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Research Article

Evaluation of biochemistry laboratory quality indicators according to the national Laboratory Error Classification System

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Abstract

Objectives: The national Laboratory Error Classification System (LECS) was developed by the Turkish Ministry of Health in 2015 to improve the quality processes of laboratories and enhance patient safety. This study was an evaluation of laboratory processes and quality indicators (QIs) in biochemistry laboratories according to the LECS criteria.

Methods: This retrospective study included 4757 samples of a total of 649,001 samples collected between October 1, 2015 and December 30, 2016 and classified according to the LECS. The data regarding the number and type of rejected samples were obtained from the laboratory information system of Balıkesir State Hospital. Laboratory processes were also analyzed according to the LECS categories and counted on a monthly basis. The data were expressed as percentages.

Results: The rate of error in the pre-, intra-, and post-analytical phase was 81.7%, 1.7%, and 16.6%, respectively. Overall, the most common error type was a clotted sample (0.28%). The primary location of error was the emergency service (25.6%). The time intervals during which the most errors occurred were 8:00-12:00 and 12:00-16:00 (30%). The professional group that made the most errors was the nurse group (64.6%).

Conclusion: Different QIs have been used in clinical laboratories in Turkey and in the world in recent years to comply with the requirements of accreditation standards. In the present study, QIs were evaluated according to the LECS. These indicators provide a means to compare the performance of individual laboratories. These results may contribute to future laboratory test procedures and reduce error rates.

Keywords: Laboratory error classification system, laboratory error, laboratory process, quality indicators

Clinical laboratories play an important role in improving patient care and safety. All phases of the laboratory total testing process (TTP) should be assessed, monitored, and improved to increase safety and health outcomes [1]. In today's practice, the errors of a clinical laboratory have an entirely new meaning. Errors are thought to be more common in the pre- and post-analytical phases than in the analytical phase. Quality indicators (QIs) are fundamental tools to monitor and improve these processes. QIs enable users to quantify the quality of a selected aspect of care by comparing it against another criterion [2]. According to the international standards for clinical laboratory accreditation (International Organization for Standardization [ISO] Medical Laboratories–Particular Requirements for Quality and Competence standard 15189: 2012) "the QIs can measure how well an organization meets the needs and requirements of users and the quality of all operational processes" and "the laboratory shall establish QIs to monitor and evaluate performance throughout critical aspects of pre-examination, examination, and post-examination processes" [3]. Therefore, the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) developed the Laboratory Errors and Patient Safety project and identified a list of valuable QIs to promote the reduction of errors in the TTP and to improve quality and patient safety, as evaluated by some international laboratories and preliminary results [4].

In response to these developments, the national Laboratory Error Classification System (LECS) was developed in Turkey by the

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Table 1. Laboratory QIs organized according to LECS for all-analytical phases

No	Phases	QIs
	Pre-analytical	**Test request errors**
1		• Inaccurate test request
2		• Missing/incorrect information on test request
3		• No regulation of pathology request form
4		• Unregistered sample
5		• Incorrect recording
6		• Cancelation of registration because the patient cannot receive the sample
		Misidentification of patient/sample
7		• Taking sample from the wrong patient
8		• Misidentification of sample Incorrect sample type
9		• Incorrect container or tube
10		• Empty container
11		• Taking samples with expired tube
12		• Unlabeled sample
13		**Missing sample**
	Pre-analytical	**Suitability of sample**
14		• Incorrect sample type
15		• Insufficient sample volume
16		• Hemolyzed sample
17		• Clotted sample
18		• Lipemic sample
19		• Icteric sample
		Storage/transport of sample
20		• Not sending the sample in fixative
21		• Not recording the sampling time
22		• Sample not delivered to laboratory
23		• Unsuitable transportation condition
24		• Excessive transportation time
25		• Sample stored at improper temperature
26		**Rejection of the sample**
27		**Automation failure**
28		**Repeated sample**
		Suitability of reagent
29		• Expected reagent detection
30		• Expected material detection
31		• The requested material/reagent does not arrive
32		• Incorrect material/reagent ordered
33		• Material transfer with improper conditions
34		• Material stored in improper conditions
35		• Improper preparation of the media
36		• Inadequate laboratory temperature
	Intra-analytical	**Suitability of analyzer/device**
37		• No device maintenance
38		• Analyzer fault
39		• Device pipetting error
		Unacceptable performances in EQA/IQA
40		• Unacceptable performance in EQA
41		• Working test in inappropriate ICQ performance
42		• Inappropriate IQC
		Inappropriate test procedure
43		• Insufficient homogenization of the sample
44		• Inappropriate test procedure
45		• Planting mistake
46		• Incorrect incubation temperature
47		• Incorrect incubation time
48		• Improper painting technique
49		• Inappropriate dilution
50		• Inappropriate solution usage
51		• Mixing of samples
	Post-analytical	
52		Incorrect evaluation of the results
53		Incorrect technical approval
54		Data transcription error
55		Incorrect report
56		Inappropriate turnaround times
57		Notification of critical values
58		Loss of patient outcomes
59		Other

EQA: External quality assurance; ICQ: ; IQA: Internal quality assurance

Turkish Ministry of Health to improve the TTP of laboratories, increase patient safety, and to define common QIs to be used as a benchmark between laboratories [5]. This system consists of 5 main sections: laboratory error type, stage, location of the error, professional group, and time of the error [5]. The aim of the present study was to evaluate the total laboratory process and QIs in biochemistry laboratories according to the LECS.

Materials and Methods

This retrospective study included 4757 samples of a total of 649,001 samples collected between October 1, 2015 and December 30, 2016. The number and type of rejected samples were obtained from the laboratory information system of Balıkesir State Hospital. According to the LECS developed by the Turkish Ministry of Health, there are 8 laboratory test groups: clinical

chemistry (2 analyzers: the Cobas 8000 and 6000; Roche Diagnostics, Basel, Switzerland), which encompasses 33 tests, such as metabolites, enzymes, electrolytes, lipids, and drug levels; glycated hemoglobin (HbA1c); immunoassays (3 analyzers: Abbott Architect i2000; Abbott Diagnostics, Lake Forest, IL, USA), which comprises 26 tests, such as thyroid function, fertility hormones, tumor markers, and cardiac markers; hematology (3 analyzers: Mindray BC6800; Mindray Bio-Medical Electronics, Shenzhen, China), which includes a 22-parameter cell blood count; coagulation (2 analyzers: Ceveron alpha; Diapharma, West Chester, OH, USA), which has 4 tests: prothrombin time, active partial thromboplastin time, fibrinogen, and D-dimer; erythrocyte sedimentation rate (ESR) (1 analyzer: Berkgun SDM-100 xxxxxx); urinalysis (2 analyzers: Iris iQ200; Beckman Coulter, Brea, CA, USA), both chemical and sediment analysis; and blood gases (1 analyzer: ABL 800 Flex; Radiometer Medical, Bronshoj, Denmark).

Laboratory processes were also organized according to the LECS. This system consists of 5 main sections: laboratory QIs (Table 1) (58 QIs and 1 category for "other"), all phases (pre-phase: 36 QIs, intra-analytical: 15 QIs, post-analytical: 7 QIs and 1 "other"), location of the error (clinic, intensive care, emergency department, outpatient clinic, surgery, blood approval unit, sample receiving unit, laboratory, or other), professional group (physician, nurse, intern student, laboratory technician, medical secretary, transfer personnel, patient, relatives of patient, and unknown), and time error intervals (00:00-04:00, 4:00-08:00, 08:00-12:00, 12:00-16:00, 16:00-20:00, 20:00-23:59, and unknown) [5]. The QIs were calculated every month based on all of these criteria. The results were expressed as percentages, calculated using the following formula: the number of rejected samples/total number of samples for each category.

The samples were drawn with routine venipuncture using the order of blood draw suggested by the Clinical and Laboratory Standards Institute [6]. In this study, sodium-citrate Vacutainer tubes (Becton Dickinson and Co., Franklin Lakes, NJ, USA) were used for coagulation tests and ESR evaluation, tubes with gel separator were used for clinical chemistry and immunoassay tests, and dipotassium ethylenediaminetetraacetic acid tubes were used for hematology and HbA1c measurement. The samples were then transferred to the laboratory by trained staff for processing. At the time of sample retrieval, technicians visually checked the samples in terms of volume, labeling, clotting, and simultaneously matched the label with the requisition form, and accepted the samples accordingly. Any incongruity was recorded in the laboratory information system. The samples were allowed to clot, they were centrifuged at 1500g for 10 minutes, and then brought to the analyzers.

Statistical analysis

Statistical analysis was performed using the SPSS for Windows, Version 15.0 (SPSS Inc., Chicago, IL, USA) software. The descriptive data were expressed as percentages.

Table 2. Error percentages for pre-analytical, analytical and post-analytical Phases

	Biochemistry	Immunoassays	HbA1C	Hematology	Urinalysis	Blood gases	Coagulation	ESR	Total samples
Total samples	169717	110856	27073	205068	54412	10009	41134	30732	649001
Pre-analytical phase (n)	665	156	180	1512	76	275	729	293	3886
Within phase* (%)	17.1	4.0	4.6	38.9	2.0	7.1	18.8	7.5	100
Within all phases** (%)	14.0	3.3	3.8	31.8	1.6	5.8	15.3	6.2	81.7
Within all samples***(%)	0.39	0.14	0.66	0.74	0.14	2.75	1.77	0.95	0.60
Analytical phase (n)	53	18	-	2	1	2	3	-	79
Within phase (%)	67.09	22.78	-	2.53	1.27	2.53	3.80	-	100
Within all phases (%)	1.11	0.38	-	0.04	0.02	0.04	0.06	-	1.66
Within all samples (%)	0.03	0.02	-	0.00	0.00	0.02	0.01	-	0.01
Post-analytical phase (n)	92	136	45	79	90	47	144	59	792
Within phase (%)	11.6	17.2	5.7	10.0	11.4	5.9	18.2	7.4	100
Within all phases (%)	1.93	2.86	0.95	1.66	1.89	0.99	3.03	1.24	16.65
Within all samples (%)	0.05	0.22	0.17	0.04	0.17	0.47	0.35	0.19	0.12
All phases (n)	810	410	225	1593	167	334	876	352	4757
Within all phases (%)	17.0	8.6	4.7	33.5	3.5	7.0	18.4	7.4	100
Within all samples (%)	0.48	0.38	0.83	0.78	0.31	3.34	2.13	1.15	0.73

*Formula of error rate within a single phase (pre-, analytical, or post-): % rejected samles/total number for a phase); ** Formula of error rate within all phases (pre- +analytical-+post-): % rejected samles/total number for all phases; *** Error frequency rate within all samples: % rejected samples/total number of samples.
ESR: Erythrocyte sedimentation rate; HbA1c: Glycated hemoglobin.

Table 3. The error frequencies rate of laboratory QIs according to laboratories

	Total rejected samples	Biochemistry, %	Immunoassays, %	HbA1C, %	Hematology, %	Urinalysis, %	Blood gases, %	Coagulation,.%	ESR, %	Total, %
Total samples		169717	110856	27073	205068	54412	10009	41134	30732	649001
Pre-analytical phase										
Inappropriate test request	16	0.01	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Misidentification error	59	0.00	0.01	0.00	0.01	0.00	0.01	0.02	0.07	0.01
Incorrect container	446	0.05	0.06	0.08	0.04	0.03	0.19	0.14	0.32	0.07
Incorrect sample type	148	0.02	0.02	0.00	0.01	0.01	0.14	0.09	0.08	0.02
Insufficient sample volume	756	0.04	0.04	0.04	0.08	0.10	0.17	0.83	0.14	0.12
Sample hemolyzed	501	0.22	0.01	0.00	0.01	0.00	0.00	0.23	0.00	0.08
Sample clotted	1842	0.00	0.00	0.53	0.58	0.00	2.18	0.44	0.33	0.28
Samples not delivered	42	0,01	0.01	0.00	0.00	0.00	0.03	0.00	0.00	0.01
Unsuitable transportation	35	0.02	0.00	0.00	0.00	0.00	0.01	0.00	0,00	0.01
Excessive transportation time	6	0,002	0.00	0.00	0.001	0,00	0.00	0.00	0.00	0,00
Other	35	0.01	0.01	0.00	0,00	0,01	0,02	0,01	0,00	0,01
Analytical phase										
Analyzer fault	13	0.004	0.00	0.00	0.00	0.00	0.002	0,005	0,00	0.002
Device pipetting error	4	0,002	0.000	0.00	0.00	0.00	0.00	0.002	0.00	0.001
Unacceptable performance in EQA	62	0.03	0.02	0.00	0.00	0.00	0.00	0.00	0.00	0.01
Post-analytical phase										
Inappropriate turnaround time	792	0.05	0.22	0.17	0.04	0.17	0.47	0.35	0.19	0.12
Total error rate	4757	0.48	0.38	0.83	0.78	0.31	3.24	2.13	1.15	0.73

This table describes the error percentage for all samples (total number of samples: 649,001). The formula of the error frequency rate: % rejected samples/total number of samples.
ESR: Erythrocyte sedimentation rate; EQA: External quality assurance; HbA1c: Glycated hemoglobin.

Table 4. Error percentage by phase according to location of the error

	Pre-analytical phase, % (n=3886)	Analytical phase, % (n=79)	Post-analytical phase, % (n=792)	Total, % (n=4757)
Clinic	19.6	-	-	16.0
Intensive care unit	19.6	-	-	16.0
Emergency department	25.6	-	-	20.9
Outpatient clinic	12.7	-	-	10.4
Sample receiving unit	22.1	-	-	18.1
Sample acceptance unit	-	-	-	-
Laboratory	0.4	100.0	100.0	18.6
Other	-	-	-	-

Results

In this study, of a total of 649,001 samples, 4757 (pre-analytical phase: 3886, analytical phase: 79, post-analytical phase: 792) were registered as rejected due to an error according to the LECS laboratory quality processes. During a 1-year period, the error frequency for all phases and for all samples was 0.73% (Table 2). The error rate of the pre-, intra-, and post-analytical phase was 81.7%, 1.7%, and 16.6%, respectively, for all processes. The rate of each analytical phase according to the specific labora-

Table 5. Error percentage according to professional group

	Pre-analytical phase, % (n=3886)	Analytical phase, % (n=79)	Post-analytical phase, % (n=792)	Total, % (n=4757)
Doctor	-	-	-	-
Nurse	64.6	-	-	52.8
Intern student	-	-	-	-
Laboratory technician	33.2	100	100	45.4
Medical secretary	0.7	-		0.6
Transfer personnel	1.5	-	-	1.2
Other personnel	-	-	-	
Patient	-	-	-	
Patient relatives	-	-	-	
Unknown	-	-	-	

Table 6. Error percentage by time interval

	Pre-analytical phase, % (n=3886)	Analytical phase, % (n=79)	Post-analytical phase, % (n=792)	Total, % (n=4757)
00:00-04:00	3.8	-	10.6	4.9
04:00-08:00	21.3	-	20.3	20.8
08:00-12:00	30.0	-	20.2	27.8
12:00-16:00	30.4	-	12.6	26.9
16:00-20:00	8.8	-	15.2	9.7
20:00-24:00	5.7	-	20.2	8.1
Unknown	0	100.0	1.0	1.80

tory test groups is shown in Table 2. The error rate for the IQs according to the laboratory test group is illustrated in Table 3. The most common error type was a clotted sample in the pre-analytical phase (47.1%), unacceptable performance (78.5%) of external quality assurance (EQA) in the analytical phase, and improper turnaround time (100%) in the post-analytical phase. The errors are categorized according to department in Table 4, by professional group in Table 5, and by time interval of occurrence in Table 6.

Discussion

Data on the error rate in the clinical laboratory setting are of utmost importance to identify the TTP risk of the laboratory and to compare the results with other laboratories. In the present study, we retrospectively evaluated the total laboratory process and QIs in biochemistry laboratories according to the LECS developed by the Turkish Ministry of Health. Our results indicated that the error rate of the pre-, intra-, and post-analytical phase in our laboratory was 81.7%, 1.7%, and 16.6%, respectively. In previous studies, the error rate was 46% to 68% for the pre-analytical phase, 7% to 13% for the analytical phase, and 13% to 20% for the post-analytical phase [7, 8, 9]. Our results are consistent with previously published results. In our study, the total error frequency was 0.73% during a 1-year period (pre-analytical phase: 0.60%, analytical phase: 0.01%, post-analytical phase: 0.12%). Atay et al. [10] reported a total rejection rate of 0.65% for the pre-analytical phase in their laboratories. In another study, the pre-analytical error rate was found to be 0.8% [11]. Sakyi et al. [12] found a pre-analytical, analytical, and post-analytical error rate of 3.7%, 0.1% and 0.9%, respectively.

According to the LECS, 36 QIs are included in the pre-analytical phase. The defined criteria for microbiology and pathology laboratories and the criteria for laboratory warehouse material management are included. A hospital information management system (HIMS) is used for warehouse management and warehouse planning in our hospital. There was no error according to the predefined QI in these categories. A clotted sample was the most common QI error in the laboratory in the pre-analytical process of the study, accounting for 38% of the total error and 47.1% of the pre-analytical errors. This was followed by insufficient sample volume and a hemolyzed sample. The results of our study are consistent with the results of other studies performed in Turkey, which have demonstrated that a clotted sample was the most common error in the pre-analytical phase (54.3-55.8%), followed by insufficient sample volume and hemolyzed sample errors [13,14]. In the pre-analytical phase, the error rate was greatest (38.9%) in the hematology test group. When assessed by laboratory test group,

a clotted sample was the most frequently seen QI error for hematology, ESR, and blood gases; insufficient sample volume for coagulation; and a hemolyzed sample for biochemistry.

According to the LECS, 15 QIs are reported in the analytical phase. Since there was no specific manual testing in our laboratory and we used automated systems, device and improper working errors were eliminated. As in our laboratory, internal and EQA programs are actively used by clinical laboratories to identify analytical phase accuracy. Our laboratory also conducts daily internal quality control (IQC) and EQA on a regular basis (typically monthly). In our study, the most frequent error type in the analytical phase was unacceptable performance in EQA (78.5%). The formulation process for these criteria has been not specified in the LECS system. In our study, the total number of unacceptable performance EQA tests was considered an error. The calculation of EQA was made according to the formula of unacceptable performances in EQA/total test number. The rate was found to be 1.92% in our study. In a review study conducted by Sciacovelli [4], this rate varied between 1.4% and 4.9%. IQC is also routinely carried out, and if there is an IQC incompatibility, the error is corrected and routine laboratory testing is performed according to these results. In the present study, we found no error in the IQC. A criterion related to IQC in the LECS is not to work in the IQC and the other one is to continue working in the IQC incompatibility. According to these 2 criteria, we found no error.

In addition, 7 criteria related to the post-analytical phase were evaluated. Results that were not provided on time are among the errors. The error type found in the post-analytical phase was inappropriate turnaround time (100%). In this study, the error rate of inappropriate turnaround time was 0.12%. The rate in the preliminary data from the IFCC working group for the same criterion was between 0.02% and 8.9%. The IFCC working group recommends <0.4% optimal values [4,15]. We were unable to measure the criteria for the other post-analytical phases. This may be due to the fact that the use of an automated HIMS reduces the error rate considerably at our facility.

In the LECS, the department in which the laboratory error is made, the time of the error, and the professional group responsible for the error are primary criteria. In our study, the main location of errors recorded was the emergency service (25.6%). Emergency services are different from other services, because the patient density is high and working conditions are difficult. As seen in various studies, emergency services are the most common units for pre-analytical error [16,17].

The professional group responsible for the largest portion of errors was the nurse group (64.6%). Regular education of healthcare personnel to prevent laboratory errors is important. Corrective-preventive action is performed according to the current situation in our hospital. In addition, the physician, health personnel (nurse, laboratory technician staff), secretary, trainee student, and transport staff regularly receive training in laboratory processes, blood collection, and sample transport once a year. Studies in the literature have demonstrated the preliminary effects of continuing education on laboratory errors [17-20].

The peak time intervals when errors occurred were between 8:00-12:00 and 12:00-16:00 hours (30%). These are the hours when the hospital is most active and the patient volume is high.

All of these results are critical to reducing errors and to improving patient safety. Based on these results, corrective preventive actions can be initiated, training programs can be implemented, and the results of remedial activities can be followed in the future using the root cause analysis.

Furthermore, QI should include all stages from the TTP test order to the interpretation of the results [4]. The QIs developed by the IFCC working group include 56 key processes (37 pre-, 7 intra-, and 15 post-analytical phase) [15]. These QIs are also used in the LECS (36 pre-, 15 intra-, and 7 post-analytical phase, and others). Additionally, this national system includes data of place, time, and professional group, using sub-parameters. The source of the error can be analyzed using advanced tracking systems, and based on these results, outcomes can be improved using a standard method across the country to improve patient safety.

The LECS was jointly developed for use by biochemistry, microbiology, and pathology laboratories. In addition to the common criteria, each laboratory has specific criteria. The main advantage of this system in terms of patient safety is that it uses a standard methodology to analyze errors in the laboratory and has created a common terminology to be used between laboratories. Another advantage is that the LECS is a system that can add optional sub-parameter codes, which enables an advanced level of follow-up of the error source in laboratories with a high-patient capacity. To illustrate, when there is a frequent occurrence of clinical illness and clinical analysis is requested during the pre-analytical phase, a sub-parameter can be added to the clinical parameters. Therefore, it is possible to make a more detailed analysis in the LECS without any deviation. On the other hand, the lack of a standardized calculation method for QIs is the main disadvantage of the LECS, which can lead to unnecessary data collection and time loss.

There are 15 quality criteria for the analytical phase and 7 quality criteria for the post-analytical phase. The limitations of our study include the fact that we evaluated only 3 quality criteria for the analytical phase and 1 quality criterion for the post-analytical phase. The reason for this is the immediate release of errors in the analytical process, and the fact that there may be mistakes in the records of the LIS. In addition, the lack of laboratory feedback by clinicians in the post-analytical process makes it difficult to detect errors.

Conclusions

In conclusion, QIs have been used in clinical laboratories in Turkey and in the world in recent years to comply with the requirements of accreditation standards; however, due to different methods used for the identification and management

of QIs, the results obtained by different laboratories cannot be compared. Therefore, we suggest that the identification of standardized QIs is the mainstay for quality assessment in laboratory medicine and patient safety. In the present study, we evaluated the LECS system and laboratory results. We believe that our study results will contribute to future laboratory TTP and to reducing error rates.

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