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Assessment of Preanalytical Errors by Six Sigma Method and the Pareto Principle Analysis

Preanalitik Hataların Altı Sigma Metodu ve Pareto Prensibi Analizi ile Değerlendirilmesi

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ABSTRACT

Aim: In this study, we aimed to evaluate the preanalytical errors over a five year period using the Six Sigma methodology and Pareto Principle in the clinical biochemistry laboratory.

Methods: Five-year sample rejection data between January 2015 and December 2019 in the clinical biochemistry laboratory were analyzed and classified according to the reasons for rejection. Six Sigma levels for the total and each preanalytical error were calculated with Westgard online formula. Preanalytical errors were evaluated according to their frequencies ranks and percentages with Pareto principle.

Results: The overall rate of five-year total critical preanalytical errors was 1.91% and the sigma level was 3.6. According to Pareto's chart, the three most common errors among the five-year preanalytical rejections were clotted sample (42.49%, sigma value:4), insufficient sample (23.53%, sigma value:4.2), and wrong container (8.01%, sigma value:4.5).

Conclusion: Six Sigma is a quality management methodology used to evaluate laboratory performance processes according to universal quality criteria. Calculated sigma values of preanalytical errors in our laboratory were within the acceptable range. However, planned regulatory activities for frequently observed preanalytical errors should be a laboratory management strategy to reduce these error rates and improve our laboratory performance.

Key Words: Six Sigma; Quality Control; Preanalytical Errors

ÖZET

Amaç: Bu çalışmada, klinik biyokimya laboratuvarımızda altı sigma metodolojisi ve Pareto prensibi kullanılarak beş yıllık süreçteki preanalitik hataların değerlendirilmesi amaçlanmıştır.

Yöntem: Klinik biyokimya laboratuvarında Ocak 2015 ve Aralık 2019 tarihleri arasında gerçekleşen beş yıllık numune red verileri analiz edildi ve reddetme nedenlerine göre sınıflandırıldı. Toplam ve her bir preanalitik hata için gerçekleşen red verilerinin altı sigma düzeyleri, Westgard online formülü kullanılarak hesaplandı. Preanalitik hatalar, Pareto prensibi kullanılarak sıklık sıraları ve yüzdelerine göre değerlendirildi.

Bulgular: Beş yıllık toplam kritik preanalitik hataların genel oranı %1,91 ve sigma düzeyi 3,6 idi. Beş yıllık veriler Pareto grafiğine göre değerlendirildiğinde en sık karşılaşılan preanalitik hatalar pıhtılaşmış numune (%42,49, sigma değeri: 4), yetersiz numune (%23,53, sigma değeri: 4,2) ve yanlış numune kabı (%8,01, sigma değeri: 4,5) olarak belirlendi.

Sonuç: Altı Sigma, laboratuvar performans süreçlerini evrensel kalite kriterlerine göre değerlendirmek amacıyla kullanılan bir kalite yönetim metodolojisidir. Laboratuvarımızdaki preanalitik hataların hesaplanan sigma değerleri kabul edilebilir aralıktaydı. Ancak sık gözlenen preanalitik hatalara yönelik planlanan düzenleyici faaliyetler, bu hata oranlarının azaltılması ve laboratuvar performansımızın geliştirilmesi için bir laboratuvar yönetim stratejisi olmalıdır.

Anahtar Kelimeler: Altı Sigma; Kalite Kontrol; Preanalitik Hatalar

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Introduction

Clinical laboratories assume a critical role in patient safety. Therefore, they must enforce quality management and provide quality reports to produce more accurate and reproducible test results. The performance processes in laboratories consist of preanalytical, analytical, and post-analytical phases. The preanalytical phase is the period from the planning of which tests will be requested to the starting of the laboratory analysis [1]. Although all phases of the laboratory process are important for quality management, the majority of laboratory errors (46-68%) occur in the preanalytical phase [2]. The preanalytical phase consists of test requests, patient identification, sample collection, labeling, transportation, pipetting, and centrifugation. In case of any negligence in these steps, preanalytical errors may occur. The fact that many of these multidisciplinary preanalytical variables are difficult to control by the laboratory is a primary reason for the high prevalence of preanalytical errors [3].

Six Sigma is a quality management method that integrates accurate and precision evaluation, error identification, and process improvement. Six Sigma is a component of the continuous improvement approach used primarily in the manufacturing world and then used in hospital quality management since 1999 [4]. In the clinical laboratory, process performance should be evaluated according to accepted quality criteria, and all errors should be determined and controlled. Six Sigma is one of the quality management methods that can be used to evaluate the laboratory performance processes within universal criteria. The universal application steps of Six Sigma are "Defining, Measuring, Analysing, Improving, Controlling" which is called the DMAIC cycle [5]. Sigma values are defined as "defects per million opportunities (DPMO)" and the Six Sigma scale ranges from 0 to 6. A sigma value of 6 corresponds to 3.4 DPMO and a sigma value of 1 corresponds to 691462 DPMO (Table 1). As the sigma values increase, the error rates decrease and the reliability of the process increases. In an evaluation of laboratory processes, the lower limit sigma value is accepted as 4 to reduce systematic errors and ensure adequate performance [6]. Expressing laboratory quality data with sigma values makes the organization of corrective and remedial initiatives practical by providing a more accurate and easy assessment of the quality level.

There are different analysis methods to evaluate the variables and errors that cause low sigma levels. The Pareto Principle is one of the methods that list errors in order of frequency to analyze the causes of problems and compare them with each other [7]. The Pareto Principle, also known as the 80/20 rule, states that roughly 80% of the effects come from 20% of the causes [8]. In other words, a small number of factors or issues often account for the majority of problems or outcomes. In the quality management process, using the Pareto Principle ensures that efforts and resources are prioritized to tackle the critical issues that have the most significant impact. It allows us to focus on addressing the vital few causes that are responsible for most of the problems, rather than wasting resources on less significant factors.

Table 1. Process sigma levels according to defects per million opportunities

Sigma Level	DPMO*
1	691462
2	308538
3	66807
4	6210
5	233
6	3.4

*DPMO: defects per million opportunities

In this study, we aimed to evaluate the preanalytical errors over a five year period using the Six Sigma methodology and Pareto Principle in the clinical biochemistry laboratory.

Material and Methods

Materials

This observational study was conducted between January 2015 and December 2019 in the clinical biochemistry laboratory of the Adıyaman University Research and Education Hospital which is 400 bedded Tertiary Care Hospital.

Methods

The central laboratory is comprised of two departments (biochemistry and microbiology) and serves inpatients, outpatients, and emergency departments. All blood samples are collected in vacutainer by nurses/clinical staff, and transported to the central laboratory mostly by pneumatic system. Urine samples are transported to the central laboratory by the patients in sterile urine containers. Laboratory technicians observe the samples and requisition forms for any pre-analytical errors. If any error is observed, the sample is rejected and the reason for rejection is entered into the laboratory information system (LIS).

Preanalytical errors and rejection criteria of samples are as follows: missing test request, wrong test request, double test request, mislabeled samples, improper transport, absent sample, empty container, wrong container, inappropriate sample type, insufficient sample, inappropriate volume, haemolysed, clotted, lipemic.

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Statistical Analysis

We analyzed the five-year sample rejection data in LIS of the biochemical laboratory and classified them according to the reasons for rejection. The annual percentages of the rejected samples and their distribution according to the reasons were calculated in Microsoft Excel 2007 software program according to the formulas below.

Total critical errors frequency= (number of the total critical errors/number of the total requests) x 100

Preanalytical errors rates according to the reasons= (number of the preanalytical errors according to the reasons/ number of the total critical errors) x 100

DPMO and Six Sigma levels for the total and each preanalytical error were calculated with Westgard online formula (www.westgard.com/six-sigma-calculators).

Preanalytical errors were evaluated according to their ffrequencies ranks and percentages with the Pareto Principle applied in Microsoft Excel 2007 software program.

Results

The annual distributions of the total critical errors and each preanalytical error in the biochemistry laboratory between January 2015 and December 2019 were shown in Table 2. According to these data, the number of total requests for five years (hemogram, coagulation, cardiac markers, biochemistry, hormones, tumor markers, urine analysis, and urine drug levels) is 2809366, and the number of the total critical errors for five years is 53686. There was a permanent increase in the total number of samples between 2015 and 2019. While the total rejection percentage was 3.05 in 2015, the following years' range was be-

Table 2. Distribution of preanalytical errors for five years

Preanalytical error	2015		2016		2017		2018		2019		TOTAL	
	N	%	N	%	N	%	N	%	N	%	N	%
Missing test request	35	0.31	6	0.07	12	0.13	10	0.08	12	0.10	75	0.14
Wrong test request	43	0.38	315	3.47	311	3.34	469	3.79	314	2.71	1452	2.70
Double test request	795	7.00	855	9.43	577	6.20	814	6.58	1037	8.96	4078	7.60
Mislabeled samples	593	5.22	224	2.47	214	2.30	237	1.92	293	2.53	1561	2.91
Improper Transport	28	0.25	144	1.59	100	1.07	99	0.80	47	0.41	418	0.78
Absent Sample	48	0.42	9	0.10	28	0.30	18	0.15	10	0.09	113	0.21
Empty container	2371	20.88	113	1.25	127	1.36	75	0.61	104	0.90	2790	5.20
Wrong container	571	5.03	778	8.58	868	9.33	995	8.04	1087	9.39	4299	8.01
Inappropriate sample type	559	4.92	268	2.96	233	2.50	171	1.38	287	2.48	1518	2.83
Insufficient sample	2592	22.82	2185	24.10	2204	23.68	2704	21.86	2945	25.45	12630	23.53
Inappropriate volume	3	0.03	53	0.58	11	0.12	10	0.08	13	0.11	90	0.17
Haemolysed	701	6.17	341	3.76	207	2.22	210	1.70	246	2.13	1705	3.18
Clotted	3007	26.47	3754	41.41	4390	47.17	6526	52.75	5136	44.38	22813	42.49
Lipemic	12	0.11	20	0.22	25	0.27	34	0.27	41	0.35	132	0.25
Total critical errors	11358	3.05	9065	1.90	9307	1.56	12372	1.83	11572	1.68	53686	1.91
Total requests	372185		476638		595772		676478		688293		2809366	

tween 1.56 and 1.90; and the five-year total rejection rate was 1.91 percent.

The DPMO and sigma values calculated for each year of the distribution of rejected samples due to preanalytical errors were given in Table 3. The sigma level of total critical errors for five years was 3.6. Sigma levels for each of the preanalytical errors ranged from 3.9 to 5.9.

Pareto's chart, which ranked the distribution of preanalytical errors according to their frequencies and cumulative percentages, was given in Figure 1. According to the chart, among the five-year preanalytical rejections, the three most common errors were clotted sample (42.49%, sigma value: 4), insufficient sample (23.53%, sigma value: 4.2) and wrong container (8.01%, sigma value: 4.5).

Discussion

In this study, the total number of samples rejected in our laboratory over five years and their distribution according to the reasons for preanalytical rejection were examined. The sigma values of the total and each of the preanalytical errors were calculated separately and their distribution according to their frequency ranks and percentages were evaluated by Pareto's analysis.

According to our results, the percentage of total preanalytical errors for five years is 1.91%; and its sigma value is 3.6. In addition, the annual sigma values calculated separately for each of the preanalytical errors were 4 or over 4. When the distribution of total critical errors by years was evaluated, it was seen that the lowest sigma value was experienced in

Table 3. DPMO and Six Sigma values for preanalytical quality indicators

Preanalytical error	2015		2016		2017		2018		2019		TOTAL	
	DPMO	Sigma	DPMO	Sigma	DPMO	Sigma	DPMO	Sigma	DPMO	Sigma	DPMO	Sigma
Missing test request	94	5.3	13	5.7	20	5.7	15	5.7	17	5.7	27	5.6
Wrong test request	116	5.2	661	4.8	522	4.8	693	4.7	456	4.9	517	4.8
Double test request	2136	4.4	1794	4.5	968	4.6	1203	4.6	1507	4.5	1452	4.5
Mislabeled samples	1593	4.5	470	4.9	359	4.9	350	4.9	426	4.9	556	4.8
Improper Transport	75	5.3	302	5	168	5.1	146	5.2	68	5.4	149	5.2
Absent Sample	129	5.2	19	5.7	47	5.5	27	5.6	15	5.7	40	5.5
Empty container	6370	4	237	5	213	5.1	111	5.2	151	5.2	993	4.6
Wrong container	1534	4.5	1632	4.5	1457	4.5	1471	4.5	1579	4.5	1530	4.5
Inappropriate sample type	1502	4.5	562	4.8	391	4.9	253	5	417	4.9	540	4.8
Insufficient sample	6964	4	4584	4.2	3699	4.2	3997	4.2	4279	4.2	4496	4.2
Inappropriate volume	8	5.9	111	5.2	18	5.7	15	5.7	19	5.7	32	5.5
Haemolysed	1883	4.4	715	4.7	347	4.9	310	5	357	4.9	607	4.8
Clotted	8079	4	7876	4	7369	4	9647	3.9	7462	4	8120	4
Lipemic	32	5.5	42	5.5	42	5.5	34	5.4	60	5.4	47	5.5
Total critical errors	30517	3.4	19019	3.6	15569	3.7	18289	3.6	16813	3.7	19110	3.6

*DPMO: defects per million opportunities

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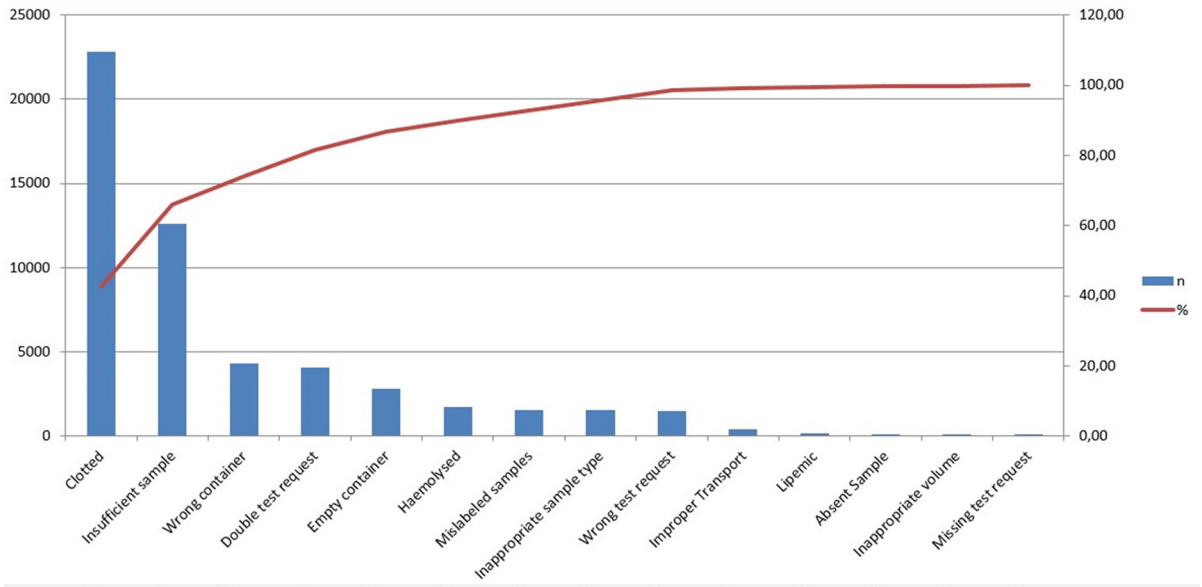

Figure 1. The Pareto's chart of preanalytical errors for five years (2015-2019)

2015, when the total number of requests was the least. The reason for this is thought to be due to the problems experienced from the hospital's moving to the new building, and installation process in 2015. Although the sigma value for the total critical errors was below 4; when 2015 and 2019 were compared, the number of total requests increased 1.85 times (total requests in 2015: n=372185; total requests in 2019: n=688293) and there was a minimal improvement in sigma values over the years (2015 sigma: 3.4, 2019 sigma: 3.7) (Figure 2). When the preanalytical errors were evaluated according to their causes, it was seen that the two most common errors for five years were clotted samples (42.49%, sigma: 4) and insufficient samples (23.53%, sigma: 4.2), respectively.

In the study of Ercan Ş. [9]. using the Six Sigma method to evaluate the reasons for preanalytical rejection for one-year period, the overall rate of critical preanalytical errors was 0.328%, with a Six Sigma value of 4.25. And although the most common cause of the error was clotted sample (32.7%; sigma: 4.375) similar to the present study, differently the error rate was lower and the sigma level was within the acceptable range. In the study of Mukhopadhyay et al. [10] using the Six Sigma method to evaluate the reasons for preanalytical rejection for two months, the overall rate of critical preanalytical errors was 2.11%, with a Six Sigma value of 3.6. These values were found close to the current study, but the duration of this study was shorter.

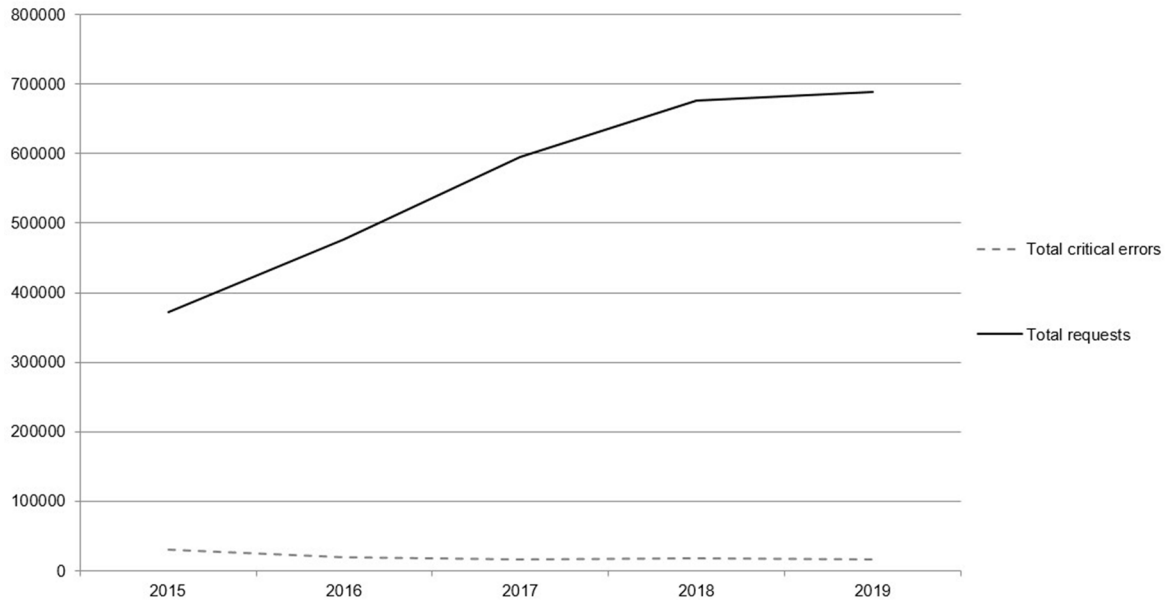

Figure 2. The alteration of total critical error and the number of total requests by years

Lay et al. [11] and Guimaraes et al. [12] evaluated the preanalytical errors and found that the overall rate of critical preanalytical errors was 2.7% and 0.57%, respectively, and the most common reasons for rejection were clotted and insufficient samples (percentages of clotted samples were 55.8% and 43.8%; insufficient samples were 29.3% and 24%, respectively). The six sigma method was not used in these two studies, and when compared with the present study according to the total critical error frequency rates, it was observed that the error rate observed in the present study (1.91%) was between those in these two studies. In addition, the most common causes of errors were found to be similar to the present study. There are many other studies in the literature that evaluated preanalytical phase performance and found that clotted and insufficient samples are common causes of rejection [13, 14, 15, 16, 17, 18]. While the total critical preanalytical error rate in the current study was similar to some studies in the literature, it was higher than most of them. In the current study, while the annual sigma values calculated separately for each of the preanalytical errors were 4 or over 4, the total error sigma level was below 4. Therefore, with this study, it was revealed that our laboratory should take regulatory and preventive actions to reduce the total error sigma rate and increase the sigma level to an acceptable level.

Pareto's chart showed that the two most common reasons for preanalytic rejection were caused by errors during phlebotomy. Clotted sample, which is the most common reason for rejection, may be caused by the excessive ratio of blood to anticoagulant in the tube and not mixing blood with anticoagulant sufficiently. This error may have been caused by the fact that the blood sample was not collected at the proper level specified on the tube during phlebotomy and then was not mixed properly. Clotted samples are not suitable for analysis as they cause inaccurate and incomplete laboratory results and cause clogging of analyzer probes. The second most common reason for preanalytical rejection in our laboratory was insufficient samples. Blood collection is accurately standardized with vacuum tubes with defined blood levels. However, in units such as neonatal, intensive care, and oncology, adequate blood can not be collected due to the incompatibility of the vascular structure of the patients. In addition, insufficient samples may be encountered due to the lack of knowledge and experience of the phlebotomists and nursing staff performing the phlebotomy procedure. An insufficient sample is not suitable for analysis because the amount of blood required for the analyzer cannot be provided.

To prevent all these errors caused mainly by the phlebotomy process and to improve the total quality management; Periodic training has been planned for technicians, nursing staff, interns, and doctors on phlebotomy, sample collection, and transportation. And also routine controls of responsible personnel were tightened during the period from blood sampling to entering the laboratory. After all development activities, the "Control" step will be carried out as the last step of the DMAIC cycle in the coming years.

In the present study, "Defining, Measuring, Analysing" steps of Six Sigma were performed to evaluate the preanalytical errors in the clinical biochemical laboratory over five years, and as the " Improving " step of Six Sigma, solutions suggestions for the most common errors were discussed according to Pareto principle. In the context of laboratory quality management, applying Pareto principle enables the identification of the most frequent or severe errors, leading to a better allocation of resources for corrective and preventive actions.

In conclusion, the Six Sigma method and the Pareto principle are effective and practical statistical approaches to solving problems, and continuous improvement should be a laboratory management strategy to make the processes more efficient and more effective.

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Ethics Committee Approval: The study was about laboratory management, thus ethical approval and informed consent were not required. Data usage permission was obtained for our study.

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References

1. Shah S, Saini R, Singh SB, Aggarwal O, Goel AK. Six Sigma Metrics and Quality Control in Clinical Laboratory. Int J Med Res Rev. 2014;2(2):140-9. doi: 10.17511/ijmrr.2014.i02.20.
2. Hammerling JA. A Review of Medical Errors in Laboratory Diagnostics and Where We Are Today. Lab Med. 2012;43(2):41–4. doi: 10.1309/LM6ER9WJR1IHQAUY.
3. Lima-Oliveira G, Volanski W, Lippi G, Picheth G, Guidi GC. Preanalytical phase management: a review of the procedures from patient preparation to laboratory analysis. Scand J Clin Lab Invest. 2017;77(3):153–63. doi: 10.1080/00365513.2017.1295317.

Acta Medica Alanya 2023;7(2): 163-169
Doi: 10.30565/medalanya.1325564

4. Oktay SB, Ayyıldız SN. Assessment of analytical process performance using the Six Sigma method: A comparison of two biochemistry analyzers. Int J Med Biochem. 2021;4(2).97-103. doi: 10.14744/ijmb.2021.14633.
5. de Araujo BV. "Lean Six Sigma in Services: An Application of the Methodology in the Attendiment Sector of an Exam Laboratory." Science Journal of Business and Management. 2020;8(3):119-31. doi: 10.11648/j.sjbm.20200803.13.
6. Carlson RO, Amirahmadi F, Hernandez JS. A primer on the cost of quality for improvement of laboratory and pathology specimen processes. Am J Clin Pathol. 2012;138(3):347-54. doi: 10.1309/AJCPSMQYAF6X1HUT.
7. Kulkarni S, Ramesh R, Srinivasan AR, Silvia CRWD. Evaluation of Preanalytical Quality Indicators by Six Sigma and Pareto`s Principle. Indian J Clin Biochem. 2018;33(1):102-7. doi: 10.1007/s12291-017-0654-5.
8. Picarillo AP. Introduction to quality improvement tools for the clinician. J Perinatol. 2018;38(7):929-35. doi:10.1038/s41372-018-0100-4.
9. Ercan Ş. The Evaluation of Rejected Samples Prevalence Using Six Sigma. Türk Klinik Biyokimya Derg. 2016;14(1):32-9.
10. Mukhopadhyay T, Shekhar S, Dagar VK, Mukhopadhyay AK. Characterization of pre-analytical errors using six sigma metrics and process capability index in a clinical biochemistry laboratory. Int J Health Sci Res. 2021;11(2):171-6. doi: 10.52403/ijhsr.
11. Lay IS, Pınar A, Akbıyık F. Classification of reasons for rejection of biological specimens based on preanalytical processes to identify quality indicators at a university hospital clinical laboratory in Turkey. Clin Biochem. 2014;47(12):1002-5. doi: 10.1016/j.clinbiochem.2014.04.024.
12. Guimarães AC, Wolfart M, Brisolara ML, Dani C. Causes of rejection of blood samples handled in the clinical laboratory of a University Hospital in Porto Alegre. Clin Biochem. 2012;45(1-2):123-6. doi: 10.1016/j.clinbiochem.2011.10.009.
13. HarsimranKaur VN, Selhi PK, Sood N, Singh A. Preanalytical Errors in Hematology Laboratory- an Avoidable Incompetence. Iran J Pathol. 2016;11(2):151-4. PMID: 27499777
14. Atay A, Demir L, Cuhadar S, Saglam G, Unal H, Aksun, et al. Clinical biochemistry laboratory rejection rates due to various types of preanalytical errors. Biochemia Medica. 2014;24(3):376–82. doi: 10.11613/BM.2014.040.
15. Öz L, Koçer D, Buldu S, Karakükcü Ç. Analysis of pre-preanalytical errors in the clinical biochemistry laboratory of Kayseri Eğitim ve Araştırma Hastanesi. Türk Klinik Biyokimya Derg. 2016;14(1):6-11.
16. Lippi G, Bassi A, Brocco G, Montagnana M, Salvagno GL, Guidi GC. Preanalytic error tracking in a laboratory medicine department: results of a 1-year experience. Clin Chem. 2006;52(7):1442-3. doi: 10.1373/clinchem.2006.069534
17. Korkmaz Ş. Evaluation of Rejected Sample Rates Using Six Sigma Method. Türk Klinik Biyokimya Derg. 2020;18(1):17-25.
18. Gajjar M, Patel A, Jain S. Monitoring of quality indicators in pre-analytical phase of testing in the clinical biochemistry laboratory of a tertiary care hospital attached with Government Medical College. IOSR- Journal of Dental and Medical Sciences. 2016;15(7):62-68. doi:10.9790/0853-15075626.