Evaluation of Quality control data of clinical chemistry parameters using six sigma metrics tool in clinical laboratory

ABSTRACT

Background: Physicians rely on laboratory results for treating patients. So it is the duty of laboratories to assure quality of the results released. So laboratory performance should be validated to maintain the quality. Six sigma has now gained recent interest in monitoring the laboratory quality.This study was designed to gauge the clinical chemistry parameters based on six sigma metrics.
Material and methods: In this retrospective study, both the internal and external quality control data of 26 clinical chemistry parameters were collected for a period of 6 months from June 2020 to November 2020 and the six sigma analysis was doneat the Central clinical biochemistry laboratory of Chettinad Hospital and research institute.
Results: AST, amylase, lipase, triglyceride, HDL, iron, magnesium, creatine kinase showed sigma values more than 6.Uric acid, total protein, ALT, direct bilirubin, GGT,cholesterol, cholesterol, calcium, TIBC and phosphorus shows sigma values between 3.5 to 6. Glucose, BUN, creatinine, albumin, Na, K, Chloride, showed sigma values less than 3.5.
Conclusion: Six sigma metrics can help in improving the quality of laboratory performance and also helps to standardisethe actual amount of QC that is required by the laboratory for maintaining quality.

Key words: *Sigma metrics, quality control, chemistry analytes*

INTRODUCTION:

Quality control plays an important role in the maintaining the quality of clinical laboratories. Internal quality control (IQAC)and external quality control(EQAS) plays an important role in assuring quality among biochemical analytes. The values reported from laboratories need to be precise and valid. There needs to be a system for proper evaluation, process improvement and management and six sigma management methodology has gained popularity in this aspect.[1]Six sigma methodology for quality control was proposed in the late 1990 ‘s and began to be utilized in health systems by 1999.

It helps to establish tolerance limits for standards.It provides a uniform way of describing quality in terms of sigma scale.To bring all operations to six sigma level,we have to bring down the number of defects to <**3.4 defects for every one million opportunities**.It comprises of five processes namely Define, Measure, Analyse, Improve and control.(DMAIC).[2,3]

It can be used to quantitatively evaluate errors in qualitative analyses in laboratories and the results are denoted as Defects per Million(DPM). Six sigma methodologiesare utilized in clinical laboratory in pre analytical and analytical tests and is utilized to evaluate biochemical assays.

Sigma score of more than 6 is considered as good performance, values between 3.5 to 6 is shows average performance and values less than 3.5 shows poor performance.[4]

In this study 26 clinical chemistry analytes were analyzed to find out the total sigma values by calculating coefficient of variation(CV), bias and total allowable error TE(a).

Six sigma analysis not only helps us to identify the defects, but also shows us how to reduce the errors in our processes.For that we can clacuate the QGI(Quality Goal Index).If the value of QGI is less than 0.8 then it shows the presence of imprecision, Values between 0.8-1.2 shows the presence of both imprecision and inaccuracy and values more than 1.2 shows inaccuracy in he processes.This inturn will help the laboratory to do the root cause analysis for the defects.

If the sigma values for some parameters are less than 6, then we have to calculate the Quality Goal Index for such parameters using the formulaBias / 1.5 x CV%.

Material and methods The current study was a retrospective study conducted in Central clinical Biochemistry laboratory, Chettinad hospital and research institute,Kelambakkam.We studied the quality control values of 26 analyzes glucose, blood urea nitrogen, creatinine, uric acid, calcium, cholesterol, triglycerides, high density lipoproteins(HDL), total Proteins(TP),albumin, Total bilirubin(TB),Direct bilirubin(DB),AST(Aspartate transaminase),ALT(Alanine amino transferase),Gamma glutamyltransferase(GGT),Sodium,Potassium,chloride,phosphorus,magnesium,Crea tine kinase,Iron, TIBC (Total Iron binding capacity),amylase and lipasewere analysed.Both Internal and External Quality control material were procured from BIO-RAD. Internal quality control data of both level 1and level 2 of all the chemistry analyses of our laboratory coming under NABL scope were collected for a period of 6 months from June 2020 to November 2020. Mean, Standard deviation and Coefficient of Variation were calculated for each level separately.

Coefficient of Variation was calculated using the formula:

Coefficient of Variation = (Standard deviation/Mean) x 100

Bias percentage for each analyte was calculated from External Quality control data. Bias percentage is the systematic difference between the expected result obtained from lab test method and that of the reference method. Clinical Laboratory Improvement Amendment (CLIA) has given acceptable performance for each hormone in terms of Total allowable error (TEa)[6].

Sigma metrics for each parameterwas calculated using the formula:

Sigma = (TEa – Bias) / CV

Quality Goal Index ratio (QGI) was calculated for those hormones with sigma value less than 6 using the formula

QGI = Bias / 1.5 x CV%

Results

Table 1: The sigma metrics calculation from TEa (Clinical Laboratory Improvement Amendment), average coefficient of variation percentage, and Bias percentage

Parameter	CV Percentage		Bias Percentage	TEa(CLIA)	Sigma	
	Level 1	Level 2			Level 1	Level 2
Glucose	2.83	2.67	3.04	10	2.46	2.61
BUN	6.48	3.51	5.67	9	0.51	0.95
CREATININE	3.84	3.23	5.01	15	2.60	3.09
uric ACID	3.42	2.65	3.3	17	4.01	5.17
Total protein	1.59	1.68	1.48	10	5.37	5.06
Albumin	2.12	2.80	4.62	10	2.54	1.92
AST	5.50	2.43	3.34	20	3.03	6.85
ALT	6.87	3.51	2.02	20	2.62	5.12
Total Bilirubin	3.90	2.02	4.69	20	3.93	7.58
Direct Bilirubin	11.86	5.37	6.44	20	1.14	2.52
ALP	18.87	2.64	4.73	30	1.34	9.58
GGT	9.45	2.77	6.47	20	1.43	4.89
Na	1.34	1.27	1.26	5	2.80	2.95
K	2.05	1.56	2.08	5	1.43	1.88
CL	2.54	2.20	1.4	5	1.42	1.63
Amylase	4.04	5.50	2.49	30	6.81	5.00
Lipase	4.88	2.54	2.36	30	5.67	10.90
TGL	3.38	4.27	2.97	25	6.52	5.16
CHOL	1.79	2.62	1.92	10	4.51	3.09
HDL	2.50	4.35	3.54	30	10.57	6.09
IRON	3.01	2.14	2.55	20	5.80	8.17
TIBC	3.15	4.18	1.89	20	5.76	4.33
CA	1.94	2.29	3.91	11	3.66	3.09
PHOS	1.99	1.72	1.89	10	4.07	4.71
MG	3.98	2.87	5.19	25	4.97	6.89
CK	3.80	4.60	3.75	30	6.91	5.71

Table 2: The Quality Goal Index calculation for parameters-Level 1 with sigma score less than 6

Parameter	Sigma	QGI	Problem

	Level 1	Level1	Level1
Amylase	6.81	0.41	Imprecision
TGL	6.52	0.59	Imprecision
HDL	10.57	0.94	Imprecision & Inaccuracy
CK	6.91	0.66	Imprecision

Table 3: The Quality Goal Index calculation for parameters-Level 2 with sigma score less than 6

Parameter	Sigma	QGI	Problem
	Level 2	Level2	Level2
AST	6.85	0.92	Imprecision
T.Bilirubin	7.58	1.55	Inaccuracy
ALP	9.58	1.2	Imprecision & Inaccuracy
Lipase	10.9	0.62	Imprecision
HDL	6.09	0.54	Imprecision
Iron	8.1	0.8	Imprecision
Mg	6.89	1.2	Imprecision & Inaccuracy

Among the parameters, glucose, BUN,creatinine, albumin,Na,K,Chloride,showed sigma values less than 3.5. Uric acid, total proteinALT, direct bilirubin,GGT,cholesterol, calcium, TIBC and phosphorus show sigma values between 3.5 to 6.AST, amylase, lipase, triglyceride, HDL, iron,magnesium,creatine kinase showed sigma values more than 6.

DISCUSSION

Quality control in laboratories plays an integral part in providing accurate results to the clinicians. The results released from the laboratories play an important role in the treatment modality along with the clinical history.

Six sigma was hence applied which focuses on collecting data, analysing the data and improving the quality of the data.

The relationship between sigma metrics and defects are as follow: 1 sigma (σ) represents6,90,000 errors/million reports, 2 sigma represents 3,08,000 errors/million reports, 3 sigma represents 66,800 errors/ million reports, 4 sigma represents 6,210 errors/million reports, 5 sigma corresponds to 230 errors/million reports and 6 sigma represents 3.4 errors/million reports.[5]In the present study the parameters, glucose, BUN, creatinine, albumin, Na, K, Chloride, showed sigma values less than 3.5. Uric acid, total protein ALT, direct bilirubin, GGT, cholesterol, calcium, TIBC and phosphorus show sigma values between 3.5 to 6. AST, amylase, lipase, triglyceride, HDL, iron, magnesium, creatine kinase showed sigma values more than 6.

The higher the sigma value,the lesser will be the errors produced. Six Sigma focuses on controlling a process to 6 SDs, which equates to 3.4 DPM opportunities. Achievement of Six Sigma quality is considered to be a standard of excellence. 3-sigma level is considered the minimum acceptable quality for a production process.If a method has a sigma value below 3, the method is considered to be unreliable and should not be used for routine test purposes. [6]

In the current study, AST, amylase, lipase, triglyceride, HDL, iron, magnesium, creatine kinase showed sigma score more than 6 and hence excellent performance. Stringent rules need not be applied for these parameters. Moreover control limits can also be relaxed to minimize false rejections.Uric acid, total proteinALT, direct bilirubin, GGT,cholesterol, calcium, TIBC and phosphorus shows sigma values between 3.5 to 6. Quality goals of these parameters can be met by applying more elaborate quality control strategies.Theglucose, BUN, creatinine, albumin, Na, K, Chloride, showed poor performance with sigma level less than 3.5. For parameters with sigma values <3.5, newer methods should be used.The number of QC runs also needs to be increased.[Table:1]The low performance of some of the parameters in our laboratory mightbe due to pre analytical,analytical and post analytical factors. The method of sample collection, transport of the sample,storage of the sample under appropriate conditions,training of the laboratory personnels,proper centrifugation of the samples,the quality of the reagents used, the working condition of the machines used and properreporting of results. We have perform a fish bone analysis considering all the factors and perform an analysis to find out the ultimate cause for the poor performance of the parameters.

The ultimate goal of six sigma methodology in clinical laboratory is to increase the quality of the medical laboratory services for best patient care.

CONCLUSION:

Six sigma can be utilised in laboratories to monitor internal quality control processes and also helps to assess the actual requirement of quality control for an analyte.it also helps to reduce analytical problems in clinical laboratories.

ETHICAL CLEARANCE:

Ethical Clearance for this study was obtainedfrom the Institutional Human Ethical Committee.

COMPETING INTERESTS DISCLAIMER:

Authors have declared that no competing interests exist. The products used for this research are commonly and predominantly use products in our area of research and country. There is absolutely no conflict of interest between the authors and producers of the products because we do not intend to use these products as an avenue for any litigation but for the advancement of knowledge. Also, the research was not funded by the producing company rather it was funded by personal efforts of the authors.

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