SIGMA METRIC PERFORMANCE OF TWO PORTABLE BLOOD GAS ANALYZERS IN ICU AGAINST CORE LABORATORY ANALYZER AT SUNWAY MEDICAL CENTRE

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ABSTRACT

KEYWORDS: Blood Gas Analyzers, Architect *ci*8200, CD Sapphire, i-STAT, EPOC

OBJECTIVE: It is of utmost importance to realize that patients will be tested in both point of care and laboratory methods, thus the difference that exists between the methods is crucial. This study was aimed to verify and select the acceptable blood gas analyzer based on imprecision data, correlation coefficient of selected assays and sigma performance of the assays carried out in two portable blood gas analyzers, EPOC and i-STAT at ICU against the laboratory analyzers, Architect *ci*8200 and CD Sapphire.

METHOD: This study was conducted from October 2014 till January 2015. The imprecision of the blood gas analyzers were studied according to EP 5-A2 protocol from Clinical and Laboratory Standards Institute (CLSI). We used Passing-Bablok regression to calculate the correlation coefficient, slope and y-intercept. In order to judge the quality of these methods and instruments we calculated the sigma metrics of the assays at decision level by using analytical quality requirements from Clinical Laboratory Improvement Amendments (CLIA). The desirable specifications for imprecision and bias were taken from Ricos Biological Variation Database.

RESULTS: Based on the above analysis, EPOC and i-STAT showed excellent imprecision for all parameters except for pCO2 in EPOC. As for the slope of regression, Sodium, Potassium, Glucose and Hemoglobin showed a correlation coefficient of more than 0.900.The three analyzers showed variable sigma performances and not all assays met the minimum performance goal of 3.0.

CONCLUSION: This study enables us to select the acceptable method based on imprecision; correlation coefficient and sigma performance, and at the same time establish a proper quality control plan for poor performing assays.

INTRODUCTION

Six Sigma is well accepted quality management system especially at manufacturing industries such as General Electronic and Motorola[1]. For the past one decade, it has been adopted even in service industries such as healthcare institutions. Medical Laboratories can use the sigma-metric to make decisions about method quality when a new analytical system is in place. In addition to that we are also able to monitor the method quality throughout the lifetime of the system[2].

Variability of test process depends on the precision and accuracy of the measurement procedure. The analytical measurement process involves in measuring the variation to predict the defect rate and sigma-metric of the system[1]. It is crucial to determine the precision and accuracy of any measuring system prior to selecting it for use in the institutions.

The emphasis on speed test results has brought the medical world to focus on Point of care testing devices at patient's bedside. The use of blood gas analyzers as point-of-care-testing (POCT) devices enables SUNMED clinicians to make quick decisions and at the same time favors patient care. It is the utmost important to realize that the patients in SUNMED hospitals will be tested in both point of care methods and laboratory methods, thus the difference that exist between the methods is crucial and relevant to caution the clinicians about their existence.

A recently purchased blood gas analyzer intended for point of care use for ICU patients were evaluated for imprecision and bias, correlation coefficient and at the same time this study was aimed to verify the sigma performance of the selected parameters such as Sodium, Potassium, Glucose and Hemoglobin carried out in the two different portable blood gasanalyzers such as EPOC and i-STAT at ICU against the laboratory core analyzers, Architect *ci*8200 and CD sapphire.

MATERIALS AND METHOD

The study evaluation was conducted from October 2014 till January 2015 involving 40 samples taken from patients hospitalized in Intensive Care Unit, Sunway Medical Centre; it took us about four months to complete the evaluation in order to collect samples covering all range of concentrations from low, normal and high for the selected parameters.

The analyzers used in this study are as stated below:

1. EPOC – Blood Gas Analyzer
2. i-STAT – Blood Gas Analyzer
3. Architect *ci*8200 Intergrated System
4. Cell-Dyn (CD) Sapphire Haematology System

Paired blood samples in Lithium heparin and EDTA (ethylenediaminetetraacetic acid) tubes were withdrawn from the 40 consecutive adult patients for arterial and venous blood. The analysis of samples is carried out on POCT analyzers within 5 minutes and laboratory core analyzers within 30 minutes upon sample collection.

In addition to that we also studied the imprecision at medical decision level of the two blood gas analyzers according to the CLSI guideline EP 5-A2 protocol. We did single run with replicates of two for five consecutive days. The desirable specifications for imprecision and bias were taken from Ricos Database[5].

Furthermore, we used Passing-Bablok regression in Analyze-it software to calculate the correlation coefficient, slope and y-intercept. The regression equation is used to determine the bias values between the methods.

The following bias calculation was carried out for each and every assay that was compared:

Example: Sodium tested at EPOC as compared to Architect *ci*8200

$$\text{New}_{\text{level}} = (1.000 * 139.6) + 1.000$$
$$\text{New}_{\text{level}} = (139.6) + 1.000$$
$$\text{New}_{\text{level}} = 140.6$$

The bias between the old and new level is the absolute value of the difference between

$$140.6 - 139.6 = 1.0$$
$$\text{Bias} = (1.0/139.6)\text{X}100\%$$
$$=0.7\%$$

A bias of 0.7% at the level of 139.6

In order to judge the quality of these methods and instruments we calculated the sigma metrics of the assays at decision levels by using analytical quality requirements from CLIA.

Table 1: CLIA Proficiency Testing Criteria

Test or Analyte	CLIA TEa
Hemoglobin	± 7%
Potassium	± 0.5 mmol/L
Sodium	± 4 mmol/L
Glucose	± 6 mg/dL or ± 10% (greater)

The following mathematical equation was used to determine the Sigma-Metric of each and every assay that are compared:

Sigma-metric = **(TEa – Bias %) / CV**

Example for Sodium for EPOC Blood Gas Analyzer, quality requirement of ± 4 mmol/L from CLIA, TEa will be about 4/139.6 *100 = 2.87% at the level of 139.6 mmol.

EPOC Sodium Assay's Sigma – Metric = (2.87-0.72)/0.2 = 10.7

The visual assessments were demonstrated by using the method decision Chart.

RESULTS

Table 2: Representative data of Imprecision and Bias as compared to Desirable CV and Bias % from Ricos Biological Variation Database for all assays

Assay	Analyzer	Quality Control Mean	Desirable CV%	CV %	Desirable Bias%	Bias %
Sodium	EPOC Blood Gas Analyzer	139.6	0.3	0.2	0.2	0.7
Potassium		4.1	2.3	0.5	1.8	.5
Glucose		5.5	2.8	1.0	2.3	10.0
Hemoglobin		10.9	1.4	0.4	1.8	10.0
pH		7.4	1.8	0.2	1.0	N/A
pCO_2		36.0	2.4	4.0	1.8	N/A
Ca		1.2	1.1	0.5	0.8	N/A
Lactate		3.0	13.6	3.1	8.0	N/A
Sodium	I-STAT Blood Gas Analyzer	141.4	0.3	0.2	0.2	1.4
Potassium		4.5	2.3	0.5	1.8	2.2
Hemoglobin		10.2	1.4	0.4	1.8	7.5
pH		7.4	1.8	0.1	1.0	N/A
pCO_2		36.6	2.4	2.0	1.8	N/A
Ca		1.1	1.1	0.2	0.8	N/A
Sodium	Architect ci8200	141.6	0.3	0.8	0.2	0.7
Potassium		3.9	2.3	0.8	1.8	0.1
Glucose		4.8	2.8	1.1	2.3	0.3
Hemoglobin	CD Sapphire	12.2	1.4	1.8	1.8	1.6

*N/A-Not Applicable

As for the slope of regression, Sodium, Potassium, Glucose and Hemoglobin showed a correlation coefficient of more than 0.900 when compared to the main lab core analyzers. The regression equation is used to calculate the bias value at the quality control mean level. The bias value is required to calculate the sigma-metric performance of the assays.

Table 3: Summary of the correlation coefficient, slope and Y-intercept for the four assays calculated by using Passing-Bablok regression

Assay	Method	correlation coefficient, r	slope	y-intercept
Sodium	EPOC Vs Architect *ci*8200	0.950	1.000	1.0000
	i-STAT Vs Architect *ci*8200	0.967	1.000	2.0000
Potassium	EPOC Vs Architect *ci*8200	0.991	0.950	0.1025
	i-STAT Vs Architect *ci*8200	0.993	1.000	-0.1000
Glucose	EPOC Vs *ci*8200	0.966	1.000	0.5500
Hemoglobin	EPOC Vs CD Sapphire	0.930	1.154	-1.1810
	i-STAT Vs CD Sapphire	0.903	1.038	-1.1420

As seen in the table above some of the methods does not meet the Ricos Database desirable specifications for imprecision and bias. As we know the goals are quite tight and not practically achievable by any of the instruments therefore we need to consider on choosing a more practical set of quality goals, thus the Laboratory decided to choose CLIA Proficiency Testing criteria as the total allowable error for this study instead of Ricos goals.

Figure 1, 2, 3 and 4 below shows comparison of Sigma – Metric for the assays on different analyzers

Figure 1: Method Decision Chart for Sodium –CLIA Goals

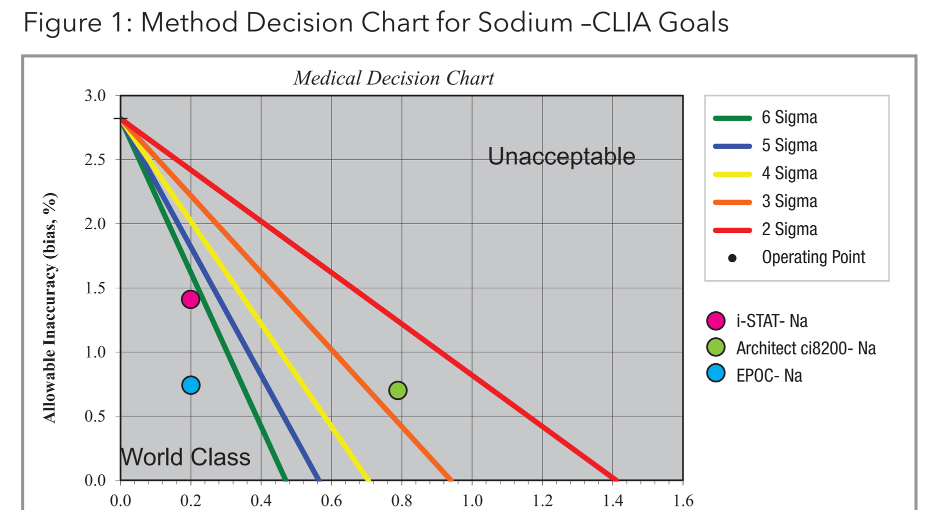


Figure 2: Method Decision Chart for Potassium –CLIA Goals

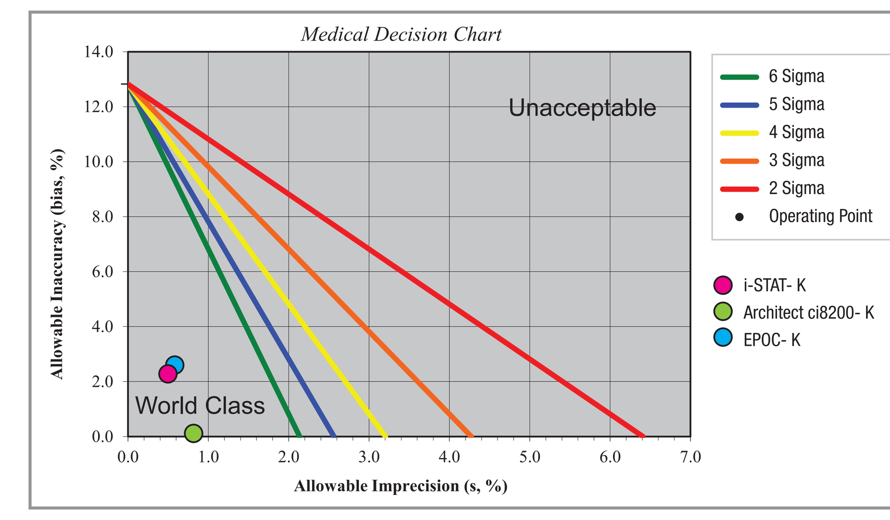


Figure 3: Method Decision Chart for Glucose –CLIA Goals

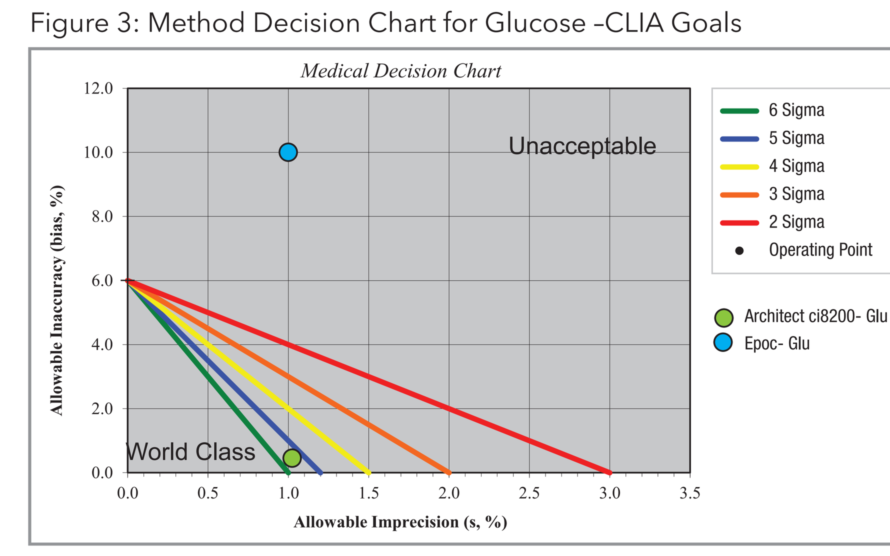
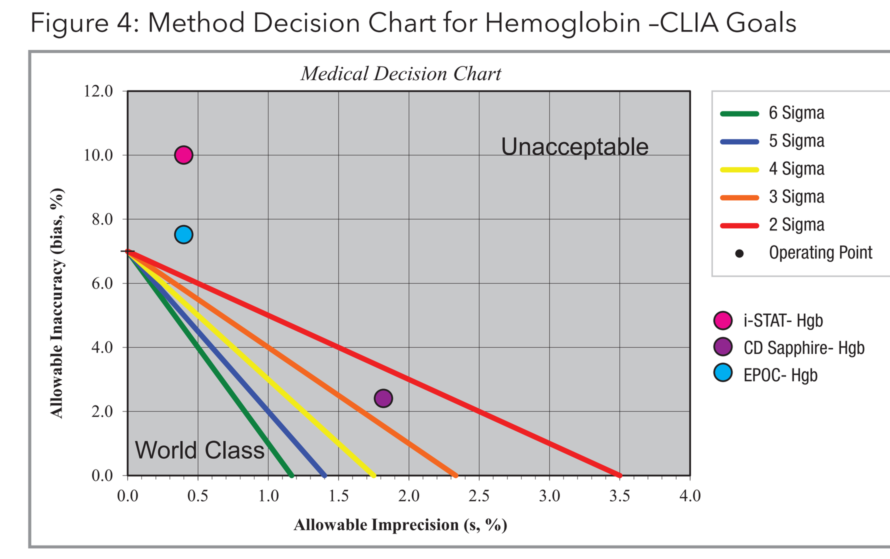


Figure 4: Method Decision Chart for Hemoglobin –CLIA Goals



The visual assessment of each instruments by assays are demonstrated using the Normalized Sigma-Metric Method Decision Chart. For assays that has a value of Sigma performance lower than three such as EPOC-Glucose, EPOC- Hemoglobin, i-STAT Hemoglobin and Architect *ci*8200- Sodium requires close monitoring by increasing the frequency of quality control runs.

CONCLUSION

A sigma performance of 3.0 is the minimum requirement for routine use of any assays and any assays with a sigma metric of 6.0 and above is considered world class quality. This study enables us to understand the limitations of each assay either as a poor performing one or world class quality. The blood gas analyzers and core laboratory analyzers showed variable sigma performances and not all the assays met the minimum performance goal of 3.0. We need to understand SUNMED patients are definitely required to run their test runs on both methods, so the difference is crucial and it is also important to notify the clinicians on the poor performing assays and caution the clinicians on the biases between the methods. This study indeed explained to us that by just looking at the high Correlation Coefficient and good imprecision performance is not sufficient to accept the methods. In addition to that the study has also demonstrated that it is unwise to reduce the frequency of quality control runs as per manufacturers' claim for the POCT systems either by test card lot or once per month. Indeed, some methods require more efforts in quality control and not less. Therefore our laboratory should establish a proper quality control plan (QCP) for poor performing assays.

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