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Original Research Article

Study of Sigmametrics in Central Laboratory Biochemistry at ACSR Government Medical College and Hospital, Nellore

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Abstract:

Introduction: Quality control is important in a laboratory to detect errors and to reduce false rejections. Sigma measures how far a given process deviates from perfection. Sigmametrics can be applied wherever an outcome of a process has to be measured. A poor outcome is counted as an error or defect. Sigma metrics shall be calculated from CV, percentage bias and total allowable error for the parameters by the following formula: sigma= (TEa- bias%) / CV%. The quality goal index (QGI) ratio represents the relative extent to which both bias and precision meet their respective quality goals.

Aims and Objectives: 1. To understand the value of Six Sigma performance and apply it to quantify our laboratory performance on Sigma metrics. 2. To estimate the quality goal index of the biochemical parameters

Materials and Methods: The study was conducted in the central biochemistry laboratory at ACSR Government medical college Nellore. We run internal quality control level 1 and level 2 daily. We participate CMC VELLORE EQAS program for chemistry II parameters. In this study the control data for a period of six months from January to June 2020 on nine parameters were studied for sigmametrics. Inclusion criteria: Only those parameters enrolled for external quality control (i.e Chemistry II) were included in the study. Institutional ethical committee clearance was obtained.

Results & Discussion: In our study sigma values for nine biochemical parameters were calculated from both internal quality and external quality control values as sigma calculation requires C.V, Bias and TEa values. Quality Goal index calculation in our study revealed that 37 values were due to imprecision, 36 values showed inaccuracy and 11 values were due to both imprecision and inaccuracy and 24 values showed six sigma (N=108). Sigma metric analysis helps to improve the quality of lab performance by giving a scope for thorough root cause analysis.

Conclusion: In our laboratory world class performance was obtained for analytes uric acid, bilirubin, albumin and triacylglycerol. Application of sigmametrics helps to reduce number of control measurements and control limits. Calculation of Quality Goal Index helps to identify whether the error was due to imprecision or inaccuracy or both.

Keywords: Sigma, Sigma Metrics, EQAS, QGI, RCA.

Introduction

Quality control is important in a laboratory to detect errors and to reduce false rejections. Internal quality control which is performed daily helps in deciding whether the results are reliable enough to be released to the physician. EQAS which is done by the third party every month gives information on the accuracy or bias in the system & methods used in that particular lab. [1]

Quality assurance means delivery of relevant and effective medical care in accordance with the standards. It is to ensure that the effective activities required are executed in a proper, professionally acceptable manner. [2] Sigma in statistics is used to represent the standard deviation which is an indicator of the degree of variation in a set of processes. Sigma measures how far a given process deviates from perfection. Six Sigma is one of the popular quality management system tools employed for process improvement. [3]

Sigma methodology can be applied wherever an outcome of a process has to be measured. A poor outcome is counted as an error or defect. This is quantified as defects per million (DPM). Six sigma process is one in which 99.999666% of the products manufactured are statistically expected to be free of defects. Six sigma concentrates, on regulating a process to 6 SDs, represents 3.4 DPM (defects per million) opportunities. [4]

Sigma metrics shall be calculated from CV, percentage bias and total allowable error for the parameters by the following formula: sigma= (TEa-bias%) / CV%

CV% is the analytical coefficient of variation of the test method. Coefficient of variance (CV) is calculated as follows. C.V % = S.D /Mean x 100. Bias is the systematic difference between the expected results obtained by the laboratory's test method and the results that would be obtained from an accepted reference method. 5 Bias = (observed value- true value/true value) X 100.

TEa: It is the total allowable difference from accepted reference value seen in the deviation of single measurement from the target value. TEa values of various parameters shall be taken from (CLIA) guidelines. [6]

Six-Sigma incorporates robust techniques such as Define-Measure-Analyze-Improve-Control and RCA to find and eliminate defects and variations within a process. It also offers an unbiased evaluation of analytical methods and instrumentation along with a judicious plan needed for active implementation. [7]

The quality goal index (QGI) ratio represents the relative extent to which both bias and precision meet their respective quality goals.8 This was used to analyze the reason for the lower sigma in analytes, i.e., the problem is due to imprecision or inaccuracy or both. The QGI ratio was calculated using the following formula, QGI = Bias/1.5 × CV%. [8,9]

Aims and Objectives:

1. To understand the value of Six Sigma performance and apply it to quantify our laboratory performance on Sigma metrics.

2. To estimate the quality goal index of the biochemical parameters

Materials and Methods

The study was conducted in the central biochemistry laboratory at ACSR Government medical college Nellore. Our Biochemistry department laboratory is equipped with fully auto analyser. We run internal quality control level 1 and level 2 daily. Westgard-rules were applied for the interpretation of the IQC results. The rules 13s, 22s, R4s, 41s, and 10X rules were considered as rejection, and 12s was considered as a warning rule for the respective run. We participate CMC VELLORE EQAS program for chemistry II parameters.

In this study the control data for a period of six months from January to June 2020 on nine parameters were studied for sigmametrics. The parameters included in the study were glucose, urea, creatinine, total bilirubin, total protein, albumin, total cholesterol, triacylglycerol and uric acid. Inclusion criteria : Only those parameters enrolled for external quality control (i.e Chemistry II enrolled nine parameters) were included in the study. Other parameters not enrolled for EQAS were excluded from the study. Institutional ethical committee clearance was obtained. Sigma values were calculated from the data available both from internal and external quality control.

Results:

Table 1: Table No 1: C.V from January to June months for the biochemical parameters (Level 1 control)

	Jan	Feb	March	April	May	June
Glucose	2.7	5.9	6.7	2.64	9.4	2.66
Urea	2.6	5.3	2.8	1.3	1.4	2.1
Creatinine	1.7	4.2	11.7	2.1	13.97	4.5
T. Bilirubin	3.7	5.8	6.8	2.1	3.6	3.1
T. Protein	3.6	4.2	4.8	3.25	13.25	3.4
Albumin	5.7	5.8	6	3.22	17.0	4.1
Uric acid	9.5	11	13.16	1.5	4.5	1.6
T. Cholesterol	3.3	3.95	6.1	2.9	6.5	2.5
Triacylglycerol	3.2	5	5.1	2.1	6.7	2.7

Table 2: C.V from January to June months for the biochemical parameters (Level 2 control)

	Jan	Feb	March	April	May	June
Glucose	3.5	5	6.3	2.8	2.3	2.24
Urea	2.4	4.6	5.6	2.4	2.3	3.2
Creatinine	1.75	3.7	11.3	2.5	3.2	4.1
T. Bilirubin	10.5	7.6	4.8	4.0	2.2	1.8
T. Protein	4.25	21.4	5.6	2.6	3.8	3.3
Albumin	5.1	7.5	5.7	2.4	2.57	2.6
Uric acid	1.85	2.3	5.5	1.1	1.43	1.9
T. .Cholesterol	4.1	4	6.8	3.5	3.7	3.9
Triacylglycerol	5.7	4	5.4	2.6	3.9	3.4

Table 3: Sigma values from January to June months for the biochemical parameters (Level 1 control)

	Jan	Feb	March	April	May	June
Glucose	4.5	1.2	1.11	4.2	1.3	3.1
Urea	1.2	2.5	3.8	4.1	3.9	3.8
Creatinine	4.2	1.4	0,5	3.1	2.1	2.2
T. Bilirubin	2.5	4.3	3.6	4.3	4.5	7.6
T. Protein	5.4	3.1	2.7	6.7	1.96	5.0
Albumin	3.4	2.1	2.1	5.4	1.76	3.8
Uric acid	3.2	2.5	2.12	10.1	5.6	12.7
T. Cholesterol	5.9	6.2	4.0	6.4	4.3	8.4
Triacylglycerol	6	3.7	3.6	8.2	4.3	6.3

Table 4: Sigma values from January to June months for the biochemical parameters (Level 2 control)

	Jan	Feb	March	April	May	June
Glucose	3.5	1.5	1.2	4.0	5.2	3.75
Urea	1.2	2.4	4.9	4.8	4.3	5.2
Creatinine	4.1	1.6	0.5	2.7	0.7	0.3
T. Bilirubin	0.8	3.3	5.2	4.2	6.1	7.6
T. Protein	4.6	0.6	2.3	8.4	6.8	5.1
Albumin	3.8	1.7	2.2	7.2	11.6	6.1
Uric acid	16.5	12.1	5.0	10.7	17.9	12.8
T. Cholesterol	4.7	6.1	3.6	5.3	4.94	5.3
Triacylglycerol	3.4	4.6	3.4	6.6	7.4	5.0

Table 5: Quality Goal index for biochemical parameters (N=108)

	None	Imprecision	Both	Inaccuracy
Number	24	37	11	36
QGI Percentage	22.22	34.25	10.18	33.33

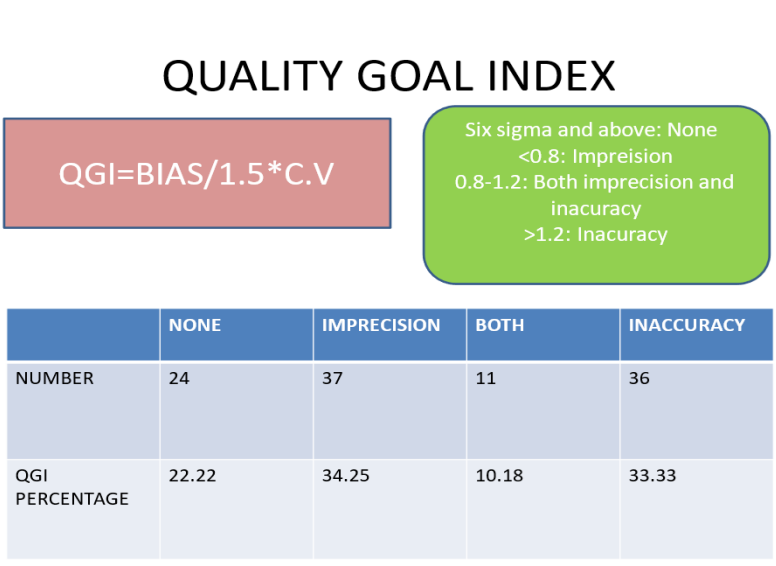

Table 5: Quality Goal Index

Table 6: Interpretation of Biochemical parameters (N= 108) under different sigma values during the months January to June for Level 1 and Level 2 control.

	<2 sigma	>2 and <3 sigma	>3 and <6 sigma	6 sigma and more
Level 1 control (Jan to March)	5	5	15	2
Level 1 control (April to June)	3	2	14	8
Level 2 control (Jan to March)	8	3	13	3
Level 2 control (April to June)	2	1	12	12

Discussion

The methodology employed to implement lean six sigma in our Central Laboratory was DMAIC, i.e., define, measure, analyze, improve, and control. Every step of sample processing should be carefully reviewed and monitored to reduce errors improve the quality of sample processing.[10]

Sigma metrics was calculated from CV, percentage bias and total allowable error for the parameters by the following formula: sigma= (TEa- bias%) / CV%

CV% is the analytical coefficient of variation of the test method. Coefficient of variance (CV) was calculated as follows. C.V% = S.D /Mean x 100. Monthly CV obtained for each parameter was tabulated for both control 1 and 2 sera for a period of six months.

Monthly Bias was taken from eqas report. TEa: It is the total allowable difference from accepted reference value seen in the deviation of single measurement from the target value. TEa values of various parameters shall be taken from (CLIA) guidelines [6]

Simple guidelines for choosing the Westgard rules and levels of QC as proposed by Westgard are as follows [21]:

- ≥6σ :– 2 levels of QC per day with a 1 3.5s greater rule
- 5σ :– 2or 3 levels of QC per day with a 1 2.5s or 1 3s rule
- 4σ:– 3or 4 levels of QC per day with a 1 3s / 2 22s / R 4s / 4 1 s rule
- 3.5σ :– 6 of QC per day with a 1 3s / 2 22s / R 4s / 4 1 s rule
- <3.5σ :– maximum affordable levels of QC per day with a 13s/2 22s/R 4s/4 1s rule. [11,12]

Following the calculation of Sigma, the analytes were grouped based on their values as follows:13 1). Sigma 6: Analytes with World-class performance 2). Sigma >3 < 6: Analytes showing excellent to marginal performance. 3). Sigma >2 < 3: Analytes showing poor performance. 4) Sigma < 2 unacceptable.

In our study sigma values for nine biochemical parameters were calculated from both internal quality (C.V as shown in Table No 1 and 2 for level 1 and 2 controls respectively) and external quality control (Bias) values. Sigma values for six months from January to June are shown in Table No 3 and 4 for level 1 and level 2 controls respectively.

We have divided the sigmametrics calculation into two blocks each one taking into account the values for a period of three months. During block 1 period i.e from January to March we had problem with technical team, problems with lamp, reagent refrigeration in the instrument etc. Hence we had more number of biochemical parameters with unacceptable, poor and marginal performance in block 1. During the months of April, May and June, recruitment of technicians, training on quality control to technical team, replacement of lamp in fully auto analyser, peltair replacement for correction of reagent refrigeration etc were the problems addressed. Hence sigma values with world class performance i.e six sigma values improved in block 2 as shown in table no 6.

Sigmametric analysis helps to improve the quality of lab performance. The analysis would give scope for improvement as a thorough Root Cause Analysis (RCA) can be done. Quality Goal Index (QGI) calculation was planned for those analytes less than six sigma.

The QGI and RCA are performed to identify the causes for poor and unacceptable performance and the number of QC runs is determined accordingly. The QGI can be calculated using the formula Bias%⁄CV%. It helped in determining the cause for lower sigma-metrics and thereby improves the choice of quality control. A value < 0.8 indicated that imprecision, whereas a value > 1.2 indicated inaccuracy. [13,14]

In our study Quality Goal index calculation revealed that 37 values were due to imprecision, 36 values showed inaccuracy and 11 values were due to both imprecision and inaccuracy and 24 values showed six sigma (N=108) as shown in table no 5.

Another guideline as published by Cooper et al, suggests grouping of tests as per sigma performance and QC strategy as follows. [15]

- >6σ (excellent tests) –one QC per day (alternating levels between days) and a 13s rule.
- 4σ–6σ (suited for purpose) –two levels of QC per day and the 12.5s rule.
- 3σ–4σ (poor performers) –combination of rules with two levels of QC twice per day.
- <3σ (problems) – maximum QC, three levels, three times a day. Preferably testing specimens in duplicate.

Sunil Kumar Nanda et al concluded in their study that ALP was the best performer with a sigmametrics value of 8.4 and chloride had the least sigmametrics value of 1.4. 4.

B. Vinodh Kumar and Thuthi Mohan et al showed that on applying sigma metrics for the analytical phase in their laboratory, ALP, magnesium, triglyceride, and HDL-C showed a sigma value >6 and the problem analytes were noted to be urea, albumin, cholesterol, and magnesium with sigma value <3.9

Conclusion: In our laboratory world class performance was obtained for the analytes uric acid, bilirubin, albumin and triacylglycerol. Least to marginal performance was obtained for other analytes. Application of sigmametrics helps to reduce number of control measurements and control limits. Calculation of Quality Goal Index helps to identify whether the error was due to imprecision or inaccuracy or both. Root cause analysis can be done for those analytes with least sigma performance and thereby quality of laboratory can be improved. Hence sigmametrics can be applied not only as self-assessment tool but to check the reliability of report.

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