

Sigma metrics calculation in clinical Biochemistry laboratory - pathway for quality improvement

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Received: 10th February 2021; **Accepted:** 27th December 2021; **Published:** 01st January 2022

Abstract: *Background:* Limitations of Internal quality control (IQC) and external quality assessment system (EQAS) like cost for repeated analysis is a challenge to most of the clinical Biochemistry laboratories. Six sigma system is a part of lean laboratory practices. The higher the sigma value, chance of false test results are less likely. *Aim:* To calculate sigma metrics of liver function parameters in laboratory and using it to decide on the QC strategy using Westgard Sigma rules for reliable and accurate report. *Methods:* IQC data for Total bilirubin, Direct bilirubin, AST, ALT, ALP, Total protein & Albumin were analysed for 6 months. Sigma value is calculated and Quality goal index used to identify the reason for low sigma value. *Results:* Both AST and ALP in level 1 and AST, ALT and ALP in Level 2 has sigma value above 6. Parameters which showed sigma value between 3-6 are ALT and Albumin in Level 1 and BIT and TP in level 2 QC. Parameters which showed sigma value below 3 are BIT, BID & TP in Level 1 & BID and Albumin in Level 2 QC. *Conclusion:* Appropriate control limits and control measurements can be adapted for each parameters with westgard sigma rule and laboratories can use it as a self-assessment tool.

Keywords: Six sigma, Liver function tests, Quality goal index.

Introduction

An evolution in quality assessment & management, Six sigma system, has been implemented widely in healthcare, business and industries. It was developed by Motorola to eliminate defects, decrease variability in processing, reduce cost of products. It provides a more quantitative frame work for process performance [1].

Routine quality control procedures followed in most of the laboratories to ensure the quality of reports are Internal quality control (IQC) which is done in a day to day basis and external quality assessment system (EQAS) done on a monthly basis. They will give information on bias or accuracy in the system and method used in the lab. Both are expensive if repeat analysis has to be done. Six sigma system helps a laboratory consultant to decide which test require more quality control runs per day and helps in prioritizing which test are at risk. Six sigma system usually applied for tests with high impact on patient care and is a part of lean laboratory

practices in quality improvement. Sigma is a uniquely defined scale with which we can assess the performance of a lab. It evaluates the process by counting errors and converting it into defects per million opportunities rate [2].

Sigma value (σ) 6 corresponds 3.4 error per million reports and sigma 1 corresponds to 690000 errors per million reports [5]. Scaling of Sigma indicates how often errors are likely to occur: the higher the sigma value, chance of false test results are less likely. So, when performance falls below 3 sigma, the process is considered as unstable and unacceptable and should not be used for routine test purposes [3-5]. Even though the usefulness and advantages of six sigma practices in clinical laboratories have become popular, very few laboratories are practicing it [6-8]. Also sigma values can be used as a guide to decide on the QC strategy using Westgard Sigma rules [9] to produce quality report. Analytical procedure should achieves a good

sigma levels for a quality (reliable & accurate) report & it is the responsibility of laboratories to keep professional standards and maintain the quality of procedures. So as a part of quality initiative in our laboratories, this study has been done to calculate sigma metrics of liver function parameters (LFT) to plan quality control (QC) strategy for it which has high impact on patient care and routine patient management.

Material and Methods

This observational Study has been conducted in clinical Biochemistry laboratory. Internal quality control (IQC) data (Bio-Rad) of LFT (Total bilirubin, Direct bilirubin, AST, ALT, ALP, Total protein & Albumin) parameters analysed retrospectively over a period of 6 months (181 days - level 1 and level 2 values) in fully automated modular equipment. Institutional ethical committee clearance had been obtained to carry out the study.

Inclusion criteria: The analytes included were internal quality control data (Level 1, Level 2) of Total bilirubin, Direct bilirubin, AST (Aspartate amino transferase), ALT (Alanine amino transferase), ALP (Alkaline phosphatase), TP

(Total protein) & Albumin from January 2019 to June 2019 (181 days). IQC used to calculate bias, CV%, mean & standard deviation for each levels. Total allowable error (TEa) values of various parameters were taken from Clinical Laboratories Improvement Act (CLIA) guidelines [10].

Sigma value is calculated by the equation

$$\text{Sigma} = (\text{TEa} - \text{bias}) / \text{CV}\%$$
 Quality goal index (QGI) [11] used to assess the cause for low sigma value.

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

Statistical analysis is done in excel sheet. Sigma Values were represented in graphs from January 2019 to June 2019 for each analytes.

Results

Table 1 shows the Total allowable error (TEa) obtained from CLIA guidelines, Bias and CV value of different parameters. Out of 7 parameters analysed, highest BIAS and CV for level 1 QC was observed Total bilirubin (10.085 & 6.66) and Direct bilirubin in Level 2 QC (7.98 & 4.315).

Table-1: TEa %, Bias %, CV % for Liver function parameters for Level I (L1) & Level 2 (L2) (January 2019 to June 2019)

Parameter	TEa	BIAS (L1)	BIAS (L2)	CV (L1)	CV (L2)
Total Bilirubin (BIT)	20	10.085	6.88	6.66	3.32
Direct Bilirubin (BID)	20	7.925	7.98	6.52	4.315
AST	20	1.474	.353	2.56	2.245
ALT	20	1.347	2	3.68	2.55
ALP	30	5.44	.63	2.64	2.37
Total Protein (TP)	10	1.51	1.02	2.92	2.85
Albumin	10	1.1251	1.79	2.1	2.87

Table-2: Sigma value for Liver function parameters for Level I & Level 2 QC (January 2019 to June 2019)

Levels	Level 1			Level 2		
	<3	3-6	>6	<3	3-6	>6
Parameters	BIT-1.48				BIT-3.95	
	BID-1.85			BID-2.78		
			AST-7.26			AST-8.75
		ALT-5.07				ALT-7.05
			ALP-9.3			ALP-12.39
	TP-2.91				TP-3.15	
		ALBUMIN-4.22		ALBUMIN-2.86		

Fig-1: Sigma value for parameters for Level 1 (SIGMA 1) & Level 2(SIGMA 2) QC in (January 2019 to June 2019)

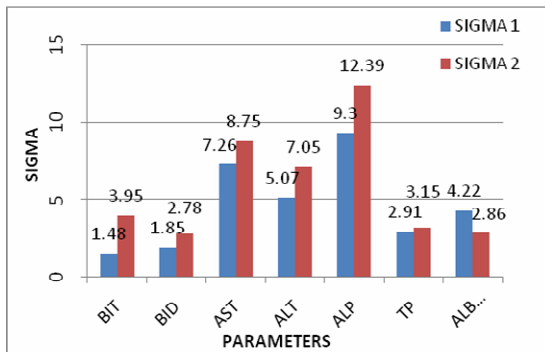


Table 2 & Figure 1 depicts the sigma value obtained for liver function parameters in Level1 & Level 2 QC. It shows that both AST and ALP in level 1 and AST, ALT and ALP in Level 2 has sigma value above 6 . Parameters which showed sigma value between 3-6 are ALT and Albumin in Level 1 and BIT and TP in level 2 QC .Those Parameters which showed sigma value below 3 are BIT, BID & TP in Level 1 & BID and Albumin in Level 2 QC.

Table-3: Quality goal index for parameters for Level I & Level 2 QC in (January 2019 to June 2019)

Parameter	QGI for level 1	QGI for level 2
BIT	1 -Imprecision & Inaccuracy	1.38 - Inaccuracy
BID	0.81- Imprecision & Inaccuracy	1.23- Inaccuracy
TP	0.34- Imprecision	0.23- Imprecision
Albumin	0.35- Imprecision	0.41- Imprecision

Quality goal index of parameters with low sigma calculated .Value <0.8 indicates imprecision ,0.8-1.2 indicates imprecision and inaccuracy , >1.2 indicates inaccuracy. It showed that for BIT and BID is due to imprecision and inaccuracy in Level 1 and inaccuracy in level 2. For TP and Albumin in both the levels due to imprecision.

Discussion

Sigma metrics is a quality control baseline with which a laboratory can design their on quality control strategy for each parameters based on the

priority and their impact on patient management. Schoenmaker et al specified importance of sigma metrics application and its use in designing QC. Six sigma aims at monitoring a process to 6 SDs, representing 3.4 DPM (defects per million) opportunities [12-14]. QC strategy for particular analyte can be designed using westgard sigma rule after sigma metrics calculation of it.

In this study we have analysed sigma metrics of liver function parameters over a period of six months. Similar Sigma studies with different Biochemical parameters were done by Usha S et al, Vijatha et al, Nikunj et al, Justice Afrifa et al Bhavna sing et al, Sunil Nanda et al etc [1-2, 4-8, 12-19]. Variations in sigma values between this study and others can be attributed to the difference in the instrument used, quality control material used and other pre & post analytical conditions.

Sigma scale is from 0-6. Sigma value of 3 is considered the minimal acceptable performance for a process. When performance falls below 3 Sigma, the process is considered unstable and unacceptable and should not be used for routine test purposes. Usually healthcare and clinical laboratories appear to be operating in a 2 to 3 Sigma environment. Parameters whose sigma is > 6, stringent internal QC rules need not be adopted.

In this study we found out that, the liver function parameters with sigma value more than 6 were observed in AST and ALP of level 1 QC and AST, ALT, ALP of level 2QC. Hence these parameters can be reported from the laboratory with utmost confidence. The parameters with sigma value less than 3 were BIT,BID & TP in level 1 QC and BID and Albumin in level 2 QC. Quality goal index (Table 2) of parameters with low sigma showed that these parameters need root cause analysis and also stringent internal quality control measures should be taken before reporting.

We have also observed difference in sigma value for the same parameter in different QC levels. The reason for the difference could be preparation of QC, batch no or any random error which has to be taken care of. The

parameters which demonstrated wide variation in the sigma values for both the levels of QC like Albumin should be evaluated with discretion by following Westgard sigma rule [5].

Also Power function graph can be plotted for each parameters to select the right QC rule for each parameters by considering Probability for error detection (P_{ed}) and Probability for false rejection (P_{fr}) [20]. By following Westgard sigma rule the laboratory would be able to select the right QC (frequency of internal quality control & number of control) for instrument & laboratory [21]. Sigma metrics in combination with a rational QC design for each analyte can reduce the frequency of repeat analysis and thereby reducing the consumption of resources. Thus clinical laboratories will be able to produce reliable, reproducible, accurate test results so that

both patients and clinicians can rely upon quality reports.

Conclusion

Sigma metrics helps to Streamline routine test procedures and it also helps in assessing and comparing the performance of various tests using IQC, peer comparison and proficiency testing in the form of EQAS in the laboratory. With routine six sigma practice, appropriate control limits and control measurements can be adapted for each parameters. It can be a more efficient way to assess the quality by matching the QC rules to the analytical quality of each individual assay. Clinical laboratories can use it as a quality baseline and can be used as a self-assessment tool regarding the performance & to check the reliability of report.

Financial Support and sponsorship: Nil

Conflicts of interest: There are no conflicts of interest.

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Cite this article as: Meera S and Nithya KN. Sigma metrics calculation in clinical Biochemistry laboratory - pathway for quality improvement. *Al Ameen J Med Sci* 2022; 15(1): 27-31.

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