Journal of Cardiovascular Disease Research

ISSN:0975 -3583,0976-2833 VOL12, ISSUE 03, 2021

A CLINICAL LABORATORY ASSESSMENT OF SIGMA METRICS OF FREQUENTLY ASSAYED BIOCHEMICAL PARAMETERS

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ABSTRACT

Background: The focus of the Six Sigma quality management methodology is on finding and eliminating errors to raise operational quality. The use of Six Sigma in laboratory procedures makes it possible to identify errors and use cutting-edge ways to save costs without compromising quality. In order to analyse the study biochemical laboratory's performance and to design and choose the best strategy for enhancing the performance of problematic analytes, the laboratory set out to assess the process performance of commonly examined parameters on a sigma scale. **Methods:** Retrospective data collection for quality control was conducted between June and September 2022. Sigma metrics were derived using "Total Allowable Error (TEa)," "Coefficient of Variation (CV)," and "Average Bias" for six biochemical parameters measured on the Analyser following the Clinical Laboratories Improvement Act (CLIA). To determine the root of the fault, the Quality Goal Index(QGI) of the problematic analytes were generated. **Results:** The first three of the following parameters—cholesterol, amylase, HDL, triglycerides, SGOT, and SGPT—produced good sigma values, while triglycerides, SGOT, and SGPT fared badly. Finally, the Quality Goal index was determined for the parameters if the issue is brought on by imprecision, inaccuracy, or both. **Conclusion:** The study's conclusions indicate that sigma metrics is a useful tool for assessing the analytical performance of a clinical biochemistry laboratory and that strong internal Quality Control (IQC) requirements are not required for parameters with Sigma between 3-6**.** However, prior to routine usage, root cause investigation and technique performance improvement should be carried out for a problem analyte with a sigma metric below 3.

Keywords*: Total allowable error, Bias, Six Sigma, quality goal index, Coefficient of variation;*

I Introduction

Medical laboratories are complex, dynamic businesses that continually seek to reduce costs while upholding high requirements for test quality[1]. These days, laboratories must manage growing workloads, including a wider range of parameters with constrained staffing, provide findings of the highest calibre within the allotted turnaround time, and do it in an economical manner[2]. The most recent management trend, Six Sigma, has been described as a repackaging of traditional quality management ideas, methods, and tools/techniques. The sigma number, which is expressed as "defects per million(DPM)," indicates the likelihood that mistakes or defects may occur. By using six Sigma in the lab, the number of mistakes or defects produced by the lab may be measured. Application of six Sigma to laboratory operations can be used to evaluate laboratory performance[3]. In addition to offering a dispassionate evaluation of analytical techniques and equipment,

ISSN:0975 -3583,0976-2833 VOL12, ISSUE 03, 2021

sigma metric analysis also makes vital design data accessible for practical application. QC processes that are suitable for identifying deviations are essential for the clinical interpretation of the test[4]. Each analyte has a very different quality requirement. Because blood electrolyte levels, for instance, are tightly controlled physiologically, even slight variations are likely to have a clinically significant impact for a clinically relevant shift that justifies further research or therapy, liver enzymatic activity, in contrast, exhibits substantially wider changes. As a result, much greater increases are necessary. With supporting data for process development and an explanation of how many Sigma fit inside the tolerance limits, six Sigma offers a more quantitative framework for assessing process performance[5]. So, the sigma scale is used to rate quality, with three sigmas serving as the least acceptable Sigma for ordinary performance and six sigmas serving as the target for world-class quality. When six Sigma is used in a clinical laboratory, the test method's performance is calculated using normal QC processes, and the test's quality standards are specified in terms of the total allowable error. Additionally, it calls for ongoing data analysis, computing a six-sigma value [Sigma value = TEa - bias)/CV], improvising a procedure based on the analysis of the data, and long-term follow-up[6]. As the very minimum of quality, the 3-sigma level of process performance is thought to be appropriate. The association between the number of product defects wasted operational expenses, and customer satisfaction is represented by the sigma metrics. Utilising Six Sigma in a laboratory entails quantifying test performance using conventional quality control techniques, outlining the test's quality requirements, data analysis, and sigma value computation, then process recovering based on the analysis's findings and closely monitoring it. It may be concluded that when the sigma value rises, the test's reliability and consistency improve, lowering operational expenses. Given the foregoing, we aimed to quantify the process performance of a few commonly monitored metrics to assess the laboratory's performance on the sigma scale. Doing so will help us determine and select the best course of action for enhancing the performance of the target analyte[7,8].

I. Objective

To appreciate the significance of "Six Sigma performance" and use it to compute the Sigma metrics performance of regularly used biochemical parameters.

II. Methods and Materials

We want to share the sigma measures that were logged over a four-month period in our clinical biochemistry lab (June 2022–September 2022). Internal statistical QC data were gathered over a 4-month period utilising an automated chemical analyser from the Instrumentation Laboratory. By joining Bio-Rad, materials for IQC were purchased, and information for external quality control was obtained. Scheme for External Quality Assurance (EQAS). Both levels of QC material, level I and level II, were analysed before running patient samples. SGPT, SGOT, Triglyceride, Cholesterol, HDL and Amylase were among the analytes examined with the use of the Coefficient of Variation, Total Allowable Error, and Average Bias, Sigma metric value applying CLIA criteria[9,10]. By establishing the CV and Bias for each analyte using data from 4 months of internal QC and the EQAS, the lab's quality control was validated. The statistical analysis was performed using the updated version of Microsoft Office Excel. The sigma metrics for each analyte were calculated using the equation below.

A) Measurement Variables

i) Total Allowable Error: One measurement's departure from the desired value represents the maximum permissible deviation from the accepted reference value. Guidelines under the CLIA were used to determine the TEa values for various parameters.

ISSN:0975 -3583,0976-2833 VOL12, ISSUE 03, 2021

ii) Bias: The systematic difference between the outcomes that would be obtained utilising a well-accepted reference approach and the anticipated outcomes from the laboratory's test protocol is known as Bias. Testing for proficiency led to bias "(Bio-Rad EQAS)."

"Bias (%) = (Mean of all laboratories using same instrument and method – Our mean) X 100 / Mean of all laboratories using same instrument and method."

iii) Variance Coefficient: It is the "analytical coefficient of variation" for the test method. Using internal QC material data, CV was calculated for all of the metrics.

"CV (%) = (Standard deviation X 100) / laboratory mean."

The calculation of sigma metrics was done for all parameters using the formula below from CV%, average Bias, and TEa:

Process Sigma Σ (σ) = "(TEa - bias) / CV%"

iv) Quality Goal Index: The QGI Ratio indicates how closely Bias and accuracy adhere to the respective quality objectives. Analysing the cause of lower sigma values in the problematic analytes is meant to determine if the issue is brought on by imprecision, inaccuracy, or both[11].

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

The following are the requirements for interpreting the QGI of the issue analytes with poor sigma performance: - A QGI of "0.8 or less indicates imprecision," a "QGI of 0.8 to 1.2 indicates both imprecision and inaccuracy," and "a QGI of 1.2 or more indicates inaccuracy."

IV. Results

HDL, Cholesterol and Amylase all generated satisfactory sigma values, but SGPT, SGOT, and Triglycerides fared poorly (**Table 1, 2, 3).** The achievement of six Sigma is regarded as the benchmark for determining the best quality metric. Application of six Sigma to laboratory operations can be used to evaluate laboratory performance. It is not necessary to establish strict internal QC guidelines when the process sigma value is between 3-6 or more than 6. For less than three, it is necessary to follow guidelines.

Table1: Monthly Bias for the metrics from June to September 2022

Metric	Jun.	Jul.	Aug.	Sept.	Avg.
SGPT	12	10	12	13	11.75
SGOT	4.19	12.31	4.12	16.31	9.23
Cholesterol	5.1	3.15	4.02	3.52	3.94
Triglyceride	16.09	4.10	2.17	3.11	6.36
HDL	23.49	21.87	12.11	9.02	16.62
Amylase	4.09	4.01	5.94	5.07	4.77

ISSN:0975 -3583,0976-2833 VOL12, ISSUE 03, 2021

Table 2:Average Bias, TEa, CV, and Sigma value for levels 1 and 2 of Quality Control

Metrics	Tea%	vg. ias	Level 1		Level 2	
			CV	Sigma value	CV	Sigma value
SGPT	25	11.25	4.82	2.85	3.88	3.54
SGOT	20	9.29	4.98	2.15	4.96	2.16
Cholesterol	15	3.9	2.15	5.16	2.08	5.34
Triglyceride	20	6.39	4.74	2.87	4.69	2.9
HDL	30	16.79	2.26	5.84	2.57	5.14
Amylase	30	4.78	4.51	5.59	4.58	5.51

Table 3: SigmaValues of Biochemical Parameters

Metrics	Level 1	Level 2
SGPT	2.85	3.54
SGOT	2.15	2.16
Cholesterol	5.16	5.34
Triglyceride	2.87	2.9
HDL	5.84	5.14
Amylase	5.59	5.51

Table 4: Displaying the issue analytes' CV%, Average Bias, and Sigma values, as well as calculating the QGI ratio to identify the issue

Analytes	CV%		Average Bias	Sigma		QGI Ratio		Issue	
	Level 1	Level 2		Level 1	Level 2	Level 1	Level2	Level 1	Level 2
SGPT	4.82	3.88	11.25	2.85	3.54	1.55	1.93	Inaccuracy	Inaccuracy
SGOT	4.98	4.96	9.29	2.15	2.16	1.24	1.24	Inaccuracy	Inaccuracy
Triglyceride	4.74	4.69	6.39	2.87	2.9	0.89	0.9	Imprecision and inaccuracy	Imprecision and inaccuracy

V. Data Interpretation and Discussion

Three analytes (SGPT, SGOT, and Triglycerides) with an average sigma value of less than three were found to have errors in the current study's retrospective review of sigma metrics during the analytical phase. The difference in the instruments, the quality control material employed, and various pre and post-analysis variables may be responsible for variations in the sigma values achieved. To identify the root of mistakes, the QGI ratio was determined for each of the six. For SPT and SGOT, the issue was determined to be inaccuracy, whereas imprecision and inaccuracy were both the root of the mistake for triglycerides. Similar studies have

ISSN:0975 -3583,0976-2833 VOL12, ISSUE 03, 2021

been conducted, and total allowable error is the maximum amount of mistakes that can occur without undermining the value of the test results for medical purposes. It is used to define acceptable analytical performance for the evaluation of the analytical performance of a specific instrument, for the validation of quality control, and as a way to gauge the consistency or comparability of findings for analytes measured on various systems[12]. To guarantee clinical value, TEa establishes the upper limit for combined imprecision (random error) and bias/inaccuracy (systematic error) that is allowed in a single test result. A predetermined quality criterion also assures consistency across various laboratory analysers. The total allowable error for the analytes in the current investigation was derived from several industry standards. This established permissible error levels that are neither too lax in overlooking the underlying mistakes nor too strict about causing erroneous outlier alerts. The many sources of total permissible error limitations for the study's parameters are shown in **Table 2.** The study has shown that sigma metrics are a reliable instrument for evaluating the analytical performance of a clinical chemistry laboratory and that strict internal QC requirements are not necessary for procedures with sigma 3-6[13]. Prior to routine use, underlying cause analysis and procedure performance improvement must be carried out for an issue analyte with a sigma metric under 3. Poor sigma performance (less than 3) also calls for the adoption of a more modern and effective method because, in such cases, even after numerous QC runs, the test's quality cannot be assured.

VI. Conclusion

The use of six sigma concepts will help to improve IQC processes and offer the scientific foundation for recommendations for the quantity of QC that is really required. The best option for resolving analytical and management issues in laboratory medicine and reducing mistakes to a minimal level is the Six Sigma approach. We used a sigma scale to evaluate six clinical chemistry analytes at two levels. Cholesterol, HDL and Anylase, a sigma value of 3-6, were discovered, indicating that these substances do not require strict quality control. For SGOT, SGPT and Triglyceride Sigma were found to be lower than 3, necessitating the adoption of a better procedure as well as stricter QC checks and the implementation of guidelines. The diagnostic and healthcare industries are constantly challenged to improve diagnosis, raise quality standards, and reduce costs. The budget for the laboratory as well as the quality of reports, may be significantly impacted by operational inefficiencies. Therefore, identifying the bottlenecks is essential for increasing operational productivity. Using Six Sigma in laboratory procedures enables the detection of faults and the application of state-of-the-art cost-reduction techniques without compromising quality. Generally, laboratories base the frequency and volume of their daily IQC runs on the guidelines established by accrediting bodies. Yet, each laboratory is required by good laboratory practice to develop a unique "Individual Quality Control Plan" based on "Sigma metric analysis." By doing this, unnecessary QC runs that are repeated and cause waste are avoided, which lowers the institution's operational costs.

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