ORIGINAL ARTICLE

Quality Assurance in Thyroid Profile with the Six Sigma Matrix

Nikunj Modi[1], Dharmesh Gamit[2]

[1]Assistant Professor, Dept. of Biochemistry, Shri M P Shah Govt. Medical College, Jamnagar, Gujarat (India), [2]Assistant Professor, Dept. of Biochemistry, GMERS Medical College, Valsad, Gujarat (India)

ABSTRACT

BACKGROUND AND OBJECTIVES: In present days quality satisfaction is necessary for every tests performed in any laboratory. It is must for patient safety as well to build up confidence in laboratory staff. Not only that it creates good reputation of laboratory also. And this all together strengthen the laboratory services as well help to establish more and more laboratory parameters with quality. In routine Internal quality control (IQC) is done and also External quality assurance scheme (EQAS) are performed to check quality of parameters. With the help of score like CV% and SDI are calculated to improve and to maintain quality of laboratory. Now a days, Six sigma is also used for quality check. We want to calculate this sigma matrix as quality marker in thyroid profile. The study is aimed to calculate sigma value in thyroid profile and compare it with existing Internal and External quality assurance scheme. **METHODS:** Study was conducted at Clinical Biochemistry Laboratory, Guru Gobind singh Govt. Hospital, Jamnagar, Gujarat. There are IQC samples are run per ELISA plate and EQAS samples on monthly basis in the Clinical Biochemistry Laboratory. Retrospectively we utilize data of IQC and EQAS of four months and find out sigma value to check quality of thyroid profile. **RESULTS:** We found different sigma value for TSH, T3 and T4. **CONCLUSION:** Present study demonstrated that sigma value is useful marker to check quality level in thyroid profile. This sigma value evaluates both important data of IQC and EQAS. To achieve high sigma value is challenging to quality management personnel of laboratory, but it will be helpful to monitor quality level in thyroid profile.

Keywords: IQC, EQA, Six sigma, Thyroid Profile

INTRODUCTION

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.[1] It has been documented that performance and outcome measures can improve the quality of patient care. Such measures support accountability and enable the comparison over time between providers, evaluating the effectiveness of delivered services and the improvement in patient safety through the development and monitoring of specific indicators.[2]Six Sigma is a combination of certain tools and techniques that provides laboratory quality practitioners with a means to improve processes and reduce cycle times. This approach incorporates the use of Six Sigma methodology, which inherently focuses on gathering data, analysing the collected data, and thereafter improving the process yield, as well as the Lean methodology which identifies key areas of variation.[3]Applications to analytic processes have been described by Westgard. When assessing quality on the σ scale, the higher the σ metric, the better the quality. According to Nevalainen et al, "average products, regardless of their complexity, have a quality performance value of about 4 σ. The best, or 'world class quality,' products have a level of performance of 6 σ." 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

Corresponding Author:
Dr Dharmesh Gamit
MD (Biochemistry),
Dept. of Biochemistry, GMERS Medical College, Valsad, Gujarat (India).
Contact No: 7405591054
Email: zpatani6@gmail.com

achieved. [4] We analyzed internal IQC data and EQAS data of thyroid profile for seven 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 four months were analyzed retrospectively for thyroid profile which were run on semi automated Elisa reader and washer. We are using company provided Quality control for Internal Quality control material and it is ready to use. QC materials were assayed along with patient samples. QC was run with each new plate of Elisa. First mean and standard deviation (SD) were calculated and from that CV% (Coefficient of Variation) was calculated from IQC data of TSH, T3 and T4 with the formula CV% = (SD/Mean) * 100. We have joined EQAS programme and 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 internal control level. 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. The most recent and extensive listing of biologic goals has been provided by Ricos et al., which is taken as reference value. These values are in accordance with CLIA guidelines.[5]

OBSERVATIONS

Month wise and cumulative Bias of TSH, T3 and T4 are given in table no. 1. CV% of Internal Quality Control given month wise and cumulative for four months given in table no. 2. Sigma matrix of parameters is given in table no. 3, in which we got sigma value (σ) in between 2 to 3 for TSH. While lower side of sigma value [(σ) ≤ 3.0] for T3 and T4.

Table 1: Bias% month wise and average for Thyroid Profile.

Parameter	April Bias %	May Bias %	June Bias %	July Bias %	Average Bias %
TSH	2.40	0.70	0.70	4.30	2.03
T3	0.80	0.80	2.60	4.10	2.08
T4	1.10	1.10	1.20	1.90	1.33

Table 2: CV% calculated from control, month wise and cumulative for Thyroid Profile.

Parameter	April CV%	May CV%	June CV%	July CV%	Cumulative CV%
TSH	8.50	8.10	7.80	7.50	7.98
T3	5.50	5.20	5.70	4.80	5.30
T4	5.90	5.80	5.70	5.00	5.60

Table 3: Sigma value monthwise and cumulative for Thyroid Profile.

Parameter	April Sigma (σ) value	May Sigma (σ) value	June Sigma (σ) value	July Sigma (σ) value	Cumulative Sigma (σ) value
TSH	2.51	2.84	2.95	2.59	2.72
T3	1.53	1.62	1.16	1.07	1.35
T4	1.00	1.02	1.02	1.02	1.01

DISCUSSION

Most quality improvement activities begin with measurement and feedback. However, according to a famous aphorism by Albert Einstein "Not everything that counts can be measured; not everything that can be measured counts". Therefore, the development and the adoption of reliable quality indicators play a key role in projects for improving the quality of laboratory services. A consensus has been achieved on the need to assure quality in laboratory medicine according to a patient-centered viewpoint and in the total testing process. This process embraces all steps from the moment the test is chosen during patient evaluation to the point when the test result is interpreted and a clinical conclusion is developed.[6] 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. Functioning at the 3-sigma level is regarded as the minimum acceptable level of quality. The six sigma idea asserts an

association between the numbers of product defects, wasted operating costs and levels of customer satisfaction. It can be inferred that as sigma increases, the consistency and steadiness of the test improves, thereby reducing the operating costs.[7] 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. 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.[8] Commonly, a Z score of less than 1.0, from zero is excellent and up to 2.0 it is acceptable. If we talk about SDI zero indicates perfect comparison, an SDI < 2.0 is acceptable and > 2.0 is unacceptable. But exact number of errors done by the laboratory cannot be assessed by running internal and external QCs.[9]The current day healthcare system is content if their process functioning lies within ±2 Standard Deviations (SD) of the mean. In a Gaussian distribution, this would result in only a 4.5% defect rate, but considering the potential of healthcare usage, this would translate into an appalling 45,400 DPM opportunities. These figures would be of little solace to an already ill patient. The clinical diagnostic laboratories are content if their results enclose ±2 SD or ±3 SD limits. In other words, they find defect rates of 45,400 DPM opportunities and 2,700 DPM opportunities as acceptable performance. It may well be argued that little is gained from improving a process performance beyond the five sigma (233 DPM) level. It is felt that six sigma method applications can actually tolerate small shifts in the process mean and not increase the defect rate that significantly. With a six sigma process, we are assured that the process is still producing results within the desired specifications and with low defect rates. The six sigma process provides an added advantage by being easily monitored with any Quality Control (QC) procedure unlike a process at five sigma or lower sigma levels where the choice of QC procedure is more important.[10]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.[11] There are difficulties to get satisfactory sigma matrix, if TEa% of parameter is at lower side. If total allowable error of parameter is at higher side then there are more chances to get good sigma value.[12]On another hand Sigma value is inherently dependent on TEa definition given by various guidelines. In spite of getting acceptable CV some 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.[13]

CONCLUSION

There are different sigma values for TSH T3 and T4 in the study. Even after getting satisfactory CV% and SDI for TSH, its sigma level is near to satisfactory mark. For T3 and T4 CV% and SDI were within accepted range, but it's not upto mark in sigma matrix. All these together concluding that, sigma value moreover depended on TEa% even after getting satisfactory CV% and SDI. All together concluding sigma matrix is good indicator but it's like challenge to get and maintain good sigma value for those who have low TEa%.

REFERENCES

1. 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.
2. M. Plebani et al., Quality indicators in laboratory medicine: A fundamental tool for quality and patient safety, Clinical Biochemistry 46 (2013) 1170–1174.
3. 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.
4. James O. Westgard, PhD, and Sten A. Westgard, MS, An Assessment of σ Metrics for Analytic Quality Using Performance Data From Proficiency Testing Surveys and the CLIA Criteria for Acceptable Performance. Am J Clin Pathol, 2006,125, 343-354.
5. Ricos C, Alvarez V, Cava F, Garcia-Larvia JV, et al. Current databases on biological variation:pros, cons and progress. Scand J Clin Lab Invest. 1999; 59:491-500.
6. M. Plebani et al, Quality indicators in laboratory medicine: A fundamental tool for quality and patient safety. Clinical Biochemistry 46 (2013) 1170–1174.
7. Bhawna Singh, Binita Goswami, Vinod Kumar Gupta, Ranjna Chawla, Venkatesan Mallika. Application of Sigma Metrics for the Assessment of Quality Assurance in Clinical Biochemistry Laboratory in India: A Pilot Study Ind J Clin Biochem (Apr-June 2011) 26(2):131–135.
8. Nitinkumar G. Chaudhary et al, application of six sigma for the quality assurance in clinical biochemistry laboratory – a retrospective study. Int j res med. 2013; 2(3);17-20.
9. Kirankumar P. Chauhan et al, Six sigma in clinical biochemistry: It matters, measure it. International Journal of Clinical Biochemistry and Research, July-September2017 ;4(3): 270-274.
10. Kalra J, Kopargaonkar A. Quality improvement in clinical laboratories: a six sigma concept. Pathol Lab Med Open J. 2016; 1(1): 11-20. doi:10.17140/PLMOJ-1-104.
11. 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.
12. Nikunj Modi, Application of Six sigma test in Clinical Biochemistry Laboratory. Int J Res Med. 2017; 6(2); 75-78.
13. Dr. Bhakti Gami et al, Sigma metrics as a quality marker for analyzing electrolytes in laboratory, International Journal of Advanced Research (2013), Volume 1, Issue 7, 197-201.