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Retrospective Study

Assessment of quality control system by sigma metrics and quality goal index ratio: A roadmap towards preparation for NABL

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Abstract

AIM

To study sigma metrics and quality goal index ratio (QGI).

METHODS

The retrospective study was conducted at the Clinical Biochemistry Laboratory, PGIMS, Rohtak, which recently became a National Accreditation Board for Testing and Calibration of Laboratories accredited lab as per the International Organization for Standardization 15189:2012 and provides service to a > 1700-bed tertiary care hospital. Data of 16 analytes was extracted over a period of one year from January 2017 to December 2017 for calculation of precision, accuracy, sigma metrics, total error, and QGI.

RESULTS

The average coefficient of variation ranged from 2.12% (albumin) to 5.42% (creatinine) for level 2 internal quality control and 2% (albumin) to 3.62% (high density lipoprotein-cholesterol) for level 3 internal quality control. Average coefficient of variation of all the parameters was below 5%, reflecting very good precision. The sigma metrics for level 2 indicated that 11 (68.5%) of the 16 parameters fall short of meeting Six Sigma quality performance. Of these, five failed to meet minimum sigma quality performance with metrics less than 3, and another six just met minimal acceptable performance with sigma metrics between 3 and 6. For level 3, the data collected indicated eight (50%) of the parameters did not achieve Six Sigma quality performance, out of

which three had metrics less than 3, and five had metrics between 3 and 6. QGI ratio indicated that the main problem was inaccuracy in the case of total cholesterol, aspartate transaminase, and alanine transaminase (QGI > 1.2), imprecision in the case of urea (QGI < 0.8), and both imprecision and inaccuracy for glucose.

CONCLUSION

On the basis of sigma metrics and QGI, it may be concluded that the Clinical Biochemistry Laboratory, PGIMS, Rohtak was able to achieve satisfactory results with world class performance for many analytes one year preceding the accreditation by the National Accreditation Board for Testing and Calibration of Laboratories. Aspartate transaminase and alanine transaminase required strict external quality assurance scheme monitoring and modification in quality control procedure as their QGI ratio showed inaccuracy.

Key words: Sigma; Quality goal index; Bias; Imprecision; Inaccuracy; Coefficient of variation

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Core tip: As the majority of tests take place in the biochemistry laboratory, it plays a major role in patient care. Therefore, it is necessary to follow a proper quality management system to provide accurate and precise reports to patients. National Accreditation Board for Testing and Calibration of Laboratories accreditation is an important benchmark for "A" grade quality. Sigma metrics is also a well-known self-assessment tool to guide quality control strategy design. On the basis of sigma metrics and quality goal index ratio, it may be concluded that the Clinical Biochemistry Laboratory, PGIMS, Rohtak was able to achieve satisfactory results with world class performance for many analytes one year preceding accreditation by the National Accreditation Board for Testing and Calibration of Laboratories.

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INTRODUCTION

Over 60% of tests are carried out in a clinical biochemistry laboratory. Therefore, it plays a major role in diagnosing and managing diseases. It is imperative to follow a proper quality management system (QMS) to provide accurate and reliable reports in an agreed upon time frame^[1]. The Clinical Biochemistry Laboratory, PGIMS, Rohtak, (CBL, PGIMS, Rohtak) is a National Accreditation Board for Testing and Calibration

of Laboratories (NABL) accredited lab as per the International Organization for Standardization (ISO) 15189:2012. It has become the first laboratory in the government sector attached to a postgraduate institute to be accredited by NABL in the whole North India region.

In a CBL, total testing process consists mainly of three stages: pre-analytical phase, analytical phase, and post-analytical phase. QMS includes strict compliance at all phases as error can occur at any step. In the mid-1980s, a revolution came in QMS that reduced the cost of products, decreased variability in processing, and eliminated defects. This evolution was Six Sigma methodology that was developed by a Motorola engineer named Bill Smith^[2]. Sigma metrics is an important tool to evaluate the errors in quality control of a laboratory system. Sigma is a metric that quantifies the performance of a process at a rate of defects-per-million^[3]. The sigma value indicates how often errors are likely to occur. The higher the sigma value, the lower the chance of false test results by the laboratory. It can easily quantify the exact number of errors by combining bias, precision, and total allowable error (TEa). A sigma level < 3 is an indication of a poor performance procedure, whilst a good performance is indicated by a sigma level > 3. Sigma level of 6 or greater indicates world-class performance^[2].

To calculate precision and bias, internal quality control (IQC) and external quality assurance scheme (EQAS) are being carried out in our laboratory. IQC is run daily as per NABL guidelines and is interpreted by Levy Jennings' charts and Westgard's rules. The samples to be analyzed are run only when the IQC results are within control limits. EQAS sample is run monthly and is interpreted by Z score or Standard Deviation Index (SDI). Z-score is a calculated value that tells us how many standard deviations (SDs) a control result has shifted from the mean value, which is expected for that material^[2]. Quality goal index (QGI) is a newer parameter to represent the relative extent to which both bias and precision meet their respective quality goals.

The CBL, PGIMS, Rohtak is a large laboratory catering to 500 outpatient samples and 300 inpatient samples per day. The laboratory has regularly run IQC and EQAS for several years. To obtain the NABL accreditation by our large, government laboratory was a daunting task. However, once a system was established, the task became achievable and motivated us to share our experience regarding EQAS data from the year preceding the NABL accreditation.

The aim of the present study is to measure the sigma metrics and QGI for individual parameters in the scope for NABL accreditation.

MATERIALS AND METHODS

The retrospective study was conducted at the CBL, PGIMS, Rohtak, which provides laboratory service to a > 1700-bed tertiary care hospital. Data was extracted

over a period of one year from January 2017 to December 2017. A total of 16 analytes were included in the study which were: glucose, urea, creatinine, total bilirubin, total protein, albumin, calcium, phosphorus, uric acid, total cholesterol, triglyceride, high density lipoprotein-cholesterol (HDL-cholesterol), aspartate transaminase (AST), Alanine Transaminase (ALT), alkaline phosphatase (ALP), and amylase. All parameters were run along with IQC and EQAS. IQC data was analyzed for imprecision and EQAS data for inaccuracy. The parameters were done on a Randox Suzuka autoanalyzer by using Randox kits obtained from the manufacturer following the standard operating procedures at CBL.

As per laboratory policy, two levels of controls (level 2: normal and level 3: pathological, Randox Laboratories Limited) were run twice daily along with monthly EQAS lyophilized sample obtained from Christian Medical College, Vellore throughout the study period. The laboratory follows the Westgard's rule to accept and reject the run. 1_{3s} , 2_{2s} , R_{4s} , 4_{1s} , and $10x$ were considered a rejection, and 1_{2s} as a warning rule for each respective run. Mean, SD, and coefficient of variance (CV) were calculated for each month for both levels. The laboratory receives EQAS sample in three batches of four samples every year. The sample was reconstituted and analyzed the same day. All the EQAS samples were handled as routine patient samples and were analyzed by the senior lab technician on duty without his knowledge. Reports were uploaded before the 20th of every month. On the 4th of the next month SDI was checked. SDI within 0 ± 2 was considered acceptable. Bias was also noted.

Sigma metrics

Mean of the CV of both levels and bias was calculated and used for estimating sigma metrics by the following formula:

$$\text{Sigma} = (\text{TEa} - \text{Bias})/\text{CV}^{[4]}$$

Where, TEa is total allowable error, and bias and CV are the indicators of systematic and random errors, respectively. The minimum acceptable performance of process was a 3 sigma level.

QGI

QGI represents the relative extent to which both bias and precision meet their respective quality goals. It was calculated using the following formula:

$$\text{QGI} = \text{Bias}/1.5 \text{ CV}$$

QGI represents the reason behind lower sigma value *i.e.*, imprecision, inaccuracy, or both. For analytes which fall short of Six Sigma quality, a QGI score of < 0.8 indicates imprecision, $\text{QGI} > 1.2$ indicates inaccuracy, and QGI score 0.8-1.2 indicates both imprecision and inaccuracy^[4].

Coefficient of variation

The coefficient of variation (CV) is the SD expressed as

a percentage and is a measure of the variability of an assay^[5].

$$\text{CV} = (\text{SD}/\text{Mean}) \times (100)$$

Bias

Bias is the systematic difference between the expected results obtained by the laboratory test method and the results that would be obtained from an accepted reference method^[6].

TEa

TEas were followed as per the Clinical Laboratory Improvement Amendments (CLIA) guidelines^[1]. Total error (TE) of parameters was also calculated by the following formula^[7]:

$$\text{TE} = \text{Bias} + 1.65\text{CV}$$

RESULTS

Tables 1 and 2 summarize the CV % of level 2 and level 3 IQC, respectively for 16 biochemical parameters from January 2017 to December 2017 along with their average values. The average CV ranged from 2.12% (albumin) to 5.42% (creatinine) for level 2 IQC and 2% (albumin) to 3.62% (HDL-cholesterol) for level 3 IQC. Average CV of all the parameters is below 5% reflecting very good precision. Table 3 summarizes the bias % obtained from EQAS from CMC Vellore for 16 parameters and their average for the same duration. Table 4 summarizes the average CV %, average bias %, TEa (CLIA), calculated TE, and sigma metrics of the 16 parameters.

The sigma metrics for level 2 indicated that 11 (68.5%) of the 16 parameters fell short of meeting Six Sigma quality performance. Of these, five failed to meet minimum sigma quality performance with metrics less than three and another six just met minimal acceptable performance with sigma metrics between three and six. For level 3, the data collected indicated that eight (50%) of the parameters did not achieve Six Sigma quality performance, out of which three had metrics less than 3 and five had metrics between 3 and 6. Calculated TEa of all the parameters were less than specified TEa (CLIA) except for AST and ALT. Table 5 summarizes the results of sigma metrics of various parameters. Table 6 summarizes the QGI ratio of analytes with lower sigma values (< 3). QGI ratio indicated that out of five and three parameters of level 2 and level 3, which failed to meet Six Sigma quality performances, the main problem was inaccuracy in the case of total cholesterol, AST, and ALT ($\text{QGI} > 1.2$), imprecision in the case of urea ($\text{QGI} < 0.8$), and both imprecision and inaccuracy for glucose.

DISCUSSION

Currently, it is a requirement to constantly verify the pre-analytical, analytical, and post-analytical processes

Table 1 The CV % of 16 parameters of level 2 internal quality control for a period of one year (Jan-Dec, 2017) and their average

Parameter	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Average
Glucose	2.04	1.81	2.12	1.98	2.99	2.07	4.74	2.96	3.07	4.01	2.94	2.17	2.74
Urea	3.13	4.27	3.87	5.84	4.08	5.30	4.43	4.08	3.89	3.70	3.61	4.39	4.21
Creatinine	7.02	8.30	8.02	7.15	4.47	3.38	6.28	4.13	3.45	4.02	4.26	4.66	5.42
Total bilirubin	2.88	3.89	3.27	2.93	2.52	4.60	4.75	4.62	2.99	2.54	4.07	4.86	3.66
Total protein	1.95	2.18	2.67	2.94	3.81	2.99	3.03	3.00	3.83	3.99	2.34	3.27	3.00
Albumin	0.99	2.55	2.04	0.96	3.40	2.18	1.86	1.86	2.27	1.94	3.00	2.47	2.12
Calcium	2.09	2.90	2.76	2.70	2.75	2.38	2.57	2.55	2.06	3.24	2.74	1.85	2.54
Phosphorus	5.48	6.83	6.70	4.47	5.40	6.72	4.52	3.58	3.87	3.68	4.22	3.54	4.91
Uric acid	3.63	4.17	2.73	3.59	3.64	3.81	2.80	3.21	3.36	2.53	2.66	2.6	3.22
Total cholesterol	2.26	1.86	3.42	2.17	2.53	4.16	3.64	2.62	2.38	2.87	3.00	3.49	2.86
Triglyceride	3.74	4.95	5.07	5.30	7.17	5.07	5.36	3.96	3.62	4.23	5.13	3.29	4.74
HDL cholesterol	5.08	3.43	5.68	1.74	4.56	2.85	4.57	3.89	3.14	2.90	2.94	3.56	3.69
AST	5.74	6.18	6.79	4.22	4.59	4.97	5.72	4.31	3.49	3.40	4.38	3.56	4.77
ALT	5.82	6.10	4.80	5.09	5.25	5.39	5.56	5.64	1.99	3.05	4.90	3.46	4.75
ALP	2.98	3.59	2.81	2.56	2.51	2.87	3.02	3.77	2.26	5.97	4.17	2.84	3.27
Amylase	4.03	5.70	4.71	4.24	4.00	3.14	5.47	4.72	4.10	3.30	3.07	3.87	4.19

CV: Coefficient of variation; IQC: Internal quality control; HDL: High-density lipoprotein; AST: Aspartate transaminase; ALT: Alanine transaminase; ALP: Alkaline phosphatase.

Table 2 The CV % of 16 parameters of level 3 internal quality control for a period of one year (Jan-Dec, 2017) and their average

Parameter	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Average
Glucose	1.20	1.31	1.59	1.50	1.96	1.65	2.80	2.05	4.32	2.45	1.76	1.90	2.04
Urea	2.60	2.91	3.50	4.40	3.23	3.84	3.41	3.36	3.65	4.02	3.28	2.60	3.40
Creatinine	3.34	3.49	5.29	4.77	2.75	1.97	3.10	3.03	2.98	2.95	2.92	2.16	3.22
Total bilirubin	2.50	2.35	2.52	2.05	2.35	3.34	2.86	3.99	2.12	3.91	2.66	2.71	2.78
Total protein	2.36	2.41	1.96	2.36	3.84	2.90	2.75	4.24	3.50	3.82	3.25	3.34	3.06
Albumin	2.25	1.95	3.29	1.73	1.69	1.84	1.99	1.69	1.86	1.74	1.96	2.02	2.00
Calcium	1.37	2.95	2.57	2.54	2.00	2.21	2.92	2.93	2.14	2.22	2.34	2.2	2.36
Phosphorus	3.50	4.85	4.77	4.78	3.85	4.02	2.22	1.88	1.62	2.78	2.41	2.61	3.27
Uric acid	2.90	3.03	2.33	2.12	2.66	2.42	3.56	2.51	2.54	1.97	3.11	2.23	2.61
Total cholesterol	2.09	1.30	2.86	2.35	2.61	4.61	2.30	3.91	2.03	2.57	2.6	2.79	2.66
Triglyceride	2.50	2.26	3.61	2.85	3.18	4.22	3.80	2.70	1.98	2.72	3.49	2.83	3.01
HDL cholesterol	3.03	3.72	4.19	1.95	5.17	4.54	5.22	2.91	1.97	4.35	4.1	2.35	3.62
AST	2.12	3.40	2.65	2.75	3.45	2.55	3.48	3.76	3.95	2.92	3.62	2.70	3.11
ALT	3.19	2.81	3.09	2.89	4.45	2.66	4.22	4.32	2.89	2.67	2.56	3.11	3.23
ALP	2.93	2.61	2.67	2.74	2.59	2.53	2.53	2.3	2.30	4.08	2.82	2.90	2.75
Amylase	3.10	3.51	3.57	3.47	3.30	2.84	5.30	2.25	3.03	3.42	2.73	3.33	3.32

CV: Coefficient of variation; IQC: Internal quality control; HDL: High density lipoprotein; AST: Aspartate transaminase; ALT: Alanine transaminase; ALP: Alkaline phosphatase.

of the laboratory by internal or external audit. Sigma metrics is an important self-assessment tool to guide QC strategy design. It helps to improve the process quality by removing defects. We analyzed 16 parameters for sigma metrics over one year (January-December, 2017). Similar studies have been conducted by Singh *et al*^[8], Adiga *et al*^[2], Iqbal *et al*^[3] and Nanda *et al*^[9], but none of these assessed the cause of low sigma, *i.e.*, either imprecision, inaccuracy, or both. Only a single study in literature could be found that carried out both sigma metrics and QGI^[10].

The Six Sigma model is similar to Total Quality Management, which follows a "Plan, Do, Check, Act" cycle. The basic scientific model in Six Sigma metrics is "Define, Measure, Analyze, Improve and Control." The Six Sigma model has the extra step of control, which is important in modern quality management. This step

helps in preventing the recurrence of defects, *i.e.*, if an error is detected, it has to be solved it and prevented from affecting the process again. With this step, errors are effectively decreased until a desirable degree of quality is obtained^[11]. The same is to be followed for the parameters with lower sigma values to attain desirable performance level, as continual improvement is necessary as per ISO standards for good laboratory practices.

In this study, four parameters (albumin, uric acid, HDL-cholesterol, and ALP) showed a sigma of > 6 for both level 2 and level 3 of IQC showing excellent performance, while creatinine, total bilirubin and amylase showed > 6 for level 3 IQC only. Total cholesterol, AST, and ALT were short of sigma metrics with a value < 3 for both level 2 and level 3. Glucose and urea showed < 3 sigma for level 2 only. Nanda *et al*^[9] and Kumar

Table 3 The bias % obtained from external quality assurance scheme from CMC Vellore for 16 parameters for a period of one year (Jan-Dec, 2017) and their average

Parameter	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Average
Glucose	10.8	-9.7	6.1	1.2	1.2	6	3.8	3.2	0.9	7.5	8.5	4.5	3.66
Urea	-3.8	-7.2	-2.5	-2.2	2.2	-12.2	-1.8	-5.4	4	-10.1	-1.6	5.3	-2.94
Creatinine	-8.3	-13.6	-18.8	-7.7	-10.9	-9.1	-9.9	14.3	-7.5	-14	0	-10.7	-8.01
Total bilirubin	0	-20	-4.8	5.4	5.9	-5.9	-4	-10	3.3	-3.8	6.2	10.9	-1.4
Total protein	-4.2	-14	-2	-6	-2	-9.6	-5.8	-8.3	-6.2	-10	-8.2	-4.1	-6.7
Albumin	-3.3	-16.1	-6.5	-9.4	-12.9	-15.6	-6.3	-10	-10	-6.5	0	-3.3	-8.32
Calcium	1.2	-0.8	4.1	-4.3	3.1	-1.6	2.2	3.4	1.1	2.1	15.7	12.6	3.23
Phosphorus	-12.8	-37.5	-20.6	-15.8	-12.5	-9.3	-25.9	-4.4	-20	1.9	-18.8	7.3	-14
Uric acid	-14.5	-20.4	-16.2	-11.6	-22.9	-3.3	-4.8	-26.7	-5.7	-7.1	-8.3	-5.5	-12.2
Total cholesterol	-0.6	-6.4	1.8	2	-1.9	-3.5	3.3	6	26.9	8.9	15.8	8.7	5.08
Triglyceride	9.1	-1.3	4	5.9	-2.8	6.5	12.2	1.5	15.5	17.5	11.5	9.4	7.41
HDL cholesterol	-12.1	-23.6	-19.4	-14.7	-18	-27.7	-13	-15	-17.4	-18	-15.3	-14.6	-17.4
AST	20	2.4	20.7	7.6	0.8	5.8	13.7	17.8	20.1	11	14.8	24.3	13.2
ALT	33.5	12.3	22	-3.6	6.7	-4.3	13.2	-11.9	18.3	7.6	29	29.6	12.7
ALP	-5.6	-5	4.3	-8.3	-6	-18.2	-6.1	-4.5	1.5	6.6	7.3	3.2	-2.56
Amylase	12.4	-0.7	17.9	4.8	8.2	4.8	15.1	15.3	17.6	5.9	-1.6	16.4	9.67

CV: Coefficient of variation; EQAS: External quality assurance scheme; HDL: High-density lipoprotein; AST: Aspartate transaminase; ALT: Alanine transaminase; ALP: Alkaline phosphatase.

Table 4 Sigma metrics (Level 1 and 2) and quality goal index ratio (Level 1 and 2) of 16 parameters calculated from coefficient of variation (Level 1 and 2), total allowable error (Clinical Laboratory Improvement Act), and bias %, for a period of one year (Jan-Dec, 2017)

Parameter	CV%		Bias %	TEa (CLIA)	TE (calculated)		Sigma	
	Level 2	Level 3			Level 2	Level 3	Level 2	Level 3
Glucose	2.74	2.04	3.66	10	8.18	7.03	2.31	3.11
Urea	4.21	3.4	-2.94	9	4.01	2.67	2.84	3.51
Creatinine	5.42	3.22	-8.01	15	0.93	-2.7	4.25	7.15
Total bilirubin	3.66	2.78	-1.4	20	4.64	3.19	5.85	7.7
Total protein	3	3.06	-6.7	10	-1.75	-1.65	5.57	5.46
Albumin	2.12	2	-8.32	10	-4.82	-5.02	8.64	9.16
Calcium	2.54	2.36	3.23	11	7.42	7.12	3.06	3.29
Phosphorus	4.91	3.27	-14	10	-5.9	-8.6	4.89	7.34
Uric acid	3.22	2.61	-12.2	17	-6.89	-7.89	9.07	11.19
Total cholesterol	2.86	2.66	5.08	10	9.8	9.47	1.72	1.85
Triglyceride	4.74	3.01	7.41	25	15.23	12.38	3.71	5.84
HDL cholesterol	3.69	3.62	-17.4	30	-11.31	-11.43	12.85	13.09
AST	4.77	3.11	13.2	20	21.07	18.33	1.43	2.19
ALT	4.75	3.23	12.7	20	20.54	18.03	1.54	2.26
ALP	3.27	2.75	-2.56	30	2.84	1.98	9.96	11.84
Amylase	4.19	3.32	9.67	30	16.58	15.15	4.85	6.12

CV: Coefficient of variation; TE: Total error; CLIA: Clinical Laboratory Improvement Act; HDL: High-density lipoprotein; AST: Aspartate transaminase; ALT: Alanine transaminase; ALP: Alkaline phosphatase.

Table 5 Sigma metrics of various parameters

Sigma metrics	Level 2	Level 3
< 3	Glucose, urea, total cholesterol, AST, ALT	Total cholesterol, AST, ALT
3-6	Creatinine, total bilirubin, total protein, calcium, phosphorus, triglyceride	Glucose, urea, total protein, calcium, triglyceride
> 6	Albumin, uric acid, HDL-cholesterol, ALP	Creatinine, total bilirubin, albumin, uric acid, HDL-cholesterol, ALP, amylase

HDL: High-density lipoprotein; AST: Aspartate transaminase; ALT: Alanine transaminase; ALP: Alkaline phosphatase.

et al^[10] reported four parameters with < 3 sigma metrics. The lowest value for sigma was found for total cholesterol (1.72) at level 2 and the highest value for

HDL-cholesterol (13.09) at level 3. For parameters showing lower sigma values, root cause analysis is done. Strict monitoring as well as increased frequency

Table 6 Quality goal index ratio of analytes performed low for sigma for accuracy and precision problem

Analytes	Qc levels	Bias%	CV%	Sigma	QGI	Problem
Glucose	Level 2	3.66	2.74	2.31	0.89	Imprecision and inaccuracy
Urea	Level 2	-2.94	4.21	2.84	0.47	Imprecision
TC	Level 2	5.08	2.86	1.72	1.18	Inaccuracy
	Level 3	5.08	2.66	1.85	1.27	Inaccuracy
AST	Level 2	13.2	4.77	1.43	1.84	Inaccuracy
	Level 3	13.2	3.11	2.19	2.83	Inaccuracy
ALT	Level 2	12.7	4.75	1.54	1.78	Inaccuracy
	Level 3	12.7	3.23	2.26	2.62	Inaccuracy

QGI: Quality goal index ratio; AST: Aspartate transaminase; ALT: Alanine transaminase; TC: Total cholesterol.

of IQC run is required. QGI ratio for parameters with sigma < 3 depicted inaccuracy in the case of TC, AST, and ALT (QGI > 1.2), imprecision in the case of blood urea (QGI < 0.8), and imprecision and inaccuracy in the case of glucose. There are certain limitations in the sigma metrics system because we have observed no problems in the CV % and bias % of glucose (level 2), urea (level 2), and TC (level 2 and level 3), but sigma is showing a lesser value. In the case of AST and ALT, the calculated TE is higher compared to the allowable error as per CLIA, which is reflected in the QGI and sigma metrics. In our opinion, if TE of an analyte is within allowable error limits specific for that analyte, bias % and CV % might be more reliable than sigma metrics. However, this claim needs to be supported by further studies.

On the basis of sigma metrics and QGI, it may be concluded that the CBL, PGIMS, Rohtak was able to achieve a quality of results that allowed a NABL accreditation to the laboratory as per ISO standard 15189:2012. AST and ALT required strict EQAS monitoring and modification in quality control procedure as their QGI ratio showed inaccuracy. Although sigma metrics is a well-known industrial standard, it might not be applied universally for all the analytes.

ARTICLE HIGHLIGHTS

Research background

Accreditation is a formal recognition from a third party body, which demonstrates the competence and capability to carry out a certain task it is claiming to do.

Research motivation

Over 60% of tests are carried out under clinical biochemistry section; hence it plays a critical role in diagnosing and managing diseases. It is imperative to follow a proper quality management system by the laboratory so as to provide accurate and reliable reports in an agreed upon time frame.

Research objectives

Assessment of the analytical phase of quality control system by sigma metrics and quality goal index ratio (QGI).

Research methods

This retrospective study was conducted at the Clinical Biochemistry Laboratory, PGIMS, Rohtak, which recently became a National Accreditation Board for Testing and Calibration of Laboratories (NABL) accredited lab per the International Organization for Standardization (ISO) 15189:2012 and provides

service to a > 1700-bed tertiary care hospital. Data of 16 analytes were extracted over a period of one year from January 2017 to December 2017 for calculation of precision, accuracy, sigma metrics, total error, and QGI.

Research results

The average coefficient of variation of all the parameters was below 5%, reflecting precision. The sigma metrics for level 2 indicated that five of the sixteen parameters fell short of meeting minimal Six Sigma quality performance. For level 3, the data collected indicated three of the parameters do not achieve minimal Six Sigma quality performance. QGI ratio indicated that the main problems were inaccuracy in the case of total cholesterol, aspartate transaminase, and alanine transaminase (QGI > 1.2), imprecision in the case of urea (QGI < 0.8), and imprecision and inaccuracy for glucose.

Research conclusions

On the basis of sigma metrics and QGI, it may be concluded that the Clinical Biochemistry Laboratory, PGIMS, Rohtak was able to achieve satisfactory results with world class performance for many analytes one year preceding the NABL accreditation as per ISO standard 15189:2012.

Research perspectives

Although sigma metrics is a well-known industrial standard, it might not be applied universally for all the analytes.

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