ISSN NO. 2320-5407

Journal homepage: http://www.journalijar.com

INTERNATIONAL JOURNAL OF ADVANCED RESEARCH

RESEARCH ARTICLE

Application of Sigma Metrics for the assessment of analytical quality in clinical biochemistry laboratories in Sudan: A Pilot Study

Alneil Abdallah Hamza, Abubakr Ibrahim Mohamed

Manuscript Info

Manuscript History:

Received: 15 September 2015
Final Accepted: 22 October 2015
Published Online: November 2015

Key words:

****Corresponding Author***

Alneil Abdallah Hamza

Abstract

Background: The ultimate goal of clinical laboratories in healthcare service is to provide accurate, precise, relevant and comprehensive data that can be applied to the medical management of patient. Therefore, the evaluation of laboratory performance is critical to maintaining accurate laboratory results. However, six sigma provide uniquely defined scale with which clinical laboratories performance can be assessed. This study aimed to evaluate the analytical quality in 10 clinical laboratories in Khartoum state using the sigma metrics application.

Materials and Methods: The six months (January to June 2012) internal quality control (IQC) and inter-laboratory peer comparison data for 10 clinical biochemistry laboratory was analyzed targeting glucose; urea and creatinine. For target parameters in each laboratory, Coefficient of variation (CV) was calculated from IQC, percentage bias was calculated from inter-laboratory peer comparison and total allowable error was followed as per Clinical Laboratory Improvement Amendment (CLIA). Sigma metrics were calculated from CV, percentage bias and total allowable error for target parameter in each laboratory.

Results: CVs were found to be < 5% for glucose, urea and creatinine in (9, 8, and 4) Out of 10 laboratories; respectively. For glucose test sigma value (>3) was attained by 2 out of 10 laboratories whereas all laboratories achieved unacceptable sigma values (<3) for urea and creatinine tests.

Conclusion: These study findings revealed that all the laboratories achieved unsatisfactory sigma values for targeted parameters. This demonstrates poor performance and low consistency of testing results. These laboratories need an appropriate interpretation of daily IQC data and develop prompt corrective and preventive actions to monitor the routine performance of the testing processes.

INTRODUCTION

Clinical laboratories are particularly important discipline among healthcare services, because physicians make their decisions mostly in accordance with laboratory results[1]. The term “quality control” (QC) has been introduced in the clinical laboratory setting many decades ago, and refers to the statistical quality control that is commonly used in laboratories to monitor the routine performance of testing processes, detect possible errors, and correct problems before test results are reported. The analytical quality still remains the primary issue, because none of the other laboratory quality characteristics matter unless analytical quality is achieved[2].

First of all, quality planning must be used to define quality standards which are the foundation for quality laboratory processes, quality control (QC), quality assessment (QA), and quality improvement[3]. New quality assessment (QA) systems such as Six Sigma have become more popular because they offer a different approach to problems in the clinical laboratory. The Six Sigma strategy measures the degree to which any process deviates from its goal. Any process can be evaluated in terms of a sigma metric that describes how many sigma fit within the tolerance limits[4]. However, six sigma is a widely-accepted quality management system, to eliminate or reduce all variation in a process. A process that achieves the goal of Six Sigma delivers both quality and efficiency. 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[5].

Materials and Methods

This hospital based study was conducted at 10 clinical biochemistry laboratories in Khartoum state from January to June 2012. All of the laboratories use semi-automated spectrophotometers for the specimens' analysis. Control materials were obtained from Biosystem Company, Barcelona Spain. Normal and pathological levels of QC materials were assayed before commencing patient samples every day. Internal statistical QC data were documented in hard copies on daily basis. Glucose, urea and creatinine normal QC data were extricated for a period of six months.

Statistical analysis

CV%: Coefficient of variations (CVs) is between day imprecision were calculated for each analyte from Biosystems internal QC.

Bias%: Bias is the systematic difference between the expected results obtained by the laboratory's test method and the results that obtained from an accepted reference method. The reference may be consensus reference like proficiency program or an inter-laboratory peer comparison program. Percentage bias for the analytes was calculated from Khartoum state inter-laboratory peer comparison program.

Total allowable error: Laboratory quality specifications are often defined in terms of allowable total errors limits (TEa). If the difference between true concentration of an analyte and the reported concentration in patient's specimens exceeds TEa, the result considered to be unreliable. Total allowable error was followed as per Clinical Laboratory Improvement Amendments (CLIA) guidelines.

Sigma metrics: for the various analytes sigma values were calculated from CVs, percentage bias and total allowable error by the following formula:

Sigma = (TEa % – Bias %) /CV%

Results

Table 1 illustrates the six months calculated average values of coefficient of variation (CVs) for normal quality control run in 10 laboratories for different parameter. The CV% was found to be < 5% for glucose, urea and creatinine tests, in (9, 8, and 4) out of 10 laboratories respectively.

Table 2 demonstrates the results of percentage bias which was calculated from Khartoum state inter-laboratory peer comparison program from January to June 2012for the different parameters and the average was calculated. For

glucose, urea and creatinine average bias was <3 in (1, 1, and 0 lab), whereas (3, 6, and 1 lab) laboratories had bias percentage between 3.1-6 and bias percentage was observed > 6 in (6, 3 and 8 lab) out of 10 laboratories respectively.

Table 3 highlights that for glucose test, sigma values > 3 were observed in only 2 out of 10 laboratories whereas 8 laboratories achieved sigma metric range 0.5-2.6. For urea and creatinine tests all the laboratories achieved sigma values range (0.4-2.6) and (0.2-2.2) respectively. Figure 1 depicts the numbers of laboratories and achieved sigma values for glucose, urea and creatinine.

Discussion

Quality in clinical laboratory has huge impact on diagnosis and patients management[6]. Therefore a good laboratory practice require that laboratories design their quality control procedure (QC) to assure that reported patient results meet the quality required for intended use[7]. In this study we used coefficient of variation (CV) to describe the variation of a test and general perception about the performance of testing methods. The CVs expresses the variation as a percentage of the mean and 5% or less generally denote a good method performance whereas CVs of 10% and higher implies unsatisfactory performance[8]. Our study results show that normal QC CVs% were range (1.8-5.3), (2.2-5.7) and (5.1%- 7.5%) for glucose, urea and creatinine tests respectively. Out of 10 laboratories, high CVs >5% was achieved by (1, 2, and 6) laboratories for glucose, urea and creatinine tests respectively. These findings reflect that the analytical process stable for glucose and urea testing in most of the laboratory whereas most of the laboratories presented unstable analytical process with wide fluctuation around the true concentration for creatinine testing.

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 worl[9]. In industries outside of healthcare, 3 Sigma is considered the minimal acceptable performance for a process. In contrast to other industries, healthcare and clinical laboratories appear to be operating in a 2 to 3 Sigma environment[10]. the sigma metrics is based on the statistical concept, laboratory error can be reduced by maintaining 6 standard deviations between the parameter average and it upper and lower limits[7].

In the present study the 10 laboratories performance achieved sigma values range (0.5-3.2) for glucose test with observations that 7 laboratories achieved sigma values of <2. This result to some extent similar to the results that reported previously by James O Westgard et al., that sigma value for glucose found to be between 2.9-3.3[10] whereas Afrifa et al., reported sigma values < 2 for glucose test[11].

In our study, for urea test 9 out of 10 laboratories achieved sigma values of <2 with observed range (0.4-2.6). This result was similar to the findings Afrifa et al., reported sigma values of < 2 for urea test[11] whereas Bhawna Singh et al., reported sigma values of <3 for both levels of QC was observed for urea test[12]. The study result show that 8 out 10 laboratories achieved sigma values of <2 with observed range (0.2-2.1) for creatinine test. This result was similar to the finding that reported by Afrifa et al., that sigma values for creatinine test were < 2, [11] and was not similar to the finding that reported by Bhawna Singh et al., that creatinine depicted a sigma value of > 6[12].

Conclusion

The assessment of laboratories performance on sigma scale demonstrated wide variation in the sigma values for the three biochemical parameters. These laboratories need to evaluate their methods with comprehensive revision of the QC strategy and strictly follow Westgard multi rules as well as increase of QC runs so as to minimize this variation.

Reference

1. Forsman RW. Why is the laboratory an afterthought for managed care organizations? *Clin Chem*1996; 42:813-6.
2. Westagard JO. Internal quality control: planning and implementation strategies: Ann Clin Biochem 2003; 40:593-611.
3. Westgard JO, Barry PL. Beyond quality assurance: committing to quality improvement. Lab Med. 1989;20:241–7.
4. Coskun A. The reliability of calculated laboratory tests. Clin Chem Lab Med 2005; 43:880–2.
5. Coskun A. Six Sigma and laboratory consultation. Clin Chem Lab Med 2007; 45:121–3.
6. Agarwal, R., Chaturvedi, S., Chhillar, N., Goyal, R., Pant, I. and Tripathi, C.B. (2012) Role of Intervention on Laboratory Performance: Evaluation of Quality Indicators in a Tertiary Care Hospital. *Indian Journal of Clinical Biochemistry*, **27**, 61-68. http://dx.doi.org/10.1007/s12291-011-0182-7.
7. Sunil KN, Lopamudra R. Quantitative Application of Sigma Metrics in Medical Biochemistry Journal of Clinical and Diagnostic Research. 2013 Dec, Vol-7(12): 2689-2691.
8. Westgard JO, Klee GG. Quality management. In: Burtis CA, Ashwood ER, Bruns DE, editors. Tietz textbook of clinical chemistry. 4th ed. Philadelphia: Saunders; 2006.
9. Nevalainen D, Berte L, Kraft C, Leigh E, Picaso L, Morgan T.Evaluating laboratory performance on quality indicators with six sigma scale. Arch Pathol Lab Med. 2000; 124(4):516–9.
10. James O. Westgard, 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. J Vet Diagn Invest. 2008; 20: 536–44.
11. Afrifa, et al. Application of sigma metrics for the assessment of quality control in clinical chemistry laboratory in Ghana: A pilot study. Nigerian Medical Journal | Vol. 56 | Issue 1 | January-February | 2015.
12. Bhawna S, Binita G,Vinod KG, Ranjna C,Venkatesan M. 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.

Table 1 Coefficient of variation average calculated from six months normal IQC

Labs	Glucose	Urea	Creatinine
Lab1	2.4	2.8	4.1
Lab2	2.2	2.3	5.1
Lab3	1.8	2.2	4.8
Lab4	4.6	4.7	5.9
Lab5	3.8	5.7	4.8
Lab6	4.6	4.3	5.1
Lab7	2.9	3.4	4.6
Lab8	2.4	4.3	6.1
Lab9	2.6	3.1	7.3
Lab10	5.3	5.1	7.5

Table 2 Bias% average calculated from inter-laboratory comparison program

Labs	Glucose	Urea	Creatinine
Lab1	2.4	4	9.8
Lab2	3.3	2.9	4.6
Lab3	5.4	5.2	11.4
Lab4	7.5	5.3	11.1
Lab5	8	6.6	4.3
Lab6	3.6	5	8.2
Lab7	6.7	4.8	11.1
Lab8	6.1	4.6	13.6
Lab9	6.6	6.4	11.1
Lab10	7.2	7.2	9.6

Table 3 Sigma values achieved by each laboratory for the analytes

Labs	Glucose	Urea	Creatinine
Lab1	3.2	1.8	1.3
Lab2	3.0	2.6	2.1
Lab3	2.6	1.8	0.7
Lab4	0.5	0.8	0.7
Lab5	0.5	0.4	2.2
Lab6	1.4	0.9	1.3
Lab7	1.1	1.2	0.8
Lab8	1.6	1.0	0.2
Lab9	1.3	0.8	0.5
Lab10	0.5	0.4	0.7

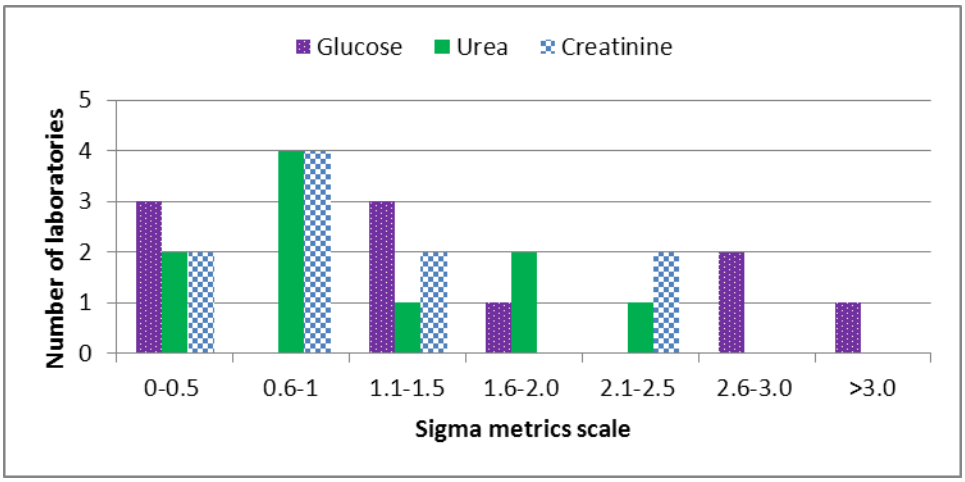

Figure 1 number of laboratories and achieved sigma values