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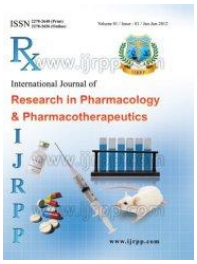

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Evaluating performance of our clinical biochemistry laboratory by application of sigma metrics & other quality indicators- A pilot study

Dr. Arpita Patel*[1], Payal Patel[2], Dr. Shilpa Jain[3]
Assistant professor [1], Junior lecturer [2], Professor & head of department[3]
Department Of Biochemistry, S.S.G. Government Medical College, Vadodara, India.
***Corresponding author: Dr. Arpita Patel**

ABSTRACT

Ensuring quality of laboratory services is the need of the hour in the field of health care. Six Sigma is a new management philosophy that seeks a nonexistent error rate, keeping in mind that we aimed to gauge our laboratory performance by sigma metrics. Internal quality control (QC) data was analysed retrospectively over a period of 6 month from February 2015 to July 2015. Laboratory mean, SD and coefficient of variation were calculated for all the parameters. We studied parameters which are in scope of NABL of our Laboratory. Quality assessed on sigma scale with a bench mark for minimum process performance of 3sigma and a goal for world class quality of 6 Sigma (σ). Satisfactory sigma value (>6) were elicited for ALP & Total Bilirubin. We have achieved sigma metrics of the range 3-5 for Albumin, AST, ALT, Total Cholesterol, Creatinine, Total Protein, Uric Acid, Glucose and Direct Bilirubin signifying acceptable laboratory performance with a scope for improvisation. Blood Urea performed poorly on the sigma scale with <3 sigma. The findings of our exercise emphasize the need for detailed evaluation and adoption of ameliorative measures in order to effectuate six sigma standards for all the analytical processes.

Keywords: Six sigma, Coefficient of variation, Total allowable error, Bias, Quality control

INTRODUCTION

Quality planning defines quality standards which are the foundation for quality laboratory processes, quality control (QC), quality assessment (QA), and quality improvement [(1).] In last decade, the initiative for quality assurance and quality improvement in laboratories has been driven predominantly by the requirement of regulatory and accrediting agencies. The clinical laboratory improvement Amendments of 1988 require that a clinical laboratory's quality assurance program include evaluation of each of the steps of the total testing process. As might be expected, the size of analytic errors that need to be detected by QC will depend on the process capability; therefore, the sigma metric also is useful for assessing the adequacy of QC procedures and practise. Thus, with the aid of Six Sigma principles and metrics, it is possible to assess the quality of laboratory testing processes and the QC that is needed to ensure that the desired quality is achieved [(8)]. Sigma (σ) is the mathematical symbol for standard deviation (SD)[(2)]. Six sigma philosophy purports that there is a direct correlation between the numbers of product defects wasted operating costs, and the level of customer satisfaction. Consequently, as sigma increases, process reliability improves, operating costs go down, and customer satisfaction increases. Six sigma provides a more quantitative frame work for evaluating process performance with evidence

for process improvements and describes how many sigma fit within the tolerance limits[3]. Quality is assessed on the sigma scale with a criterion of 3 sigma as the minimum allowable sigma for routine performance and a sigma of 6 being the goal for world class quality[4]. The present study was undertaken to evaluate the quality of the analytical performance of clinical chemistry laboratory of SSG hospital based in Vadodara, India on sigma scale.

MATERIALS AND METHODS

We aim to present the sigma metrics observed in our clinical chemistry laboratory in SSG hospital during a period of 6 months. Our clinical biochemistry laboratory caters to a 1500 bedded Primary care Hospital. Internal statistical QC data extricated from Roche cobas c311Fully automated closed system biochemistry analyzer for the period of 6 months from February 2015 to July 2015. Control materials were obtained from Biorad, US. Both normal (L1) and pathological (L2) levels of QC materials were assayed 2 times before commencing reporting of patients samples every day. Various parameters scrutinized were Albumin, Alkaline phosphatise (ALP), Alanine transaminase (ALT), Aspartate transaminase (AST), Total cholesterol, Creatinine, Total Protein, Uric acid, Urea, Glucose, Total Bilirubin, Direct Bilirubin. Validation of quality control of our lab was done by calculating 6 months mean from the data of internal QC and External Quality Assurance Scheme (EQAS) to establish the CV and bias respectively. For each analytes. The Sigma metrics for the various analytes was calculated by the following equation.

$\sum(\sigma) = (TEa - bias)/CV$

[TEa = Total allowable error, CV= coefficient variation]

TEa values of various parameters were taken from the Clinical Laboratories Improvement Act (CLIA) guidelines [5].

Bias was calculated from the external Quality assurance records using the following formula

$$\textbf{Bias}(\%) = \frac{\text{(Mean of all laboratories using same instrument and method - our mean)}}{\text{(Mean of all laboratories using same instrument and method)}} \text{ X } 100$$

CV was determined from the calculated laboratory mean and calculated standard deviation procured from the internal QC data over the last 6 months:

CV (%) = (Standard deviation x 100) / laboratory mean

RESULT

Bias was calculated from data of external quality assurance program provided by Randox (RIQAS) for the months of February to July 2015 for the different parameters and average calculated. Average bias for l was <3 for 2 chemistries (Total cholesterol, Glucose), 3-6 for 7 chemistries (ALP, Albumin, AST, Creatinine, Urea, Total bilirubin, Direct bilirubin, Total protein, Uric acid) and >6 for ALT. This is tabulated in Table 1.

Table: 1 Percentage bias calculated from RIQAS results for a period of 6 months

Parameter	Month1	Month2	Month3	Month4	Month5	Month6	Average bias
Albumine	3.3	1.7	2.51	3.79	5.18	1.81	**3.04**
ALP	5.19	3.28	4.89	9.35	5.31	1.091	**4.85**
ALT	6.04	4.11	0.2	8.87	20	7.49	**7.78**
AST	6.67	4.6	2.03	0.77	7.15	1.7	**3.82**
T. Cholesterol	1.93	3.15	1.41	3.99	2.97	0.01	**2.24**
Creatinine	2.92	5.23	4.9	2.24	8.39	2.55	**4.37**
Total Protein	3.83	3.61	3.8	7.76	0.41	1.62	**3.50**
Uric acid	4.68	8.55	4.79	0.85	6.33	6.07	**5.21**

Urea	4.72	2.34	4.7	4.66	7.6	0.6	**4.10**
Glucose	3.61	1.96	2.48	4.9	3.78	0.01	**2.79**
Total Bilirubin	9.3	3.03	6.66	2.97	0.62	6.67	**4.87**
Direct Bilirubin	1.55	9.22	6.02	3.55	3.12	5.67	**4.85**

Table 2 highlights %TEa, Average bias, Coefficient of variation (CV) and Sigma values of the two levels of quality control for the different parameters. TEa <10 for the urea signifying the criticality of this analyte. ALP have been assigned a higher TEa of 30% as mentioned in CLIA guidelines. The coefficient of variation (CV) varied from 2.0 (Total protein) to 5.1(Direct bilirubin) for Quality control L1 and for L2 CV varied from 2.1 (Glucose) to 4.5 (Direct bilirubin).

Table: 2 Table showing the average calculated bias%, TEa%, CV & **σ** value for period of six month

Parameter	**TEa (%)**	**Average bias**	**L-1**		**L-2**	
			CV	**σ**	**CV**	**σ**
Albumine	10	3.04	2.08	**3.34**	2.43	**2.86**
ALP	30	4.85	4.3	**5.84**	3.23	**7.78**
ALT	20	7.7	5.16	**2.38**	2.78	**4.42**
AST	20	3.82	4.15	**3.89**	2.76	**5.86**
T. Cholesterol	10	2.24	2.53	**3.06**	2.51	**3.09**
Creatinine	15	4.37	3.03	**3.5**	2.71	**3.92**
Total Protein	10	3.5	2.03	**3.2**	2.23	**2.91**
Uric acid	17	5.21	2.85	**4.13**	3.48	**3.48**
Urea	9	4.1	3.76	**1.3**	3	**1.63**
Glucose	10	2.79	2.46	**2.93**	2.1	**3.43**
Total Bilirubin	20	4.87	3.81	**3.97**	2.3	**6.57**
Direct Bilirubin	20	4.85	5.18	**2.92**	4.58	**3.3**

The sigma value >6 was observed for ALP and Total bilirubin for L2. We have achieved sigma metrics of the range 3-6 for 8 parameters namely Albumin, ALP, AST, Total cholesterol, Creatinine, Total protein, Uric acid and Total bilirubin for L1 and for L2 ALT, AST, Total cholesterol, Creatinine, Glucose, Uric acid and direct bilirubin. A Sigma value of <3 for Both the levels of QC was observed for urea and for ALT, Glucose, Direct bilirubin L1 and for Albumin, Total protein L2.(Table 2).

Table 3 depicts RIQAS results for one of the 6 months of the study period (July). Total score (TS) allows the laboratory rise to assess their performance. TS relate the percentage difference between the lab results and the mean for comparison to a target CV. On The basic of this results bias was calculated.

Table: 3 Showing mean of RIQAS, mean of our lab, Total score (TS) & Percentage bias from RIQAS result of month July

Parameter	Mean for comparison	Our result	TS	%Bias
Albumine	4.32	4.4	117	1.89
ALP	120.11	107	75	10.91
ALT	34.59	32	77	7.49
AST	36.25	36	120	1.7
T. Cholesterol	157.41	155	119	0.017
Creatinine	1.41	1.45	117	2.55
Total Protein	5.9	6.0	117	1.62
Uric acid	5.64	5.3	66	6.07
Urea	44.26	44	120	0.60
Glucose	107.01	107	120	0.017
Total Bilirubin	1.51	1.43	94	5.67
Direct Bilirubin	1.14	1.08	120	5.67

DISCUSSION

Attainment of six sigma is envisaged as the gold standard for defining world class measure of quality. Six sigma concentrates on regulating a process to 6 SDs, which represents 3.4 DPM opportunities [(6)]. Functioning at the 3-sigma level is regarded as the minimum acceptable level of quality. Laboratory performance can be appraised with the application of six sigma in laboratory functions[(7)]. When the method sigma is C6, stringent internal QC rules need not be adopted. In such cases, false rejections can be minimized by relaxing control limits up to 3 s. A method sigma below 3 calls for the adoption of a newer and better method as quality of the test cannot be assured even after repeated QC runs [(8)]. Employing six sigma in laboratory involves quantifying the performance of the test using standard QC methods; specifying the quality requirements for the test (TEa); scrutinizing the data and computing a six sigma value (sigma (r) = [TEa - bias)/CV]); recuperating the process based on the results of analysis; and required follow up[(9)]. Total allowable error (TEa) refers to the degree of change that needs to be detected in an analyte for a clinically important decision to be made with regard to further investigation or treatment [(5)]. Bias or inaccuracy, emphasizes lack of agreement among methods being compared Systematic error is detected as positive or negative bias for a given analytical method. Coefficient of variation (CV) is used to describe the variation of a test. The CV expresses the variation as a percentage of the mean[(5)]. In the laboratory functions, the CV is preferred mode of variance determination when the SD increases in proportion to concentration. The CV also provides a general perception about the performance of a method. CVs of 5% or less generally denotes a good method performance, whereas CVs of 10% and higher implies unsatisfactory performance. QC materials are used for monitoring the performance of analytical methods. When applying any criteria (including Westgard rules) for acceptability of control data, determination of probability for rejection is paramount importance [(10)]. The term probability of false rejection (Pfr) is used signifies a situation where there are no analytical errors present except for the inherent imprecision or random error of the method. Probability of error detection (Ped) is the term used to describe where an analytical error occurs in addition to the inherent random error. It has been observed that a high probability of error detection and a low probability of false rejection are desirable [(11)]. We obtained sigma>6 for ALT & Total bilirubin L2. This implies that the analytical method in use is appropriate for detecting high values. The QC strategies that should be

implemented in such cases need not be draconian and we can release the patient's results immediately. Blood urea being the worst performer in our laboratory. We are using GLDH method for urea which needs special attention for revamping performance. It is importance to explore urea method performance. Other parameters like ALT, Glucose, Direct Bilirubin (level-1) & Albumin, Total Protein (Level- 2) also shows bad performance (sigma<3), diverting special attention to them mandatory for good performance. Most of other parameters demonstrated sigma metrics 3 to 6 signifying acceptable laboratory performance with a scope for improvisation. The main limitation in our work is we cannot include some critical parameters like sodium, potassium & creatinine kinase due to lack of data like CV% & Bias% and also lack of knowledge about the corresponding Pf_8 and Ped for different analytes. This would have made our results and interpretation more explicit and ultra-precise.

CONCLUSION

The application of Six Sigma principles and metrics would greatly improve the proposed EQAS process and also facilitate the inculcation of ideal analytical methodologies for improve laboratory performance. It is also imperative appropriate QC strategies in order to judicious use of QC.

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