

# "SIX SIGMA" STANDARD AS A LEVEL OF QUALITY OF BIOCHEMICAL LABORATORIES

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Primljen/Received 28. 09. 2022. god.

Abstract: The principal role of biochemical laboratories is responsibility for reliable, reproducible, accurate, timely, and accurately interpreted analysis results that help in making clinical decisions, while ensuring the desired clinical outcomes. To achieve this goal, the laboratory should introduce and maintain quality control in all phases of work. The importance of applying the Six Sigma quality model has been analyzed in a large number of scientific studies. The purpose of this review is to highlight the importance of using six sigma metrics in biochemical laboratories and the current application of six sigma metrics in all laboratory work procedures. It has been shown that the six sigma model can be very useful in improving all phases of laboratory work, as well as that a detailed assessment of all procedures of the phases of work and improvement of the laboratory's quality control system is crucial for the laboratory to have the highest level of six sigma. Clinical laboratories should use Sigma metrics to monitor their performance, as it makes it easier to identify gaps in their performance, thereby improving their efficiency and patient safety. Medical laboratory quality managers should provide a systematic methodology for analyzing and correcting quality assurance systems to achieve Six Sigma quality-level standards.

*Keywords:* six sigma, biochemical laboratory, quality control.

## **INTRODUCTION**

Six Sigma is a systematic approach that aims to improve work processes through the identification, measurement, and analysis of process problems (1). Sigma ( $\sigma$ ) is one in which it is statistically expected that 99.999666% of the manufactured products have

Prihvaćen/Accepted 17. 11. 2022. god.

no defects. For process control at 6 SD, Six Sigma represents the possibilities of 3.4 DPMO (defects per million opportunities). This means that increasing the Sigma plays a role in increasing the consistency and stability of the test, thus reducing costs for the health-care facility (2). An average product, regardless of its complexity, generally has a sigma value of approximately  $4\sigma$ . The best or "world-class" product has an effect of  $6\sigma$  (3).

The correlations between Sigma metric and defect are:

- 1  $\sigma$  is equal to 690 000 errors or DPMO reports,
- 2  $\sigma$  is equal to 308 000 DPMO reports,
- 3  $\sigma$  is equal to 66 800 DPMO reports,
- 4  $\sigma$  is equal to 6 210 DPMO reports,
- 5  $\sigma$  is equal to 230 DPMO reports and
- 6σ is equal to 3.4 DPMO reports (4).

Lean Six Sigma methodology is a new business management strategy in the field of healthcare and is very well incorporated into the process of quality control and patient satisfaction (5).

Healthcare systems are special organizations that face complicated tasks. To overcome these tasks, they should use the DMAIC (define, measure, analyze, improve, control) principle of Lean Six Sigma to provide the best possible service. The use of DMAIC offers rules on how to improve the system of quality services focused on patient satisfaction. These guidelines can improve procedures and steps in the laboratory process (6).

Six Sigma uses two methods to improve the quality: DMAIC and DMADV (define, measure, analyze, design, verify). DMAIC principle is used for process improvement while DMADV is used for product and process design. The DMAIC principle has five stages that lead to the improved work quality. The first four phases are implemented as management and statistical tools that facilitate the understanding of the process and the problems associated with it, as well as finding the cause of the problem and appropriate solutions. The fifth phase is the phase of finding the cause of the problem and improving the quality of work (7).

The Six Sigma ( $\sigma$ ) metric was first applied in the biochemical laboratory by David Nevalainen in 2001. A new field, not without controversy, challenges, and debate. But since 2001, a toolkit has been developed that allows laboratories to harness the power of Six Sigma to assess the quality of work (8).

Although the Six Sigma concept comes from the industrial sector, some of the world's leading medical laboratories are beginning to apply this concept with great success. The main task of the biochemical laboratory is to provide accurate, reliable, reproducible, timely, and correctly interpreted analysis results that support clinical decision-making, while the ultimate goal must be to ensure the desired clinical outcomes. To fulfill the stated task, the laboratory should implement and maintain the quality of all laboratory work phases, concentrating on the economy. In recent years, biochemical laboratories have been struggling with a growing workload with a wider range of analyzes with the same or fewer workers while always needing to provide an accurate result with faster processing time and high quality. The laboratory influences more than 70% of medical decisions, such as admission, treatment, and discharge, and accounts for less than 5% of all healthcare costs. However, there are increasing expectations from the biochemical laboratory to reduce their costs with the same or often higher quality and standard. The way to solve this situation is to simplify all laboratory phases and avoid "defects" not only from the analytical but also from the pre-and post-analytical part. The Six Sigma model enables quality improvement with a focus on providing "value" and improving performance through the complete elimination of errors, and by that, we mean everything that does not add value to our products or services (9).

In the biochemical laboratory, we can define errors as incorrect results that differ from the actual value by more than the total allowable error. The "tolerance limit" and "offset" mentioned in the Sigma industrial formula are the same as the total, allowable, error and the analytical bias in laboratory work JO Westgard adapted this formula and introduced this one that can be applied in the laboratory:

Sigma =  $(TE_a - |B|) / SD$ 

• TE<sub>a</sub> - total allowable error,

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• B - bias
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• SD – standard deviation (9).

This formula can be used to estimate the proportion of incorrect results or the analytical failure rate resulting from the combined effects of bias and inaccuracy. With biases  $\geq 1$  SD, the one-sided probability is considered, and the area outside the nearest total allowable error generally represents the failure rate (9).

Quality assessment using the Six Sigma model provides evidence of the achieved analytical efficiency in relation to user requirements and is of great importance for identifying and prioritizing important improvements in the quality control of laboratory phases (10). The calculation of the Sigma value is the best risk predictor for laboratory testing but also a parameter used to design the selection of the statistical quality control method needed to detect errors (11). The Six Sigma metric corresponds to 3.4 errors per million determinations (12).

# APPLICATION OF SIX SIGMA MODELS IN BIOCHEMICAL LABORATORIES

# Pre-analytical phase and Six sigma metrics

The importance of applying the Six Sigma quality models has been analyzed in many scientific studies. Improving the pre-analytical procedure in the laboratory using Six Sigma was the aim of the study by Bayat H et al. This study was conducted over a year. More than 1.4 million samples and more than 54 thousand pre-analytical error reporting forms, such as insufficient patient data, sample data, and hemolyzed, lipemic, and insufficient samples were reported, and the total number of errors was summed and reported as DPM and  $\sigma$ . In 75% of test report forms, the diagnosis wasn't present and  $\sigma < 1$  was obtained, and for other errors such as sampling time, sigma values were below 3. For insufficient samples and inappropriate blood-to-anticoagulant ratio, sigma the value was 4.3 (4). In al TC et al. showed how using Lean Six Sigma metrics can improve medical laboratory efficiency and reduce turn-around time (TAT), which belongs to the post-analytical phase. In their longitudinal study, they showed that using Lean Six Sigma the pre-analytical phase, in their case, could be shortened by 3h and 22.5 minutes and that the analytical procedure could be shortened from 68 to 59 minutes. They also showed that error-prone steps and potential biological risks for laboratory staff were reduced by 30% to 3%. (8) The aim of the study by Elbireer et al. was to describe how the quality of entering laboratory data was raised to a higher level by using this model. The Six Sigma Quality Improvement research group examined

	Authors	Year	Study type	Total number of ICQs of all analytes	Sigma value for all ICQs analytes	Collection period
1.	Nanda SK et al. [2]	2013.	Retrospective study	13	$5 - \ge 6$ 4 - 3 - 6 $4 - \le 3$	October 2012 – March 2013
2.	Afrifa J et al. [17]	2015.	Retrospective study	12	12 - ≤ 3	January – March 2014
3.	Nar R et al. [21]	2017.	Retrospective study	18	$6 - \ge 6$ 10 - 3-6 2 - $\le 3$	June – August 2015
4.	Iqbal S et al.[22]	2017.	Cross-sectional study	10	$3 - \ge 6$ 2 - 3 - 6 5 - $\le 3$	October 2014 – March 2015
5.	Mao X et al. [19]	2018.	Retrospective study	20	$9 - \ge 6$ 7 - 3-6 $4 - \le 3$	April – August 2017
6.	Kumar BV et al. [18]	2018.	Retrospective study	16	$4 - \ge 6$ 7 - 3-6 5 - $\le 3$	July 2015 – June 2016
7.	Xia Y et al. [23]	2018.	Retrospective study	42	$13 - \ge 6$ 18 - 3 - 6 $11 - \le 3$	January – December 2016
8.	Mahmood B et al. [26]	2018.	Prospective study	6	$3 - \ge 6$ 1 - 3 - 6 $2 - \le 3$	22/5/2017 - 27/7/2017
9.	Liu Q et al. [20]	2019.	Retrospective study	6	6 - ≥ 6 (app.st.) 6 - ≤ 6 (EQA, RCPA, RiliBÄK)	January – June 2017
10.	Sayeed S et al. [27]	2019.	Retrospective study	8	3-3-6 5-<3	Three months
11.	Đido V et al. [28]	2019.	Prospective study	6	$1 - \ge 6$ 4 - 3 - 6 $1 - \le 3$	March – April 2018
12.	Taher J et al. [29]	2019.	Cross-sectional study	18	$9 - \ge 6$ 9 - 3 - 6	
13.	Zhou Et al. [11]	2020.	Retrospective study	19	$5 - \ge 6$ 9 - 3-6 $5 - \le 3$	01/01/2018 - 10/07/2018
14.	Teshome M et al. [16]	2021.	Cross-sectional study	14	1 - 3 - 6 $13 - \le 3$	10/02/2020 - 10/07/2020
15.	Liu Y et al. [24]	2021.	Retrospective study	13	NCCL: $2 - \ge 6$ 9 - 3 - 6 $2 - \le 3$ EFLM: $5 - \ge 6$ 4 - 3 - 6 4 - < 3	October 2017 – September 2018
16.	Peng S et al. [25]	2021.	Retrospective study	18	$5 - \ge 6$ 11 - 3-6 2 - $\le 3$	January – June 2018
17.	Goel P et al. [30]	2021.	Cross-sectional study	10	$4 - \ge 6$ 4 - 3 - 6 2 - < 3	February – July 2019

 Table 1. Chronological presentation of the application of the six sigma methodology

 for internal controls of different types of analytes

Abbreviations: app. st. = "appropriate" quality standards derived from biological variation; EQA = external quality assessment; RCPA = quality requirements of the Royal College of Pathologists of Australasia; RiliBÄK = standards from the 2015 quality guide created by the German medical laboratory quantitative analysis and quality assessment committee; NCCL = National CenterFor Clinical Laboratories; EFLM = European Federation of Clinical Chemistry and Laboratory Medicine. several factors, such as formulating objectives, recording data entry errors to examine the effectiveness, analyzing all data, and determining the root cause of erroneous laboratory data entry. Ultimately, the team applied control measures to address the main cause and sustain improvement. After launching this project, there was a reduction in errors from 423 errors ( $\sigma =$ 4.34) in a month to approximately 166 per month ( $\sigma =$ 4.65) in a year. The research group found the average cost of identifying and correcting errors to be \$16.25 per error. Therefore, reducing errors by approximately 250 errors per month in one year saved approximately \$50.000 (13). On the other hand, Vanker et al. analyzed the use of the principles of Six Sigma metrics to determine the degree of errors in the registration of tests in the Laboratory Information System and to determine their potential clinical impact. In this research, the tested samples were compared with the tests registered in the Laboratory Information System. Out of 47,543 tests, 72 errors were recorded, leading to an error rate of 0.15%, which equates to  $\sigma = 4.4$ . A review of patient records showed that this error could have affected the patient's clinical care. This research has shown that the clinical impact of errors made during the pre-analytical phase of laboratory work is possible. A lower percentage of errors can be ensured by using the Six Sigma program (14). Another study that aimed to examine the frequency and type of preanalytical errors leading to sample rejection was conducted on 19,002 samples. The sample rejection level was unsatisfactory with  $\sigma = 3.6$ . Their result showed that a higher proportion of errors (73.3%) occurred during sample collection as opposed to errors related to patient identifications (26.6%). The most common pre-analytical error was the hemolyzed sample (64.0%) (15). The research of preanalytical errors during one whole year was the aim of the research of Zorbozan N et al. According to their results, the lowest sigma values were for hemolyzed samples (4.36), samples with inadequate anticoagulant-to-sample ratio (4.68) and coagulated samples (4.78).

#### Analytical phase and Six sigma metrics

The most common errors that can occur during the analytical process in medical laboratories are non-linear results used without retesting, questionable results that are contradictory, EQC failure, IQC result failure, and failure to perform daily IQC (16). Therefore, Table 1 shows the previous estimates of six sigma metrics for different analytes, where sigma was calculated from internal control I (normal) and II (abnormal/pathological). The results of both I and II internal controls  $\sigma \ge 6$  are classified as  $\sigma \ge 6$ . As

shown in Table 1, a large number of studies, based on the analysis of certain biochemical parameters and the assessment of internal control, showed an unsatisfactory level of sigma (< 3) which shows instability and low reliability of results (17, 18, 19). We can say that a more detailed evaluation of analytical performances is needed by strengthening quality control to achieve the highest possible level of six sigma for a medical laboratory, as some studies have shown (2, 12, 20-31). The lowest sigma value was observed for the following parameters: sodium (17, 19), potassium (18), chloride (2, 17, 22), urea (18, 19, 21, 27), creatinine (22, 26, 27), total protein (2, 22), albumin (2, 22, 23, 27), cholesterol (17, 18, 22, 27), total bilirubin (18, 22, 27), glucose (17, 22), some tumor markers (Ca 125, AFP) (20) and some hormones (fT4, prolactin, testosterone, and insulin) (21).

### Postanalytical phase and Six sigma metrics

In the already mentioned research by Zorbozan N et al., the research aimed to examine the post-analytical errors of laboratory work. Two indicators of this phase of work were examined, namely: the number of critical values from the validation of the results to the notification of the patients and the clinicians who ordered the test. For both indicators in this research, there were no errors and the sigma value was > 6. The reason for the excellence of their results is explained by the implementation of a system that automatically sends a message to the patient in case of critical values, and such a system is connected to their laboratory information system. In addition, the sigma value was calculated for tests with the exact time interval between the specimens received in the laboratory to the time of reports dispatched with verification (TAT - turn around time) was determined. The lowest sigma values were for the TAT of Potassium 3.84 and TAT of Troponin (I or T) 4.10, while the TAT of INR was > 6 (31).

#### CONCLUSION

The Six Sigma model is known as the latest principle of quality management and is often used in many fields, such as industry, business, and the healthcare system. It represents a powerful management tool and enables specific rules that can contribute to reducing the occurrence of errors. The Six Sigma methodology uses a particular approach to solving problems that are mainly based on statistical tests.

Clinical laboratories should use Sigma metrics to monitor their performance, as this makes it easier to identify gaps in their performance, thereby improving their performance and patient safety. Quality managers in medical laboratories should be required to provide a systematic methodology for analyzing and correcting quality assurance systems to achieve Six Sigma quality-level standards. **Conflict of Interests:** The authors declare no conflicts of interest related to this article.

#### **Funding: None**

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# Acknowledgment None.

#### Sažetak

# "SIX SIGMA" STANDARD KAO NIVO KVALITETA BIOHEMIJSKIH LABORATORIJA

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Glavna uloga biohemijskih laboratorija je odgovornost za pouzdane, ponovljive, tačne, pravovremene i pravilno interpretirane rezultate analiza koji pomažu u donošenju kliničkih odluka, a istovremeno osiguravaju željene kliničke ishode. Za postizanje ovog cilja treba uspostaviti i održavati kontrolu kvaliteta svih faza rada laboratorija. Važnost primene Six Sigma modela kvaliteta analizirana je u velikom broju naučnih istraživanja. Cilj ovog preglednog članka je dati uvid u važnost primene Six Sigma metrike u biohemijskim laboratorijama, kao i u dosadašnju primenu ovog modela u analitičkim postupcima laboratorijskog rada. Pokazalo se da ovaj model može biti vrlo koristan u poboljšanju

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svih faza laboratorijskog rada, kao i da postoji potreba za detaljnom procenom analitičkih postupaka i jačanjem sistema kontrole kvaliteta laboratorija kako bi se postigao najviši nivo. Kliničke laboratorije trebale bi koristiti Sigma metriku za praćenje svoje produktivnosti, jer se tako olakšava prepoznavanje nedostataka u njihovom radu, čime se poboljšava njihova efikasnost i sigurnost pacijenata. Menadžeri kvaliteta medicinskih laboratorija trebali bi osigurati sistemsku metodologiju za analizu i unapređenje sistema osiguranja kvaliteta kako bi se dostigli najviši standardi nivoa kvaliteta.

*Ključne reči*: šest sigma, biohemijska laboratorija, kontrola kvaliteta.

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*How to cite this article:* Pasic A, Sehercehajic E. Six sigma standard as a level of quality of biochemical laboratories. Sanamed. 2022; 17(3): 203-208. Doi: 10.5937/sanamed0-40408.