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# Sigma Metrics of Electrolytes – A Pilot Study

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**Abstract**

Background: *Six sigma is a process quality measurement and improvement program used in industries. Sigma methodology can be applied wherever an outcome of a process is be measured. Six sigma provides a more quantitative frame work for evaluating process performance with evidence for process improvement and describes how many sigma fit within the tolerance limits. Sigma metrics can be used effectively in laboratory services.*

Objectives: *The present study was undertaken to evaluate the quality of the analytical performance of electrolyte analyzer by calculating sigma metrics by different guidelines. Z score was calculated to assess the functioning of the analyzer.*

Methodology: *The study was conducted in the clinical biochemistry laboratory of Karwar Institute of Medical Sciences, Karwar. Sigma metrics of electrolytes was calculated. Z scores for all the three parameters were calculated.*

Results and interpretation: *We have sigma values <3 for sodium,potassium and chloride with CLIA and RILIBAK guidelines. With RCPA sigma for chloride was more than 3. Sigma value was highest when calculated using RCPA guidelines.Our Z scores were excellent as score for sodium was between 0-minus 1,that for potassium and chloride were between 0 and plus 1.*

Conclusion: *Sigma metrics helps to assess analytical methodologies and augment laboratory performance. It acts as a guide for planning quality control strategy. It can be a self -assessment tool regarding the functioning of clinical laboratory.*

**Key words***: sigma, z score, electrolytes*

## 1. INTRODUCTION

Accurate test results are very important in healthcare system since physician's decisions mostly rely on the laboratory results. The evaluation of laboratory performance is critical to maintain accurate laboratory results. Six sigma is the latest version of Total Quality Management. It is Quantitative goal for process performance.

The Sigma scale is easily interpreted and appreciated by laboratories. Sigma values can be calculated for both qualitative and quantitative assays. The Sigma scale provides guidelines for assay improvement and monitoring.

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) [1-3]. These steps are universal and could be applied to all sectors of industry, business, and healthcare. The sigma value indicates how often errors are likely to occur; the higher the sigma value, the less likely it is that the laboratory reports defects or false test results.

There are a few studies done on sigma metrics of electrolytes in laboratory medicine [4-6].There are hardly any studies which report sigma value of more than three for electrolytes.

Aim of our study was to

- Study sigma metrics of electrolytes by using CLIA,RCPA and RILIBAK so as to assess the functioning of electrolyte analyzer
- Calculate the total allowable error in our laboratory and compare it with that with other guidelines, thereby evaluate the functioning of the instrument as well as adequacy of the methodology being followed.
- Calculate z score of the analytes to assess the functioning of the analyzer

## 2. MATERIALS AND METHODOLOGY

The study was conducted in the clinical biochemistry laboratory of Karwar Institute of Medical Sciences, Karwar. This is a 400 bedded ,tertiary care center in which department of biochemistry was newly established. Aim of our study was to analyze sigma metrics of electrolytes so as to assess the functioning of electrolyte analyzer.

The study protocol was approved by institutional human ethics committee.

Internal quality control (IQC) data of electrolytes were analyzed retrospectively over a period of 2 months July 2015 and August 2015 with Roche electrolyte analyzer that works on the principle of Ion selective electrodes. Pathological (L2) levels of QC materials were assayed before commencing reporting of patient samples every day. Sigma value was calculated with the following formulas;

### 2.1. Total Allowable Error

It is the total allowable difference from accepted reference value seen in the deviation of single measurement from the target value. $TE_a$ values of various parameters were taken from Clinical Laboratories Improvement Act(CLIA) guidelines [7],RCPA [8] and RILIBAK [9] guidelines.

### 2.2. Bias

Bias is the systematic difference between the expected results obtained by the laboratory's test method and the results that would be obtained from an accepted reference method. Bias was derived as follows;

$$\text{Bias (\%)} = \frac{\text{Mean of all laboratories using same instrument and method} - \text{our mean}}{\text{mean of all laboratories using same instrument and method}} X100$$

CV% is the analytical coefficient of variation of the test method. Coefficient of variance (CV) was calculated as follows.

$$CV\% = \frac{Standard\ deviation}{Laboratory\ Mean} X\ 100$$

Sigma metrics were calculated from CV, percentage bias and total allowable error for the parameters by the following formula:

$\Sigma\ (\sigma) = (TE_a - \text{bias}) / CV\%$ [$TE_a$ - total allowable error ,CV% - Coefficient of variance]

$TE_a$ observed in our assay was calculated using the formula,

$TE_{a\ observed} = \text{bias} + \%CV \times 2$

Thus observed $TE_a$ is compared with that obtained by different guidelines.

**Z score** was calculated for all the three parameters. Z score is calculated value that tells how many standard deviations a control is from the mean expected. It is calculated using the below formula;

Z score = (mean of reference method - obtained mean)/ standard deviation

It is ideal at 0, excellent between 0-1, acceptable between 1-2, not acceptable when exceeds 3. Statistical analysis was by descriptive statistics.

## 3. RESULTS

The calculated parameters like mean, standard deviation, , bias, z score, total allowable error, coefficient of variation and sigma values are presented in the following three tables (Table 1-3).

**Table1.** *Showing calculated parameters in the laboratory*

| | Mean | Standard deviation | %CV | Z score | Bias |
|---|---|---|---|---|---|
| **Sodium** | 144.67 | 4.65 | 3.2 | -0.178 | 0.57 |
| **Potassium** | 6.88 | 0.42 | 6.13 | 0.355 | 2.22 |
| **Chloride** | 114 | 1.41 | 1.2 | 0.99 | 1.24 |

**Table2.** *Total allowable error by different guidelines*

| | CLIA | RCPA | RILIBAK | Observed TEa |
|---|---|---|---|---|
| **Sodium** | 2.85 | 5 | 2 | 6.97 |
| **Potassium** | 12 | 8 | 5 | 14.46 |
| **Chloride** | 5 | 8 | 3 | 3.64 |

**Table3.** *Sigma values as per different guidelines*

| | SIGMA CLIA | SIGMA RCPA | SIGMA RILIBAK |
|---|---|---|---|
| Sodium | 0.71 | 1.38 | 0.45 |
| Potassium | 1.6 | 0.94 | 0.45 |
| Chloride | 3.13 | 5.68 | 1.47 |

## 4. DISCUSSION

Z score obtained in our study are between 0-1 for potassium and chloride,between 0-minus 1 for sodium (table 1). Ideal z score is 0 which is difficult to achieve. Our results are excellent as far as z scores are concerned.

We have obtained 0.57% decrease in the mean for sodium as compared to the reference value whereas potassium and chloride means are elevated by 2.18% and 1.2% respectively as compared to reference values (table 1).

Percentage bias was less than 3 for all the three parameters (table 1).

The CV expresses the variation as a percentage of the mean [1]. In the laboratory functions, the CV is preferred mode of variance determination when the SD increases in proportion to concentration. The CV also provides a general perception about the performance of a method. CVs of 5% or less generally denotes a good method performance, whereas CVs of 10% and higher implies unsatisfactory performance. We have obtained CV less than 5 for sodium and chloride whereas less than 10 for potassium (table 1).

Total allowable error(TEa) values vary in different guidelines. As per rules, observed TEa must be lesser than that by guidelines or close to it. However our TEa is greater than that by taken guidelines for sodium and potassium suggesting a need to re-evaluate methodology and instrument (table 2). But there are several guidelines which have higher TEa[10] which implies that we cannot conclude just based on TEa.

TEa is less for electrolytes suggesting the criticality of the analytes and also it suggests a stringent quality control.As sigma depends on TEa, its value also varies.

In our study, sigma value for both sodium and potassium are less than 3 as per all the three guidelines. Only chloride has sigma value in acceptable range (table 3). The reason for this being calculation of sigma based on TEa which is different in different guidelines. Sigma calculated by using RCPA guidelines is highest whereas that with RILIBAK is lowest for all the parameters.

The parameters which demonstrated wide variation in the sigma values for both the levels of QC should be evaluated with discretion. The methodology should be re -evaluated. There is also a need to strictly follow Westgaurd multi rules as well as increase the number of QC runs so as to abolish this discrepancy. It is of utmost important to practice stringent maintenance of ISE unit to alleviate inaccuracies resulting in poor performance of ISE module.

The practice of correlating the results with clinical features and results of other related analytes will aid to overcome the limitations that we have confronted during the interpretation of QC and

corresponding sigma metrics. We also propose the custom of critical appraisal of the sigma values of all the parameters on a regular basis to achieve exceptional quality.

QC materials are used for monitoring the performance of analytical methods. When applying any criteria (including Westgard rules) for acceptability of control data, determination of probability for rejection is paramount importance [11]. The term probability of false rejection ($P_{fr}$) is used signifies a situation where there are no analytical errors present except for the inherent imprecision or random error of the method. Probability of error detection ($P_{ed}$) is the term used to describe where an analytical error occurs in addition to the inherent random error. It has been observed that a high probability of error detection and a low probability of false rejection are desirable[12].

There is another school of thought which opines that sigma value for a particular parameter also depends on its biological variation. For example, 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.

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 criteria we choose, causes change in six sigma level.

The main limitation in our work is the lack of knowledge about the corresponding $P_{fr}$ and $P_{ed}$ for the analytes due to lack of appropriate software as a result of financial constraints.

## 5. CONCLUSION

To conclude, 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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Conflicts of interest - NIL

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