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Original Research Article

A retrospective study to evaluate the performance of internal quality control in a biochemistry laboratory using sigma metrics

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ABSTRACT

Aims: To evaluate the performance of internal quality control in a biochemistry laboratory using Sigma metrics.
Settings and Design: Data were extracted from December 2018 to November 2019 from a Tertiary care hospital, Coimbatore.
Materials and Methods: The data regarding internal quality control (IQC) and external quality assurance scheme (EQAS) were collected for 14 biochemical parameters. Sigma metrics were calculated using total allowable error (TEa), Coefficient of variance (CV) and percent bias for the above mentioned parameters. Quality goal index (QGI) ratio was used to analyze the reason for the lower sigma in analytes.
Statistical analysis used: Coefficient of variance (CV) from the calculated laboratory means and calculated standard deviation. Sigma metrics was calculated from CV%, TEa and Bias. Quality goal index ratio was calculated from CV% and Bias.
Results: In this study four parameters AST, ALP, Triglycerides and Amylase with sigma values >6; Six parameters Total Protein, ALT, HDL, Glucose, Calcium and Cholesterol with sigma values 3 to 6 and four parameters Albumin, Uric acid, Creatinine, and Urea with sigma values <3. For all analytes <6 sigma level, the quality goal index (QGI) was <0.8 indicating the parameters which needed improvement in imprecision, except for total protein and cholesterol whose QGI >1.2 indicated inaccuracy.
Conclusions: In the present study Sigma value was highest for ALP (7.81) and lowest for Urea (1.27). Use of alternative methods can be done for the parameters whose sigma values less than 3 to improve their performance are recommended.

1. Introduction

Clinical laboratories are backbone of health care system, since final decisions mostly depends on laboratory results for diagnosis of diseases. Hence it is important that the clinical laboratory should yield an accurate test result. In order to achieve a valid laboratory test results we must establish and maintain a good quality control mechanism.[1]

The testing process in the clinical laboratory consists of three phase's pre-analytical phase, analytical phase, post-analytical phase. In the pre-analytical phase we have two sub-phases includes one that occurs outside the laboratory and the other one within the laboratory. The errors can occur at any of these phases and sub-phases. To overcome these errors we need a valid quality control approach which is universally acceptable and affordable.[2]

There are two quality control measures employed to assess the analytical phase in a biochemistry laboratory. First one is internal quality control (IQC) and the second one is External quality control or External Quality Assurance Scheme (EQAS). IQC is a sample material whose matrix is identical to the patients sample and has an established concentration range available in two or three levels covering the medical decision points. These quality control measures help in evaluating the accuracy of our results. But the quantification of errors is not expressed through IQC or

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EQAC. Here comes the Sigma metrics, which helps us in quantification of errors and expressing our quality goals.[2]

Bill Smith, the father of Six Sigma, decided to measure defects per million opportunities. It consists of five steps: Define, Measure, Analyze, Improve, and Control (DMAIC). The Six Sigma Scale typically runs from 0 to 6, but a process can actually exceed Six Sigma, if variability is sufficiently low as to decrease the defectrate.[3]

Table 1: Level of Sigma metrics and the corresponding defects per million tests[4]

Six sigma level	Percentage accuracy	Defects per million
6	99.9997	3.4
5	99.98	233
4	99.4	6210
3	93.3	66807
2	69.1	308537
1	31	698000

With the aid of six sigma principles and metrics, it is possible to ensure that the desired quality is achieved. Therefore we have applied sigma metrics to evaluate the performance of 14 routine parameters run in Karpagam Faculty of Medical Sciences and Research, Coimbatore, Tamilnadu.

2. Materials and Methods

2.1. Study design

Retrospective study (Record based).

2.2. Study setting

Karpagam Faculty of Medical Sciences and Research, Coimbatore, Tamilnadu.

2.3. Study period

December 2018 – November 2019 (1 Year).

2.4. Study procedure

This study was conducted in the clinical biochemistry laboratory of Karpagam Faculty of Medical Sciences and Research, Coimbatore, Tamil Nadu. The one year data of internal quality control were collected for the following 14 parameters: Glucose, Urea, Creatinine, Total protein, Albumin, Calcium, Uric acid, Cholesterol, Triglycerides, HDL, AST (SGOT), ALT (SGPT), ALP and Amylase.

Sigma metrics were calculated using total allowable error (TEa), Coefficient of variance (CV) and percent bias for the above mentioned parameters. Two levels of clinical chemistry controls were used for each parameter and tested twice a day. External quality control and internal quality control data of 14 analytes from December 2018 to November 2019 were analysed.

The quality goal index (QGI) represents the relative extent to which both bias and precision meet their respective quality goals. 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.

2.5. Statistical analysis

The TEa values of various parameters were taken from Clinical Laboratories Improvement Act (CLIA) guidelines.

Bias was computed from external quality assurance records with following formula:

Bias = (Lab mean - Group mean) x 100 / Group mean.

Coefficient of variance (CV) is the analytical coefficient of variation of the test method. It was determined from the calculated laboratory mean and calculated standard deviation procured from 12 months of IQC data:

CV% = (standard deviation /laboratory mean) x 100%.

The Sigma metrics was calculated with following formula:

Sigma metrics = (TEa - Bias %) / CV%

Quality goal index ratio was calculated using the formula:

$QGI = Bias/(1.5 \times CV\%)$

Table 2: Criteria for interpreting Quality Goal Index Ratio[4]

QGI	Problem
<0.8	Imprecision
0.8-1.2	Imprecision and Inaccuracy
>1.2	Inaccuracy

3. Results

The present study analyzed the 14 biochemical analytes and interpreted using sigma metrics. The investigator have calculated mean, SD, CV%, Bias% and sigma values for each parameter at level I and level II. CV% was calculated from internal QC data for each parameter and Bias% was calculated from EQUAS data. TEa was taken from CLIA guidelines. With these data sigma value was calculated using the formula mentioned in the statistics section.

In the level I QC out of 14 parameters assessed AST, ALP and Amylase have sigma values more than or equal to 6; Glucose, total protein, Triglycerides, HDL and ALT have scored 3 to 6 and urea, Creatinine, albumin, calcium, uric acid and cholesterol scored less than 3(Table 3).

In the level II QC out of 14 parameters assessed Triglycerides, AST, ALP and Amylase have sigma values more than or equal to 6; Glucose, total protein, calcium, cholesterol, HDL and ALT have scored 3 to 6 and urea, Creatinine, albumin and uric acid scored less than 3 (Table 4).

Table 3:

S.No	Variable	Standard mean	Lab mean	SD of lab value	CV %	TEa %	BIAS %	Sigma	QGI	Problem
1	Glucose	84	81.88	1.89	2.31	10	2.06	3.44	0.6	Imprecision
2	Urea	34.4	34.97	1.8	5.15	9	2.44	1.27	0.3	Imprecision
3	Creatinine	2.5	2.62	0.2	7.63	15	2.25	1.67	0.2	Imprecision
4	Total Protein	6.35	6.23	0.1	1.61	10	3.26	4.20	1.4	Inaccuracy
5	Albumin	3.9	3.94	0.14	3.55	10	1.69	2.34	0.3	Imprecision
6	Calcium	8.52	9	0.43	4.78	11	0.41	2.22	0.1	Imprecision
7	Uricacid	6.52	5.96	0.31	5.20	17	4.85	2.34	0.6	Imprecision
8	Cholesterol	248	245.95	6.19	2.52	10	5.95	1.61	1.6	Inaccuracy
9	Triglycerides	185	209.81	10.28	4.90	25	2.78	4.53	0.4	Imprecision
10	HDL	51.5	59.06	3.71	6.28	30	5.23	3.94	0.6	Imprecision
11	AST(SGOT)	37.9	38.17	0.89	2.33	20	4.09	6.82	1.2	None
12	ALT(SGPT)	29.3	30.82	1.29	4.19	20	3.1	4.04	0.5	Imprecision
13	ALP	117	113.73	4.11	3.61	30	4.4	7.08	0.8	None
14	Amylase	61.6	58.89	2.11	3.58	30	8.38	6.03	1.6	None

Table 4:

S No.	Variable	Standard Mean	Lab Mean	SD of lab value	CV %	TEa %	Bias %	Sigma	QGI	Problem
1	Glucose	286	274.11	5.56	2.03	10	2.06	3.91	0.7	Imprecision
2	Urea	105	106.32	2.97	2.79	9	2.44	2.35	0.6	Imprecision
3	Creatinine	5.76	5.98	0.44	7.36	15	2.25	1.73	0.2	Imprecision
4	Total Protein	4.5	4.48	0.07	1.56	10	3.26	4.31	1.4	Inaccuracy
5	Albumin	3.07	2.87	0.08	2.79	10	1.69	2.98	0.4	Imprecision
6	Calcium	12.1	11.29	0.35	3.10	11	0.41	3.42	0.1	Imprecision
7	Uricacid	10.5	10.82	0.5	4.62	17	4.85	2.63	0.7	Imprecision
8	Cholesterol	99.2	96.95	1.21	1.25	10	5.95	3.25	3.2	Inaccuracy
9	Triglycerides	89.4	93.68	3.43	3.66	25	2.78	6.07	0.5	None
10	HDL	28	27.29	1.46	5.35	30	5.23	4.63	0.7	Imprecision
11	AST(SGOT)	201	198.41	5.1	2.57	20	4.09	6.19	1.1	None
12	ALT(SGPT)	94	93.96	3.76	4.00	20	3.1	4.22	0.5	Imprecision
13	ALP	501	487.95	15.99	3.28	30	4.4	7.81	0.9	None
14	Amylase	404	433.92	13.56	3.13	30	8.38	6.92	1.8	None

For all analytes whose sigma values less than 6, QGI values were calculated and problems were identified. In both level I and level II QC imprecision (QGI<0.8) was the common problem identified other than for total protein and cholesterol where the problem identified was inaccuracy (QGI>1.2).

4. Discussion

Six sigma metrics is used to evaluate the Quality control of performance in Biochemistry Laboratory. Schoenmaker et al. study mentioned the importance of sigma metrics in Quality control using sigma values. In this study 14 laboratory parameters were assessed over a period of 1 year. Six sigma metrics improves the quality of process outputs by analyzing and abolishing the source of defects and reducing variability in laboratory parameters. Identification of test with low sigma values (< 3σ) indicate that actions should be taken to improve analytic quality or the lab should use alternate methods and reagents.

In the present study, performances of 14 parameters of clinical chemistry were assessed with sigma scale for both levels QC (normal and abnormal). Among them, 3 parameters in level I and 4 in level II showed sigma value >6, 8 parameters in level I QC and 10 parameters in level II QC showed sigma value more than 3, whereas, 6 parameters showed sigma value less than 3 in Level I and 4 parameters in Level II QC showed sigma less than 3.

Similarly pattern was observed in different studies which are summarized below (Table 5)

The sigma values of >6 were seen in ALP, AST, Amylase (in level I QC) and ALP, AST, Amylase, Triglyceride (in level II QC). Similar result was obtained in the study conducted by Kavitha Aggarwal et al., with ALP, Amylase, AST and Triglyceride in level I and ALP, Amylase, AST,

Table 5:

Studies	Number of parameters at each level and their sigma values					
	Level I			Level II		
	>6	3-6	<3	>6	3-6	<3
Vinod kumar et al[4]	4	7	5	5	8	4
Kavitha aggarwal et al[2]	6	7	7	7	7	6
Sharma kumar et al[5]	5	9	5	5	3	11

ALT and Triglyceride in level II.[2]

In the present study sigma values of 3 to 6 was seen in Total Protein, ALT, HDL, Glucose, Calcium and Cholesterol. Other studies conducted in different parts of country shows similar parameters with sigma values from 3 to 6. In the study conducted by Vinodh Kumar et al[4] Total protein, ALT and Calcium were common to present study with sigma values ranges from 3 to 6; Vijatha et al[1] Total protein, Glucose and Cholesterol; Sharma et al Glucose and Cholesterol.

The sigma values of <3 (in both levels) were seen in Albumin, Uric acid, Creatinine, and Urea. Similar to the present study parameters, in a study conducted by Vinodh Kumar et al[4] the parameters with <3 sigma values were Urea, Albumin and Cholesterol; Kavitha Aggarwal[2] et al. Cholesterol, Creatinine and Albumin; Sharma Kumar et al Calcium and urea and Vijatha et al.[1] urea.

Highest sigma value was observed in ALP with 7.81 and lowest sigma value was 1.27 for urea. The highest and lowest sigma values and their parameters in other studies are, Vijatha et al[1] Triglyceride (10.7) and Urea (1.8); Vinodh Kumar et al[4] Triglyceride (10.45) and Cholesterol (1.5); Xuehuui et al[5] Amylase (19.93) and Urea (2.6); Kavitha Aggarwal et al[2] Amylase (14) and Urea/Glucose (2.3); Sharma et al Triglyceride (9.55) and Calcium (1.96);

For all analytes whose sigma values less than 6, QGI values were calculated. The major problem identified was imprecision (QGI<0.8), but for total protein and cholesterol the problem identified was inaccuracy (QGI>1.2). Similar results were obtained in a study conducted by Vinodh Kumar et al[4] where cholesterol was the only parameter with inaccuracy as the problem and rest were imprecision.

In the present study, AST, ALP, Triglyceride and Amylase showed sigma value more than 6. Thus, no strict IQC rules are required for these parameters. Since urea and Creatinine showed sigma value less than 3 in both level QC, therefore, appropriate scrutiny is required for monitoring the performance of this parameter, to provide quality test results.

5. Conclusion

The main role of a laboratory is to produce accurate test results. Six sigma helps in assessing and comparing the performance of various tests using IQC, peer comparison and proficiency testing in the form of EQAS. Therefore, it is easy to apply and helps in streamlining the routine test procedures. With routine six sigma practice, the 2s QC practices can be replaced with appropriate control limits and control measurements. Applying six sigma prevents us from applying stringent criteria in a laboratory and thus reducing false rejections.

6. Source of Funding

None.

7. Conflict of Interest

The authors declare that there is no conflict of interest regarding the publication of this article

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