ORIGINAL ARTICLE

APPLICATION OF SIX SIGMA FOR THE QUALITY ASSURANCE IN CLINICAL BIOCHEMISTRY LABORATORY – A RETROSPECTIVE STUDY

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ABSTRACT

BACKGROUND: This study was aimed to adopt Sigma metrics for the assessment of quality assurance in clinical Biochemistry laboratory. Quality assurance of laboratory services is the need of present time in the health care which required quality planning, quality control (QC), quality assessment (QA) and quality improvement. The six sigma concept which is an evolution in quality management that is being widely implemented in the corporate world and is also considered as the universal measure of quality. Health care sector can be benefited by implementation of Six sigma for quality assurance, which provides a general methodology to describe performance on sigma scale and it also provides a more quantitative framework for evaluating process performance and more objective evidence for its improvement. **MATERIALS AND METHODS:** In the present study, internal and external quality control data were analyzed retrospectively for the period from June to September 2012. Laboratory mean, standard deviation, coefficient of variation and bias were calculated for the selected parameters. Sigma was calculated for level I & II of internal quality control (IQC). **RESULTS:** Satisfactory sigma values (≥3) were elicited for blood glucose, ALP, total protein, triglyceride, HDL, uric acid and amylase, while SGPT, SGOT and cholesterol performed poorly on the sigma scale. **CONCLUSION**: Results of our study draw the attention towards meticulous appraisal and execution of quality measures to improve sigma standards of all the analytical processes. Although Six Sigma provides benefits over prior approaches to quality management, it also creates newer challenges for laboratory practitioners.

Keywords: Quality assurance, Quality control, Quality assessment, Six sigma

INTRODUCTION

Quality planning in clinical laboratories includes defining quality standards as the basis for quality laboratory processes, quality control (QC), quality assessment (QA), and quality improvement.Quality control validation is used to determine the statistical QC procedures appropriate for distinguishing variations, which are critical for clinical interpretation of the test.[1] Quality requirement varies greatly between analytes. For example, serum electrolyte levels are strictly regulated physiologically: therefore, small changes are likely to be clinically significant.

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In contrast, liver enzymatic activities show much larger variations; therefore, much greater increases are required to cause a clinically significant change that warrants further investigation or treatment.[2] Six Sigma has been characterized as the latest management fad to repackage old quality management principles, practices, and tools/techniques.[3] Sigma (σ) is the mathematical symbol for standard deviation (SD).[4] Six Sigma was developed at Motorola by an engineer Bill Smith in the mid 1980s. It was proclaimed as a new approach to improving quality through statistical measurements and benchmarking. Sigma methodology can be applied wherever an outcome of a process is be measured. A poor outcome is counted as an error or defect, which is quantified as defects per million (DPM). Six sigma provides a more quantitative frame work for evaluating process performance with evidence for process improvement and describes how many sigma fit within the tolerance limits.[5] Approximately 99.73% of all results from a normal population (i.e., results that are equally distributed above and below the mean) fall within 3 SDs of the mean. 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. Performance at the 3 sigma level is considered the minimum acceptable quality for a production process.[6] In simpler terms, a higher sigma metric means the systematic error that must be detected to ensure accurate results by the use of statistical QC is large and should be more easily detected. A lower sigma metric means QC must detect smaller systematic errors, which is more difficult. The six sigma idea asserts an association between the numbers of product defects, wasted operating costs and levels of customer satisfaction.

MATERIALS AND METHODS

Our aim is to present the sigma metrics observed in our ISO 15189:2007 (NABL - National Accreditation Board for Testing and Calibration Laboratories, India) accredited clinical biochemistry laboratory in Sir T. General Hospital, Bhavnagar (Gujarat-India) during a period of 4 months (June 2012- September 2012). Internal statistical QC data was taken from the ILAB-650 fully automatic chemistry analyzer [Instrumentation Laboratory - USA] for the period of 4 months. Internal Quality Control materials were obtained from Bio-Rad, USA and external quality control data was obtained by participating in External Quality Assurance scheme (EQAS) of Bio-Rad. Both levels of QC materials level I & II were assayed before running patient samples. Next QC cycle was run after commencing the reports of 75 samples (As per NABL 15189:2007 guidelines).[7] Various analytes studied were Blood Glucose, SGPT, SGOT ALP, Total Protein, Triglyceride, Cholesterol HDL, Uric acid and Amylase. Validation of quality control of our lab was done by calculating mean from the data of 4 months internal QC and External Quality Assurance Scheme (EQAS) to establish the CV and bias respectively, for each analyte. Microsoft office excel 2007 software was used for statistical analysis. The sigma metrics for the various analytes was calculated by the following equation:

Sigma (σ) = (TEa-Bias) / CV

[TEa—total allowable error, CV—coefficient of variation] TEa values of various parameters were taken from the Clinical Laboratories Improvement Act (CLIA) guidelines.

Bias was computed from the external Quality assurance records using the following formula:

Bias (%) = (mean of all laboratories using same instrument and method - our mean)/(mean of all laboratories using same instrument and method) ×100.

Coefficient of variance (CV) was determined from the calculated laboratory mean and calculated standard deviation procured from the internal QC data over the last 4 months:

CV (%) = (Standard deviation ×100)/Laboratory mean.

RESULTS

Satisfactory sigma values (≥3) were elicited for blood glucose, ALP, total protein, triglyceride, HDL, uric acid and amylase while, SGPT, SGOT and cholesterol performed poorly on the sigma scale (Table 1,2,3). Achievement of six sigma is termed as the gold standard for defining world class measure of quality. Laboratory performance can be appraised with the application of six sigma in laboratory functions. When the method sigma is ≥6, stringent internal QC rules need not be adopted. In such cases, false rejections can be minimized by relaxing control limits up to 3 SD.

DISCUSSION

To achieve six sigma is considered as the gold standard for defining world class measure of quality. In clinical laboratory, six sigma methodology give attention on regulating a process within 6 standard deviations which represents 3.4 defects per million opportunities.[8] Process performance at the 3-sigma level is considered as the minimum acceptable level of quality. The sigma metrics represent the correlation among numbers of product defects, wasted operating costs and customer satisfaction. Therefore, as sigma increases, the consistency, reliability, steadiness and overall performance of the test improves, thereby decreasing the operating costs.[9] When the method quality goals are set at six sigma, stringent internal QC rules are mandatory. However, false rejections rate should also be kept in mind which can be minimized by relaxing control limits up to 3 SD. On other hand, if method is performing at sigma level below 3, it will require to implement a newer and better method because quality of the test cannot be assured even after multiple QC cycles.[10] Application of six sigma in clinical laboratory involves calculating the performance of the test method using standard QC procedures and also specifying the quality requirements for the test in term of total allowable error (TEa). It also require continuous scrutiny of the data, computing a six sigma value (sigma (σ) = [TEa - bias)/CV]), improvisation of process based on the data analysis and long term follow up.[11]

Table 1: Month wise Bias of parameters during June – September 2012

Parameter	June	July	August	September	Average
Glucose	0.00	5.46	10.4	2.0	4.4
SGPT	13	09	11	12	11.2
SGOT	3.59	14.37	5.23	17.2	10.1
ALP	19.56	10.35	3.72	5.83	13.9
Total Protein	1.57	6.36	0.41	1.25	2.39
Cholesterol	5.7	2.37	4.12	3.64	3.96
Triglyceride	15.10	3.90	1.46	2.73	5.7
HDL	32.78	30	11.1	8.0	20.4
Uric Acid	*	0.32	3.81	1.98	2.0
Amylase	4.18	3.73	6.01	9.67	5.8

*Result were not obtained for particular parameter

Table 2: Bias, TEa, CV and Sigma value for quality control level 1 and 2

Parameter	Total Allowable Error [TEa (%)]	Average Bias	Level 1		Level 2	
			Coefficient of variance (CV)	Sigma value (σ)	Coefficient of variance (CV)	Sigma value (σ)
Glucose	10	4.46	1.84	3.0	1.81	3.05
SGPT	20	11.29	4.83	1.8	3.48	2.5
SGOT	20	10.08	4.96	2.0	4.96	2.0
ALP	30	3.96	4.86	3.3	4.71	3.4
Total Protein	10	2.39	2.53	3.0	2.40	3.17
Cholesterol	10	3.96	2.15	2.8	2.08	2.9
Triglyceride	25	5.79	4.74	4.04	5.19	3.7
HDL	30	20.47	2.26	4.2	2.57	3.57
Amylase	30	5.89	6.51	3.7	4.58	5.26
Uric acid	17	2.03	3.74	4.0	4.22	3.54

Table 3: Sigma Values of Various Biochemical Parameters

Parameter	Sigma - level 1	Sigma - level 2
Glucose	3.0	3.05
SGPT	1.8	2.5
SGOT	2.0	2.0
ALP	3.3	3.4
Total Protein	3.0	3.17
Cholesterol	2.8	2.9
Triglyceride	4.04	3.70
HDL	4.2	3.57
Amylase	3.7	5.26
Uric Acid	4.0	3.54

The quality requirements, expressed as total allowable error. (TEa), should indicate 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. For example, the reference interval for canine albumin used in the laboratory is 25–41 g/l. A decrease in albumin from 25 to 24 g/l (a 4% change) is unlikely to stimulate further investigation, so a change as small as this does not need to be detected. However, a change from 25 to 22.5 g/l (a 10% change) is more likely to be clinically significant.[12] Internal and external QC materials are used for monitoring the performance and outcome of analytical methods. When process performance is validated against Westgard rules or any other quality criteria for acceptability of control data, probability for rejection and probability of error detection are of paramount importance.[13] The term probability of false rejection (Pfr) is used to describe 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. For achievement of world class quality it is desirable to have a high probability of error detection and a low probability of false rejection.[14]

CONCLUSION

Satisfactory sigma values (≥3) were elicited for blood glucose, ALP, total protein, triglyceride, HDL, uric acid and amylase, while SGPT, SGOT and cholesterol performed poorly on the sigma scale. 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. Employing six sigma in laboratory involves quantifying the performance of the test using standard QC methods.The application of six sigma methodology is necessary to minimize both variance and quality control processes to improve the compliance with the vital specifications. Sigma metrics will also assist the application of superlative analytical methodologies in order to enhance laboratory performance. Therefore, clinical biochemists should set the reasonable quality goals for the laboratories as well as also look after the inherent random errors and performance potential of biochemistry analyzers. It is also crucial to execute appropriate QC planning to facilitate the most excellent laboratory performance.

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