

ORIGINAL RESEARCH

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The effect of education and 4-year experience in the evaluation of preanalytical process in a clinical chemistry laboratory**Medine Alpdemir¹, Mehmet Fatih Alpdemir¹, Zulfıye Akil²**¹Balıkesir State Hospital, Ministry of Health, Department of Clinical Biochemistry, Balıkesir, Turkey²Education Unit of Hospital, Balıkesir State Hospital, Ministry of Health, Balıkesir, Turkey

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Abstract

Preanalytical errors have an important ratios in all laboratory processes. To reduce laboratory errors, the IFCC working group on Laboratory Errors and Patient safety (WG-LEPS) developed laboratory quality indicators (QIs) for the preanalytical process. The purpose of this study is to evaluate QIs of the preanalytical process over a 4-year period and show the effect of education. In this study, Balıkesir State Hospital biochemistry laboratory were retrospectively evaluated as rejected sample for four years (between 1st of January 2014 – 31st of December 2017). We examined QIs for preanalytical processes such as; misidentification errors (QIs-5), unintelligible test requests (QIs-6), lost-not received samples (QIs-7), incorrect container/tube (QIs-9), samples hemolyzed (QIs-10), sample clotted (QIs-11), insufficient sample volume (QIs-12), incorrect sample type (QIs-13, unsuitable transportation (QIs-14) and improperly labeled tube (QIs-15). In our hospital, regular training is given to hospital staff and laboratory staff at least twice a year for sample taking, specimen storage and transfer training, as well as laboratory staff, laboratory processes and management of improperly sample. In our study, the preanalytical process error frequency was 0.64%, 0.63%, 0.58% and 0.76% for all years respectively. It is seen that the most frequent error frequency is clotted sample (0.31, 0.32, 0.28 and 0.27 respectively). Other the most common errors was insufficient sample and incorrect container/tube (0.18, 0.15, 0.12, 0.07 and 0.18, 0.07, 0.07, 0.03, respectively). Our results were well below the optimum values recommended by IFCC-WG-LEPS. In order to achieve all these desired goals for QI, the training process must be sustainable and standardized and repeated at appropriate intervals.

Keywords: Laboratory preanalytical errors, quality indicators, laboratory process, laboratory error management, education**Introduction**

The preanalytical phase, which encompasses all the activities necessary to obtain an appropriate biological sample, is an important part of the total test process [1]. Preanalytical errors constitute 60-70% of errors in the total test process. Clinical laboratories also need to be aware of the error rates in order to determine the level of risk, to perform the necessary remedial actions, and to ensure comparability between laboratories. The IFCC WG-LEPS has also developed quality indicators to detect and reduce errors in laboratory processes and to provide inter-laboratory harmonization at the same time [2]. In addition, The European Federation of Clinical Chemistry and Laboratory Medicine (EFLM) identified the objectives of the preanalytical phase working group (WG-PRE) for the standardization of the

main preanalytical phase steps (such as test request, transport and storage, patient preparation, sample intake, management of inappropriate samples, QIs, patient identification, pediatric- newborn sample intake) and harmonization [3].

It is important to be aware that the most important sources of error in the laboratory diagnosis are the fact that they occur in the preanalytical phase. In this process it is important to develop the laboratory quality culture, to maintain the training activities and to ensure harmonization. Reducing preanalytical error rates, avoiding misdiagnosis and malpractice, adapting to service quality standards, increasing patient and employee safety, and avoiding workload and economic losses are achieved through regular education [4]. Thus, the preanalytical process may be appropriate, effective and standardized.

We aimed to evaluate the efficacy of preanalytical process and education in a clinical laboratory for 4 years, starting from these reasons for our study.

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Materials and Methods

This study was made retrospectively. The samples number in the time period between 1 January 2014-30 December 2017 were obtained by laboratory information system of the Balıkesir State Hospital. Table 1 was given rejected sample number for four years.

Table 1. Total and rejected samples by years

Years	2014	2015	2016	2017
Number of samples rejected	3371	3850	3886	3700
Total number of samples	530504	613160	671001	489156
Ratio (%)	0.64	0.63	0.58	0.76

We analyzed that identification errors (QIs-5), test request errors (QIs-6), loss-sample rejection (QIs-7), incorrect container/tube (QIs-9), hemolyzed sample (QIs-10), clotted sample (QIs-11), inadequate sample volume (QIs-12), incorrect sample type (QIs-13), improper transfer (QIs-14) and improperly labelled tube (QIs-15). The results were evaluated as percentage. The calculation formulas for each QIs are given in table 2. Laboratory QIs performance was classified as optimal, desirable, minimum, and unacceptable in according to IFCC WG-LEPS quality objectives (Table 4) (5). The error rates of QIs according to years for the preanalytical process are showed in figure 1.

Table 2. Quality indicators of preanalytical phase and calculation formulas

Quality indicators (QIs)	Calculation formula
QIs-5	Percentage of: Number of misidentified samples/Total number of samples.
QIs-6	Percentage of: Number of unintelligible requests/Total number of requests
QIs-8	Percentage of: Number of samples lost- not received/ Total number of samples.
QIs-9	Percentage of: Number of samples collected in wrong container/Total number of samples.
QIs-10	Percentage of: Number of samples with hemolyzed (clinical chemistry)/Total number of samples (clinical chemistry)
QIs-11	Percentage of: Number of samples clotted/Total number of samples with an anticoagulant
QIs-12	Percentage of: Number of samples with insufficient sample volume/Total number of samples.
QIs-13	Percentage of: Number of samples of wrong or inappropriate type (i.e. whole blood instead of plasma)/Total number of samples.
QIs-14	Percentage of: Number of samples transported at inappropriate /Total number of samples.
QIs-15	Percentage of: Number of unlabelled samples/Total number of samples.

Table 3. Training plan and frequency by staff groups

Staff	Training topics	Training frequency	Evaluation of training effectiveness
Doctor	Laboratory processes Appropriate utilization of clinical laboratory tests	Twice a year	
Nurse	Test request Sample collection Sample storage and transfer Patient preparation	Twice a year (intermediate trainings when needed)	
Phlebotomist	Sample collection Sample storage and transfer Patient preparation	Twice a year (intermediate trainings when needed)	Pre-Test ve Post-Test applications
Laboratory technician	Blood collection Sample storage and transfer Management of improper samples Laboratory processes (QIS) Laboratory safety	Twice a year (intermediate trainings when needed)	
Sample transfer staff	Sample storage and transfer	Twice a year (intermediate trainings when needed)	

The laboratory test groups are eight types, including clinical chemistry (metabolites, enzymes, electrolytes, lipids, drug levels), glycosylated hemoglobin (HbA1c), immunoassays (thyroid function tests, fertility hormones, tumor markers, cardiac markers), hematology (22 parameter cell blood count), coagulation (prothrombin time, active partial thromboplastin time, fibrinogen, D-dimer), erythrocyte sedimentation rate (ESR), urinalysis (chemical and sediment analysis), stool (fecal occult blood test) and blood gases.

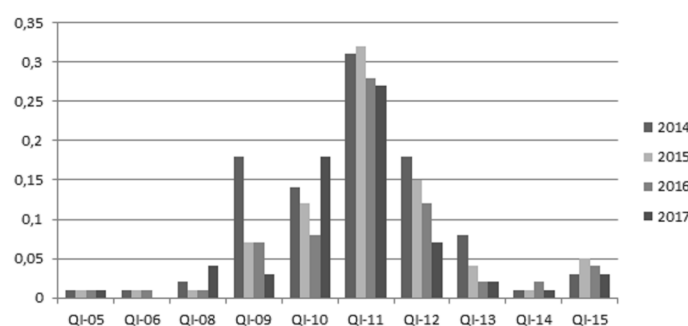
Personnel trainings were conducted regularly at least once, as indicated in table 3. The effectiveness of the trainings was

evaluated by pre-post application. 70% of 116 doctors, 93% of 791 nurses, 100% of 30 laboratory technicians, 88% of 369 medical secretaries and 85% of 400 sample transfer personnel were trained. The effectiveness of training was assessed according to the percentage of correct answers before and after the training. Additional training was given to subjects whose post-test was less than 80% correct. Laboratory quality indicators were evaluated every three months. In this evaluation, sub-analysis were made according to the place where the error was made, according to occupational groups. According to this, additional trainings were organized. Training plans were evaluated by laboratory experts and the education committee.

Table 4. Assessing the frequency of QIs according to years for the preanalytical process

Pre-analytical error	QIs	2014	2015	2016	2017	IFCC			
						Opt	Des	Min	Una
	QIs-05	0.01	0.01	0.01	0.01	<0.40	0.40-0.50	0.51-0.60	>0.60
Inintelligible test requests	QIs-06	0.01	0.01	0.01	0.00	<0.2	0.2-0.25	0.41-0.50	>0.50
Lost-not received samples	QIs-08	0.02	0.01	0.01	0.04	<0.2	0.20-0.40	0.41-0.60	>0.60
Incorrect container/tupe	QIs-09	0.18	0.07	0.07	0.03	<0.07	0.07-0.113	0.114-0.20	>0.20
Samples hemolyzed	QIs-10	0.14	0.12	0.08	0.18	<1	1.0-1.5	1.6-2.0	>2.0
Samples clotted	QIs-11	0.31	0.32	0.28	0.27	<0.5	0.5-1.0	1.1-2.0	>2.1
Insufficient sample volume	QIs-12	0.18	0.15	0.12	0.07	<0.4	0.40	0.81-1.2	>1.20
Incorrect sample type	QIs-13	0.08	0.04	0.02	0.02	<0.2	0.20-0.30	0.31-0.40	>0.40
Unsuitable transportation	QIs-14	0.01	0.01	0.02	0.01		<0.1		
Improperly labelled tube	QIs-15	0.03	0.05	0.04	0.03	<0.07	0.07-0.15	0.16-0.20	>0.20

Opt: Optimum, Des: Desirable, Min: Minimum, Una: Unacceptable

**Figure 1.** The error rates of QIs according to years for the preanalytical process

Results

In our study, the preanalytical process error frequency was 0.64%, 0.63%, 0.58% and 0.76%, respectively by years. When we look at all years, it is seen that the most frequent error frequency is clotted sample (QIs-11) (0.31, 0.32, 0.27 and 0.37, respectively, for years). This was followed by an incorrect container/ tube (QIs-9), insufficient sample volume (QIs-12) and hemolyzed sample (QIs-10). The preanalytical process QIs error frequency was quite below the optimal values suggested by IFCC WG-LEPS (Table 4).

Distribution according to the most frequently performed services of preanalytical error; blood collection units (25%), emergency services (24%), intensive care unit (20%), inpatient clinics (15%), surgery services (12%) and outpatient clinic (4%). The profession group that made the preanalytical error most frequently; nurses and laboratory technicians working in blood collection units (30%), nurses working in other services (55%), medical secretaries (10%) and sample transfer personals (5%).

During the 4-year period, training was given twice a year. According to the analysis of the 3-month service error rates, additional trainings were organized to the emergency department, intensive care, outpatient clinic and blood receiving unit. The percentage of correct answers before and after the training was 62% and 91% for 2014, 85% and 96% for 2015, 84% and 97% for 2016 and 88% and 95% for 2017 respectively.

Discussion

IFCC WG-LEPS set acceptable performance criteria from lab QIs data obtained with the participation of international laboratories. However, it was aimed to monitor and control the activities of the entire total test process [2,5].

In this study, we performed an assessment of the frequency of errors in the QIs of the laboratory preanalytical processes within a 4-year period. We also assessed the effect of in-service training to increase the awareness of the preanalytical phase after graduation to health personnel and to reduce the error rates. According to the results obtained during the 4-year period, the QIs of the preanalytical phase were below the optimum rates recommended by the IFCC.

There are publications showing that the prevalence of preanalytical errors in the literature is between 0.2% and 3.4% [6,7,8]. The error rate in our study was found to be 0.64%, 0.63%, 0.58% and 0.76%, respectively. The most frequent causes of errors in our study are the clotted sample (QIs-11), the insufficient sample (QIs-12), the inappropriate tube (QIs-09) and the hemolyzed sample (QIs-10). Lippi et al. found that hemolyzed samples, inadequate samples volume, and clotted samples were the most common preanalytical errors [9]. In another study, Özcan et al. determined the most frequent preanalytical errors as clotted sample and wrong sample collection [10]. Avci et al. identified the most common preanalytical errors for public health laboratories as clotted specimens, specimens that did not reach the laboratory/lost and unsuitable sample specimens [11]. Hemolyzed samples, inadequate samples, and incorrect sample taking were shown as the first three causes in the study of Plebani et al. [12]. In the study of Rattan et al. determined most frequency preanalytical errors as incorrect specimens received, hemolyzed samples and specimens not received [13]. As seen in these studies, preanalytical errors change according to the class of the laboratory or service differences.

Identifying and documenting a problem for the identification of quality and quantity in laboratory medicine is an important step. The technological applications in laboratories have facilitated the follow-up and documentation of the development of the

laboratory information system (LIS). In our study, it was seen that the most frequently performed parts were the blood collection unit (25%), emergency services (24%) and intensive care unit (20%). The determination of the origin of the error, the regular training according to the obtained data and the initiation of the corrective preventive action ensured to keep it below a certain level even if it does not prevent the error.

Education for preanalytical process harmonization and standardization is one of the leading objectives of the international preanalytical working groups. WG-PRE was determined all stages involved in this process. In addition to, IQs defined by IFCC WG-LEPS are designed to cover all steps of the pre-analytical phase [3,5]. In our training program in the light of this information, which covers the most important parts of the preanalytical phase, test request, patient identification, patient preparation, sample collection, sample transferring and storage, and management of inappropriate samples were emphasized. The pretest and posttest was used to evaluate the effectiveness of the training. When we examined the correct answer rates of pretest-posttest, pretest correct answer rates of the health care personals were low in the first year of study, but this rate has increased considerably in recent years.

Many studies have shown that training reduces the frequency of errors when examining the effect on the preanalytical process. In one of these studies, Özcan et al. observed that the preanalytical error rates decreased during the following months after training [10]. In their study, however, the frequency of preanalytical error increased again in the months following the training. It has been shown that the frequency of education given as the reason for this is inadequate. In 2011-2012, Aykal et al.'s study, the training was shown to have a positive effect in the reduction of rejected samples [14]. In their study, in-service trainings on health personnel were given education concerning with the sample collection and the period before analysis, and technological developments were shared related with these processes Through these trainings, communication between laboratories and clinics has been improved, working efficiency and motivation have been increased. In another study, Avci et al. found a decrease in the preanalytical error rates in the results of the training and technological improvement carried out in the public health laboratory. Unacceptable error rates identified by QIs in the first year of this study were acceptable as a result of training in the second year [11]. In study of Avci et al., family physicians and health care staff of the family health centers were trained about the preanalytical phases. In the their study of Lillo et al.[15], demonstrated how the numbers of preanalytical errors related to unsuitable samples in a hospital setting decrease following two improvement strategies that new technology and training activities and how their effects were measured by monitoring indicators. In their study, The set of indicators was used to monitor the improvement related to clotted, hemolyzed, insufficient, and uncollected samples. In resulting of their working, there was a reduction in all types of preanalytical sample errors by application of the improvement strategies. The indicators demonstrated that the unavailable, insufficient, and clotted samples decreased between two- and three-fold, whereas hemolyzed samples errors benefited more from these improvement strategies. In another study Arslan et al. determined the level of knowledge about this process of the phlebotomist with pretest and

posttest to reduce preanalytical errors. Training was provided to 454 health workers, many of whom were nurses. The proportion of correct answers as a result of pretest and posttest application increased from 59.1% to 92.1%. In addition, preanalytical error rate decreased from 0,6% to 0,5% after the training [4]. In our study, while the correct answer rate for the pre-test for the first year was 62%, this rate rised over 80% in the following 3 years. These results are indicated of the increased knowledge of the healthcare personnel in relation to the preanalytical process.

When we examined the laboratory QIs performances in according to years in this study, it was seen that the error rates decreased year after year (except QIs-8 and QIs-10 for 2017). When we investigated reason of the error for QIs-8, the hospital information system in our hospital was changed in this year, resulting in a higher QIs-8 error rate. The reason for the increase in the error rate for QI-10 was caused by the increase in the summer term (one month) the number of trainee students in the emergency service. The additional training is given to the emergency medical staff and trainee students to reduce the error rate in the next month. In our study, the determined QIs by IFCC- WG-LEPS according to the recommended performance targets, only QIs-9 was in the minimum range (0.114-0.20) in 2014 year and then decreased to the desirable level (0.07-0.113) in 2015 and 2016 years. QIs-9 error rate reached an optimal level (<0.07) in 2017 years. We think that the error rates of examined all QIs in our study are very good levels because of the effectiveness of the applied education policy. In order to control the preanalytical process, the implementation of regular training program for healthcare professionals should needed to identify, detect and monitor of the laboratory errors for preanalytical phase. Thus, in this process, laboratory error numbers decrease, patient safety develops and health system results improve.

Conclusion

Consequently, in order to achieve all these desired goals for QI, the training process must be sustainable and standardized and repeated at appropriate intervals. Information about the preanalytical process can be updated by training new staff and regularly repeating training for senior staff. Conditions affecting patient safety resulting from preanalytical errors on this side will be minimized.

Competing interests

The authors declare that they have no competing interest

Financial Disclosure

The financial support for this study was provided by the investigators themselves.

Ethical approval

Before the study, permissions were obtained from local ethical committee.

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