Original Research Paper

Volume - 7 | Issue - 6 | June - 2017 | ISSN - 2249-555X | IF : 4.894 | IC Value : 79.96

Biochemistry

Six Sigma : a breakthrough strategy for evaluating analytical quality in clinical biochemistry laboratory of a tertiary care hospital

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ABSTRACT There is no dearth of evidence to show that ensuring quality assurance is presently considered as a basic need in all sectors including laboratory service. In the clinical biochemistry laboratory application of six Sigma rule is a quality management strategy that improves assay quality by identifying biased and imprecise assays.We aimed to evaluate our laboratory performance by using sigma metrics. Internal quality control (QC) data obtained from clinical biochemistry laboratory of College of Medicine and Sagore Dutta Hospital was analyzed retrospectively over a period of 6 months from July 2016 to December 2016 . Sigma factor were calculated for most of the laboratory parameters. Parameters with Sigma values (>6) such as alkaline phosphatase, triglyceride, HDL considered as satisfactory. Parameters such as SGPT and cholesterol with Sigma <3 considered as poor. The findings of our study will emphasize on the need of evaluating ongoing quality assurance programme and adoption of corrective measures in order to implement six sigma standard in Quality Control for all the analytical processes.

KEYWORDS : Six sigma, Quality control, bias

Introduction:

Quality is meeting the predetermined requirements to the satisfaction of the users for a particular substance or a service. Quality assurance is now of utmost importance in clinical biochemistry laboratory services. It is sum of total of all activities that are undertaken to ensure generation of reliable and accurate results[1].Six sigma is an evolution in quality management that is being widely implemented in business and industry in the new millennium. The principles of Six sigma was adopted by Motorola in early 1990s and won the award of Malcolm Baldridge Quality Award. Sigma (σ) is the mathematical symbol for standard deviation (SD). The application of sigma metrics for assessing analytical performance depends on measuring the process variation and determining process capability in sigma units.Any process can be evaluated in terms of a sigma metric and it describes how many sigma's fit within the tolerance limits. Two methods can be used to assess the process performance in terms of a sigma metric. One approach is to measure outcomes by inspection. The other approach is to measure variation and predict process performance. Measurement of outcome is done by calculating defects per million(DPM) and converting it into sigma metric. A defect rate of 0.033% would be considered excellent in any healthcare organization whereas error rates from 1 to 5% are often considered acceptable. A 5% error rate corresponds to a 3.15 sigma performance, and a 1% error rate corresponds to 3.85 sigma. Quality is assessed on the sigma scale with criteria of 3 σ as the minimum allowable sigma for routine performance and a sigma of 6 σ being the goal for world-class quality[2]. Our present study was undertaken to evaluate the quality of the analytical performance using sigma scale for certain parameters in a clinical Biochemistry laboratory of a tertiary care hospital i.e. College of Medicine and Sagore Dutta Hospital.

Materials and Methods:

We aim to present the sigma metrics of various parameters observed in our clinical Biochemistry laboratory in College of Medicine and Sagore Dutta Hospital during a period of 6 months from July 2016 to December 2017. Various parameters that will be scrutinized are sugar,urea creatinine, triglyceride, cholesterol, HDl, LDL, bilirubin, SGOT ,SGPT. ALP ,total protein ,albumin, uric acid . Internal statistical QC data was extricated from the EM 360 Autoanalyzer for the period of 6 months from July 2016 to December 2016. Control materials were obtained from Transasia. Both normal (L1) and pathological (L2) levels of QC materials were assayed before commencing reporting of patient samples every day. Precision has been defined as the closeness of agreement between independent results of measurements obtained under stipulated conditions. The degree of precision is usually expressed on the basis of statistical measures of imprecision, such as *CV%*. CV% is calculated from Internal Quality Control (IQC) data with the formula CV% = (SD/Mean)* 100.

Trueness is defined as closeness of agreement between the average value obtained from a large series of results of measurements and the true value. The difference between the average value and the true value is the *bias,* which is expressed numerically and so is inversely related to the trueness. Bias% is calculated from External Quality Assurance Scheme (EQAS) with the formula:Bias% = [(Our lab result - Peer group mean) / (Peer group mean)]*100. Total allowable errors will be followed as per Clinical Laboratory Improvement Amendments (CLIA) guidelines[1].

Sigma (σ) value is calculated with the formula Sigma metrics (σ) = (TEa % - Bias %) / CV% where TEa% is Total allowable error percentage and CV% is Coefficient of Variation. Sigma values of parameter under investigation were calculated using this formula.

Results: Monthly CV% of all the analytes is shown July 2016 to December 2016 in chart 1 and chart 2. Sigma values of parameter under investigation were portrayed in chart 3.

Chart 1: CV% of Level 1 control (Month JULY to December)

Parameter	July	August	September	October	November	December	Avg
GLUCOSE	3.26	2.90	2.04	2.89	3.14	2.79	2.83
UREA	2.69	2.97	1.89	2.60	2.69	4.4	2.87
CREATININE	3.74	4.87	2.96	8.4	3.96	4.14	4.67
URIC ACID	3.24	3.12	3.03	2.8	2.9	2.9	2.9
SGPT	7.27	11.62	7.2	12.01	8.2	7.1	8.89
SGOT	5.74	6.6	7.03	5.2	5.3	7.3	6.19
ALP	4.48	2.9	2.63	2.8	2.3	4.19	3.2
BT	5.51	4.2	7.02	5.3	6.0	6.4	5.73
BD	8.16	7.9	5.56	3.9	6.76	5.4	6.25
TOTAL PROTEIN	3.03	3.1	2.3	2.26	2.5	3.0	2.6
ALBUMIN	2.60	2.2	2.5	2.4	2.42	2.20	2.3
CHOLESTEROL	3.60	3.0	1.89	2.5	3.19	1.73	2.63
TRIGLYCERIDE	3.44	2.9	2.02	2.80	2.3	2.72	2.69
HDL	8.4	1.7	2.32	3.1	3.01	3.5	3.66
LDL	4.3	2.1	1.6	1.75	3.16	2.5	2.55

Chart 2: CV% of Level 2 control (Month JULY to December)

Parameter	July	August	September	October	November	December	Avg
Glucose	2.42	2.5	3.85	4.9	2.17	2.92	3.20
Urea	2.64	2.12	2.71	3.6	1.42	3.03	2.57
creatinine	2.59	2.83	3.67	6.6	2.0	3.11	3.44
URIC ACID	2.33	2.51	4.6	3.64	1.49	2.89	2.87
SGPT	4.09	5.72	6.23	4.59	5.13	4.71	5.03
SGOT	4.4	4.8	4.2	5.1	5.02	4.87	4.71
ALP	3.3	3.8	3.4	3.51	3.3	3.99	3.5
BT	3.6	4.02	3.80	5.06	3.0	3.70	3.85

BD	2.59	2.5	5.1	4.51	3.3	3.04	3.50
TOTAL PROTEIN	1.96	2.9	4.16	4.72	1.74	3.15	3.07
ALBUMIN	2.12	3.2	4.85	3.07	1.21	2.3	2.79
CHOLESTEROL	2.73	4.01	3.57	4.4	1.98	2.78	3.2
TRIGLYCERIDE	2.6	2.8	3.74	4.3	2.07	3.06	3.06
HDL	2.7	2.5	5.64	5.04	2.10	2.49	4.2
LDL	4.54	3.01	4.50	5.62	2.40	2.04	3.6

In our present study out of 15 parameters only 3 parameters i.e ALP, triglyceride and HDL showed sigma more than six ,9 analytes showed 3 to 6 sigma in both the control levels and only 2 parameter reveled less than 3 sigma performance in one control level.(chart 3)

Chart 3: % bias, TEa and Sigma value of different parameters

Parameter	% bias (Avg)	Total allowable error	Level 1 control CV% (Avg)	Sigma	Level 2 control CV% (Avg)	Sigma
GLUCOSE	0.308	10%	2.83	3.46	3.20	3.02
UREA	0.28	9%	2.87	3.11	2.57	3.39
CREATININE	0.87	15%	4.67	3.02	3.44	4.10
URIC ACID	0.41	17%	2.9	5.72	2.87	5.78
SGPT	0.55	20%	8.8	2.2	5.03	3.89
SGOT	0.43	20%	6.1	3.2	4.71	4.16
ALP	0.52	30%	3.2	9.21	3.5	8.42
BT	.335	20%	5.73	3.44	3.85	5.17
TOTAL PROTEIN	.011	10%	2.6	3.84	3.07	3.24
ALBUMIN	0.68	10%	2.3	4.05	2.79	3.34
CHOLESTEROL	0.768	10%	2.63	3.54	3.2	2.88
TRIGLYCERIDE	0.22	25%	2.69	9.53	3.06	8.09
HDL	0.4	30%	3.66	8.22	4.2	7.04

Discussion:

It is conventional practice to run the Internal and External quality controls to assess precision and accuracy in a routine clinical biochemistry laboratory. . Both normal (L1) and pathological (L2) levels of QC materials were assayed before commencing reporting of patient samples every day. In this practice, laboratory personnel usually follow the Westgard multirules for internal quality assurance and EQAS for external quality. In External Quality Assurance Services (EQAS) when ' Z ' score (or) Standard Deviation Index (SDI) is between +2 and -2, it is considered as satisfactory. If Z-score is out of this range it indicates the process is biased. 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 [3]. 3-sigma level is regarded as the minimum acceptable level of quality. The Six Sigma scale runs from zero to six, but a process can actually exceed Six Sigma, if variability is sufficiently low as to decrease the defect rate. In industries outside of healthcare, 3 Sigma is considered the minimal acceptable performance for a process. When performance falls below 3 Sigma, the process is regarded to be essentially unstable and unacceptable.[4] The six sigma idea emphasizes an association between the numbers of product defects, wasted operating costs and levels of customer satisfaction. It can be deduced that as sigma increases, the consistency and steadiness of the test improves, thereby reducing the operating costs. allowable error.[5]

In contrast to other industries, healthcare and clinical laboratories appear to be operating in a 2 to 3 Sigma environment. Six sigma scale has the power to provide a universal bench mark. It allows the comparison between different instruments, different labs and different methods all over the world. In our present study out of 15 parameters only 3 parameters i.e ALP, triglyceride and HDL showed sigma more than six ,9 analytes showed 3 to 6 sigma in both the control levels and only 2 parameter reveled less than 3 sigma performance in one control level. Manchana Lakshman et al opined that in their study11 of 23 analytes showed above six sigma performances, 10 analytes showed 3 to 6 sigma .Sigma metrics of abnormal level (level 2) showed 11 of 23 analytes showed above six sigma performances, 12 analytes showed the performance between 3 and 6.erformance, 2 analytes showed less than 3 sigma performances in normal level (level 1)[6].According to study done by Nanda SK et al ALP was the best performer when it was gauzed on the sigma scale.[5] Though many laboratories are following the ISO 15189 guidelines and participating in the Internal and external quality control programmers but they areunable to achieve the six sigma performance. Six sigma being the goal for world-class quality, there is a need to implement the sigma metrics in the laboratories [6].Sigma metrics in combination with a rational QC design for each analyte can improve the quality there by reducing the wastage[4].Schoenmaker et al described the importance of application of sigma metrics and preparation of rational QC design based on the sigma values with the help of westgard operational specifications chart (OPSpecs chart) in clinical biochemistry laboratories[7]. Iqbal S opined that application of sigma rules provided the practical solution for improved and focused design of QC procedure[8]. 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 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. Clinical biochemists should develop realistic quality goals for the laboratories keeping in mind inherent random errors and performance capability of biochemistry analyzers. It is also imperative to implement appropriate QC strategies in order to augment the judicious use of Qc[9].

Conclusion:

Implementation of six sigma rules in clinical biochemistry laboratory will not only minimize error but also increase compliance. Parameters with demonstrated poor performance in sigma matrix should be evaluated with discretion. Analytical methodology of the parameters that demonstrated <3 sigma should be reevaluated. Most of the parameters that demonstrated sigma 3 to 6 signifies acceptable sigma with a chance for improvisation. In this present state we should implement six sigma in Quality control strategies in order to augment laboratory performance.

Acknowledgement: Professor Dr Indranil chakraborty, Department of Biochemistry, College of Medicine and Sagore Dutta Hospital

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