Effective Incorporation of Performance Standards in Quality Control Systems

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Abstract

Introduction: A statistically designed quality control (QC) method can effectively detect errors in the analytical system while minimizing false rejection. While most laboratories use standard statistical QC processes, with or without Westgard multi-rules to evaluate quality, few incorporate performance standards in their QC systems. Setting performance standards or quality goals allows the laboratory to determine the sigma value of each test. The sigma metric guides the selection of optimal QC rules specific to the quality level achieved by each analyte.

Objective: Emphasize the role of performance standards in quality control systems. The analytical performance of 5 analytes (AST, sodium, magnesium, glucose, and creatinine) were used as examples.

Design and methods: Internal quality control data from May 2016 to November 2016 was used to assess the method performance of the 5 analytes included in the study. The calculated performance characteristics include cumulative mean and SD, mean bias, analytical system total error, sigma metric, and critical systematic error.

Results: The study demonstrated that 4 analytes (AST, creatinine, glucose, magnesium) out of 5 performed above 6 sigma metric. Sodium recorded a poor performance with a sigma value less than 3. It was determined that a single rule, 1_{3s} was sufficient to control AST, creatinine, glucose, and magnesium, while more stringent QC rules $1_{3s}/2_{2s}/R_{4s}/4_{1s}/8_x$ need to be adopted for sodium.

Conclusion: This study demonstrates that setting quality goals is essential to improve quality monitoring systems. Laboratories can statistically evaluate the size of analytical error and determine if the probability of producing clinically misleading patient results or unacceptable proficiency tests is greater than 5%.

Background

Laboratories use standard statistical QC to control the quality of quantitative tests. With QC limits mostly set at ± 2SD, the false rejection rate is predicted at 5% for one level of control and increases with the number of control. Quality goals or performance standards are the acceptable limits for both random and systematic analytical errors. They are expressed as total allowable error (TEa). By setting performance standards, laboratories are able to determine the level of quality of each test in sigma metric, and select the optimal QC rules and frequency to control it. The goal is to achieve an error detection ≥90, while keeping false rejection rate below 5%. Quality goals also allow the periodic evaluation of the performance of the analytical system through the calculation of monthly critical systematic error (ΔSEc).

Materials and Methods

This was a retrospective study and the analytical platform used was Vitros 350. Two levels of control material from Bio-Rad were run daily. Every QC result generated within the period of May 1st to November 30th 2016 was included in the study, except for those rejected with valid reason. The peer group method mean for each analyte, obtained from the Bio-Rad inter-laboratory comparison program, was used as the true target value (TTV) for each level of control. TEa was based on CLIA limits for acceptable method performance.

The following performance characteristics were calculated in excel:

- Mean Bias (Bias) = Measured mean – Method group mean
- The analytical system total error (TE) = IBiasI +2SD
- Sigma metric (σ) = (TEa – IBiasI)/SD
- Critical systematic error (ΔSEc) = (TEa – IBiasI)/SD -1.65

Results

Table 1: Evaluation of method performance and calculation of sigma metric based on 6 months of QC data.

Quality control	Level 1 (normal)					Level 2 (abnormal)				
Quality indicators	TEa	TE	Bias	SD	σ	TEa	TE	Bias	SD	σ
AST (U/L)	8.43	1.66	0.06	0.8	10.5	46.48	11.4	1.6	4.9	9.2
Creatinine (mg/dL)	0.3	0.05	0.01	0.02	13.9	0.85	0.35	-0.08	0.14	5.7
Glucose (mg/dL)	8.10	3.52	1.72	0.9	7.1	27.31	7.7	0.7	3.5	7.6
Magnesium (mg/dL)	0.51	0.17	0.08	0.05	9.4	0.96	0.21	1.8	0.07	12.9
Sodium (mEq/L)	4	3.6	1.8	0.9	2.4	4	**4.5**	2.3	1.1	1.5

TEa-Total error allowable, TE-Total error, ΔSEc- Critical systematic error, σ- Sigma metric, SD-Standard deviation.

Table 2: Monthly critical systematic error (ΔSEc)

	Level 1 (normal) ΔSEc					Level 2 (abnormal) ΔSEc				
Month	AST	Creat	Glu	Mg	Na	AST	Creat	Glu	Mg	Na
May	8.81	**27.4**	7.8	8.6	1.5	11.3	**7.11**	14.8	10.5	0
June	12.3	26.4	**6.9**	**19.9**	**0.2**	11.8	**17.1**	**8.5**	13	0.1
July	8.69	27.4	7.3	12.7	**2.9**	15.6	16.4	14.5	12.9	**0.3**
Aug	10.3	26.4	10.1	**6.95**	0.4	**16.7**	16.6	12.5	**9.73**	0
Sept	**14.1**	25.4	8.0	11.7	1.1	12.6	17.1	10.7	10.8	0
Oct	**7.45**	**13.4**	**10.1**	12	2.5	11.1	12.6	14.7	**16.2**	0.2
Nov	12.3	27.4	8.1	8.35	1.2	**9.0**	16.4	**15.4**	13.9	0.1

Figure 1 & 2: Variation in critical systematic error (ΔSEc) for AST and creatinine from May to November

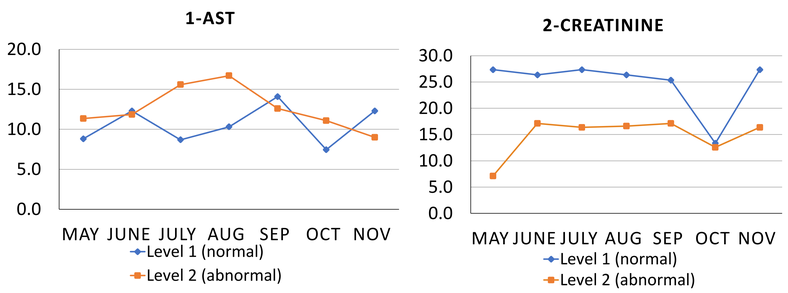
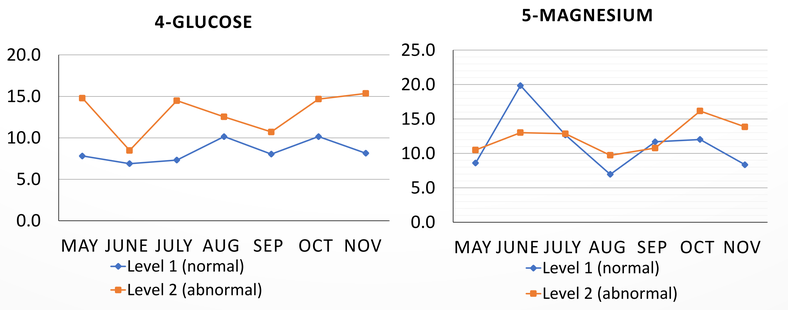
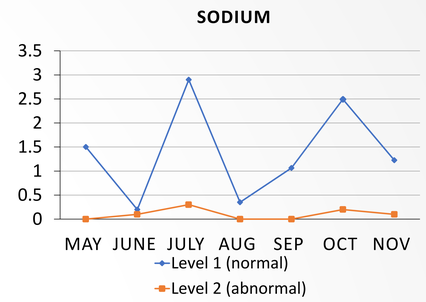


Figure 3 & 4: Variation in critical systematic error (ΔSEc) for glucose and magnesium from May to November



Results (con't)

Figure 5: Variation in critical systematic error (ΔSEc) for sodium from May to November



Conclusion

Setting quality goals is essential to improve quality monitoring systems. They guide the selection of QC limits and frequency specific to the quality level (sigma score) of each analyte.

- AST, magnesium, and glucose achieved a sigma metric >6 on both levels of QC.
- Creatinine performed between 5 to 6 sigma and is classified a capable assay.
- Sodium recorded a sigma score < 3 and is regarded as a poor performer. Maximum QC rule, increased QC frequency, and frequent evaluation is needed to improve error detection.

Table:3 Comparison of the current and recommended QC system

QC systems	Sigma	QC rules	N	R	Analytes
Current	N/A	$1_{2s}/2_{2s}/1_{3s}/4_{1s}/R_{4s}$	2	1	AST, Glu, Mg, Creat, Na
Recommended	≥ 6	1_{3s}	2	1	AST, Glu, Mg, Creat L1
	5	$1_{3s}/2_{2s}/R_{4s}$	2	1	Creat L2
	4	$1_{3s}/2_{2s}/R_{4s}/4_{1s}$	2	2	
	<4	$1_{3s}/2_{2s}/R_{4s}/4_{1s}/8_x$	2	4	Na

N- Number of control, R-Number of run, Glu- Glucose, Mg-Magnesium, Na- Sodium, Creat L1- Creatinine level 1 (normal), Creat L2- Creatinine level 2 (abnormal)

The monthly critical systematic error (ΔSEc) tracks the performance of the analytical system relative to the quality goals (TEa) set. A ΔSEc of 0, as seen in sodium level 2 for the months of May, August, and September, indicates that the probability of producing clinically misleading patient results or unacceptable proficiency tests in those months is greater than 5%.

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