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Application of Sigma Metrics for Quality Improvement in OGH Laboratory's Analytical Chemistry

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Abstract: ***This study explores the application of sigma metrics as a tool for improving quality in the OGH laboratory's analytical chemistry processes. The research uses IQC EQC data from Aug 2021 to Dec 2021, and the results show significant improvements in certain areas, with Uric acid and ALP showing world class quality results. The study concludes with recommendations for more stringent application of Westgard rules for analytes with σ<3.***

Keywords: Sigma metrics, Quality improvement, Analytical chemistry, West gard rules

1. Introduction

Clinical judgements about patients rely on clinical laboratory results. In order to obtain the most precise and consistent test findings, clinical laboratories should assess process performance and reduce laboratory mistakes. [1]. Laboratories should evaluate their process performance according to scientifically accepted quality criteria. This assessment includes the percentage of sample errors and rejections in the pre-analytical phase, the accuracy and precision measurement of test results in the analytical phase, and critical values reporting and test turnaround times in the post-analytic phase [2]. Clinical laboratories approve the validity of the analysis process according to quality control procedures for each analyte. Quality control consists of internal quality control (IQC) and external quality control (EQC) measures. IQC generally employs 2 or 3 levels of clinical decision points and daily IQC results are interpreted using control charts, such as the Levy-Jennings and Westgard rules. EQC samples are provided to clinical chemistry laboratories by an external agency once a month for use in analyzing and reporting [1].

Errors in the analytical process include both systematic and random errors, both of which have fundamental characteristics like imprecision and correctness. Bias and coefficient of variation (CV), respectively, are the terms used to express these characteristics. Bias and CV for each test can be used to determine total error (TE) (TE=Bias+1.65CV) [3]. Reports like the US Clinical Laboratory Implementation Amendments of 1988 (CLIA'88) and the German RiliBK give a measure known as the acceptable total error (TEa) [4, 5]. Evaluation of the process performance of a clinical laboratory is essential for comparison with laboratories around the world and to ensure high quality standards. During the analytical phase, variables can be assessed according to quality control and calibration procedures [6]. Analytical process performance can be evaluated using process sigma levels, quality indicators, and patient test results [7]. Six Sigma is a quality management method that integrates accurate and precision evaluation, error identification, and process improvement. The Six Sigma method has been used in hospital quality management since 1999 [8]. The universal application steps are to define, measure, analyze, develop, and control. The sigma value can be calculated by laboratories using the TEa and bias and CV % levels [sigma= (TEa %-bias %) /CV %]. A higher sigma level reflects greater consistency and stability of laboratory tests. A low sigma value indicates poor quality, defined as defects per million opportunities (DPMO).

2. Significance

The significance of this study lies in its potential to enhance the quality of analytical processes in the OGH laboratory, thereby improving the accuracy and reliability of test results. This could have far reaching implications for patient care and treatment outcomes.

Aim: To estimate the sigma metrics of OGH laboratory.

3. Materials & Methods

IQC & EQC data from Aug 2021 to Dec 2021 taken and Calculated 6σ by using the below formula.

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

TEa (Total Error allowable) values were taken according to CLIA guidelines. CV% = Extent of variation with respect to mean.

Bias = Discrepancy between our Lab & peer group labs.

4. Results & Observations

Average Bias, Average CV% & sigma metrics calculated for 6 months for both L1 & L2

ANALYTE	TEa	Bias%	Average CV(L1)	Sigma (L 1)	Average CV(L2)	Sigma (L2)
Glucose	10	1.11	2.61	3.40	2.50	3.55
Urea	9	5.09	1.34	2.91	3.51	1.11
Creatinine	15	1.9	3.3	3.96	2.39	5.69
T.Bil	20	5.04	2.2	6.8	2.5	5.98
T.Protein	10	2.18	3.1	2.54	3.03	2.60
Albumin	10	2.1	3.06	2.58	3.27	2.46
Uric acid	17	3.3	1.46	9.38	1.8	7.6
Cholesterol	10	3.4	3.87	1.73	3.59	1.88
Triglyceride	25	17.8	1.52	4.73	2.4	3.0
Na	5	1.01	1.16	3.43	1.25	3.19
k	6	0.75	1.15	4.56	1.23	4.26
cl	5	0.78	1.25	3.37	1.19	3.54
AST	20	2.6	3.67	4.74	2.45	7.10
ALT	20	1.7	5.84	3.13	5.29	3.45
ALP	30	1.26	4.24	6.77	3.87	7.42

- Uric acid & ALP showed world class quality results (σ >6).
- K+ (potassium) has minimum bias of 0.75 %.
- ALT had CV % >5% rest have <5%.
- Urea, Total protein, Albumin, cholesterol levels showed σ <3.

5. Conclusion

The application of sigma metrics in the OGH laboratory has shown promising results in improving the quality of analytical processes. Notably, Uric acid, ALP showed world class quality results. However, areas such as Urea, Total protein, Albumin, and Cholesterol levels showed <3, indicating a need for further improvement. The study underscores the importance of stringent application of Westgard rules for analytes with <3. The findings of this study could give future efforts to enhance the quality of analytical processes in clinical laboratories.

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