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Original Research Article

Application of six sigma metrics and method decision charts in improvising clinical Chemistry laboratory performance enhancement

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ABSTRACT

Background: Six sigma is a powerful tool which can be used by laboratories for assessing the method quality, optimizing Quality Control (QC) procedure, change the number of rules applied, and frequency of controls run .The aim of this study was to quantify the defects or errors in the analytical phase of laboratory testing by sigma metrics and then represent the sigma value in Method Decision Chart.
Methods: A retrospective study was conducted in a tertiary care hospital in Bhubaneswar, India. The clinical chemistry laboratory has been NABL accredited for the past 5 years and strictly quality checked. Internal and external quality control data was collected for a period of six months from January - June 2018 for 20 biochemical analytes. Sigma metrics for each parameter was calculated and plotted on method decision chart.
Results: The sigma metrics for level 2 indicated that 6 out of the 20 analytes qualified Six Sigma quality performance. Of these seven analytes failed to meet minimum sigma quality performance with metrics less than three and another seven analytes performance with sigma metrics was between three and six. For level 3, the data collected indicated that seven out of 20 analytes qualified Six Sigma quality performance, six analytes had sigma metrics less than 3 and seven analytes had sigma metrics between 3 and 6.
Conclusion: In our study Sigma value was highest for amylase and lowest for potassium. Use of alternative methods and/ or change of reagents can be done for potassium to bring the sigma value within an acceptable range.

Keywords: Bias, Imprecision, Method decision chart, Quality control, Quality Goal Index, Sigma metrics

INTRODUCTION

Laboratory services may make up 5% of a hospital's budget but they are the mainstay in 60-70% of all critical decision-making such as admittance, discharge and medication.[1] The testing process in a clinical chemistry laboratory consists of three phases namely pre-analytical phase, analytical phase and post-analytical phase. All the three phases are prone to error.

Laboratory error can be defined as any defect or deviation of result from true value. Internal Quality Control (IQC) and External Quality Assurance Service (EQAS) are presently the procedures that are being used for quality control in the analytical phase. The IQC shows the amount of variation that occurs in our results in the form

of imprecision while EQAS helps in evaluating the accuracy or trueness of our results. For a lab the result generated is a form of product. All Production processes always have a certain tendency for error generation. In 1981, Dr. James O. Westgard proposed several statistical process control rules used with Levey-Jennings chart for evaluating Quality Control (QC) performance.[2] However the quantification of error in the analytical process cannot be expressed through IQC or EQAS procedures. Here comes the roll of Six Sigma which can help us in expressing our quality goals.

Sigma metrics is about measuring or counting the number of defects. Sigma is denoted by a Greek letter "σ" and used to measure the standard deviation. Defects or laboratory errors can be counted and converted to defects-per-million (DPM). This DPM can then be converted into a Sigma metrics. Six sigma is the ideal goal or world class quality equivalent to 3.4 defects per million. Six sigma originated at Motorola in 1987 which was meant to mainly focus on defect reduction and improved yield. Bill Smith started it in the pager making unit to reduce defects and got breakthrough results. This was later modified and adapted by many companies.[3-5]

In 2001, David Nevelainen did a first study which benchmarked the laboratory quality in six sigma scale.[6] Since then Six Sigma tool have been used by laboratories to check method quality, QC optimization, change the number of rules and controls run and to change the frequency of QC. Xuehui Mao et al used Six sigma to assess quality of an instrument and Yong Xia et al, utilized six sigma for risk assessments connecting test results to patient care.[7,8]

So, six sigma can be used as a tool not only to count defects but also to assess analytical methods, optimize QC plans and compare analytical quality of instruments and so on. Laboratories face quality challenges and need to continually improve their processes and work cultures, six sigma would be an added tool in the quality process which will help laboratories in their self-improvement.

Method Decision Chart is another tool that converts all the Sigma metrics into a simple visual graph. Method Decision Chart is also known as Sigma Bull's Eye graph, this chart arranges the imprecision along the x-axis and bias along the y-axis. Sigma metrics zones is also displayed on this graph, 6 σ zone (world class quality) is closest to the graph's origin, followed by a 5σ zone (Excellent), 4σ zone (Good), 3σ zone (Marginal), 2σ zone (Poor), and the remainder of the graph below 2σ, is tagged as unacceptable.[9]

As analyte gets closer to the bull's eye, that means their Sigma metrics are higher and fewer defects are being generated. As analyte perform further away from the bull's-eye, they are generating more defects, adding more error to the patient's test result, and ultimately could be confounding and confusing to the clinicians, not helping to confirm a diagnosis and guiding treatment.

The aim of this study is to quantify the defects or errors in the analytical phase of laboratory testing by sigma metric and then represent the sigma value in Method Decision Chart. For this purpose, sigma metric analysis was done for 20 analytes, using the internal and external quality control as quality indicators. Result of sigma metric analysis was utilized to identify the gaps and need for modification in the strategy of laboratory quality control procedure.

METHODS

The Retrospective study was undertaken in the This study was conducted in the central laboratory of a tertiary care teaching hospital in Bhubaneswar, India. The laboratory is accredited for past five years. Internal and external quality assurance scheme data was collected for a period of six months from January - June 2018 for 20 biochemical analytes were included in this study.

Inclusion criteria

- The analytes which were in the NABL scope of laboratory were included for the study.
- The analytes that were run on a daily basis.

Analytes included

Albumin (ALB), Alkaline phosphatase (ALP),Alanine aminotransferase (ALT), amylase (AMY), Aspartate aminotransferase (AST), Total bilirubin (T BIL), Calcium (Ca^{2+}), Total cholesterol(T CHOL), Creatinine (CREAT), Gamma Glutamyl Transferase (GGT), Glucose (GLU), HDL cholesterol (HDL-C), Magnesium (Mg), Phosphorus (P), Potassium (K^+), Sodium (Na^+), Total protein (TP), Triglyceride (TRIG), Urea (UREA), Uric acid (UA).

Exclusion criteria

- The analytes which were not in the NABL scope of laboratory were excluded for the study.
- The analytes that were not run on a daily basis.

The analysers Instruments used were Cobas Integra 400 Plus, Vitros 5600 and Accu Lab Enlite.

Statistical analysis

Software used for data analysis - Vitros 6 σ tool was used for calculation and analysis.

Daily laboratory work load was divided into two shifts; each shift was comprised of 12 hours. According to laboratory policy of internal quality control program, two levels (normal, L2 and pathological L3) of control material (Randox, UK) were being used in each run of

12hours.Westgard rules were applied for the interpretation of quality control results. Westgard rules of 1_{3s}, 2_{2s}, R_{4s}, 4_{1s} and 10_{x} were considered as rejection and 1_{2s} as warning sign for the respective run. Laboratory is participating monthly in the external QC survey of RIQAS (Randox International Quality Assessment Scheme, Randox Laboratories, United Kingdom). The results obtained from internal and external QC scheme, were used to estimate the sigma metrics. Laboratory and peer group mean result of analytes were retrieved from monthly external QC program records.

Formulae used for statistical analysis

Six sigma calculation

Sigma metrics for each parameter was calculated using the following formula

$$\text{Sigma} = (\text{TEa} - \text{Bias}) / \text{CV}$$

Where, TEa is total allowable error, Total allowable error (TEa) indicates allowable difference from the true values. The TEa values of various parameters were taken from Clinical Laboratories Improvement Act (CLIA) guidelines.[10]

Bias is the systematic difference between the results obtained by the laboratory's test method and the results obtained from peer group mean. Bias was obtained from external quality assurance records with following formula

$$\text{Bias} = (\text{Lab mean} - \text{Peer group mean}) \times 100 / \text{Peer group mean.}$$

The average bias of six months period was used for sigma value calculation.

CV is the coefficient of variation of the analytical test method. It was determined from the calculated laboratory mean and calculated standard deviation was obtained from 6 months of IQC data

$$\text{CV\%} = (\text{standard deviation} / \text{laboratory mean}) \times 100\%.$$

Bias and CV are the measures of systematic and random errors, respectively.

The minimum acceptable performance of process was three sigma and six sigma is world class performance.

Quality goal index ratio

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, QGI >1.2 indicates inaccuracy, and QGI score 0.8-1.2 indicates both imprecision and inaccuracy.

RESULTS

The present study analysed the sigma for 20 analytes run on Cobas Integra 400 Plus, Vitros 5600 and Accu Lab Enlite.

Table 1 summarizes the average CV % of level 2 and level 3, average bias %, sigma metrics (L2 and L3) and Quality Goal Index (QGI L2 and L3) of the 20 parameters.

Table 2 summaries the performance of the 20 analytes on sigma metrics scale subdivided into three levels i.e. more than 6, 3to 6 and less than 3.

Table 3 shows the list of analytes performing low on sigma metrics (< 3.0 sigma) and cause for low sigma value.

Six sigma for level-2 - The sigma metrics for level 2 indicated that 6 analytes (ALP, AMY, AST, GGT, Mg, TRIG) out of the 20 analytes qualified Six Sigma quality performance. Of these 7 analytes (CREAT, GLU, PHOS, K+, Na+, TP, CHOL) failed to meet minimum sigma quality performance with sigma metrics < 3 and another 7 analytes(ALB,ALT,TBIL,Ca^{2+},HDL-C,Urea,UA) performance with sigma metrics was between 3 and 6.

Six sigma for level-3 for level 3, the data collected indicated that 7 analytes (ALP, ALT, AMY, AST, GGT, Mg, TRIG) out of the 20 analytes qualified Six Sigma quality performance; 6 analytes (ALB,CREAT,GLU,K+, Na+, TP) had sigma metrics less than 3 and 7 analytes(HDL-C,PHOS,TBIL,Ca^{2+},UREA,CHOL,UA) had sigma metrics between 3 and 6.

Method decision charts

Figure 1 and 2 shows method decision chart for level 2 and 3 in which imprecision is along the x-axis and bias along the y-axis. Sigma metrics zones are also displayed on this graph, 6 σ zone (world class quality) is closest to the graph's origin, followed by a 5σ zone (Excellent), 4σ zone (Good), 3σ zone (Marginal), 2σ zone (Poor), and the remainder of the graph below 2σ, is tagged as unacceptable.

Table 1: Summary of Sigma metrics (Level 2 and 3) and Quality Goal Index Ratio (Level 2 and 3) of 20 parameters calculated from total allowable error, CV% (Level 2 and 3) and bias % (January- June 2018).

	TEa	Average Bias%	CV%		Sigma Score		Quality Goal Index Ratio	
Analytes			Level-2	Level-3	Level 2	Level 3	Level 2	Level 3
Albumin	10	2.5	2.0	2.6	3.8	2.9	0.8	0.6
ALP	30	5.1	2.2	3.7	11.3	6.7	1.5	0.9
ALT	20	3.3	4.0	2.7	4.2	6.2	0.6	0.8
Amylase	30	3.4	1.9	2.1	14.0	12.7	1.2	1.1
AST	20	1.7	2.2	1.8	8.3	10.2	0.5	0.6
Bilirubin, total	20	2.4	3.3	4.1	5.3	4.3	0.5	0.4
Calcium	11	2.1	1.8	1.7	4.9	5.2	0.8	0.8
Cholesterol, total	10	2.2	2.7	2.5	2.9	3.1	0.5	0.6
Creatinine	15	4.3	4.7	4.5	2.3	2.4	0.6	0.6
Gamma GGT	22.2	2.9	2.0	2.2	9.7	8.8	1.0	0.9
Glucose	10	3.9	2.6	2.3	2.3	2.7	1.0	1.1
HDL-C	30	12.1	3.2	3.0	5.6	6.0	2.5	2.7
Magnesium	25	3.7	2.3	2.2	9.3	9.7	1.1	1.1
Phosphorus	10	3.1	2.6	2.3	2.7	3.0	0.8	0.9
Potassium	5	2.8	1.5	1.6	1.5	1.4	1.2	1.2
Sodium	5	0.9	1.7	2.0	2.4	2.0	0.4	0.3
Total protein	10	3.3	2.3	2.5	2.9	2.7	1.0	0.9
Triglyceride	25	5.3	2.6	2.6	7.6	7.6	1.4	1.4
Urea	19.2	3.7	3.9	3.5	4.0	4.4	0.6	0.7
Uric acid	17	4.8	2.7	2.5	4.5	4.9	1.2	1.3

Table 2: Performance of the analytes on sigma metrics.

Six sigma level	Level -2	Level -3
Above 6 Sigma	ALP, AMY, AST, GGT, Mg, TRIG	ALP,ALT,AMY,AST,GGT ,Mg, TRIG
5 .9 – 3.0 Sigma	ALB ,ALT, TBIL, Ca^{2+}, HDL-C, UREA,UA	HDL-C,PHOS,TBIL,Ca^{2+}, UREA,CHOL,UA
Below 3.0 Sigma	CREAT,GLU,PHOS, K+, Na+, TP,CHOL	ALB ,CREAT,GLU, K+, Na+, TP

Table 3: List of analytes performing low on sigma metrics (below 3.0 sigma) and cause for low sigma value.

Analytes	QC Level	CV %	BIAS %	Sigma	QGI	Cause
Creatinine	Level 2	4.7	4.3	2.3	0.6	Imprecision
	Level 3	4.5		2.4	0.6	Imprecision
Glucose	Level 2	2.6	3.9	2.3	1.0	Imprecision &
	Level 3	2.3		2.7	1.1	Inaccuracy
Phosphorus	Level 2	2.6	3.1	2.7	0.8	Imprecision
Potassium	Level 2	1.5	2.8	1.5	1.2	Imprecision &
	Level 3	1.6		1.4	1.2	Inaccuracy
Sodium	Level 2	1.7	0.9	2.4	0.4	Imprecision
	Level 3	2.0		2.0	0.3	Imprecision
Total protein	Level 2	2.3	3.3	2.9	1.0	Imprecision &
	Level 3	2.5		2.7	0.9	Inaccuracy
Albumin	Level 3	2.6	2.5	2.9	0.6	Imprecision
Cholesterol	Level 2	2.7	2.2	2.9	0.5	Imprecision

In method decision chart we can see that amylase is closest to the origin or bull's eye which means sigma metrics is highest and very few defects or errors are generated while potassium is farthest indicating lowest

sigma value and generates more defects beyond acceptable limit.

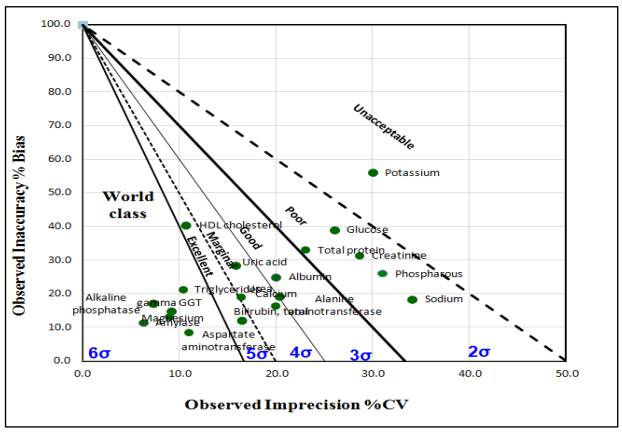

Figure 1: Sigma method decision chart for level - 2. Inaccuracy (bias, trueness) is on the y-axis. Imprecision (CV) is on the x-axis.

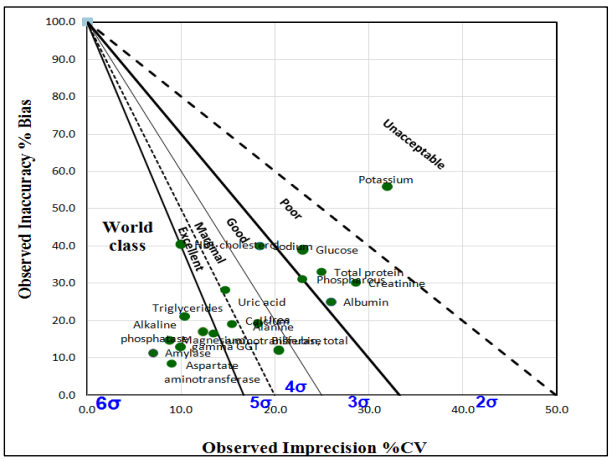

Figure 2: Sigma method decision chart for level - 3. Inaccuracy (bias, trueness) is on the y-axis. Imprecision (CV) is on the x-axis.

World class quality is attained for amylase, AST, ALP, GGT, triglyceride and magnesium.

Quality ranges from good to excellent for ALT, uric acid, HDL-cholesterol, calcium and bilirubin. Method decision chart also shows that quality is poor to unacceptable for glucose, creatinine, total protein, albumin, phosphorus, sodium and potassium.

DISCUSSION

Sigma metrics was used for traditional risk assessment i.e. connecting test results to patient care by Yong Xia et al. Cao and Qin used sigma metrics to evaluate the quality of reagents.[8,11] Six sigma is a powerful tool which can be used by laboratories for various purposes like assessing the method quality, optimizing QC procedure, change the number of rules applied, number of controls run and change the frequency of QC run. Even quality of instrument can be assessed by using sigma metrics.

In our study we analysed 20 analytes on sigma metrics and method decision chart was plotted for these analytes. We found that in our laboratory, performance for Amylase, AST, ALT, GGT, Triglyceride and Magnesium are more than six sigma. Sigma value was highest for amylase and lowest for potassium. On method decision chart we can see that amylase is closest to the origin or bull's eye which means sigma metrics is highest and very few defects or errors are generated while potassium is farthest indicating lowest sigma value and generates more defects beyond acceptable limit. World class quality is attained for amylase, AST, ALT ,GGT, triglyceride and magnesium therefore quality control rules followed for these analytes can be relaxed i.e. only 1_{3s} or even wider control limit can be used for these analytes . If we translate this sigma metric to the frequency of quality control run, then a minimum of 1000 patient samples can be run between each quality control run. Probability of false rejection will be greatly reduced which will ultimately lead to reduced reagent consumption, save time and labour. Total allowable error is also high for these analytes.

The study done by Chakravarthy S et al has reported a sigma value of 16.8, 12.0 and 9.1 for amylase which is very close to the value in our study i.e. 14.0 and 12.7. Bhawna Singh et al also reported a value of 11.2 and 11.7 for amylase. [12,13]

For ALT, AST and ALP sigma value of >6 was reported by Nanda et aland Mao et al which is also very close to the results obtained in our study. Verma M et al also reported a value of 9.9 and 11.8 for ALP while the sigma value for AST and ALT is <3 in their study. [7,14,15]

In our study Sigma value for triglyceride is also more than 6 which is in consensus with study done by Adiga US et al while Manchana Lakshman et al reported a very high sigma value of 29.6 and 24.4 for triglyceride.[16,17] Sigma value for GGT and magnesium is reported by very few studies, Chakravarthy S et al found >6 value for both of these analytes.[12] Kumar et al reported sigma value >6 for magnesium we also found sigma value of more than > 6 which is world class performance.[18]

For Total Bilirubin, HDL-C , Urea , Uric acid ,Calcium, Albumin (level -2), Phosphorus (level -3) and Total Cholesterol(level-3) sigma value obtained in our study was between 3 to 6 which is similar to the other studies with a little bit of difference .

A low sigma value of <3 but >2 was obtained for Creatinine, Glucose, Total Protein, Sodium, Phosphorus (level-2), Cholesterol (level-2) and Albumin (level-3) which is also somewhat similar finding to the study done by Bhawna Singh et al ,Nanda et al and Kumar et al.[13,14,18] These analytes performed poorly on sigma

metrics but still when we analyse these parameters on method decision chart they are within acceptable limit.

Potassium performance was extremely poor for both the QC levels, sigma level being <2. This finding was similar to other studies.[13,14,18] It was also below the acceptable limit on method decision chart but CV% and Bias % were within acceptable limit. Here comes the role of sigma metrics which also takes into account total allowable error which is very low for Potassium and Sodium. Total allowable error is very less i.e. 5 for both sodium and potassium indicating the critical nature of these analytes and also reference range is very narrow particularly for potassium. Use of alternative methods and change of reagents can be done for potassium to bring the sigma value within acceptable range. Adiga US et al showed in their pilot study on sigma metrics of electrolytes also emphasized upon stringent maintenance of ISE unit to decrease inaccuracies.[19]

Table 4: Sigma metric tools for QC design and frequency.

Sigma metric	Control rule	QC frequency
Six sigma	1_{3s}, n=2	1 per 1000 patient samples
Five sigma	1_{3s}/2 2s/ r 4s, n=2	1 per 450 patient samples
Four sigma	13s/2 2s/ r 4s/4 1s, n=4	1 per 200 sample samples
Three sigma	all "Westgard Rules" n=6	1 per 45 patient samples
Two sigma and below	max "Westgard Rules" n=6	1 per 10 patients samples

Sigma scale range from one to six though the sigma value can exceed six for certain parameters for which total allowable error is more than 20%. Minimal acceptable sigma level for manufacturing industries is 3 which may be different for clinical chemistry laboratory as shown by method decision chart in which minimum acceptable level is 2. Like Verma M et al authors also observed that sigma metrics scale has certain limitations while applied to the clinical chemistry laboratory.[15] However it can be applied with certain precautions and not to overestimate the error leading to false rejection, wastage of labour, control materials, calibrators and reagents. If applied cautiously sigma metrics can prove to be a very powerful tool in error detection and further reducing cost, labour, effort by optimizing QC according to the sigma analysis.[20] Table 4 shows Sigma metric tools for QC design and frequency.

As sigma metric increases –

- Fewer QC rules needed
- Fewer controls needed
- Fewer recalibrations
- Fewer outliers
- Fewer trouble shooting experiences
- Fewer technical support calls and service visits.

CONCLUSION

In our study Sigma value was highest for amylase and lowest for potassium. Sigma analysis is a continuous procedure and by taking the help of method decision curves along with it, may improvise on decision making in the clinical chemistry lab regarding frequency of control run, use of Westgard rules, optimizing QC procedures and thus can contribute optimally to patient healthcare quality without incurring loss on reagents, control materials, calibrators, labour and effort.

Impact statement

There will be over-all benefit to the entire patient population due to stringent quality maintenance in the laboratories. Six sigma calculations will be an added tool in quality assurance scheme that will help in warranting for a change in method or reagent when they fail to reach the expected mark. It will optimize resource management by decreasing the frequency of QC run. Since both imprecision and bias are taken into account, Six sigma involves a more holistic approach to quality management in medical testing laboratories. In laboratory evidence based medicine, further reinforcement of quality through this tool gives an insight on choice of test methodology, reagent as well as maximum utility of the laboratory investigations not only for the lab personnel but also the treating physicians.

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