Evaluation of Quality Control in Clinical Chemistry Using Sigma Metrics

Abstract

Introduction

Six sigma improves the quality of outputs by analyzing and abolishing the source of defects and reducing variability in the manufacturing industry. It can be used as a self -assessment tool for laboratories when making their quality control frequency and strategy. Clinical laboratories tests with low sigma values (< 3σ) indicate that the analytical quality of the lab needs to be improved.

Aim

The aim of the study was to evaluate clinical chemistry laboratory performance using six sigma metrics to improve quality.

Materials and methods

Five parameters from renal and liver function tests were studied over a period of 6 months (Dec 2016-May2017). Data from IQC and EQA participation was used. The analytes were plasma creatinine, aspartate transaminase(AST), alanine transaminase(ALT), total serum protein, total and direct bilirubin.

Sigma metrics was calculated using total allowable error as per CLIA recommendations. Bias was calculated from HUQAS EQA participation while coefficient of variation was calculated from IQC data collected during the above mentioned months.

Results.

Clinical chemistry had sigma metrics below 3, the highest sigma value was 2.01 while the lowest sigma value was 0.85.

Conclusion

Clinical chemistry analytes had sigma levels less than 3, method performance improvement with stringent internal quality control and correct setting of control limits need to be applied. Application of sigma metrics in addition to daily internal quality control can identify analytical deficits and improvement in clinical laboratories

INTRODUCTION

Six sigma improves the quality of outputs by analyzing and abolishing the source of defects and reducing variability in the manufacturing industry. It can serve as a self -assessment guide for clinical laboratories by quantifying the exact number of errors made by the laboratory .The correlation between the sigma metrics and errors are as follows: 1 sigma (σ) corresponds to 690,000 errors per million reports, 2 sigma corresponds to 308,000 errors per million reports, 3 sigma corresponds to 66,800 errors per million reports, 4 sigma corresponds to 6,210 errors per million reports, 5 sigma corresponds to 230 errors per million reports and 6 sigma corresponds to 3.4 errors per million reports (1)

The best quality products have a level of performance of 6σ. Average products are said to have a quality performance value of about 4σ(2).

Six Sigma metrics are now being used assess the quality of laboratory testing processes and the quality control process (QC) that is needed to ensure that the desired quality is achieved (3).

Materials and Methods

Five parameters from renal and liver function tests were studied over a period of 6 months (Dec 2016-May2017). Data from IQC and EQA participation was used. The analytes were plasma creatinine, aspartate transaminase (AST), alanine transaminase (ALT), total serum protein, total and direct bilirubin.The tests were run on HumaStar 200 platform

Sigma metrics was calculated using total allowable error (TEa) as per the Clinical laboratory Improvement Amendements (CLIA) recommendations (3) .TEa is the acceptable difference percentage from the two values.

Bias was calculated from HUQAS EQA participation. Bias was calculated using the EQA values using the formula

$$\text{Bias} = \frac{(\text{lab mean} - \text{group mean})}{\text{group ean}} \times 100$$

The mean bias was used for sigma value calculation.

Coefficient of variation percentage was calculated from IQC data from Dec 2106-May. The formula used was

CV% = (standard deviation / laboratory mean) x 100%.

The Sigma metrics was calculated with following formula: Sigma metrics = (TEa - Bias%) / CV%(2) .

Results

Table 1 showing mean from normal and pathological IQC data from Dec 2016-May 2017.

Parameter	Normal		Pathological		
	Mean	SD	Mean	SD	
Creatinine	1.06	0.12	4.48	0.38	
Urea	27.22	2.29	67.42	5.75	
GPT	29.90	3.22	131.87	8.59	
GOT	32.47	3.36	154.58	9.44	
Total Protein	79.14	3.71	84.34	4.39	
Albumin	4.13	0.32	4.32	0.33	
APDEA	199.75	23.19	945.25	108.10	
D.Bilirubin	1.58	0.14	3.15	0.35	
T.Bilirubin	1.62	0.25	3.56	0.43	

Table 2 showing bias (%) calculated from EQA participation (HUQAS)

Parameter	A	B	C	D	E	Average bias
Creatinine	0.61	11.05	0	9.05	2.02	4.64
Urea						
GPT	8.92	16.20	12.09	1.17	8.40	9.37
GOT	3.26	13.21	5.31	10.30	6.50	7.72
T.protein	2.82	5.67	7.53	6.81	2.50	5.07
Albumin						
APDEA	8.98	9.09	11.66	13.17	2.67	9.11
D.Bilirubin	2.24	2.33	5.42	4.26	4.26	3.74
T,Bilirubin	8.57	3.74	6.72	10.17	6.70	7.18

Table 3 Showing TEa, Bias CV

			Normal	Normal	Pathological	Pathological	
Parameter	TEa%	Av.Bias	CV	SIGMA	CV	SIGMA	
Creatinine	15	4.64	11.02	0.94	8.52	1.22	
Urea	9		8.03		8.52		
GPT	20	9.37					
GOT	20	7.72	10.03	1.22	6.11	2.01	
T.protein	10	5.07	4.69	1.05	5.21	0.94	
Albumin	10		7.76		7.57		
APDEA		9.11	11.61		11.44		
D.Bilirubin	20	3.74	8.87	1.83	11.15	1.46	
T.Bilirubin	20	7.18	15.12	0.85	11.93	1.07	

Discussion

Accurate results are expected from all clinical laboratories to aid in diagnosing, treating, monitoring and prognostication of patient's conditions. Using six sigma metrics to analyze a laboratory's performance helps reduce the number of erroneous results.

Clinical chemistry analytes studies had sigma levels below 3 for both normal and pathological values, the highest sigma value was 2.01 while the lowest sigma value was 0.85.

For less than 3 sigma, it is recommended that method performance should be improved. The number of internal QC runs done daily should be increased, SD control limits be revised and set correctly, and tighter adherence to the Westgard rules(1).

Sigma values can be used as a guide in the laboratory for the internal quality control strategy and acceptability. For parameter with a 6 σsigma process (or higher), it is recommended to use 3.5 SD control limits and run 2 controls per day. (N number of controls to be run per day. For a 5 sigma process, use 3.0 SD control limits with n=2 have to be used; For a 4 sigma process, use 2.5 SD control limits with n=4 have to be used (1).

According to Westgard "for a six sigma process, use 3.5 SD control limits with N (number of controls to be run per day) 2 have to be used…; for a 3 sigma process, use a multi rule procedure with n of 6 or 8 have to be used" (3).

Conclusion

All clinical chemistry analytes had sigma metrics below 3. The highest sigma value was 2.01 while the lowest sigma value was 0.85.

Application of sigma metrics in addition to daily internal quality control can identify analytical deficits and improvement in clinical laboratories.

Recommendation

The number of internal QC runs done daily for the clinical chemistry analytes should be increased, SD control limits be revised and set correctly, and tighter adherence to the Westgard rules.

References

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