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Sigma metrics of thyroid hormones

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Abstract
Introduction: Six sigma is a process used for quality measurement and improvement in industries. Sigma methodology can be used whenever an outcome of a process has to be measured. Sigma metrics can be used effectively in laboratory services. The objectives of the present study were to evaluate the quality of the analytical performance of hormone analyzer by calculating sigma metrics and to calculate Z score 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 thyroid hormones was calculated. Z scores for all the three parameters were calculated.
Results: We have sigma values > 3 for T3 and TSH. Sigma was <3 for T4.Our Z scores were excellent for T3 and TSH as it was between 0 and 1.It was acceptable for T4 as it was between 1 and 2.
Conclusion: Our methodologies for thyroid hormones need a re-evaluation so as to improve the quality. 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.

Keywords: sigma, z score, thyroid hormones

Introduction

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.

Physician's decisions mostly depend on the laboratory result which necessitates an accurate test results in healthcare system. Laboratory performance needs a detailed evaluation so as 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 can be easily interpreted and applicable to assess laboratory performance. Sigma values can be calculated for both qualitative and quantitative assays. The Sigma scale guides assay improvement and monitoring. 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.

All laboratory procedures are prone to errors because in many tests, the rate of human intervention is higher. It appears that the best solution for analyzing problems in clinical laboratories is the application of Six Sigma methodology.

There are a few studies done to the best of our knowledge on sigma metrics of thyroid hormones in laboratory medicine.

Aim of our study was to

- Study sigma metrics of thyroid hormones
- Calculate z score of the analytes to assess the functioning of the analyzer

Materials and Methodology

Study design

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 thyroid hormones so as to assess the functioning of hormone analyzer that works on the principle of chemiluminescence. We also aimed to calculate z-scores.

The study protocol was approved by institutional human ethics committee. Internal quality control data of thyroid hormones, T3, T4 and TSH were analyzed retrospectively over a period of 6 months in 2015 with Maglumi hormone analyzer that works on the principle of chemiluminescence. Sigma value was calculated with the following formulas;

Total Allowable Error

It is the total allowable difference from accepted reference value seen in the deviation of single measurement from the target value. The most recent and extensive listing of biologic goals has been provided by Ricos *et al*., [4] which is taken as reference value. These values are in accordance with CLIA guidelines.

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;

$$\text{Bias (\%)} = \frac{\text{Mean of all laboratories using same instrument and method} - \text{our mean}}{\text{Mean of all laboratories}} \times 100$$

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

$$CV\% = \frac{Standard\ deviatio}{Laboratory\ Mean} \times 100$$

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

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

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;

$$Z\ score = \frac{mean\ of\ reference\ method - obtained\ mean}{Standard\ deviation} \times 100$$

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

Results

Low SD and CV values are obtained for T3 and TSH whereas high values for T4.We have sigma values > 3 for T3 and TSH. Sigma was <3 for T4.These values are represented in Table 1.Our Z scores were excellent for T3 and TSH as it was between 0 and 1.It was acceptable for T4 as it was between 1 and 2. These are represented in Table 2.

Table 1: Sigma metrics for thyroid hormones\

Hormones	Observed mean	Reference mean	Standard deviation	Coefficient of variation	Bias	Sigma
T3	5.6	5.72	0.204	3.6	2.09	3.01
T4	98.528	129.67	17.124	17.38	24.02	0.979
TSH	3.089	3.32	0.291	9.4	6.96	3.32

Table 2: z scores for thyroid analysis

Grading	Range	Hormones		
		T3	T4	TSH
Excellent	0-1	0.59		0.79
Acceptable	1-2		1.82	
Not acceptable	>3			

Discussion

We have analyzed internal quality control for thyroid hormones over a period of 6 months (July – December 2015) and assessed for sigma metrics. There is a scarcity of literature on sigma metrics of hormones. We have done similar studies that is sigma metrics of analytes with chemistry analyzer and electrolytes with electrolyte analyzer in our laboratory [5, 6].

To calculate sigma, we have calculated mean, standard deviation (SD), coefficient of variation (CV) and bias.

SD quantifies the closeness of numerical values in relation to each other. Since SD increases as the concentration of analyte increases, CV can be regarded as statistical analyzer. Since CV is the ratio of two, it cancels that effect. CV is therefore standardization of the SD that allows comparison of variability estimates regardless of analytes concentration.CV is dimensionless and does not vary with changes in measurement units.

We have obtained higher CV for T4 whereas lower CV for T3 and TSH.As CV is correlated to precision. Lesser the CV, better is the precision. This suggests that precision is high for T3 and TSH.

Bias is the difference between the measured value and actual value. It is used to describe the inaccuracy of the method. Lower the bias more is the accuracy. In our study we have obtained low bias values for T3 and TSH. This suggests that the methods for measurement of above mentioned analytes are accurate. But high bias value for T4 suggests that its measurement method needs an evaluation.

The Six Sigma scale ranges from zero to six, but a process can actually exceed Six Sigma, if variability is sufficiently low as to decrease the defect rate. In industries, 3 Sigma is considered to be the minimal acceptable performance for a process. When performance falls below 3 Sigma, the process is considered to be essentially unstable and unacceptable [7]. We have sigma values <3 for T4 whereas just above 3 for T3 and TSH. It implies that procedures for T3 and TSH are in minimal acceptable standards whereas that for T4 needs a serious evaluation.

Based on z-scores, our results are excellent for T3 and TSH, acceptable for T4.But this is not sufficient in health care sector as a single error may take a life. We need to achieve good results with regard to sigma metrics.

For less than 3 sigma that is for T4 method performance must be improved before the method can be used for routine production [8]. Sigma below 3 calls for improvement in the method as quality of the test cannot be assured even after repeated QC runs [9]. A very strict internal QC has to be followed for these parameters, and the frequency of internal QC should be increased and corrective action should be taken for these parameters. Upgraded analyzers and better methodologies may help in achieving sigma values.

Thus sigma metrics values are useful in setting the internal QC acceptability criteria. For a 3 sigma process, use a multi rule procedure with number of QC of 6 or 8 have to be used. For a 4 sigma process, use 2.5 SD control, limits or a multi rule procedure with n=4 have to be used. For a 5 sigma process, use 3.0 SD control limits with n=2 have to be used. For a 6 sigma process (or higher), use 3.5 SD control limits with N (number of controls to be run per day) =2 have to be used. That is QC should be run at higher frequency need to be run for analytes attaining sigma between 4-5 and 3-4 respectively.

Functioning at the 3-sigma level is regarded as the minimum acceptable level of quality. The six sigma idea asserts an association between the numbers of product defects, wasted operating costs and levels of customer satisfaction. It can be inferred that as sigma increases, the consistency and steadiness of the test improves, thereby reducing the operating costs. As sigma increases, the consistency,

reliability, steadiness and overall performance of the test improves, thereby decreasing the operating costs [10].

Consider testing specimens in duplicate. Total quality management works on plan, do, check and act rules whereas sigma metrics works on define, measure, analyze, improve, control.

When process performance is validated against Westgard rules or any other quality criteria for acceptability of control data, probability for rejection and probability of error detection are of paramount importance [11].

Conclusion

Our methodologies for thyroid hormones need a re-evaluation so as to improve the quality. 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.

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