, considering the number of requested tests, were observed in cardiopulmonary resuscitation (CPR), operating room, oral and maxillofacial surgery, and general surgery wards (Table 2).

Table 3 shows the frequency of errors. Most of the errors were related to CBC sampling with a frequency of 456 (36.87%), followed by hemolysis of the sample with a frequency of 417 (29.38%). The fewest errors were observed in lipemic samples with a frequency of 2 (0.08%).

According to the results of the present study, no significant relationship was observed between pre-analytical errors and clinical wards ($P = 0.124$). The total number of ABG tests ordered was 13 838 in one year, with sample clotting reported in 0.65% of cases. Moreover, 2.13% of the 2494 blood cultures were reported to be clotted.

Discussion

In the present study, the results of 104 008 tests were examined, and 2299 pre-analytical errors were observed. Errors in biochemical, hematology, microbiology blood culture samples, and patient identification method and sending the samples accounted for 30.83%, 35.58%, 2.34%, and 31.23% of the errors, respectively. In a study conducted by Englezopoulou et al in 2016 in Italy, tests of 18 407 patients were reviewed. A total of 908,917 tests

Table 1. Frequency of Errors in Terms of the Type of Sample in Different Units of the Laboratory

Laboratory Unit	Number	Percent
Serum (biochemistry, hormones, and serology)	709	30.83
Samples with EDTA/citrate anticoagulants (hematology and coagulation)	818	35.58
Culture samples (microbiology)	54	2.34
Error in identifying, requesting, and sending the samples	718	31.23
Total	2299	100

Table 2. Frequency of the Pre-analytical Errors in Clinical Wards

Ward	Number of Tests Per Year	Number of Errors	Error Percentage	Error Percentage for Each Ward*	*P* Value
Internal	4736	204	8.87	4.30 (CI95%: 2.2–7.1)	0.051
General surgery	3836	20	9.56	5.7 (CI95%: 3.4–6.1)	
Oral and maxillofacial surgery	536	37	1.60	6.9 (CI95%: 5.5–8.2)	
Urology	12948	173	7.62	1.33 (CI95%: 0.5–2.2)	
Orthopedics	6293	224	9.74	3.55 (CI95%: 2.4–5.3)	
Oncology	9298	304	13.2	3.46 (CI95%: 1.4–5.6)	
CPR	561	73	13.17	13.01 (CI95%: 11.2–14.9)	
Operation room	221	16	0.69	7.23 (CI95%: 5.5–9.1)	
Emergency	4019	133	5.78	3.3 (CI95%: 2.4–4.3)	
Neurosurgery	6411	156	6.78	2.4 (CI95%: 1.5–4.1)	
ICU	16753	609	26.48	3.63 (CI95%: 2.2–4.8)	
Screen	34929	127	5.53	0.36 (CI95%: 0.1–0.6)	
CCU	2467	23	1.0	0.93 (CI95%: 0.5–1.1)	
Total	104008	2299	100	—	

CPR, cardiopulmonary resuscitation; ICU, intensive care unit; CCU, cardiac care unit.
*Sample Rejection Ratio; based on the number of tests requested in the same ward.

Table 3. The Frequency of Various Types of Error in the Studied Cases

Type of Error	Number of Tests	Number of Errors	Percentage of the Total Errors	Error Percentage for Each Category
Wrong code	104008	196	12.39	0.0019 (95% CI:0.0016–0.0021)
Request without sample delivery	104008	156	13.21	0.0015 (95% CI: 0.0013–0.0017)
Sample without request	104008	146	9.23	0.0014 (95% CI: 0.0012–0.0016)
Not prepared for the test	104008	26	1.64	0.0002 (95% CI: 0.0001–0.0003)
Delay in sending the samples	104008	36	2.27	0.0003 (95% CI: 0.0002–0.0005)
Mistakes in transporting the samples	104008	89	5.62	0.0009 (95% CI: 0.0007–0.001)
Lacking label with two identifiers	104008	36	1.57	0.0003 (0.0002–0.0005)
Distorted or incomplete label	104008	6	0.26	0.0001 (95% CI: 0.0000–0.00011)
Wrong label	104008	56	2.44	0.0005 (95% CI: 0.0004–0.0007)
Wrong anticoagulant or tube	104008	17	0.74	0.0002 (0.0001–0.00022)
Anticoagulant disproportion	59205	130	7.20	0.0022 (95% CI: 0.0018–0.0026)
Inadequate sample size	104008	150	17.47	0.0014 (95% CI: 0.0012–0.0017)
Hemolysis	104008	417	29.38	0.004 (95% CI: 0.0036–0.0044)
Lipemic	100131	2	0.08	0.00002 (95% CI: 0.00001–0.00005)
Errors in taking samples	104008	10	0.43	0.0001 (95% CI: 0.00004–0.00016)
CBC clotting	36778	456	32.31	0.0124 (95% CI: 0.01127–0.01353)
PT and PTT clotting	18550	167	7.29	0.009 (95% CI: 0.008–0.0104)
ABG clotting	1383	90	3.93	0.0651 (95% CI: 0.0521–0.0781)
Blood culture clotting	2494	53	2.33	0.0213 (95% CI: 0.0156–0.027)
Total	—	2299	100	—

CBC, complete blood count; PT, prothrombin time; PTT, partial thromboplastin time, ABG, arterial blood gases.

were performed on the patients during the treatment process in the hospital, including 674944 hematology tests, 440 of which had pre-analytical errors, and 233973 bio-pathological tests, 325 of which showed pre-analytical errors.[9] In the present study, the number of tests was much smaller but more pre-analytical errors occurred.

The results of the present study indicated that the most prevalent pre-analytical errors were observed in CBC clotting (32.32%), hemolysis (29.38%), and insufficient sample size (17.47%).

The review study conducted by Plebani in 2010 on the pre-analytical, analytical, and post-analytical phases indicated that most errors were made in the pre-analytical phase (in sample identification) and that fewest errors were made in the analytical phase by the laboratory.[7]

The results of the present study showed that in spite of the differences between pre-analytical errors in different clinical wards, no statistically significant difference was observed. However, there were more pre-analytical errors in the CPR, operation room, and also maxillofacial and

general surgery wards. In line with the results of the present study, a study conducted by Ashakiran et al[10] indicated that there was no difference in the pre-analytical errors across different wards. Moreover, clinical wards were considered ineffective in making pre-analytical errors in a study conducted by Ehrmeyer.[12] However, in a study conducted by Dikmen et al, most errors occurred in the pediatric and adult emergency departments, followed by the ICU. Furthermore, among ICU wards, neuro-ICU had the highest rate of rejection of samples sent to the laboratory.[17] The results of the present study indicated that between March 2017 and March 2018, the most frequent pre-analytical error types were CBC clotting (32.31%), hemolysis (29.38%), insufficient sample size (17.47%), request without sample delivery (13.21%), and wrong code (12.39%). From 2008 to 2009, Chawla et al investigated the pre-analytical errors in outpatient and hospitalized patients for one year and found that the pre-analytical error rate in patients was 1.9% and that the most important cause was hemolysis (1.1%).[25] In outpatients, the pre-analytical error rate was 1.2%, which was mostly due to inadequate sample size in our study. Some other causes of pre-analytic errors were requesting the wrong test, misidentifying the patient, choosing the wrong container for the sample, and choosing the wrong label for the container; all these errors were investigated in the preset study.

In a study conducted by Atay et al[18] in 2014 in Turkey, the total rate of sample rejection was 0.65%, which 2.28% was related to coagulation tests. In their study, the rates of hemolysis, sample clotting, and insufficient sample size were 8%, 24%, and 34%, respectively. In the present study, the rates of hemolysis, sample clotting (related to CBC, PT, PTT, and blood culture), and insufficient sample size were 29.38%, 43.53%, and 17.47%, respectively, which indicated that hemolysis and sample clotting rates were significantly higher in the studied hospital compared with other studies. The sample rejection rate was 2.21% in the present study, which was more than three times higher than it was in the study by Atay et al (0.65%).[18]

In a study conducted by Dikmen et al in Turkey, the total rate of sample rejection in the tests sent to the emergency department laboratory was 6%, which was almost three times higher than that of the present study.[17] In a study conducted by Narang et al in 2016 in the Netherlands,[20] the total pre-analytical error rate was 0.38%, most of which was related to sample clotting (0.28%), inadequate sample size (0.06%), and wrong samples (0.02%), which is in line with the present study in terms of higher error rate in clotting in the samples sent to the laboratory. In a study conducted by Giménez-Marín et al, over a five-year period, the sample rejection rate was 13.54%, which was mostly due to hemolysis (9.76%), not collecting urine samples (1.66%), and sample clotting (1.41%).[21]

In a study conducted by Grecu et al[22] in 2014 in Romania, the total pre-analytical error was reported to be 0.8%. The most reported errors were hemolysis and then sample clotting cases.[20] The total sample clotting rate (CBC, PT, PTT, ABG, and blood culture) was 0.73% in the present study, 0.28% in the total accepted samples in the study conducted by Narang et al,[20] and 43.2% of the total pre-analytical errors in the study by Grecu et al.[22] These numbers show that sample clotting rate in the rejected samples was significantly higher in the present study compared with the other studies.

In the present study, the rate of insufficient sample size was 17.47% of the total errors, and 1.4% of the total accepted samples in a year. This rate was 0.06% of the total accepted samples in the study by Narang et al,[20] which is significantly different from the results obtained in the present study. However, in the study conducted by Atay et al[18] the incidence of inadequate sample size was reported to be 1.38% of the total accepted samples (34% of the total pre-analytical errors), which was significantly higher than the results of the present study (approximately more than double).

A cross-sectional study conducted by Chhillar et al[26] in India, published in 2011, stated that 17.3% of the pre-analytical errors endangered patients' lives, showing the importance of research on this issue. In a cross-sectional study conducted by Cakirca.[27] in Turkey, published in 2018, a total of 1.6% of the samples were rejected, which was lower than the rate observed in the present study. In the mentioned study, most of the errors occurred in transporting the samples. Moreover, in a study investigating 5500 samples conducted by Najat et al[28] in Iraq in 2017, a large number of errors occurred in the pre-analytical phase (39%), mostly due to hemolysis of samples (9%), which was in line with the results of the present study.

The comprehensive program of preventing pre-analytical errors includes five steps of documenting laboratory methods clearly, improving the training of healthcare personnel, automating the procedures, monitoring quality indicators, and developing interaction and cooperation between wards and laboratories. The documented methods must clearly explain the methods of identifying the patient, collecting and labeling the samples, sending the samples to the laboratory, and preparing them for tests. People who perform the pre-analytical parts not only need to know the right procedures, but also need to understand the importance of adhering to those procedures and know what errors may occur in the test results and affect the patients' conditions if the steps are not taken properly. In-service training should be provided for these personnel and their competence should be evaluated annually.[29] New robotic and informatics technologies can also help reduce pre-analytic errors. Entering a test request into a computer eliminates human interference and therefore eliminates clerical errors. Automatic preparation of the samples with labeling for each patient reduces the errors regarding the authentication of the samples; moreover, barcoding facilitates sample transfer and follow-up.[25,29]

In conclusion, according to the results of the present

study, the pre-analytical errors were higher compared with most of the similar studies, and the highest frequency was related to CBC clotting and hemolysis of samples. These errors can be prevented by providing more training, increasing accuracy in sampling, increasing automation such as labeling the samples (using a barcode reader) in laboratories, implementing internal and external quality control programs in order to review the pre-analytical phase, encouraging constant interaction between clinical wards and laboratories, provision of training programs for clinical ward personnel by laboratories on the pre-analytical phase, and documenting pre-analytical errors. It is also recommended that in addition to a formulated training program for the personnel, a committee including laboratory (staff), the head of the hospital, and the head nurses should be formed to investigate the causes of errors and their extent on a monthly basis.

Authors' Contribution

RMA and EJ: Study concept and design. RA and EJ: Statistical analysis. RMA, EJ and RA: Analysis and interpretation of data. EJ: Drafting of the manuscript. EJ, RMA and RA: Critical revision of the manuscript for important intellectual content.

Conflict of Interest Disclosures

The author declares no conflict of interest.

Ethical Statement

This study was approved as a GP dissertation by the ethics committee of Kerman University of Medical Sciences with the ethics code of IR.KMU.AH.REC.1396.1461.

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