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Evaluation of Rejection Rates and Reasons among Specimens Taken from Different Hospital Units

Original Article

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ABSTRACT

Background and objectives: In recent years, analytical error rates in medical laboratories have decreased significantly. It has been demonstrated that the majority of errors occur outside of the laboratory in the pre-analytical and post-analytical phases. Our study aimed to evaluate the specimen rejections that occur for various reasons in the central clinical laboratory of a teaching hospital.

Methods: The study included all specimens (emergency and routine) that were sent from different units of the hospital to the central laboratory between January and December 2019.

Results: Based on the results, 3483 (0.27%) out of 1,307,013 specimens were rejected. The rejection rate was highest for specimens from the intensive care unit (0.69%) and lowest for specimens from the outpatient clinic (0.18%). The specimen rejection rate was 0.42% and 0.22% for specimens from the service unit and emergency department, respectively. The rejection rate for specimens from the intensive care unit was significantly higher than that for specimens from the emergency department ($p<0.001$), outpatient clinic ($p<0.001$), and service unit ($p=0.010$). Although the number of specimens from the intensive care unit was lowest, it had the highest rate of specimen rejection. In our study, most analysis requests were from the outpatient clinic. However, the specimen rejection rate was lowest in this unit.

Conclusion: The results indicate that the reasons for specimen rejection may be influenced by the health status of the patient rather than the patient population.

Keywords: Hospital Units, health status, Patient.

INTRODUCTION

It has been estimated that the efficiency of laboratory results is approximately 70% in making all clinical decisions. In addition, these laboratory results constitute approximately 40-94% of all objective health recorded data. Undoubtedly, the accuracy of the laboratory results is essential for the identification, classification, treatment, and monitoring of diseases (1).

In recent years, analytical error rates in medical laboratories have decreased significantly. It has been demonstrated that the majority of errors occur outside of the laboratory in the pre-analytical and post-analytical phases (2). The pre-analytical phase involving the process of specimen preparation, transportation, and storage is considered to be the main source of error in laboratory diagnosis. This phase consists of the initial procedures of the testing process that are performed outside the direct control of the clinical laboratory (3). Traditionally, pre-analytical errors are categorized into misidentification of the test and specimen problems.

Requesting appropriate tests and completing request forms are considered to be main components of providing quality laboratory services. A model of quality indicators has been developed by the International Federation of Clinical Chemistry and Laboratory Medicine Working Group, which includes the indicators for all pre-analytical defects, including identification, specimen problems, test request errors, and deficiencies found in the request forms. It also provides the necessary framework surrounded by objective criteria that is suitable for this model in the pre-analytical phase (4). The definition, implementation, and monitoring of quality indicators play a fundamental role in the analytical process, improving the quality of laboratory services, and reducing analytical error rates. On the other hand, a number of studies have focused on the suitability of pre-analytical steps to quality indicators, their vulnerability, and the impact on laboratory results. The identification and creation of quality indicators represent a promising strategy for collecting data on quality of the testing process, particularly for detecting errors in individual steps of the pre-analytical phase. Thus, it provides useful information for quality improvement projects (5). A clinical laboratory that focuses on analytical quality is a leader in healthcare quality management and amongst the first to use quantitative statistical control methods. However, accreditation institutions are increasingly demanding that laboratories go beyond analytical quality and take responsibility for the pre- and post-analytical stages where most errors occur (6).

Studies on pre-analytical errors generally focus on the cause of the error. In the literature, there is no information about source of the errors. In addition, no study has compared the pre-analytical error rates of different units. Therefore, our study aimed to investigate the source of pre-analytical error in terms of unit and to compare pre-analytical error rates between different units. Our findings will be beneficial for improvement projects by presenting a different perspective during the re-creation of quality indicators.

MATERIALS AND METHODS

The Samsun Education and Research Hospital Ethics Committee (Decision no: KAEK 2020/5/8) approved the present retrospective study. All study procedures were in accordance with human and animal rights and complied with the principles of the Declaration of Helsinki. The study included all specimens (emergency and routine) that were sent to the central laboratory of a teaching hospital between January and December 2019. The laboratory tests were analyzed in groups of eight: clinical chemistry (three analyzers: Beckman Coulter AU5800 (California USA); total of 56 tests including metabolites, enzymes, lipids, and electrolytes); immunoassays (three analyzers: Cobas 8000 (Roche Diagnostics GmbH, Mannheim, Germany); total of 29 tests including thyroid function tests, fertility hormones, and tumor markers); hematology (three analyzers: Beckman Coulter LH 780 (California USA); total 22 parameters); blood gas (three analyzers: Radiometer, ABL 90 FLEX (Copenhagen Denmark), Urine Analyzer (Sysmex UX-2000), Glycated Hemoglobin (HbA1c) (one analyzer: Trinity Biotech Premier Hb 9210 (Wicklow Ireland)); coagulation (two analyzers: Siemens Ca 7000 (Huizingen Belgium); total 14 tests including prothrombin time, fibrinogen, and D-Dimer), and erythrocyte sedimentation rate (ESR, one analyzer: Rapida ESR 100 (Turkey). Specimens from the emergency ward were not

included in the study. In the hospital, sodium citrate tubes (3.2%) were used for coagulation tests and gel separator clot activator tubes were used for biochemistry tests (i.e. metabolites, lipids, enzymes, and electrolytes) and hormones assay (immunoassays including tumor markers, thyroid function tests, and fertility hormones). In addition, K2EDTA tubes were used for hematology and HbA1c tests (Vacutainer, BD, UK), and sodium citrate tubes (0.13 M, 1.6 ml) were used for ESR. Liquid lithium heparin-containing syringes with hypodermic needles were used for blood gas specimens and urine tubes without additives were used for urine specimens.

Specimens from the blood collection unit and service units were evaluated in the specimen acceptance unit and the appropriate specimens were accepted. Inappropriate specimens were evaluated within the scope of pre-analytical errors and rejected by entering the justification into the laboratory information system at the specimen acceptance unit. Pre-analytical defective specimens (hemolysis, clot, etc.) detected during the analysis phase by the technicians in charge were rejected, a new specimen was requested, and incorrect specimens due to analytical errors were reworked. The specimens evaluated as incorrect were recorded in the system with their justifications.

We recorded the number of rejected specimens from each ward/unit. Next, only specimens rejected due to pre-analytical errors were included in the study. The rejection rates and reasons were obtained from the hospital's information management system.

The rejection rates were compared between different units using one-way ANOVA and the *Tukey's* post-hoc test according to their total rejection rate. Moreover, rejected specimens were evaluated by categorizing them according to the reasons for rejection.

RESULTS

This study was conducted on 1,307,013 specimens sent for analysis to the biochemistry department of the hospital in 2019. The specimens were sent from the emergency unit, outpatient clinic, service unit, and intensive care unit (ICU). Overall, 3,483 (0.27%) specimens were rejected for various reasons. The rejection rate was highest in specimens from the ICU (0.69%) and lowest in specimens from the outpatient clinic (0.18%). The rejection rate in the service unit and the emergency department was 0.42% and 0.22%, respectively. The rejection rate was significantly higher in specimens from the ICU compared with other units ($P<0.01$). In addition, the rejection rate of specimens from the service unit was significantly higher than the specimens from the outpatient clinic ($p=0.029$).

The most common reasons for specimen rejection were clotting (36%), followed by insufficient volume (24.69%), hemolysis (17.89%), and incorrect order (12.35%). Other reasons of specimen rejection included incorrect container/tube (5.40%), incorrect registration (2.58%), incorrectly taken specimen (0.57%), and excess specimen (0.52%). The most common reason for rejection in each unit was clotting (Table 1).

Table 1- Reasons of specimen rejection based on different hospital units

Reasons for rejection	Emergency Number (%)	Outpatient Number (%)	Service Unit Number (%)	ICU Number (%)
Insufficient specimen	162 (32.60)	205 (17.92)	299 (26.46)	194 (27.25)
Hemolyzed specimen	91 (18.31)	76 (6.64)	338 (29.91)	118 (16.57)
Clotted specimen	203 (40.85)	367 (32.08)	349 (30.88)	335 (47.05)
Excess specimen	0 (0.00)	4 (0.35)	10 (0.88)	4 (0.56)
Incorrect container/tube	27 (5.43)	78 (6.82)	60 (5.31)	23 (3.23)
Incorrect order	9 (1.81)	347 (30.33)	48 (4.25)	26 (3.65)
Incorrect registration	5 (1.01)	53 (4.63)	21 (1.86)	11 (1.54)
Incorrectly taken specimen	0 (0.00)	14 (1.22)	5 (0.44)	1 (0.14)

Table 2 shows the comparison of specimens' rejection reasons between different units

Table 2- Comparison of specimens' rejection reasons between different units

Group 1	Group 2	Rejection rate difference (Group 1-Group 2) p-value							
		IS	HS	CS	ES	IT	IR	IO	ITS
Emergency	Outpatient	14.68 <0.001	11.67 <0.001	8.77 <0.001	-0.35 =0.001	-1.39 <0.001	-28.52 <0.001	-3.62 <0.001	-1.22 <0.001
	Service unit	6.14 <0.001	-11.60 <0.001	9.97 <0.001	-0.88 <0.001	0.12 >0.05	-2.44 <0.001	-0.85 <0.001	-0.44 <0.001
	ICU	5.35 <0.001	1.74 =0.006	-6.20 <0.001	-0.56 <0.001	2.20 <0.001	-1.84 <0.001	-0.53 >0.05	-0.14 >0.05
Outpatient	Emergency	-14.68 <0.001	-11.67 <0.001	-8.77 <0.001	0.35 =0.001	1.39 <0.001	28.52 <0.001	3.62 <0.001	1.22 <0.001
	Service unit	-8.54 <0.001	-23.27 <0.001	1.20 >0.05	-0.53 <0.001	1.51 <0.001	26.08 <0.001	2.77 <0.001	0.78 <0.001
	ICU	-9.33 <0.001	-9.93 <0.001	-14.97 <0.001	-0.21 >0.05	3.59 <0.001	26.68 <0.001	3.09 <0.001	1.08 <0.001
Service	Emergency	-6.14 <0.001	11.60 <0.001	-9.97 <0.001	0.88 <0.001	-0.12 >0.05	2.44 <0.001	0.85 <0.001	0.44 <0.001
	Outpatient	8.54 <0.001	23.27 <0.001	-1.20 >0.05	0.53 <0.001	-1.51 <0.001	-26.08 <0.001	-2.77 <0.001	-0.78 <0.001
	ICU	-0.79 >0.05	13.34 <0.001	-16.17 <0.001	0.32 =0.004	2.08 <0.001	0.6 >0.05	0.32 >0.05	0.30 =0.008
ICU	Emergency	-5.35 <0.001	-1.74 =0.006	6.20 <0.001	0.56 <0.001	-2.20 <0.001	1.84 <0.001	0.53 >0.05	0.14 >0.05
	Outpatient	9.33 <0.001	9.93 <0.001	14.97 <0.001	0.21 >0.05	-3.59 <0.001	-26.68 <0.001	-3.09 <0.001	-1.08 <0.001
	Service unit	0.79 >0.05	-13.34 <0.001	16.17 <0.001	-0.32 =0.004	-2.08 <0.001	-0.6 >0.05	-0.32 >0.05	-0.30 =0.008

IS: insufficient specimen; HS: hemolyzed specimen; CS: clotted specimen; ES: excess specimens; IT: incorrect tube; IO: incorrect order; IR: incorrect registration; ITS: incorrectly taken specimen.

DISCUSSION

In the study, we evaluated 1,307,013 specimens that were sent to the central laboratory of a teaching hospital over a 12-month period. The specimen rejection rate was determined as 0.27%. The highest rejection rate was related to the specimens from the ICU (0.69%), while the lowest rejection rate was related to specimens sent from the outpatient clinic (0.18%). The majority of rejected specimens were clotted (36%), insufficient (24.69%), and hemolyzed (17.89%).

Although the number of specimens from the ICU was lowest, it had the highest rate of specimen rejection. Hematology tubes contain anticoagulant substances such as ethylenediaminetetraacetic acid so that the blood sample can remain as whole blood. However, the blood samples must be mixed with the anticoagulant substances at a certain rate (7,8). Insufficient or excess blood sample will disrupt this rate, and the test result will be adversely affected (9).

The second highest rejection rate was related to specimens from the service units. In this unit, the most commonly rejected specimens were hemolyzed and excess specimens. Hemolysis can occur both in vivo and in vitro. Intravascular hemolysis (in vivo) is always associated with an underlying pathological always be taken by the laboratory to differentiate between in vivo and in vitro hemolysis, which is challenging (10). Simundic et al. reported hemolysis as the most common and serious pre-analytical error. They also stated that the detection and management of hemolyzed specimens are heterogeneous and need to be standardized (10). The rate of specimen rejection due to hemolysis has been estimated to be 37% in laboratories in Europe and 88% in laboratories in the USA (11,12).

The most common reason of rejection for specimens from the emergency department was specimen insufficiency. Similarly, Chiku et al. (2019) reported insufficient volume as the most common reason for specimen rejection. They also concluded that rejection rate in rural health facilities was five times higher than in a central hospital, which could be related to the lack of enough "in-service" staff training in rural health facilities (13). According to Atay et al. (2014), rejection due to clotting and insufficient specimen volume could be prevented by phlebotomy training (14). In 2021, Magwai et al. reported that training inexperienced personnel, reporting reasons for rejection, providing information on how to submit specimen types, and reporting specimen rejection reports and notes to nurses

and healthcare personnel could reduce rejection rate (15).

In our study, most analysis requests were from the outpatient clinic. However, the specimen rejection rate was lowest in this unit. In addition, this rate of rejection due to incorrect choice of tube, incorrect order, incorrect registration, and incorrectly taken specimen was higher in the outpatient clinic. Incorrect order and registration can be significantly reduced with the use of current technology. For example, wristbands with barcodes can be used to match the identity information of the patient and the requested forms.

In our study, excess specimens and incorrectly taken specimen are the least common reasons of specimen rejection. The rate of rejection to excess specimens can be prevented by in-service training. The number of incorrectly taken specimens may be influenced by the physiological state of personnel such as menstruation or exercise, hunger, satiety, posture, and medications. Cao et al. (2016) reported contamination with intravenous fluid or total parenteral nutrition solution as the most common reason of specimen rejection in a cancer center. If intravenous fluid is given to a patient, specimens should be taken from the other arm. If both arms are busy, blood can be drawn after an intravenous infusion (16).

Generally, the rejection rates in laboratories are constantly changing over time. One of the reasons for this is that science constantly renews itself over time. Rejection rates decrease over time with the development of hospital information management systems, determination of quality standards, usage of technological opportunities, and personnel training.

CONCLUSION

In this study, we evaluated the reasons for specimen rejection in the clinical laboratory according to different hospital units. The most common reasons for rejection were clotting, insufficient volume, and hemolysis. Although the number of specimens from the ICU was lowest, it had the highest rate of specimen rejection. In our study, most analysis requests were from the outpatient clinic. However, the specimen rejection rate was lowest in this unit. There results indicate that the reasons for rejection may influenced by the health status of the patient rather than the patient population. In addition, the most common reasons for rejection of specimens from the outpatient clinic were incorrect choice of tube, incorrect order, incorrect registration, and incorrectly taken specimen. However, the lowest rejection rate was found in the outpatient clinic.

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DECLARATIONS

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Ethics approvals and consent to participate

The study received approval from the Samsun Education and Research Hospital Ethics Committee (ethical code: KAEK 2020/5/8). All study procedures were performed in accordance with the human and animal rights and complied with the principles of the Declaration of Helsinki.

CONFLICTS OF İNTEREST

The authors declare that there is no conflict of interest.

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