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Research Article

Evaluation of analytical performance of tests worked on the same brand devices with six sigma metrics

Aynı marka cihazlarda çalışılan testlerin six sigma metrikleri ile analitik performansının değerlendirilmesi

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ABSTRACT

Aim: The aim of this study is that evaluate the analytical performance with six sigma metrics between the same brand devices actively working in the laboratory and answer the question of which tests will be performed on these devices according to the laboratory test working rates.

Material and Methods: In the research, all tests were studied on Abbott brand, Architeck c8000, and Architeck ci4000 model devices for 6 months. Glucose (Glc), blood urea nitrogen (BUN), creatinine (CREA), aspartate aminotransferase (AST), total cholesterol (CHOL), triglycerides (Tg), sodium (Na), potassium (K), chlorine (Cl) parameters were evaluated in the sigma values were calculated according to the performance approach. The comparisons were drew between these two devices. Total allowable error (TEa) is derived from the Clinical Laboratories Improvement Amendments (CLIA) guidelines.

Results: In the comparative follow-up performed for 6 months, the determination of the parameters to be worked on which device on monthly basis varied. Since the sigma values of the glucose, urea and creatinine tests, which are the most studied in our laboratory, are lower in the Architeck ci4000 device than the Architeck c8000 device. It was decided to run these tests only on the Architeck c8000 device. All metrics have been obtained until October 2019. An increase in the sigma value was detected with the start of working of electrolytes on a single device six months later.

Conclusıon: Six sigma metrics should be used monthly to monitor tests with particularly low biological variation to evaluate the method performance of same-brand devices which is used for thousands of tests.

Keywords: six sigma, Architeck ci4000, Architeck c8000, Westgard

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Öz

Amaç: Altı sigma ile analitik testlerin istenilen kalitede olup olmadığı ve kalitenin sayısal değeri görülebilir. Laboratuvarlara sunulan testlerin yöntem kalitesini değerlendirmek, cihazlar arasında yöntem performansını karşılaştırmak, kalite kontrol prosedürlerini yeniden gözden geçirmek konusunda altı sigma metriklerinden faydalanılmaktadır.

Gereç ve Yöntemler: Bu çalışmanın amacı; laboratuvarda aktif çalışılan aynı marka cihazlar arasındaki altı sigma metrikleri ile analitik performansın değerlendirilmesi ve laboratuvar test çalışma hızına göre bu cihazlarda hangi testlerin çalışılıp çalışılmayacağı sorusuna yanıt bulmaktır. Yapılan araştırmada bütün testler ABBOTT marka Architeck c 8000 ve Architeck ci 4000 cihazlarında 6 ay süre ile çalışılmıştır. Glukoz (Glc), üre (BUN), kreatinin (CREA), aspartat aminotransferaz (AST), total kolesterol (CHOL), trigliseritler (Tg), Sodyum (Na), potasyum (K), klor (Cl) parametreleri değerlendirilmiş testlerin sigma değerleri performans yaklaşımına göre hesaplanmış ve cihazlar arasında karşılaştırma yapılmıştır. Toplam kabul edilebilir hata (TEa), Klinik Laboratuvarları İyileştirme Yasası (CLIA) klavuzlarından alınmıştır. Bias, yeterlilik test verilerine göre belirlenmiştir. Biyokimyasal analitler için varyasyon katsayısı (CV) laboratuvarımızın IQC kayıtlarından elde edilmiştir. Sigma metrikleri (SM) = (TEa-%Bias)/ %CV formülüne göre hesaplanmıştır

Bulgular: 6 ay boyunca yapılan karşılaştırılmalı takipte ay bazında hangi cihazda çalışılması gereken parametrelerin belirlenmesi değişkenlik göstermiştir. Laboratuvarımızda en fazla çalışılan glucose, urea ve creatinine testlerinin Architeck ci 4000 cihazında sigma değerleri Architeck c8000 cihazından daha düşük olduğu için bu testlerin sadece c8000 cihazında çalışılmasına karar verildi. Elde edilen metriklere göre, 2019 Ekim ayından itibaren başlattığımız çalışmada altı ay sonra elektrolitlerin tek cihazda çalışılmaya başlanması ile sigma değerinde artış tespit edildi.

Sonuç: Altı sigma metrikleri, binlerce test yapılan aynı marka cihazların yöntem performansını değerlendirmede aylık olarak özellikle düşük biyolojik varyasyona sahip testleri takip etmek için kullanılmalıdır.

Anahtar Kelimler: altı sigma, Architeck ci4000, Architeck c8000, Westgard

Introduction

Advances in medicine and health technology, increasing patient expectations, facilitating access to health services, aging of the world population, increasing chronic diseases have accelerated health expenditures and costs in the world. This situation has challenging as an important issue for both governments and health institutions [1]. In today's competitive environment, it is indispensable to develop strategies on issues such as production, quality, customer and user satisfaction, and cost advantage in health sector as well as other institutions. In this context, it is aimed to improve institutional practices by using various techniques that are considered as post-modern [2]. Considering that 75-80% of individuals who apply to the hospital have tests in clinical laboratories, keeping the quality of the total laboratory process under control becomes a necessity in terms of institutional and national health services.

Six sigma is a strong, systematic, disciplined, problem-solving, well-organized organization designed to eliminate the source of errors identified by customers as defects and mistakes, to eliminate unnecessary activities in processes to reduce deviations, and to structure in a way that corresponds to 3.4 errors per million in statistically supported organizational effectiveness and development. It is a proactive, ongoing process improvement strategy. However, Six Sigma accepts 3.4 defect scans per million, 7 Sigma, which has come to the fore in recent years, targets 0.019 defects per million [3].

The total test process in clinical laboratories consists of 3 phases: preanalytical, analytical and post analytic. According to the studies, the estimated error rates for the phases of the total test process vary between 30-75% in the preanalytical phase, 4- 30% in the analytical phase, and 9-55% in the postanalytical phase [4]. In recent years, with the significant efforts of both laboratories and manufacturers of laboratory equipment and reagents, errors in the analytical phase of the total testing process have decreased significantly [5]. Quality standardization must begin with analytical quality in a laboratory because analytical quality is the quality characteristic required for all laboratory testing. Analytical quality is not a stand-alone quality requirement, but the other quality parameters do not matter unless analytical quality is ensured. Laboratories must be able to provide accurate test results before other quality requirements [6]. The analytical

process defines the test methods, analyzers used, internal and external quality control and calibrations which come to the fore moreover makes control of variables is more possible [7].

Six sigma uses a stepwise process called DMAIC, this abbreviation means: Define, Measure, Analyze, Improve and Control. These stages allow improving the quality of any process at the project level or throughout the organization [8]. It is valuable the strong impact on the healthcare sector, including the large number of case studies published, which are focused on hospitals and improving medical procedures [9,10]. In healthcare, it is vital to use quality management systems as six sigma for ensuring efficiency because the commission of errors may seriously cause costs of patients' life. Six Sigma method; It is a quality management tool that is based on statistical calculations, focused on process variables, and provides information about process performance. The key indicator is the process sigma level. According to, six sigma method, process performance is evaluated according to the poor-quality costs determined from the process sigma levels, and it is aimed to reduce these poor-quality costs in improvement [11]. The evaluation of the pre- and post-analysis processes together with the analysis process with the six sigma method also provides a holistic view to the process.

By means of the six sigma method, it is possible to determine the possibility of an false result in a system that is thought to be under control. Considering that tests with low sigma values show poor analytical performance, they should be followed more closely and if they do not show improvement, the need for a detailed evaluation of the analytical method will arise and perhaps a decision to change the method will be carried on. Another benefit of using Sigma values is that, it gives the opportunity to tweak control applications [12]. For example, once-daily follow-up with two levels of internal quality control (IQC) and the 1_{3S} Westgard rule is recommended for tests with a sigma value ≥6. If the Sigma value is 4-6, daily two-level control and the Westgard multiple rule of 1_{3S}, 2_{2S}, R_{4S} are applied. If the Sigma value is 3-3.99, two-level control and the 1_{3S}, 2_{2S}, R_{4S}, 4_{1S} Westgard multiple rule apply twice a day. If the sigma value is less than 3, root cause analysis should be performed and method performance should be improved before it enters routine use. In this way, it is thought that the loss of time that causes delays in both cost and results can be reduced by reducing false IQC rejections [13]. The IQC rules recommended to be applied according to sigma values by Westgard are shown in Table 1. Sigma Value Performance Definition IQC Rules.

Table 1. Recommended IQC rules according to Sigma values

igma Value	Performance Definition	IQC Rules
<3	Unsatisfactory - Method performance needs improvement	1_{3S} / 2_{2S} / R_{4S} / 4_{1S}; 2 times per a day, 3 level
3-3.99	Sufficient performance More often inspection	1_{3S} / 2_{2S} / R_{4S} / 4_{1S}; 2 times per a day, 2 level
4-6	Good/acceptable performance	1_{3S} / 2_{2S} / R_{4S}; 1 time per day, 2 level
≥6	Excellent performance	1_{3S} ;1 time per day, 2 level

The process based on this study is the clinical laboratory analytical process. Expectations from this process are to obtain accurate and reliable test results. To achieve this aim, bias values, which are the accuracy criteria, were obtained from the repeatability criterion coefficient of variation (CV) and external quality control evaluation programs, which are constantly applied in IQC programs, and these values were used in the calculation of process sigma level.

The aim of these quality control processes is to reach the quality targets determined by the authorities. These quality objectives are most commonly referred to as Allowable Total Error (TEa). The total allowable error may be determined based on the clinical significance and clinical experience of the analyte, the biological variability of the analyte, the analytical competence achieved, or the level of analytical errors. Errors that do not negate the clinical usefulness of the test may fall into the allowable total error. The laboratory can document the analytical quality by comparing its Total Analytic Error (TAH) with the allowable total error limit. For patient safety, the total analytical error should not exceed the total allowable error limit. Total analytical error (TAH) is the sum of Random Error and Systematic Error reflected in a test result. Biological variation (BV) describes the variation observed in the concentration or activity of different components in an individual, reflecting regulation by homeostatic processes in the body. High-quality BV data have been produced in recent years by the European Working Group on Biological Variation (EuBIVAS). Total acceptable error limits determined according to biological variation are lower.

In this study we evaluated the analytical performance with six sigma metrics between the same brand devices actively working in the laboratory and answer the question of which tests will be performed on these devices according to the laboratory test working rates.

Material and Methods

In this study, we inspected the performance of biochemical analytes on same brand devices as calculating six sigma metrics. The research and data collection process has been retained during 6 months in Istanbul Atlas University Medicine Hospital Clinical Laboratory. The tests of sigma metrics were calculated as a performance approach and the comparison was interpreted between same brand devices. Glucose (Glc), urea, creatinine (CREA), aspartate aminotransferase (AST), total cholesterol (CHOL), triglyceride (Tg), sodium (Na), potassium (K), clor (Cl) parameters were evaluated and all test were carried on Abbott brand, Architeck c8000, and Architeck ci4000 model devices during 6 months. Total allowable error (TEa) is derived from the Clinical Laboratories Improvement Act (CLIA) guidelines. Bias was determined based on proficiency test data. The coefficient of variation for biochemical analytes was obtained from the IQC records of our laboratory.

Sigma metrics (SM) were calculated according to the formula (SM) = (TEa-% Bias) / %CV. The parameters were sorted into 6 categories conceiving world-class performance (SM = 6 or more), excellent performance (SM = 5-6), good performance (SM = 4-5), marginal performance (SM = 3-4), poor performance (SM = 2-3) and unacceptable performance (SM is less than 2) [14]. After exclusion of IQC and outlier data each parameter CV value was determined. The external quality control data were used for each deviation of parameters. The internal QC data was removed from October 2019 and March 2020 analysis records. Quality inspection was done before each analytical process. Internal quality control data (the same lot for each laboratory and level 1 QC value was determined by manufacturers) were used to determine each parameter CV after the exclusion of outliers (QC observations that contravene 13S rule). Different control levels were studied for each month. The calculation of CV% for two levels, were converted in to only one %CV value by using equation below and one sigma metric was calculated.

Total % CV = √(Level 1)2+(level 2)2

The external control assurance (EQA) data was used for the determination of each analyte's deviation. The six-month EQA sample results are included in the study. EQA data were obtained by the average of the group which is used the same device and the same method. An external quality control program consisting of twelve-month samples was followed in each cycle. The manufacturer simultaneously provided the total number of samples for the entire cycle.

Results

Table 2 shows the performance characteristics of the parameters from Istanbul Atlas University Medicine Hospital; Sigma metrics were calculated considering the total allowable errors from the several sources as shown. Among the parameters tested on the ci4000 device in October 2019, cholesterol had the highest sigma (8.2), while urea had the lowest sigma value (2.3). Among the parameters tested on the Architeck c8000 device, AST had the highest sigma (9.7), while sodium had the lowest sigma value (2.5). In addition, since the sigma values of the glucose, urea and creatinine tests, which are the most studied in our laboratory, are lower in the Architeck ci4000 device than the Architeck c8000 device, therefore it was decided to run these tests only on the c8000 device.

As shown in Table 3, among the parameters tested on the ci4000 device in November 2019, AST had the highest sigma (6.2), while sodium had the lowest sigma value (2). Among the parameters tested on the c8000 device, AST had the highest sigma (8), while sodium had the lowest sigma value (1.9). In addition, it was observed that the sigma metric values of glucose and creatinine tests increased in the c8000 device.

As seen in Table 4, AST had the highest sigma (7.3), while sodium had the lowest sigma (2) value among the parameters tested on the ci4000 device in December 2019. Among the parameters tested on the c8000 device, AST had the highest sigma (9.7), while sodium had the lowest sigma (1.6). In addition, it was observed that the sigma metric values of glucose and creatinine tests increased in the c8000 device.

As shown in Table 4, among the parameters tested on the ci4000 device in January 2020, cholesterol had the highest sigma (7.2) while sodium had the lowest sigma value (2). Among the parameters tested on the c8000 device, AST had the highest sigma (8.1), while sodium had the lowest sigma value (3.3). In addition, it was observed that the sigma metric values of glucose, urea and creatinine tests increased in the c8000 device.

As shown in Table 6, among the parameters tested on the ci4000 device in February 2020, AST had the highest sigma (7.3), while sodium had the lowest sigma value (1.7). Among the parameters tested on the c8000 device, AST had the highest sigma (11,6) while glucose had the lowest sigma (3.8) after sodium. In addition, it was decided not to run the sodium, potassium and clor tests on the c8000 device.

As seen in Table 7, among the parameters tested on the ci4000 device in March 2020, AST (7.2) and Potassium (>6) had the highest sigma, while sodium had the lowest sigma value (3.8). Among the parameters tested on the c8000 device, urea had the highest sigma (11.8) while glucose had the lowest sigma value (4.1). It was decided not to run cholesterol and triglycerides tests on the ci4000 device. Discussion and

Table 2: Parameters tested on the ci4000 and c8000 device in October 2019

Parameters	TEa source	TEa	ci4000 %CV	ci4000 %BİAS	ci4000 sigma metrics	c8000 %CV	c8000 %BİAS	c8000 sigma metrics
Glucose	CLIA 2019	8	1.7	1.6	3.7	1.4	1.1	4.9
Urea	CLIA 2019	9	3.2	1.6	2.3	2.1	1.4	3.6
Creatinine	CLIA 2019	10	2.9	1.7	2.8	1.9	0.09	5.2
Cholesterol	CLIA 2019	10	1	1.8	>6	0.9	2.1	>6
Triglycerides	CLIA 2019	15	1.9	4.1	5.7	2.2	3.9	5
AST	CLIA 2019	15	1.8	1.8	>6	1.4	1.4	>6
Sodium	CLIA 2019	4	1	0.5	3.5	0.8	1	3.75
Potassium	BV	5.6	1.5	1.4	2.8	1.2	1.1	3.7
Clor	CLIA 2019	5	1.2	0.5	3.7	1	1.3	3.7

TEa – Total Allowable Error, CV - Coefficient Of Variation, BİAS – deviation, BV –Biological Variation, CLIA – Clinical Laboratory Improvement Amendments 2019, AST- Aspartate Aminotransferase.

Table 3: Parameters tested on the ci4000 and c8000 device in November 2019.

Parameters	TEa source	TEa	ci4000 %CV	ci4000 %BİAS	ci4000 sigma metrics	c8000 %CV	c8000 %BİAS	c8000 sigma metrics
Glucose	CLIA 2019	8				1.6	1	4.3
Urea	CLIA 2019	9				2.9	1.3	2.6
Creatinine	CLIA 2019	10				2.3	0.05	4.3
Cholesterol	CLIA 2019	10	1.2	1.6	>6	1.4	1.8	5.8
Triglycerides	CLIA 2019	15	3.4	2.9	3.5	2.8	3.4	4.1
AST	CLIA 2019	15	2.1	1.8	>6	1.7	1.4	>6
Sodium	CLIA 2019	4	1.2	0.6	2.8	1.1	0.9	2.8
Potassium	BV	5.6	1.7	1.1	2.6	1.3	0.9	3.6
Clor	CLIA 2019	5	1.2	0.6	3.6	1.1	1.2	3.4

TEa – Total Allowable Error, CV - Coefficient of Variation, BİAS – deviation, BV –Biological Variation, CLIA – Clinical Laboratory Improvement Amendments 2019, AST- Aspartate Aminotransferase.

Table 4: Parameters tested on the ci4000 and c8000 device in December 2019.

Parameters	TEa source	TEa	ci4000 %CV	ci4000 %BİAS	ci4000 sigma metrics	c8000 %CV	c8000 %BİAS	c8000 sigma metrics
Glucose	CLIA 2019	8				1.6	0.9	4.4
Urea	CLIA 2019	9				3.1	1.5	2.4
Creatinine	CLIA 2019	10				2	0.09	4.9
Cholesterol	CLIA 2019	10	1.4	1.4	>6	1	1.8	>6
Triglycerides	CLIA 2019	15	3.4	2.7	3.6	2.7	3	4.4
AST	CLIA 2019	15	1.8	1.8	>6	1.4	1.4	>6
Sodium	CLIA 2019	4	1.3	0.4	2.7	1.3	0.8	2.4
Potassium	BV	5.6	1.4	1	3.2	1.4	0.8	3.4
Clor	CLIA 2019	5	1.3	0.5	3.4	1.5	1.1	2.6

TEa – Total Allowable Error, CV - Coefficient of Variation, BİAS – deviation, BV –Biological Variation, CLIA – Clinical Laboratory Improvement Amendments 2019, AST- Aspartate Aminotransferase.

Table 5: Parameters tested on the ci4000 and c8000 device in January 2019.

Parameters	TEa source	TEa	ci4000 %CV	ci4000 %BİAS	ci4000 sigma metrics	c8000 %CV	c8000 %BİAS	c8000 sigma metrics
Glucose	CLIA 2019	8				1.4	0.5	5.3
Urea	CLIA 2019	9				1.9	0.5	4.4
Creatinine	CLIA 2019	10				2	0.08	4.9
Cholesterol	CLIA 2019	10	1.2	1.3	>6	1.1	1.3	>6
Triglycerides	CLIA 2019	15	2.2	2.8	5.5	1.7	2.8	>6
AST	CLIA 2019	15	2.1	1.4	>6	1.7	1.2	>6
Sodium	CLIA 2019	4	1.2	0.5	3.1	1	0.7	3.3
Potassium	BV	5.6	1.6	1	2.8	1.4	0.8	3.4
Clor	CLIA 2019	5	1	0.5	4.5	1.3	1.1	3

TEa – Total Allowable Error, CV - Coefficient of Variation, BİAS – deviation, BV –Biological Variation, CLIA – Clinical Laboratory Improvement Amendments 2019, AST- Aspartate Aminotransferase.

Table 6: Parameters tested on the ci4000 and c8000 device in February, 2019.

Parameters	TEa source	TEa	ci4000 %CV	ci4000 %BİAS	ci4000 sigma metrics	c8000 %CV	c8000 %BİAS	c8000 sigma metrics
Glucose	CLIA 2019	8				1.9	0.6	3.8
Urea	CLIA 2019	9				1.7	0.9	4.7
Creatinine	CLIA 2019	10				1.6	0.2	>6
Cholesterol	CLIA 2019	10	1.4	1.3	>6	1	1.7	>6
Triglycerides	CLIA 2019	15	2	2.9	6	1.7	3	>6
AST	CLIA 2019	15	1.9	1	>6	1.2	1	>6
Sodium	CLIA 2019	4	1.4	0.5	2.5			
Potassium	BV	5.6	1.6	0.8	3			
Clor	CLIA 2019	5	1.3	0.5	3.4			

TEa – Total Allowable Error, CV - Coefficient of Variation, BİAS – deviation, BV –Biological Variation, CLIA – Clinical Laboratory Improvement Amendments 2019, AST- Aspartate Aminotransferase.

Table 7: Parameters tested on the ci4000 and c8000 device in March, 2019.

Parameters	TEa source	TEa	ci4000 %CV	ci4000 %BİAS	ci4000 sigma metrics	c8000 %CV	c8000 %BİAS	c8000 sigma metrics
Glucose	CLIA 2019	8				1.9	0.1	4.1
Urea	CLIA 2019	9				0.7	0.7	>6
Creatinine	CLIA 2019	10				2.1	0.01	4.7
Cholesterol	CLIA 2019	10				1.4	0.9	>6
Triglycerides	CLIA 2019	15				1.5	2.8	>6
AST	CLIA 2019	15	1.9	1.2	>6	1.5	1.3	>6
Sodium	CLIA 2019	4	1	0.2	3.8			
Potassium	BV	5.61	0.05	0.3	>6			
Clor	CLIA 2019	5	1	0.07	4.9			

TEa – Total Allowable Error, CV - Coefficient Of Variation, BİAS – deviation, BV –Biological Variation, CLIA – Clinical Laboratory Improvement Amendments 2019, AST- Aspartate Aminotransferase.

Conclusion

The analytical process is a process in which test methods, analyzers used, internal and external quality control and calibrations come to the fore and control of variables is more possible. 26 Six sigma methodology to prove their performance emerges as an effective tool [15]. In order to provide a holistic view of the process, pre- and post-analysis processes should be evaluated together with the analysis process. While selecting the tests to be evaluated, IQC data were collected for 6 months by selecting 9 frequently requested parameters. The reason for choosing these tests is that they are frequently requested tests in our laboratory, while the patient evaluates according to the test results, more patient results are obtained. Analytical process sigma levels are calculated separately for each test. Configuring the laboratory information system is important in reducing this workload due to the processes that increase the workload, such as taking the daily EQC data used in this calculation from laboratory information system and transferring them to Microsoft Excel [16].

Researches show that the majority of laboratory errors occur in preanalytical and postanalytic processes. Miller and Sandberg suggested that the total allowable error (TEa), expressed depending on the analysis, for each analyte, the optimum clinical decision should be determined to make a clinical decision based on it [17]. Some analyte changes will affect clinical decisions when relatively large (up to 50% for alanine aminotransferase and lipase activities). However, for some analytes, a relatively minor change will affect clinical judgment, such as electrolytes [18].

Gami et al. explored how the variable outputs of different parameters differs. A high biological variation parameters such as triglyceride measured by any device will give an acceptable sigma value. Electrolytes with low biological variation, such as sodium and potassium, will give a low sigma value [18,19]. Korkmaz indicated that the reason for the poor performance was examined using QGI for analytes with sigma <3 according to CLIA, which was evaluated as poor performance. According to the result, necessary corrective and preventive actions were initiated [20].

The same observation was obtained in our results. However, as of November 2019, an increase in the sigma value has been

detected, with the electrolyte starting to work in a single device. This can be used routinely in laboratories, especially to follow tests with low biological variation.

Tufail et al. investigated how effect the differantiation of the biodiversity on several parameters. A high biological variation parameter such as triglyceride measured by any device will give an acceptable sigma value. Electrolytes with low biological variation, such as sodium and potassium, will give a low sigma value.(18) The same observation was obtained in our results. However, until November 2019, an increase in the sigma value has been detected, with the electrolyte starting to work in a single device. This can be used routinely in laboratories, especially to follow tests with low biological variation. Medina et all (2019), evaluated total of twenty (28) tests on two Abbott Architect c8000 chemistry analyzers from September 2014 to July 2019 using results of quality control mean, coefficient of variation, bias and total allowable error to compute for the six sigma value. They included both level one and level two third party quality controls in the evaluation and they used six sigma metrics allowed the laboratory to evaluate the performance of the chemistry tests objectively. The results indicated that >6.0 sigma signifies world class performance and entail application of fewer Westgard rules with fewer number of runs while those that are <3.0 need method improvement or more stringent quality control measures. The findings show that usage this monitoring and performance evaluation should definitely effect quality improvement.

In our study, the comparative follow-up performed for 6 months, the determination of the parameters to be worked on which device on monthly basis varied. Since the sigma values of the glucose, urea and creatinine tests, which are the most studied in our laboratory, are lower in the Architeck ci4000 device than the Architeck c8000 device. Since 5th month, the sigma values for sodium, potassium and clor were increased from 2.5 to 3.8 for sodium; from 3 to 6 for clor and from 3.4 to 4.9 for potassium so we have reduced all measurements in single device. Meanwhile, the calibration frequency has been increased. The frequency of calibration performed 3 times a day was increased to 4. Six sigma metrics should be used monthly to monitor tests with particularly low biological variation to evaluate the method performance of same-brand devices which is used for thousands of tests. It was decided to run these tests only on the Architeck c8000 device. All metrics have been obtained until October 2019. An increase in the sigma value was detected with the start of working of electrolytes on a single device six months later.

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References

1. Almorsy L, Khalifa M. Lean Six Sigma in Health Care: Improving Utilization and Reducing Waste. Stud Health Technol Inform. 2016;226:194-7.
2. Singh and Rathi. A structured review of Lean Six Sigma in various industrial sectors. Int. J. of Lean Six Sigma.2019: Volume: 1 Issue: 1, to Volume: 14 Issue: 1.
3. McCoy C, Douglas C. Applying Lean Six Sigma to evidence-based practice projects. Nurs Manage. 2022;53(5):35-9.
4. Jayasinha Y. Decreasing Turnaround Time and Increasing Patient Satisfaction in a Safety Net Hospital-Based Pediatrics Clinic Using Lean Six Sigma Methodologies. Qual Manag Health Care. 2016;25(1):38-43.
5. Ciulla TA, Tatikonda MV, ElMaraghi YA, Hussain RM, Hill AL, Clary JM, et al. Lean Six Sigma Techniques to Improve Ophthalmology Clinic Efficiency. Retina. 2018;38(9):1688-98.
6. Westgard S, Bayat H, Westgard JO. Mistaken assumptions drive new Six Sigma model off the road. Biochem Med (Zagreb). 2019;29(1):010903.
7. Tagge EP, Thirumoorthi AS, Lenart J, Garberoglio C, Mitchell KW. Improving operating room efficiency in academic children's hospital using Lean Six Sigma methodology. J Pediatr Surg. 2017;52(6):1040-4.
8. Jayasinha Y. Decreasing Turnaround Time and Increasing Patient Satisfaction in a Safety Net Hospital-Based Pediatrics Clinic Using Lean Six Sigma Methodologies. Qual Manag Health Care. 2016;25(1):38-43.
9. Ciulla TA, Tatikonda MV, ElMaraghi YA, Hussain RM, Hill AL, Clary JM, et al. Lean Six Sigma Techniques to Improve Ophthalmology Clinic Efficiency. Retina. 2018;38(9):1688-98.
10. Westgard S, Bayat H, Westgard JO. Mistaken assumptions drive new Six Sigma model off the road. Biochem Med (Zagreb). 2019;29(1):010903.
11. Tagge EP, Thirumoorthi AS, Lenart J, Garberoglio C, Mitchell KW. Improving operating room efficiency in academic children's hospital using Lean Six Sigma methodology. J Pediatr Surg. 2017;52(6):1040-4.

12. El-Eid GR, Kaddoum R, Tamim H, Hitti EA. Improving hospital discharge time: successful implementation of Six Sigma methodology. Medicine (Baltimore). 2015;94(12):e633.
13. Westgard SA, Goldschmidt HMJ, Ehrmeyer SS. POCT Analysts' Perspective: Practices and Wants for Improvement. J Appl Lab Med. 2020;5(3):480-93.
14. El Sharkawy R, Westgard S, Awad AM, Ahmed AOI, Iman EH, Gaballah A, et al. Comparison between Sigma metrics in four accredited Egyptian medical laboratories in some biochemical tests: an initiative towards sigma calculation harmonization. Biochem Med (Zagreb). 2018;28(2):020711.
15. Aslan D, Demir S, Laboratuvar Tıbbında Altı Sigma Kalite Yönetimi. Turk J Biochem. 2005; 30(4): 272- 278.
16. Wolcott J, Schwartz A, Goodman C eds. Laboratory Information Systems. Laboratory Medicine a National Status Report. 2008; 243-63
17. Miller WG,Sandberg S.Qualty control the analytical examination. In: Rifai N,Gay-Lussac LJ,eds. Tietz textbook of clinical chemistry and moleculer diagnostics.6th ed.Philadelphia,pa: Elsevier Saunders; 2018.
18. Gami B,Patel D,Chauhan K, Shah H,Haridas N.Sigma metrics as a qualty marker for analyzing electrolyytes in laboratory. Int J Adv Res 2013;1:197-201.
19. Adiga Usha S, Preethika A, Swathi K. Sigma metrics in clinical chemistry laboratory – A guide to quality control. Al Am een J Med Sci 2015; 8(4):281-287.
20. Korkmaz, S.2022. Sigma metric evaluation with different TEa targets in clinical biochemistry. DOI: 10.14744/ijmb.2022.81300 Int J Med Biochem 2022;5(2):120-124.