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Original Research Article

Analysis of Biochemical Parameter's Performance by Using Sigma Metrics at CIMS, Chikkamagaluru-A Retrospective Study

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Abstract:

Background: Usually, laboratory outliers have negative connotations with the reports which can impact the patient's health concomitantly. Sigma metrics is a structured tool to assess laboratory defects.

Objective: To analyze the laboratory biochemical parameter's performance through Sigma metrics & by Quality Goal Index whose sigma metrics are less than 3.

Materials & Method: A retrospective study of External Quality Control & Internal Quality Control for a period of six months from January 2024 to June 2024 at Chikkamagaluru Institute of Medical Sciences, Chikkamagaluru. A total of nine parameters which included- glucose, Urea, Creatinine, Total Bilirubin, Total Protein, Uric acid, Albumin, Total Cholesterol, and Triglycerides were assessed. Percentage Bias was calculated from EQC. Co-efficient variation was calculated from IQC. Total allowable error (TEa) was obtained from CLIA (Clinical Laboratory Improvement Amendments) guidelines. Thus, Sigma Metrics were calculated from the Co-efficient of Variation, Percentage Bias & Total Allowable Error.

Results: Uric acid and triglycerides had Sigma of 4.63 & 3.5 respectively which indicates better performance and rest parameters like glucose, urea, creatinine, Total protein, albumin & total bilirubin had less than 3 sigma which indicates poor performance.

Conclusion: Sigma metrics help to analyze the performance of various biochemical parameters in clinical laboratories. Thus, our study showed that lack of precision, which was assessed by the Quality Index Goal, is the one that contributes to poor performance.

Keywords: Sigma metrics, Coefficient of Variation, Percentage Bias, Total Allowable Error, Imprecision.

Introduction

Precise and accurate laboratory reports are the main cornerstone of the medical management system. Almost 70-75% of patient's medical care depends on laboratory reports. Laboratory is a vital area, where fallacy occurs frequently due to manpower, instrumentation, and type of QC used, reagents, calibrators, and many more.

Hence to ensure the reports in terms of sensitivity, specificity, accuracy, and precision "Quality Control" plays a significant role. Internal quality control (IQC) runs on a quotidian basis, provides precision (CV %) & interpreted by Westgard rules.

External Quality Control (EQC) runs monthly and is elucidated by the Z score and Standard Deviation Index (SDI). EQC comes up with accuracy (Bias %). But, neither IQC nor EQC assesses the exact number of defects or errors [1,2,3]. Hence, employing Six Sigma computes the performance of the process in terms of Defect Per Million Opportunities (DPMO). The association between sigma metrics and defects is as follows. 1sigma signifies 6,90,000 defects or errors per million reports, 2 sigma denotes 3,08,000 errors per million reports, 3 sigma corresponds to 66,800 errors per million reports, 4 sigma denotes 6,210 errors per million reports, 5 sigma corresponds to 230 errors per million reports, whereas 6sigma corresponds to 3.4 errors per million reports.

The higher the sigma value, the lower the defects [4,5]. Thus by applying sigma metrics and quality goal index, appropriate QC can be used, and root

cause analysis (RCA) can be done for each parameter [6,7,8].

Therefore, the need of the study is to assess the biochemical parameter's performance of glucose, urea, creatinine, uric acid, total protein, total bilirubin, albumin, total cholesterol, and triglycerides by applying the sigma metrics and to find out root cause analysis (RCA)for poor performance parameters by applying Quality Goal Index (QGI).

Methodology

A retrospective study was conducted for a period of six months from January 2024 to June 2024 at Chikkamagaluru Institute of Medical Sciences, Chikkamagaluru.

A total of 9 parameters were assessed by Internal Quality Control (IQC) & External Quality Assurance Scheme (EQAS)

Parameters included – Glucose, Urea, Creatinine, Uric acid, Total Protein, Albumin, Total Bilirubin, Total Cholesterol, and Triglycerides.

Percentage Bias was calculated by the systematic difference between expected results obtained by the laboratory test method & results that would be obtained from the accepted reference method & obtained by monthly EQAS (CMC Vellore). Indicator of accuracy & systematic error.

The coefficient of Variation (CV %) is calculated by standard deviation by mean multiplied by 100. IQC, an indicator of imprecision, obtains it & shows random errors.

Total allowable error (TEa), also known as "tolerance limit" is defined as total allowable variation for the performance of an analyte. It is obtained by both CLIA (Clinical Laboratory Improvements Amendments) [9] & BVD (Biological Variation Database) [10] guidelines.

Thus, **Sigma metrics** are calculated by the formula, TEa - %Bias/CV

The minimum acceptance limit for Sigma Metrics was considered 3.

Quality Goal Index (QGI)11 indicates reasons for lower sigma metrics either due to lower accuracy or lower precision or a combination of both as shown in the below table.

QGI =Bias/1.5 x CV%

QGI	Interpretation
<0.8	Imprecision
0.8-1.2	Both Imprecision & Inaccuracy
>1.2	Inaccuracy

Results

Percentage bias and coefficient of Variation were calculated for each month for all parameters and took the average as shown in Tables No1 to 2. Then Sigma metrics were calculated from both guidelines i.e., CLIA, BVD & QGI were calculated whose sigma metrics were below 3 to know the reason behind the poor performance in the Clinical Laboratory as shown in Table No.3

Table 1: Bias Percent Monthly Wise and Average from EQC

	Jan	Feb	March	April	May	June	Average
Glucose	0.18	0.0834	0.166	-0.185	0.114	0.217	0.959
Urea	0.0071	-0.0049	-0.067	-0.0793	-0.0057	-0.0027	-0.1525
Creatinine	0.0023	-0.0001	-0.001	-0.006	-0.001	0.0017	-0.0041
Total Bilirubin	-0.0011	-0.0005	0.0008	0.0095	0.006	0.0036	0.00305
Total Protein	0.0018	0.0003	-0.0009	-0.009	-0.0059	-0.0265	-0.0067
Albumin	0.0012	0.0024	0.0002	-0.0002	-0.002	-0.0018	-3.3
Uric Acid	0.0086	0.0048	-0.01	0.002		-0.006	0.00188
Total Cholesterol	-0.0698	0.1588	-0.0925	-0.227	-0.19	-0.0473	-0.0779
Triglycerides	-0.0735	-0.0964	-0.1376	-0.1586	-0.1665	-0.00294	-0.109

Table 2: CV% Monthly Wise and Average from IQC

	Jan	Feb	March	April	May	June	Average
Glucose	4.5	4.9	6.01	6.2	18.15	4.7	7.4
Urea	12.55	5.06	5.37	10.52	5.16	6.93	7.59
Creatinine	11.87	4.5	7.57	11.09	23.7	12.5	11.87
Total Bilirubin	10.68	12.06	5.9	5.3	11.8	9.17	9.15
Total Protein	5.67	4.25	5.21	9.3	7.7	8.43	6.76
Albumin	1.7	3.3	3.2	2.12	5.17	4.5	3.4
Uric Acid	3.53	4.7	3.7	3.3		3.12	3.67
Total Cholesterol	7.6	2.8	6.7	5.5	15.9	3.3	6.96
Triglycerides	4.7	4.8	7.2	6.5	15.4	3.9	7.08

Table 3: Shows Sigma Metrics from CLIA, BVD. Also Shows QGI Which Denotes the Root Cause for Each Parameter

	Tot. Allowable Error (CLIA)	Sigma Metrics (CLIA)	Tot. Allowable Error (BVD)	Sigma Metrics (BVD)	QGI	Problem
Glucose	10	1.3	6.96	0.92	0.47	Imprecision
Urea	9	1.2	15.5	2.06	-0.7	Imprecision
Creatinine	15	1.26	8.87	0.7	-0.0324	Imprecision
Total Bilirubin	20	2.18	26.9	0.2	0.0186	Imprecision
Total Protein	10	1.49	3.63	0.53	-0.03	Imprecision
Albumin	10	1.95	4.07	0.20	7.5	Inaccuracy
Uric Acid	17	4.63	11.97	3.2	-------	----------
Total Cholesterol	10	1.4	9.01	1.4	-0.36	Imprecision
Triglycerides	25	3.5	25.99	3.6	--------	----------

Discussion

There is a bridging gap between Quality Control & sigma metrics. The actual root cause for each biochemical parameter performance cannot be gauged by Quality Control alone. Most of the laboratories run their IQC according to the recommendations of accreditation bodies. But good laboratory practice implies that every laboratory should outline the Individual Quality Control Plan (IQCP) based on Sigma metrics which fend off the uncalled-for repeated QC runs that arouse wastage and incur more operational price on the institutions [12].

Not only that but enlisting Sigma metrics also gives an idea regarding adopting new methods of that parameter whose performance is below <3. It also helps to set IQC acceptability criteria. For a 6 or higher sigma, apply 3.5 SD (standard deviation) with control limits N=2 (where N is number of controls to be run per day), for 5 sigma, use 3SD with control limits N=2, for 4 sigma set 2.5SD with control limits N=4 to be used, for 3 sigma, use control limits N=6 or 8 and for <3 sigma, method execution should be refined before the method can be used for regular production [13].

In the present study, the retrospective evaluation of total 9 parameters were done to determine Sigma metrics. Uric acid had sigma of 4.65 and triglycerides had sigma of 3.5, rest parameters like glucose, urea, total protein, total bilirubin, total cholesterol, creatinine and albumin showed less than 3 sigma metrics. Discrepancy may be imputed due to differences in instrumentation, quality control material used, and other preanalytical issues.

Quality Goal Index (QGI) was applied to know the root cause for errors for those parameters who obtained <3 sigma metrics. Imprecision was main cause for errors in the parameters like total bilirubin, total cholesterol, total protein, urea, and creatinine.

Inaccuracy was cause for error in albumin. Total allowable error (TEa) is the amount of error acceptable of an analyte. It sets the limit for both amalgamate imprecision and inaccuracy that is random error & systematic error. By presetting TEa, it gives uniformity for multiple analysers [14]. In this current study, we took TEa guidelines both from CLIA and BVD as shown as at Table No.3

Thus, in this current study, the parameters whose performance was <3 sigma, need to be corrected by increasing the frequency of running IQC, by following very stringent QC or by adopting newer methods or by reducing imprecision factors.

Conclusion

Sigma metrics is structured tool to assess the exact number of errors/defects, helps in setting internal QC acceptability criteria, denotes whether new methods to be adopted or not and also it prevents unnecessary usage of QC material, thereby providing cost effective to the institutions. Quality Goal Index was applied when sigma metrics falls <3 helps to know the exact cause either due to imprecision or inaccuracy for each parameter (Root cause analysis). Uric acid and triglycerides had better sigma metrics compared to rest parameters.

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