ORIGINAL RESEARCH PAPER

Volume-7 | Issue-4 | April-2018 | PRINT ISSN No 2277 - 8179

INTERNATIONAL JOURNAL OF SCIENTIFIC RESEARCH

ROLE OF SIX SIGMA METRICES IN ASSESSING QUALITY CHECK OF ANALYTICAL ERRORS IN CLINICAL LABORATORY

Biochemistry

Sulekha Sinha Associate Professor, Dept. of Biochemistry, IQ City Medical College, Durgapur.

Arindam Ghosh* Assistant Professor, Dept. of Biochemistry, IQ City Medical College, Durgapur. *Corresponding author

Aritri Bir Assistant Professor, Dept. of Biochemistry, IQ City Medical College, Durgapur.

ABSTRACT

The analytical errors may be random or systematic which is denoted basically by inaccuracy and imprecision. These parameters are represented by coefficient of variation (CV) and Bias. Six sigma (σ) is a quality management tool to assay quality which combines bias, precision and total allowable error (Tea). Sigma level < 3 indicates poor performance whereas > 3 indicates good performance. This retrospective study was conducted at central laboratory of IQ City Medical College and Narayana Multispecialty Hospital. The laboratory uses the auto-analyzer Siemens Dimension and hexokinase method for glucose. The two levels of QC (L1 and L2) are run daily. The internal QC data of the analyte was extracted from the record for month June 2016. The % CV, % Bias was calculated from peer group QC reports. The σ value was calculated using TEa (from CLIA), Bias and CV. The laboratory mean and standard deviation for quality control material (L1 level) was 87.7 ± 2.08 and the same for L2 was 272.9 ± 2.4. The CV % for L1 and L2 was found 2.37 and 0.87 % respectively. The designated mean (DM) was 89.53 and 284.4 for L1 and L2 respectively. The number of laboratory (peer group) participated for L1 and L2 were 98 and 97 respectively utilizing same lot no. QC material (Biorad), same instrument and same method. The Bias for L1 and L2 was found -2.04 and -4.04 respectively. The six sigma was found 3.35 and 6.85 respectively for L1 and L2.The sigma metrices along with other quality indicators like %CV, Bias may have better impact on quality check of analytical performance in clinical laboratory.

KEYWORDS

six sigma, analytical errors, Bias, coefficient of variance, total allowable error

INTRODUCTION

For any analysis in clinical laboratory Quality control (QC) is important as it is appropriate for distinguishing the clinical interpretation.(1) The quality check of various serum analytes will determine the variation for clinical interpretation.(2) The analytical errors may be random or systematic which is denoted basically by inaccuracy and imprecision parameters. These parameters are represented by coefficient of variation (CV) and Bias.(3) Six sigma (σ) is a quality management tool to assay quality which combines bias, precision and total allowable error (TEa). Sigma level < 3 indicates poor performance whereas > 3 indicates good performance.(4)

Quality planning defines standards which helps in quality processes, quality control, quality assessment and quality improvement. Errors in clinical laboratory are mostly pre-analytical, analytical and post-analytical. The pre-analytical errors are maximum followed by post-analytical and analytical. Although analytical errors are the least, the room for improvement is still there.

The analytical errors may be random or systematic which is denoted basically by inaccuracy/bias and imprecision parameters. The difference between the average value obtained from a large series of result and true value is the bias. Precision may be defined as the closeness of agreement between independent results. Imprecision of measurement is solely related to random error of measurement. It is usually denoted by standard deviation (SD) and CV.(3,4,5)

Six sigma metrices a quality management tool combines bias, precision and TEa. Sigma level < 3 indicates poor performance whereas > 3 good performance. The aim of the study is to evaluate the analytical performance using six sigma matrices in clinical laboratory.

MATERIALS & METHODS

This retrospective study was conducted at the central laboratory of IQ City Medical College and Narayana Multispecialty Hospital, after obtaining prior permission from institutional human ethics commitee. The analyte glucose was tested to evaluate quality control. Hexokinase method was used to analyze glucose samples using the auto-analyzer Siemens Dimension. The two levels of QC (L1 and L2) were run daily. The internal QC data of the analyte was extracted from the record for month June 2016 from which the % CV was calculated. The % Bias was calculated from external peer group QC reports. The σ value was calculated using TEa (from CLIA), Bias and CV.

CV%, % Bias and σ value was calculated using following formula

$$CV\% = \frac{\text{Standard deviation}}{\text{Laboratory mean}} \times 100$$

$$\% \text{ Bias} = \frac{\text{Laboratory mean} - \text{Designated mean}}{\text{Designated mean}} \times 100$$

$$\sigma = \frac{\text{TEa} - \%\text{Bias}}{\%\text{CV}}$$

RESULT

The laboratory mean for quality control material (L1 level) was 87.7 with a SD of 2.08 and the same for L2 was 272.9 and 2.4 respectively. The CV % for L1 and L2 was found 2.37 and 0.87 % respectively. The designated mean (DM) was 89.53 and 284.4 for L1 and L2 respectively. The number of laboratory (peer group) participated for L1 were 98 utilizing same lot no. QC material, instrument and method. The number of laboratory (peer group) participated for L2 were 97 utilizing same lot no. QC material, same instrument and same method. The laboratory uses hexokinase method for glucose. The Bias for L1 and L2 was found -2.04 and -4.04 respectively. The total allowable error (TEa) for glucose as per CLIA is 10%. The six sigma was calculated and found 3.35 and 6.85 respectively for L1 and L2.(Table-1)

Table-1: Different quality indicators for glucose at the level of analytical performance

Levels of QC material	No. of lab. participated	Lab. mean	Lab. SD	Lab. CV%	Designated mean	Bias	TEa(CLIA)	sigma
L1	98	87.7	2.08	2.37	89.53	-2.04	10	3.35
L2	97	272.9	2.4	0.87	284.4	-4.04	10	6.85

DISCUSSION

The clinical laboratory usually uses CV% and different Westgard rules to check internal quality. The precision increases as CV% decreases and good precision is considered if CV% found to be ≤ 5%. The

imprecision will create low quality and high cost since it may require repeat testing. Other than precision there is Bias which creates quality issues. Six sigma metrices is a quality management tool to assay quality which combines bias, precision and TEa. In current study six sigma (for the parameter glucose) was found 3.35 and 6.85 respectively for L1 and L2. Singh et al[2] studies show six sigma levels more than 6 for few parameters (eg. Creatinine, triglyceride, amylase) whereas it was less than 3 for urea. Justice A et al[6] found sigma value less than 3 for all the parameters assessed (eg. Glucose, urea, creatinine, triglyceride). The study by Nanda et al[7] found six sigma value 3.2 for glucose. They found six sigma more than 6 for few parameters eg. Uric acid, total bilirubin, albumin, ALP etc. Similar study by Westgard et al [8] also found six sigma between 2.9-3.3 for glucose.

Achieving six sigma more than 6 is excellent. It reduces the false rejection and increases probability of error detection. The current study has been done for one parameter at two levels of QC material and for short period of 30 days. This kind of study will have still more impact if done for more parameters and for longer duration.

According to George G. Klee et al[9],"The application of six sigma principles and metrics is very valuable for all phases of the laboratory testing process. The core business of the laboratory is to produce accurate test results and, it makes sense to first apply six sigma to the analytical processes. This also is the easiest application, because there are tolerance limits in the form of acceptability criteria from peer comparison and proficiency testing programs, QC data available for estimating method precision, and peer data available for estimating method bias. Laboratories should next expand their efforts to the pre-analytical and post– analytical processes, knowing that their core process is producing the necessary analytical quality".

CONCLUSION

There are many quality indicators for analytical performances in clinical laboratory eg. %CV, Bias, Westgard rules etc. these all parameters are related to check precision or Bias. Six sigma metrices a quality management tool combines bias, precision and TEa. The sigma metrices along with other quality indicators like %CV, Bias may have better impact on quality check of analytical performance in clinical laboratory.

REFERENCES

1) Westgard JO, Barry PL. Beyond quality assurance: Committing to quality improvement. LabMed;1989;20:241-7.
2) Singh B, Goswami B, Gupta VK, Chawla R, Mallika V. Application of sigma metrices for the assessment of quality assurance in clinical biochemistry laboratory in India: A pilot study. Indian J Clin Biochem.2011:26:131-5
3) Topic E. Guidelines and recommendations for testing in diagnosis of diabetes mellitus: The role of HbA1c. Biochem Med(Zagreb) 2014;24:S1-S7
4) Westgad JO, Westgad SA. The quality of laboratory testing today: An assessment of sigma metrices for analytic quality using performance data from proficiency testing surveys and the CLIA criteria for acceptable performance. Am J Clin Pathol. 2006:125:343-54.
5) Carl AB, Edward RA, David EB. Teitz fundamentals of clinical chemistry. 6ed. Pg 206-7.
6) Justice A, Seth A, William KBA et al. application of sigma metrices for the assessment of quality control in clinical chemistry laboratory in Ghana: a pilot study. Niger Med J 2015 jan-feb;56(1):54-58.
7) Nanda SK, Lopamudra R, Quantitative application of sigma matrix in medical biohemistry, JCDR. 2013;Dec Vol-7(12):2689-2691.
8) James O. Westgard, Sten A. Westgard, MS. An Assessment of Metrics for Analytic Quality Using Performance Data From Proiciency Testing Surveys and the CLIA Criteria for Acceptable Performance. J Vet Diagn Invest. 2008; 20: 536–44
9) George GK, James O Westgard. Quality Management.In:Burtis AC,. Ashwood ER, Brurns DE, editors. Tietz Textbook of Clinical Chemistry and Molecular Diagnostics 5th edition: Philadelphia:Saunders;2012;163-204.