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RESEARCH ARTICLE

SIGMA METRICS AS A QUALITY MARKER FOR ANALYZING ELECTROLYTES IN LABORATORY

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Abstract

Quality assurance is now basic need in all sectors including laboratory services. Six sigma is an evolution in quality management that is being widely implemented in business and industry in the new millennium. So, looking at the revolution made by six sigma in business world, can we apply in health care sectors? Six sigma provides a general methodology to describe performance on sigma scale. We tried to see whether we could scale certain parameters like electrolytes on six sigma metrics or not. Laboratory mean, standard deviation and coefficient of variation were calculated for Sodium and Potassium retrospectively over a period of 9 months from September 2012 to May 2013. Sigma was calculated for different levels of internal QC. For six sigma allowable total errors were taken from three different guidelines. And we observed that there was a wide variation in sigma metrics according to different guidelines. Still, upgraded machines, other methods and biological variations may have impact on sigma level.

Introduction

Quality is meeting the predetermined requirements to the satisfaction of the users for a particular substance or a service. Quality assurance is sum of total of all activities that are undertaken to ensure generation of reliable and accurate results or data. Quality control is study of those sources of variation which are the responsibility of the laboratory, and of the procedures used to recognize and minimize them, including all sources of variation (such as random variation and bias) which arise within the laboratory between the receipt of the specimen and the dispatch of the report [1]. 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.

Sigma (σ) is the mathematical symbol for standard deviation [2]. Six Sigma metrics, which is an evolution in quality management that is being widely implemented in business and industry in the new millennium, is being adopted as the universal measure of quality to be applied to their processes, and also provides a more quantitative framework for evaluating process performance and more objective evidence for process improvement [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.

We know that certain parameters like electrolytes with narrow biological variation have stringent rules for quality control. While parameters like triglyceride having wide biological variation can have good quality control by whatever method we use to estimate them [4].We analyzed internal QC data for imprecision and EQAS data for inaccuracy of Sodium and Potassium for 9 months from September 2012 to May 2013. Sigma was calculated from these data by applying allowable total error (TEa) from different guidelines.

Material and Methods

We analyzed internal QC data in the biochemistry laboratory, part of central diagnostic laboratory of Shri Krishna hospital, Karamsad. Our clinical biochemistry laboratory provides service to 500 bedded tertiary care hospital and it is NABL accredited laboratory. Internal quality control (IQC) data of sodium and potassium was analyzed retrospectively over a period of 9 months from September 2012 to May 2013 for three different analyzers, two arterial blood gas analyzers Rapidlab 348 from Siemens Diagnostic and one electrolyte analyser AVL 9180 from Roche Diagnostics. These analyzers estimate electrolytes by Direct ISE (ion selective electrode) method. Laboratory mean, standard deviation (SD) and coefficient of variation (CV) were calculated for Sodium and Potassium for three different levels in ABG analyzers and two levels in AVL analyzer. Internal quality control material was purchased from Bio-Rad Laboratories, Irvine CA 92618 USA for ABG analyzers and from RANDOX HUM-ASY for AVL analyzer.

Sigma was calculated for different levels of internal QC using Bias, Coefficient of variance and Allowable total error (TEa).

Sigma was calculated by following formula. $\sum (\sigma) = [(TEa\ \% - bias\ \%) / CV\ \%]$.

Average Coefficient of variances of all months was taken and average bias (derived from proficiency testing) was taken to calculate sigma. CV% was determined from the calculated laboratory mean and calculated standard deviation procured from the internal QC data over the last 9 months:

CV% = (Standard deviation X 100) / Laboratory Mean

Bias was calculated from EQAS (external quality assurance scheme) data. We have joined EQAS programme of Bio-Rad Laboratories.

%Bias: {(mean of all labs using same instrument and method – our mean) ÷ mean of all labs using same instrument and method} X 100

Allowable total error (TEa) was taken from RCPA (Royal College of Pathologists of Australasia), CLIA (Clinical Laboratories Improvement Amendment) and Rilibak guidelines and comparison was done. Allowable total error (TEa) refers to the degree of change that needs to be detected in an analyte for a clinically important decision to be made with regard to further investigation or treatment [3.] An allowable total error encompasses the imprecision and bias of a single test measurement; thus, it fits the desired form of a tolerance limit [5]. TEa was 2.2% for Sodium and 4.4% for Potassium by RCPA guidelines [6], and was 2.85% for sodium and 12% for potassium by CLIA guidelines [7]. While in Rilibak guidelines, TEa was 4.5% for potassium ranging from 2 to 8mmol/L and was 3% for sodium ranging from 110 to 180mmol/L [8].

Results

Average Coefficient of variance of sodium was 1.05, 1.02 and 0.64 for Rapidlab 348 (1), Rapidlab 348 (2) and AVL 9180 analyzer respectively. And average CV for potassium was 3.57, 2.79 and 1.57 for Rapidlab 348 (1), Rapidlab 348 (2) and AVL 9180 analyzer respectively. The coefficients of variances which we obtained were within the acceptance criteria of CLIA'88 guidelines. The CV included in our scope of NABL is 5.0 for sodium and 5.5 for potassium. Table 1 shows average CV% of different levels of QC for 9 months and their average.

Bias was calculated from data of external quality assurance program provided by Bio-Rad for the months of September 2012 to May 2013 for the parameters sodium and potassium and their average was calculated. For sodium, average bias was less than 2 in all the three analyzers whereas for potassium, it was more than 2 in Rapidlab 348 (2) and AVL 9180 analyzer but less than 2 for another Rapidlab 348 (1). These results were because potassium bias was more in month of February for Rapidlab 348 (1) and was more in January for AVL 9180. Outliers were excluded from calculation.

Six sigma metrics was calculated by taking the average coefficient of variance of 9 months, average bias from EQAS and allowable total error by RCPA, CLIA and Rilibak.

Table 1: CV % of sodium and potassium for each month and its average.

COEFFICIENT OF VARIANCE (CV %)						
MONTHS	RAPIDLAB 348 (1)		RAPIDLAB 348 (2)		AVL 9180	
	SODIUM	*POTASSIUM*	*SODIUM*	*POTASSIUM*	*SODIUM*	*POTASSIUM*
SEP'12	0.77	3.91	0.70	4.74	0.69	1.27
OCT'12	0.91	3.08	0.96	2.19	0.64	1.63
NOV'12	0.62	3.23	1.13	1.13	0.65	1.42
DEC'12	0.90	2.36	0.92	3.84	0.61	1.00
JAN'13	1.62	3.86	0.70	1.47	0.59	1.86
FEB'13	1.21	4.28	0.90	3.29	0.62	1.69
MAR'13	1.22	4.30	1.30	3.84	0.63	1.54
APR'13	1.00	3.86	1.15	2.10	0.61	1.86
MAY'13	1.15	3.20	1.41	2.47	0.72	1.90
AVERAGE CV	**1.05**	**3.57**	**1.02**	**2.79**	**0.64**	**1.57**

Table 2: Average bias % (calculated from Bio-Rad EQAS) for sodium and potassium of 9 months.

NAME OF ANALYZER	AVERAGE BIAS (%)	
	SODIUM	***POTASSIUM***
Rapidlab 348 (1)	1.62	1.62
Rapidlab 348 (2)	1.05	3.10
AVL 9180	0.94	2.47

Table 3: Six sigma metrics (σ) of sodium and potassium by 3 different guidelines for TEa.

SIX SIGMA (σ) FOR SODIUM			
	Rapidlab 348 (1)	Rapidlab 348 (2)	AVL 9180
RCPA	1.09	0.56	1.96
CLIA	1.71	1.20	2.98
Rilibak	1.85	1.35	3.21

SIX SIGMA (σ) FOR POTASSIUM			
	Rapidlab 348 (1)	Rapidlab 348 (2)	AVL 9180
RCPA	0.36	0.99	1.22
CLIA	2.49	3.72	6.0
Rilibak	0.39	1.03	1.29

RCPA – Royal College of Pathologists of Australasia, CLIA – Clinical Laboratories Improvement Amendments

Discussion

Creating a quality system for the analytical process is complex. Maintaining quality system that is relevant for the analytical process is critical to cost effective operations. Living a quality system that is relevant to the analytical process is essential for good patient care.QC materials are used for monitoring the performance of analytical methods. When we apply any criteria (including Westgard rules) for acceptability of control data, determination of probability for rejection is paramount importance [9].

The proficiency testing error rate reported for the first year after CLIA'88 took effect in 1994 showed that satisfactory rates in hospital and independent

laboratories was 97%, or a defect rate equivalent to 3.4 Sigma [10]. The calculated results of six sigma metrics of both the parameters by all three guidelines are shown in the table 3. Sodium gave best result by Rilibak while potassium gave good results by CLIA. Both sodium and potassium had worst six sigma metrics by RCPA. So, six sigma metrics also depends on allowable total errors given by different guidelines.

Different parameters have different biological variation. High biological variation parameter such as triglyceride measured by any instrument will give acceptable sigma level. While electrolytes like sodium and potassium which are having low biological variation would give low results even if we perform well in our internal quality control.

Parameters can get affected by many other factors. Stored vials of control material can have changes related to environmental factors. Different sensor systems react differently toward various matrices of quality-control materials. Differences in performance between instruments can therefore be judged best from split patient-sample comparison [11.] Also machines with higher technologies like Abbott ARCHITECT ICT (Integrated Chip Technology) Electrolyte System have shown to have improved sigma value by obtaining better CV% [12].

Bias calculated by the manufactures is based on standard reference material while laboratories do it from proficiency testing. So such differences in standards given by companies and our routine outcomes in bias, CV and also difference in allowable total error, which depends on criteria we choose, causes change in six sigma level.

Conclusion

We can say that 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.

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