ORIGINAL ARTICLE

Application of Six sigma test in Clinical Biochemistry Laboratory

Nikunj Modi[1*], Tejas Shah[2]

[1,2]MD (Biochemistry), Department of Biochemistry, Shri M P Shah Govt. Medical College, Jamnagar, Gujarat (India)

ABSTRACT

BACKGROUND: Now-a-days Quality is the key aspect of Laboratory services. Mostly Internal quality control (IQC) and External quality assurance scheme (EQAS) are utilized to maintain quality in the Laboratory. With the help of this IQC and EQAS various score like CV% and Bias% are monitored to improve and to maintain quality of laboratory. Six sigma is used in industries for quality check. We want to use this six sigma as quality indicator in clinical biochemistry laboratory. **AIMS:** The study aimed to compare application of six sigma test in clinical biochemistry laboratory along with current method of Internal quality control and External quality assurance scheme as a quality indicator. **MATERIAL & METHODS:** Study was conducted at Clinical Biochemistry Laboratory, Guru Gobindsingh Govt. Hospital, Jamnagar, Gujarat. There are IQC samples are running on daily basis and EQAS samples are running on monthly basis in the Clinical Biochemistry Laboratory. Retrospectively we utilize data of IQC and EQAS of three months and find out sigma value to understand application of six sigma in Clinical Biochemistry laboratory. **RESULTS:** We found different sigma value like more than three for Plasma Glucose, Creatinine, Total Protein, Uric acid and Serum glutamate pyruvate transferase (SGPT) while less than three for Urea and albumin. **CONCLUSION:** The study demonstrated that six sigma can be useful tool to monitor quality level in Clinical Biochemistry Laboratory. This sigma matrix combine both important data of IQC and EQAS. To maintain six sigma is challenging to quality management personnel of laboratory, but it will helpful to improve quality level in the Laboratory.

Key words: Six sigma, IQC, EQAS.

INTRODUCTION

"You cannot manage what you cannot measure" is a well known and perhaps tired management mantra, but it certainly applies to improve quality and safety in laboratory medicine.[1] Quality planning defines quality standards which are the foundation 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 critical for clinical interpretation of the test.[2]

Quality Control is performed for TWO purposes: Detect errors And Avoid false rejections. It is important to see that we don't apply any stringent rules in laboratory to avoid unnecessary wastage of time, resources, manpower and avoid false rejections. Mostly in Clinical laboratories Total Quality management in the form of "Plan, Do, Check, Act". Six Sigma methodology represents an evolution in quality assessment and management that has been implemented widely in business and industry since the mid-1980s. Six Sigma methodology was developed by Motorola, Inc. to reduce the cost of products, eliminate defects, and decrease variability in processing. It consists of five steps: define, measure, analyze, improve, and control (DMAIC). These steps are universal and could be applied to all sectors of industry, business, and healthcare.[3]

There are two methodologies for assessing 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. The application of sigma metrics for assessing analytical performance depends on measuring process variation and determining "process capability" in sigma units.[4] We analyzed internal IQC data and

Corresponding Author:
Dr. Nikunj Modi,
MD Dept. of Biochemistry,
Shri M P Shah Govt. Medical College,
Jamnagar, Gujarat (India).
Contact No: 9227710925
Email: nikunjmodi86@yahoo.co.in

EQAS data of Glucose, Urea, Creatinine, Total Protein, Albumin, Uric acid and SGPT for three months. Sigma was calculated from these data by applying total allowable error (TEa) from guideline.

MATERIALS AND METHODS

The present study was conducted at Clinical Biochemistry Laboratory, Guru Gobindsingh Govt. Hospital, Jamnagar, Gujarat, in which IQC and EQAS data of three months were analyzed retrospectively for Plasma Glucose, Urea, Creatinine, Total Protein, Albumin, Uric acid and SGPT which were run on semiauto analyser Erba Chem 5 + V2. We are using Randox Quality control Level – 2 and Level – 3 for Internal Quality control material. It is in lyophilised material, which is reconstituted and Both levels of QC materials were assayed before starting patient samples. Next QC cycle was run after commencing the reports of 75 samples (As per NABL 15189:2007 guidelines).[5] First mean and standard deviation (SD) were calculated and from that CV% (Coefficient of Variation) was calculated from IQC data of Glucose, Urea, Creatinine, Total Protein, Albumin, Uric acid and SGPT with the formula CV% = (SD/Mean) * 100. We have joined EQAS programme of Randox Laboratories Ltd. As per programme we have to send monthly EQAS result and we are getting detail report of result within a week of last date of result submission. The Difference between the average value and the true value is the Bias. The Bias% was calculated from EQAS programme with the formula: Bias% = [(lab result - Peer group mean) / (Peer group mean)] * 100. On the basis of CV% and Bias%, sigma Value was calculated for both internal control levels. Microsoft office excel 2007 software was used for statistical analysis. Sigma (σ) value is calculated with the formula, Sigma metrics (σ) = (TEa % - Bias %**)** / CV%, where TEa% is Total allowable error percentage. TEa values of Glucose, Urea, Creatinine, Total Protein, Albumin, Uric acid and SGPT were taken from the Clinical Laboratories Improvement Act (CLIA) guidelines.

Table 1: Bias% month wise and average for all parameters

Parameter	April Bias%	May Bias%	June Bias%	Average Bias%
Glucose	0.26	2.5	0.9	1.2
Urea	4.5	4	4	4.2
Creatinine	5.4	0	5.1	3.5
Total Protein	2.1	3	1.4	2.2
Albumin	3.1	4.3	9.3	5.6
Uric acid	6.6	1.5	5	4.4
SGPT	8.9	0	2.2	3.7

Table 2: CV% for both control level month wise and cumulative for all parameters

	April CV%		May CV%		June CV%		Cumulative CV%	
Parameter	**Level-2**	**Level-3**	**Level-2**	**Level-3**	**Level-2**	**Level-3**	**Level-2**	**Level-3**
Glucose	2.4	2	2.5	2.2	3.5	2.2	2.1	2.1
Urea	3.1	2.9	4.4	2.7	5.2	2.9	3.1	2.8
Creatinine	3.4	3	4.3	3.5	3.9	2.1	2.9	2.8
Total Protein	2.4	3.8	3.5	4.4	3.1	4.4	2.25	4.2
Albumin	2.5	3.5	3.2	4.1	3.2	4.1	2.22	3.9
Uric acid	3.5	4	3.2	3.6	3	3.3	2.42	3.6
SGPT	3.2	3.6	3.6	3.4	4.8	3.1	2.9	3.3

Table 3: Sigma value monthwise and cumulative for all parameters.

Parameter	TEa%	April Sigma (σ) value		May Sigma (σ) value		June Sigma (σ) value		Cumulative Sigma (σ) value	
		Level-2	Level-3	Level-2	Level-3	Level-2	Level–3	Level-2	level-3
Glucose	10	4.1	4.9	3.0	3.4	2.6	4.1	4.2	4.1
Urea	9	1.5	1.6	1.1	1.9	1.0	1.7	1.5	1.7
Creatinine	15	2.8	3.2	3.5	4.3	2.5	4.7	4	4
Total Protein	10	3.3	2.1	2.0	1.6	2.8	2.0	3.5	1.9
Albumin	10	2.8	2.0	1.8	1.4	0.2	0.2	2	1.1
Uric acid	17	3.0	2.6	4.8	4.3	4.0	3.6	5.2	3.5
SGPT	20	3.5	3.1	5.6	5.9	3.7	5.7	5.6	4.8

RESULTS

Month wise and cumulative Bias of glucose, urea, Creatinine, total protein, albumin, uric acid and SGPT are given in table no. 1. CV% of Normal (level - 2) and Pathological (level - 3) controls given month wise and cumulative for the last three month given in table no. 2. Sigma

matrix of parameters is given in table no. 3, in which we got sigma value [(σ) ≥ 3.0] for glucose, creatinine, total protein, uric acid and SGPT. While lower side of sigma value [(σ) ≤ 3.0] for urea and albumin.

DISCUSSION

In support of an analytical test method being described as a service process, the American Association for Clinical Chemistry (AACC) (2011) describes an analytical method as '... a science professionally conducted with rigorous statistical analysis, quality controls, and extensive oversight', whilst Wang (2008) deliberates that the *quality improvement process* starts with a diagnostic journey of the process, where problems as well as symptoms are identified. Thereafter a hypothesis is formulated and tested, and root causes are identified. Finally, remedial action is taken and the process is then continuously monitored.[6]

Present quality assurance programs focus on the ''find a problem, fix a problem'' philosophy without regard for analyzing the underlying process that created the problem. To make significant improvements in laboratory performance, systematic approaches need to be considered. As health care begins to appreciate the lessons learned by the manufacturing and service sectors during the last 10 to 15 years and begins to implement quality system strategies, major breakthroughs such as the Six Sigma concept seem possible.[7]

In quality management, Six Sigma is accepted as "world class quality". For laboratory measurements, the sigma performance of a method can be formulated as below:

(σ) = (TEa % - Bias %**)** / CV%, where TEa% is Total allowable error percentage.[8]

The Six Sigma scale typically 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 considered to be essentially unstable and unacceptable. In contrast to other industries, healthcare and clinical laboratories appear to be operating in a 2 to 3 Sigma environment. The routine use of "2s" (i.e., 2 standard deviations or 2 SD) control limits is indicative of a complacent tradition in quality control practices. Despite the well-known problems of 2s limits – they can generate false rejection rates of up to 10 to 20%, depending on the number of controls run– many laboratories use them for all testing processes. The misuse of 2s limits in laboratory testing frequently results in erroneously-repeated controls, excessive trouble-shooting, or worse still, workarounds that artificially widen control limits to the point that laboratories can no longer detect critical analytical errors. Six sigma being the goal for world-class quality, there is a need to implement the sigma metrics in the laboratories. Sigma metrics in combination with a rational QC design for each analyte can improve the quality there by reducing the wastage.[9]

To solve analytical or managerial problems in laboratory medicine and to decrease errors to a negligible level, Six Sigma methodology is the right choice. Some may find this assertion too optimistic. To decrease the error rate, we should decrease human intervention by using high-quality technology whenever possible. However, it may not currently be possible to apply sophisticated technology to all medical disciplines equally; however, for laboratory medicine, we certainly have the opportunity to apply technology. If we continue to apply technology to all branches of medicine, we may ultimately decrease the error rate to a negligible level. Six Sigma is the microscope of quality scientists. It shows the reality and does not mask problems. The errors that we are interest are primarily analytical errors, which represent only the tip of the iceberg. However, the reality is quite different. When we see the whole iceberg and control it all, then it will be possible to reach Six Sigma level and even higher quality in clinical laboratories.[10]

If we apply sigma for parameters with narrow biological variation (like

electrolytes) which have narrow allowable total error, then chances of low sigma value increases. Sigma value is inherently dependent on TEa definition given by various guidelines. In spite of getting acceptable CV our sigma values were not satisfactory. It is important to see that we don't apply any stringent criteria in laboratory which can cause unnecessary wastage of time, resources, manpower and cause false rejections. Upgraded analyzers and better methodologies may help in achieving sigma values. [3]

CONCLUSION

There are satisfactory sigma matrixes for Glucose, Creatinine, Total Protein, Uric acid and SGPT in the study. But unsatisfactory value for urea and albumin. To give quality work, it's suggesting to do root cause analysis for those parameters, who got less than three sigma value. It also concludes that sigma matrix give combine evaluation of both IQC and EQAS. There are difficulties to get satisfactory sigma matrix, if TEa% of parameter is at lower side as in urea. If total allowable error of parameter is at higher side then there are more chances to get good sigma value as in Creatinine, Uric acid and SGPT. Irrespective of Tea%, Quality is ongoing process. So, quality personnel of the laboratory should not stop by generating CV% and Bias% of the any parameter but also monitor sigma matrix to give high end or world class quality. This is add-on challenge to management lobby of the laboratory.

REFERENCES

1. M. Plebani et al., Quality indicators in laboratory medicine: A fundamental tool for quality and patient safety, Clinical Biochemistry 46 (2013) 1170–1174.
2. Bhawna Singh, Binita Goswami, Vinod Kumar Gupta, Ranjna Chawla, Venkatesan Mallika. Ind J Clin Biochem (Apr-June 2011) 26(2):131–135.
3. Dr. Bhakti Gami, Dr. Dharmik Patel, Dr. Kiran Chauhan, Dr. Hitesh Shah And Dr. N. Haridas, Sigma Metrics As A Quality Marker For Analyzing Electrolytes In Laboratory, International Journal Of Advanced Research (2013), Volume 1, Issue 7, 197-201
4. Dr. Usha Sachidananda Adiga, Sigma metrics of thyroid hormones, International Journal of Medical and Health Research, Volume 2; Issue 4; April 2016; Page No. 40-42.
5. National Accreditation Board for Testing and Calibration Laboratories [Internet]. India: NABL 112 : Specific criteria for accreditation of medical laboratories;2008 (updated 2012 October 16; cited 2013 August 300. Available from: www.nabl-india.org.
6. Cloete, B.C. & Bester, A., 2012, 'A Lean Six Sigma approach to the improvement of the selenium analysis method', *Onderstepoort Journal of Veterinary Research* 79(1), Art. #407, 13 pages.
7. Nevalainen et al, Evaluating Laboratory Performance on Quality Indicators With the Six Sigma Scale, Arch Pathol Lab Med—Vol 124, April 2000; 516-519.
8. Coskun A. The reliability of calculated laboratory tests. Clin Chem Lab Med 2005;43:880–2.
9. Manchana Lakshman, B.Ravindra Reddy, P. Bhulaxmi, K. Malathi, Mahjabeen Salma and Swati Prakasham, Evaluation of sigma metrics in a Medical Biochemistry lab, International Journal of Biomedical Research 2015; 6(03): 164-171.
10. Abdurrahman Coskun, Ibrahim Unsal, Mustafa Serteser and Tamer Inal (2010). Six Sigma as a Quality Management Tool: Evaluation of Performance in Laboratory Medicine, Quality Management and Six Sigma, Abdurrahman Coskun (Ed.), ISBN: 978-953-307-130-5, InTech, Available from:http://www.intechopen.com/books/quality-management-and-six-sigma/six-sigma-as-a-quality-managementtool-evaluation-of-performance-in-laboratory-medicine.