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SIX SIGMA- AN APPROACH TOWARDS QUALITY MANAGEMENT IN CLINICAL BIOCHEMISTRY LABORATORY

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ABSTRACT Laboratory tests results are most important part of health care system, as they give significant medical information in diagnosis, treatment and prevention of diseases. So, it is core responsibility of any clinical laboratory to give accurate results. The accuracy is being maintained by quality controls run in the lab. Defects or errors represents poorly designed quality control system. Six sigma methodology has been pioneered by Motorola company with zero defect goal. It is a formula-based method used for evaluating errors or defects quantitatively and the results are quantified as defects per million (DPM). High sigma value indicates the good laboratory practice in quality control and management. Studies done proved that six sigma is an ideal choice to solve analytical and managerial problems in laboratory medicine.

KEYWORDS : Quality control, Quality assurance, Six sigma, Clinical laboratory

INTRODUCTION

Laboratory medicine services are an essential part of healthcare system. It is estimated that around 60- 70% of the patient related decisions are based on the laboratory results[1]. It is imperative to follow a proper quality management system to provide accurate and reliable reports in an agreed time frame[2]. Hence, in health care system, continuous improvement of the quality of lab tests results to a very high level is the need of hour.

Quality control and Quality management

First commendation for quality control was published in 1965, since than the issue of laboratory quality has progressed[3]. Buttner et al (1979) defined the quality in the clinical biochemistry laboratory as the study of sources of variations and the ++++++++procedures used to recognize and minimize them[4]. In 1990, Westgard et al gave basic work flow in designing a quality control system known as Total quality management system (TQM). It involves 5 continuous steps: Quality planning, Quality process, Quality control (QC), Quality assurance (QA), Quality improvement[5]. Along with these steps, training and involvement of lab staff and doctors are must to improve and expand the skills[6].

The credibility of clinical reports relies on accuracy and precision of the performance of analytical methods. Accuracy is the degree of conformity of a calculated quantity to its actual (true) value. Precision is the reproducibility of the analytical method. It is expressed in terms of imprecision, standard deviation (SD) or coefficient of variation (CV) or random error[7]. To maintain accuracy and precision, clinical labs generally adopt two types of QC schemes – internal quality control (IQC) and external quality control (EQC).

IQC: The main objective of internal quality control is to ensure day to day consistency. As per NABL guidelines, IQC is interpret using control charts such as Levey Jennings chart and Westgard's rules[8].

EQC: EQC is a scheme in which, QC samples are supplied by external agencies at a predefined time interval (fortnight or month). These samples are analysed and reports are sent to external agency. They study the results of all the participating laboratories and then gives feedback to all[9]. Results of EQC are interpreted by either Z-score or standard deviation index.

History of six sigma metrics system

The language of quality today is defined by International Standard Organization (ISO) 15189 document for quality management in medical laboratories[10].Quality is the conformance to the requirement of end users and six sigma is about non-conformance i.e about defects[11]. Defects are anything that causes dissatisfaction like unnecessary costs, steps, services, time loss patient morbidity or mortality[12]. For any clinical laboratory, six sigma is a technique to quantify the errors and then minimize them. Six sigma management method was pioneered by Motorola Company in 1980 by Bill Smith. The goal was to reduce the defect, decrease the cost of product and decrease the variability of processing. By adopting six sigma by the production efficiency has been improved. As clinical laboratories also resemble high volume automated factories because they are producing millions of results and the same standards of manufacturing needs to apply to the standards of medical laboratory testing[13].

Initial studies that benchmarked laboratory quality on the Six Sigma scale were done by Nevalainen D et al and Westgard JO in the year 2000 and 2001 respectively[14]. Two decades after that, Xuehui Mao et al (2018) demonstrated the application of sigma metrics in assessing the quality of an instrument in a laboratory[15]. In the same year (2018) another study done by Yong Xia et al, they elaborated the application of six sigma metrics into the traditional risk assessments that connected test results to patient care[16]. Cao and Qin evaluated the use of analytical sigma metrics by using third-party reagents, especially in developing countries where there is an assumption that reagents are interchangeable. In developing countries cheaper local reagents are being used rather than high quality reagents from original manufacturer[17].

Six Sigma became more popular because it offers a different approach to problems. The Six Sigma management model includes five processes, namely (DMAIC): Define (D) i.e., define who the customer is and their problem, Measure (M), Analyze (A) i.e analyze the data, Improve (I) improve the lab processes and Control (C) control the new plan by develop, document and implement and assure the improvements sustained[18]. In mathematical terms, sigma is the symbol for standard deviation (SD)[7]. Some studies have shown that in clinical laboratories, sigma metrics can be applied to evaluate errors or defects quantitatively and the results are quantified as defects per million (DPM)[19].

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[20]. Sigma methodology has mainly been applied in pre-analytical and analytical processes in clinical laboratories, focusing on the evaluation of biochemical and immunoassay tests[21]. The sigma metrics (σ) for the various analytes is calculated by the following equation:

$$\text{Sigma } (\sigma) = (\text{TEa-Bias}) / \text{CV}$$

TEa- total allowable error or tolerance limit. The values of various parameters were taken from the Clinical Laboratories Improvement Act (CLIA) guidelines[22].

$$\text{TE} = \text{Bias} + 1.65\text{CV}$$[23]

Bias- It is calculated from the external quality records and is an indicator of accuracy and systematic error.

Bias (%) = (mean of all laboratories using same instrument and method - our mean)/(mean of all laboratories using same instrument and method) ×100[24].

CV—coefficient of variation. It is the measure of variability of an assay and is an indicator of random error. It can be calculated by using following formula[25].

CV (%) = (Standard deviation ×100)/Laboratory mean.
The results of sigma metrics obtained after calculations are being quantified as defects per million (DPM).

TABLE-1 The relationship between sigma metrics and defects assuming a 1.5 SD shift in mean.

Sigma metrics	DPMO	Percentage defect	Percentage yield
1	691,462	69%	31%
2	308,538	31%	69%
3	66,807	6.7%	93.3%
4	6,210	0.62%	99.38%
5	233	0.023%	99.977%
6	3.4	0.00034%	99.99966%

Six Sigma focuses on controlling a process to 6 SDs, which equates to 3.4 DPM opportunities[26]. Six Sigma as a metric is defined as a statistical measure of capability of a process, it is a metric that expresses how well a process is performing and how often the errors are likely to occur. A higher sigma means higher performance and less chance of false test results by the laboratory.

(1) $\sigma < 3$ Poor performance procedure and the method is considered to be unreliable and should not be used for routine test purposes.
(2) $\sigma = 3$ Minimum acceptable quality for a production process.
(3) $\sigma > 3$ Good performance[20]
(4) $\sigma \geq 6$ World-class performance[27].

A process which is six sigma compliant will produce only 3.4 defects per million opportunities even with a 1.5 SD shift in mean value[28].

Cooper et al, suggested guidelines for QC tests as per sigma performance >6σ (excellent tests) –one QC per day (alternating levels between days) and a 13s rule. 4σ–6σ (suited for purpose) –two levels of QC per day and the 12.5s rule. 3σ–4σ (poor performers) –combination of rules with two levels of QC twice per day[29].

The six-sigma idea asserts an association between the numbers of product defects, wasted operating costs and levels of customer satisfaction. As sigma increases, the consistency, reliability, steadiness and overall performance of the test improves, thereby decreasing the operating costs[30].

Quality Goal Index (QGI): It represents the relative extent to which both bias and precision meet their respective quality goals. It was calculated using the following formula: QGI = Bias/1.5 CV. QGI represents the reason behind lower sigma value i.e., imprecision, inaccuracy, or both. For analytes which fall short of Six Sigma quality, a QGI score of < 0.8 indicates imprecision, QGI > 1.2 indicates inaccuracy, and QGI score 0.8-1.2 indicates both imprecision and inaccuracy[31].

A sigma value less than 4 ($\sigma < 4$) was used as the benchmark for the QGI analysis of analytes in this study[32]. Various studies done in 2011, 2013, 2015 purposed critical appraisal of sigma value for all biochemistry parameters on regular basis to achieve exceptional quality[33,34,35]. Study done in 2018, concluded that assessment of Six sigma is easy and reliable method to adopt as a part of quality control in all the clinical laboratories.[36]

CONCLUSION

Application of six sigma principles would significantly help in improving QC that is actually needed. Finally, the ultimate goal of six sigma methodology in clinical laboratory is to promote our medical laboratory service quality, achieve good cost-effective outcome and provide the best patient care. Assessment of Six sigma is an easy and reliable method and laboratories should implement as an advanced quality technique.

CONFLICT OF INTEREST - Nil

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