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Six Sigma Metrics를 이용한 Bayer Rapidpoint 400 혈액가스 및 전해질 분석장비의 고정 정도관리 범위의 평가

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Evaluation of Fixed Quality Control Range of Bayer Rapidpoint 400 Blood Gas and Electrolyte Analyzer with Six Sigma Metrics

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Background : Bayer Rapidpoint 400 analyzer for point of care testing (POCT) uses fixed quality control (QC) range even when the lot number of a cartridge for quality control changes. To evaluate the fixed QC range recommended by the manufacturer, we analyzed internal QC data of 9 analyzers with Six Sigma metrics.

Materials and Methods : We investigated QC data of 9 analyzers over 5 months from May to September, 2004 for 8 parameters (pH, pCO_2, pO_2, Na^+, K^+, iCa^{++}, Cl^-, and glucose). One hundred eighty six groups of QC data were analyzed with capability index (C_p=total allowable error (TEa)/3 standard deviation (SD)) and capability index considering bias (C_{pk},=(TEa-bias)/3 SD). Acceptability was evaluated with criteria of 1.33 C_{pk}, 4 sigma level or quality criteria of the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88).

Results : In 80.7% (150 of 186 groups), both C_p and C_{pk} were at or above 1.33, which indicated that the use of fixed QC range was adequate. In 19.3% (36 of 186 groups), C_{pk} was below 1.33, which indicated the inadequacy of fixed QC range. Among them 14.5% (27 of 186 groups) showed C_p below 1.33, indicating that the errors had a random factor and 4.8% (9 of 186 groups) had C_p at or above 1.33, indicating that the errors had a systematic factor.

Conclusions : The quality criteria mandated by CLIA '88 was satisfied in about 80% of study groups using fixed QC ranges, but in about 20%, more strict instrument maintenance and specimen handling by operators, and quality improvement of QC materials by manufacturer was required. ***(Korean J Lab Med 2006;26:400-7)***

Key Words : *Blood gas and electrolyte analyzer; Capability index; Capability index considering bias; Point of care testing; Quality control; Six Sigma*

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INTRODUCTION

Point-of-care testing (POCT) is a laboratory test that is done at or near the site of care. It has advantages of shortened turnaround time and rapid clinical decisions and care, but has disadvantages of difficulties in maintenance

and quality control (QC)[1-4]. Recently developed blood gas and electrolyte analyzers for POCT use a cartridge for QC and do internal QC procedures automatically. Furthermore, internal quality control data generated by POCT analyzers are transmitted online to servers in the central laboratory where the data can be checked and analyzed.

As it is very difficult to change or adjust mean and standard deviation in a POCT analyzer whenever the lot number of a cartridge for QC changes, Bayer Rapidpoint 400 POCT analyzers use a fixed QC range rather than establishing a new allowable range at the time of lot number change[5].

To evaluate the fixed QC range recommended by the manufacturer, authors investigated QC data of 9 Rapidpoint 400 analyzers over 5 months in various departments of Asan Medical Center (AMC) using Six Sigma metrics, which is an evolution in quality management that is being widely implemented in business and industry in the new millennium, is being adopted as the universal measure of quality to be applied to their processes, and also provides a more quantitative framework for evaluating process performance and more objective evidence for process improvement[6].

MATERIALS AMD METHODS

We analyzed internal QC data automatically generated every 8 hr by 9 Rapidpoint 400 analyzers in various departments of Asan Medical Center: neonatal intensive care unit (NICU), pediatric intensive care unit (PICU), cardiac surgery intensive care unit (CSICU), emergency room (ER), internal medicine intensive care unit (MICU) and four operating rooms (C4, F4, OR and ORF) over 5 months from May to September 2004. Three levels of QC materials were used. pH, pCO_2, and pO_2 were carried out in all 9 analyzers and 27 groups (9 analyzers×3 levels) of QC data were analyzed: Na^+, K^+, Ca^{++} in 8 analyzers and 24 groups (8 analyzers×3 levels); Cl^- in 7 analyzers and 21 groups (7 analyzers×3 levels); and glucose in 4 analyzers and 12 groups (4 analyzers×3 levels). Altogether, we analyzed 186 groups of QC data. These QC data were analyzed with the Six Sigma metrics such as capability index (C_p, total allowable error (TEa)/3 standard deviation (SD) and capability index considering bias (C_{pk}, (TEa-bias)/3 SD)[7].

Acceptability of fixed QC range was evaluated with criteria of 1.33 C_p, 4 sigma level or quality criteria of the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88)[8].

RESULTS

1. Total coefficient of variation (CV) (Table 1)

The CV results of QC material level I, II, and III for 8 parameters are listed in Table 1.

2. Evaluation of acceptability of fixed QC range (Table 2, 3)

In 80.7% (150 of 186 groups), both C_p and C_{pk} were at or above 1.33; in 4.8% (9 of 186 groups), C_p was at or above 1.33 and C_{pk} was below 1.33; and in 14.5% (27 of 186 groups), both C_p and C_{pk} were below 1.33.

C_{pk} was below 1.33 in 19.3% (36 of 186 groups). pCO_2 had C_{pk} below 1.33 in 88.9% (8 of 9 analyzers) of level

Table 1. Total coefficient of variation of internal QC results of 8 test items for 5 months

Test item	Level of QC materials	Target value	Total CV of internal quality control results
pH	level 1	7.1500	0.05
	level 2	7.3500	0.06
	level 3	7.5500	0.09
pCO_2	level 1	70.00	2.74
	level 2	40.00	2.28
	level 3	20.00	3.48
pO_2	level 1	150.00	1.31
	level 2	100.00	1.78
	level 3	65.00	2.26
Na	level 1	115.00	0.71
	level 2	135.00	0.73
	level 3	155.00	0.85
K	level 1	3.00	0.38
	level 2	5.00	0.37
	level 3	7.00	0.44
Cl	level 1	80.00	0.79
	level 2	100.00	0.51
	level 3	120.00	0.48
Glucose	level 1	200.00	1.32
	level 2	100.00	1.37
	level 3	50.00	2.68
Ca	level 1	1.60	1.10
	level 2	1.20	1.05
	level 3	0.80	1.47

Table 2. Six Sigma metrics of internal QC results of 8 test items for 5 months

pH	Target	TEa	Mean	SD	Bias	C_p	C_{pk}
level 1							
PICU	7.1500	0.04	7.1426	0.00284	0.0074	4.70	3.83
NICU	7.1500	0.04	7.1418	0.00427	0.0082	3.12	2.48
CSICU	7.1500	0.04	7.1491	0.00575	0.0009	2.32	2.27
MICU	7.1500	0.04	7.1401	0.00414	0.0099	3.22	2.42
ER	7.1500	0.04	7.1389	0.00286	0.0111	4.66	3.38
OR	7.1500	0.04	7.1473	0.00380	0.0027	3.51	3.27
F4	7.1500	0.04	7.1440	0.00290	0.0060	4.60	3.91
ORF	7.1500	0.04	7.1445	0.00415	0.0055	3.21	2.77
C4	7.1500	0.04	7.1396	0.00451	0.0104	2.96	2.19
level 2							
PICU	7.3500	0.04	7.3507	0.00394	0.0007	3.38	3.33
NICU	7.3500	0.04	7.3504	0.00621	0.0004	2.15	2.12
CSICU	7.3500	0.04	7.3515	0.00510	0.0015	2.61	2.52
MICU	7.3500	0.04	7.3487	0.00487	0.0013	2.74	2.65
ER	7.3500	0.04	7.3466	0.00374	0.0034	3.57	3.26
OR	7.3500	0.04	7.3540	0.00397	0.0040	3.36	3.02
F4	7.3500	0.04	7.3524	0.00356	0.0024	3.74	3.52
ORF	7.3500	0.04	7.3516	0.00281	0.0016	4.75	4.55
C4	7.3500	0.04	7.3482	0.00599	0.0018	2.23	2.12
level 3							
PICU	7.5500	0.04	7.5470	0.00639	0.0030	2.09	1.93
NICU	7.5500	0.04	7.5478	0.00822	0.0022	1.62	1.53
CSICU	7.5500	0.04	7.5498	0.00686	0.0002	1.94	1.93
MICU	7.5500	0.04	7.5474	0.00797	0.0026	1.67	1.56
ER	7.5500	0.04	7.5432	0.00549	0.0068	2.43	2.01
OR	7.5500	0.04	7.5514	0.00697	0.0014	1.91	1.85
F4	7.5500	0.04	7.5503	0.00572	0.0003	2.33	2.31
ORF	7.5500	0.04	7.5492	0.00339	0.0008	3.93	3.85
C4	7.5500	0.04	7.5460	0.00790	0.0040	1.69	1.52

pCO_2	Target	TEa	Mean	SD	Bias	C_p	C_{pk}
level 1							
PICU	70.00	5.00	70.92	1.659	0.92	1.00	0.82
NICU	70.00	5.00	71.78	2.218	1.78	0.75	0.48
CSICU	70.00	5.00	72.55	2.334	2.55	0.71	0.35
MICU	70.00	5.00	73.25	2.482	3.25	0.67	0.23
ER	70.00	5.00	73.30	2.156	3.30	0.77	0.26
OR	70.00	5.00	70.42	1.986	0.42	0.84	0.77
F4	70.00	5.00	71.39	1.361	1.39	1.22	0.88
ORF	70.00	5.00	70.49	1.088	0.49	1.53	1.38
C4	70.00	5.00	72.86	2.470	2.86	0.67	0.29
level 2							
PICU	40.00	5.00	38.31	1.034	1.69	1.61	1.07
NICU	40.00	5.00	39.51	0.896	0.49	1.86	1.68
CSICU	40.00	5.00	40.49	1.212	0.49	1.38	1.24
MICU	40.00	5.00	39.82	0.816	0.18	2.04	1.97
ER	40.00	5.00	39.34	0.945	0.66	1.76	1.53
OR	40.00	5.00	38.51	0.776	1.49	2.15	1.51
F4	40.00	5.00	39.15	0.604	0.85	2.76	2.29
ORF	40.00	5.00	39.02	0.727	0.98	2.29	1.84
C4	40.00	5.00	40.08	1.074	0.08	1.55	1.53
level 3							
PICU	22.00	5.00	21.26	0.749	0.74	2.22	1.89
NICU	22.00	5.00	22.13	0.749	0.13	2.22	2.17
CSICU	22.00	5.00	21.66	0.952	0.34	1.75	1.63
MICU	22.00	5.00	22.31	0.809	0.31	2.06	1.93
ER	22.00	5.00	21.60	0.805	0.40	2.07	1.91
OR	22.00	5.00	21.12	0.663	0.88	2.51	2.07
F4	22.00	5.00	21.89	0.663	0.11	2.51	2.46
ORF	22.00	5.00	21.75	0.566	0.25	2.94	2.80
C4	22.00	5.00	22.51	0.877	0.51	1.90	1.71

pO_2	Target	TEa	Mean	SD	Bias	C_p	C_{pk}
level 1							
PICU	150.00	15.00	151.30	1.277	1.30	3.91	3.58
NICU	150.00	15.00	151.10	1.973	1.10	2.53	2.35
CSICU	150.00	15.00	149.04	1.498	0.96	3.34	3.12
MICU	150.00	15.00	146.26	2.624	3.74	1.91	1.43
ER	150.00	15.00	151.51	0.989	1.51	5.06	4.55
OR	150.00	15.00	151.95	2.510	1.95	1.99	1.73
F4	150.00	15.00	151.39	1.739	1.39	2.88	2.61
ORF	150.00	15.00	150.96	2.370	0.96	2.11	1.97
C4	150.00	15.00	150.96	2.712	0.96	1.84	1.73
level 2							
PICU	100.00	10.00	97.42	1.314	2.58	2.54	1.88
NICU	100.00	10.00	99.80	2.736	0.20	1.22	1.19
CSICU	100.00	10.00	100.39	1.288	0.39	2.59	2.49
MICU	100.00	10.00	100.20	1.286	0.20	2.59	2.54
ER	100.00	10.00	98.19	0.835	1.81	3.99	3.27
OR	100.00	10.00	101.42	2.504	1.42	1.33	1.14
F4	100.00	10.00	97.91	1.391	2.09	2.40	1.90
ORF	100.00	10.00	99.78	2.113	0.22	1.58	1.54
C4	100.00	10.00	99.78	2.535	0.22	1.31	1.29
level 3							
PICU	65.00	6.50	62.92	1.276	2.08	1.70	1.15
NICU	65.00	6.50	63.91	1.465	1.09	1.48	1.23
CSICU	65.00	6.50	61.42	1.251	3.58	1.73	0.78
MICU	65.00	6.50	63.92	1.926	1.08	1.13	0.94
ER	65.00	6.50	63.62	0.799	1.38	2.71	2.13
OR	65.00	6.50	63.95	1.732	1.05	1.25	1.05
F4	65.00	6.50	63.38	1.222	1.62	1.77	1.33
ORF	65.00	6.50	63.50	1.859	1.50	1.17	0.90
C4	65.00	6.50	64.45	1.391	0.55	1.56	1.43

Na^+	Target	TEa	Mean	SD	Bias	C_p	C_{pk}
level 1							
PICU	115.00	4.00	114.92	1.209	0.08	1.10	1.08
NICU	115.00	4.00	114.82	0.714	0.18	1.87	1.79
CSICU	115.00	4.00	114.82	0.824	0.18	1.62	1.55
MICU	115.00	NT	NT	NT	NT	NT	NT
ER	115.00	4.00	115.15	0.741	0.15	1.80	1.73
OR	115.00	4.00	114.85	0.873	0.15	1.53	1.47
F4	115.00	4.00	114.99	0.537	0.01	2.48	2.48
ORF	115.00	4.00	114.60	0.750	0.40	1.78	1.60
C4	115.00	4.00	115.30	0.847	0.30	1.57	1.46
level 2							
PICU	135.00	4.00	133.80	1.550	1.20	0.86	0.60
NICU	135.00	4.00	134.54	0.837	0.46	1.59	1.41
CSICU	135.00	4.00	135.47	0.955	0.47	1.40	1.23
MICU	135.00	NT	NT	NT	NT	NT	NT

(Continued on next page)

Table 2. *(Continued from the previous page)* Six Sigma metrics of internal QC results of 8 test items for 5 months

Na^+	Target	TEa	Mean	SD	Bias	C_p	C_{pk}
level 2							
ER	135.00	4.00	134.77	1.069	0.23	1.25	1.18
OR	135.00	4.00	134.17	1.213	0.83	1.10	0.87
F4	135.00	4.00	134.38	0.658	0.62	2.03	1.71
ORF	135.00	4.00	134.22	0.760	0.78	1.75	1.41
C4	135.00	4.00	135.04	0.827	0.04	1.61	1.60
level 3							
PICU	155.00	4.00	152.86	2.017	2.14	0.66	0.31
NICU	155.00	4.00	154.19	1.200	0.81	1.11	0.89
CSICU	155.00	4.00	155.68	1.490	0.68	0.90	0.74
MICU	155.00	NT	NT	NT	NT	NT	NT
ER	155.00	4.00	154.48	1.177	0.52	1.13	0.99
OR	155.00	4.00	153.37	1.587	1.63	0.84	0.50
F4	155.00	4.00	153.78	0.875	1.22	1.52	1.06
ORF	155.00	4.00	153.88	0.981	1.12	1.36	0.98
C4	155.00	4.00	154.78	1.190	0.22	1.12	1.06

K^+	Target	TEa	Mean	SD	Bias	C_p	C_{pk}
level 1							
PICU	3.00	0.50	3.01	0.013	0.01	12.81	12.54
NICU	3.00	0.50	3.01	0.009	0.01	18.84	18.63
CSICU	3.00	0.50	3.01	0.012	0.01	14.42	14.27
MICU	3.00	NT	NT	NT	NT	NT	NT
ER	3.00	0.50	3.00	0.014	0.00	12.28	12.17
OR	3.00	0.50	3.01	0.013	0.01	13.01	12.69
F4	3.00	0.50	3.01	0.010	0.01	16.55	16.18
ORF	3.00	0.50	3.00	0.009	0.00	17.67	17.55
C4	3.00	0.50	3.01	0.012	0.01	14.21	13.99
level 2							
PICU	5.00	0.50	4.97	0.023	0.03	7.21	6.82
NICU	5.00	0.50	4.99	0.016	0.01	10.69	10.38
CSICU	5.00	0.50	5.01	0.024	0.01	6.92	6.79
MICU	5.00	NT	NT	NT	NT	NT	NT
ER	5.00	0.50	4.98	0.016	0.02	10.67	10.31
OR	5.00	0.50	4.98	0.021	0.02	7.92	7.66
F4	5.00	0.50	4.98	0.015	0.02	11.05	10.61
ORF	5.00	0.50	4.98	0.017	0.02	9.92	9.45
C4	5.00	0.50	4.99	0.017	0.01	10.07	9.82
level 3							
PICU	7.00	0.50	6.97	0.037	0.03	4.45	4.18
NICU	7.00	0.50	7.01	0.027	0.01	6.12	6.04
CSICU	7.00	0.50	7.03	0.031	0.03	5.46	5.10
MICU	7.00	NT	NT	NT	NT	NT	NT
ER	7.00	0.50	7.00	0.023	0.00	7.09	7.03
OR	7.00	0.50	6.99	0.043	0.01	3.90	3.80
F4	7.00	0.50	6.98	0.025	0.02	6.56	6.30
ORF	7.00	0.50	6.99	0.032	0.01	5.22	5.06
C4	7.00	0.50	7.00	0.028	0.00	5.85	5.81

iCa^{++}	Target	TEa	Mean	SD	Bias	C_p	C_{pk}
level 1							
PICU	1.60	0.25	1.63	0.015	0.03	5.60	5.01
NICU	1.60	0.25	1.64	0.026	0.04	3.16	2.65
CSICU	1.60	0.25	1.63	0.019	0.03	4.38	3.88
MICU	1.60	NT	NT	NT	NT	NT	NT
ER	1.60	0.25	1.62	0.025	0.02	3.32	3.03

iCa^{++}	Target	TEa	Mean	SD	Bias	C_p	C_{pk}
level 1							
OR	1.60	0.25	1.62	0.015	0.02	5.64	5.13
F4	1.60	0.25	1.62	0.011	0.02	7.70	7.13
ORF	1.60	0.25	1.62	0.013	0.02	6.20	5.64
C4	1.60	0.25	1.62	0.019	0.02	4.50	4.15
level 2							
PICU	1.20	0.25	1.22	0.010	0.02	8.50	7.98
NICU	1.20	0.25	1.23	0.019	0.03	4.47	4.00
CSICU	1.20	0.25	1.21	0.015	0.01	5.39	5.12
MICU	1.20	NT	NT	NT	NT	NT	NT
ER	1.20	0.25	1.21	0.019	0.01	4.46	4.20
OR	1.20	0.25	1.22	0.010	0.02	8.48	7.66
F4	1.20	0.25	1.22	0.008	0.02	10.07	9.45
ORF	1.20	0.25	1.22	0.009	0.02	9.30	8.50
C4	1.20	0.25	1.21	0.013	0.01	6.60	6.21
level 3							
PICU	0.80	0.25	0.81	0.010	0.01	8.64	8.37
NICU	0.80	0.25	0.80	0.013	0.00	6.21	6.17
CSICU	0.80	0.25	0.80	0.012	0.00	7.07	6.97
MICU	0.80	NT	NT	NT	NT	NT	NT
ER	0.80	0.25	0.81	0.017	0.01	4.86	4.66
OR	0.80	0.25	0.81	0.015	0.01	5.38	5.08
F4	0.80	0.25	0.81	0.007	0.01	11.32	10.76
ORF	0.80	0.25	0.81	0.008	0.01	10.00	9.62
C4	0.80	0.25	0.81	0.012	0.01	7.21	6.81

Cl^-	Target	TEa	Mean	SD	Bias	C_p	C_{pk}
level 1							
PICU	80.00	4.00	81.18	0.388	1.18	3.44	2.42
NICU	80.00	NT	NT	NT	NT	NT	NT
CSICU	80.00	4.00	79.06	0.286	0.94	4.65	3.56
MICU	80.00	NT	NT	NT	NT	NT	NT
ER	80.00	4.00	81.19	0.393	1.19	3.39	2.38
OR	80.00	4.00	80.90	1.396	0.90	0.95	0.74
F4	80.00	4.00	81.03	0.396	1.03	3.36	2.50
ORF	80.00	4.00	80.71	0.876	0.71	1.52	1.25
C4	80.00	4.00	81.49	0.717	1.49	1.86	1.17
level 2							
PICU	100.00	5.00	100.52	0.501	0.52	3.32	2.98
NICU	100.00	NT	NT	NT	NT	NT	NT
CSICU	100.00	5.00	99.74	0.887	0.26	1.88	1.78
MICU	100.00	NT	NT	NT	NT	NT	NT
ER	100.00	5.00	100.20	0.450	0.20	3.71	3.56
OR	100.00	5.00	100.17	0.377	0.17	4.42	4.27
F4	100.00	5.00	100.16	0.371	0.16	4.49	4.35
ORF	100.00	5.00	100.30	0.460	0.30	3.62	3.40
C4	100.00	5.00	100.46	0.513	0.46	3.25	2.95
level 3							
PICU	120.00	6.00	119.94	0.700	0.06	2.86	2.83
NICU	120.00	NT	NT	NT	NT	NT	NT
CSICU	120.00	6.00	120.09	0.578	0.09	3.46	3.41
MICU	120.00	NT	NT	NT	NT	NT	NT
ER	120.00	6.00	119.76	0.629	0.24	3.18	3.05
OR	120.00	6.00	119.35	0.519	0.65	3.85	3.44
F4	120.00	6.00	119.60	0.589	0.40	3.40	3.17
ORF	120.00	6.00	119.51	0.575	0.49	3.48	3.19
C4	120.00	6.00	120.03	0.472	0.03	4.24	4.22

(Continued on next page)

Table 2. *(Continued from the previous page)* Six Sigma metrics of internal QC results of 8 test items for 5 months

Glucose	Target	TEa	Mean	SD	Bias	C_p	C_{pk}
level 1							
PICU	200.00	20.00	197.3	2.03	2.7	3.28	2.84
NICU	200.00	NT	NT	NT	NT	NT	NT
CSICU	200.00	NT	NT	NT	NT	NT	NT
MICU	200.00	NT	NT	NT	NT	NT	NT
ER	200.00	NT	NT	NT	NT	NT	NT
OR	200.00	NT	NT	NT	NT	NT	NT
F4	200.00	20.00	198.1	1.95	1.9	3.43	3.10
ORF	200.00	20.00	199.4	3.68	0.6	1.81	1.76
C4	200.00	20.00	196.1	2.68	3.9	2.48	2.00
level 2							
PICU	100.00	10.00	100.5	1.44	0.5	2.32	2.21
NICU	100.00	NT	NT	NT	NT	NT	NT
CSICU	100.00	NT	NT	NT	NT	NT	NT
MICU	100.00	NT	NT	NT	NT	NT	NT
ER	100.00	NT	NT	NT	NT	NT	NT
OR	100.00	NT	NT	NT	NT	NT	NT
F4	100.00	10.00	101.2	1.11	1.2	3.01	2.64
ORF	100.00	10.00	100.7	1.73	0.7	1.92	1.79
C4	100.00	10.00	98.9	1.21	1.1	2.76	2.45
level 3							
PICU	50.00	5.00	49.9	0.97	0.1	1.72	1.68
NICU	50.00	NT	NT	NT	NT	NT	NT
CSICU	50.00	NT	NT	NT	NT	NT	NT
MICU	50.00	NT	NT	NT	NT	NT	NT
ER	50.00	NT	NT	NT	NT	NT	NT
OR	50.00	NT	NT	NT	NT	NT	NT
F4	50.00	5.00	50.4	0.89	0.4	1.87	1.73
ORF	50.00	5.00	50.6	1.56	0.6	1.07	0.95
C4	50.00	5.00	48.8	2.21	1.2	0.75	0.57

Abbreviations: TEa, total allowable error; SD, standard deviation; bias, assigned value minus mean; C_p, capability index, total allowable error (TEa)/3 SD; C_{pk}, capability index considering bias, (TEa - bias)/3 SD; PICU, pediatric intensive care unit; NICU, neonatal intensive care unit; CSICU, cardiac surgery intensive care unit; MICU, internal medicine intensive care unit; ER, emergency room; OR, F4, ORF and C4, a kind of name for operating rooms; NT, not tested.

I, 55.6% (5 of 9 analyzers) of level II, and 33% (3 of 9 analyzers) of level III; pO_2 in 33.3% (3 of 9 analyzers) of level III; Na^+ in 11% (1 of 9 analyzers) of level I, 44.4% (4 of 9 analyzers) of level II, and 77.8% (7 of 9 analyzers) of level III; Cl^- in 33.3% (3 of 9 analyzers) of level I; and glucose in 50.0% (2 of 4 analyzers) of level III.

Among those with C_{pk} below 1.33, 4.8% (9 of 186 groups) had C_p at or above 1.33. pCO_2 had C_p at or above 1.33 in 22.2% (2 of 9 analyzers) of level II; pO_2 in 33% (3 of 9 analyzers) of level III; Na^+ in 11.1% (1 of 9 analyzers) of level II, and 11.1% (1 of 9 analyzers) of level III; Cl^- in 22.2% (2 of 9 analyzers) of level I.

Both C_{pk} and C_p were below 1.33 in 14.5% (27 of 186 groups). pCO_2 had C_{pk} and C_p both below 1.33 in 88.9% (8 of 9 analyzers) of level I, 33.3% (3 of 9 analyzers) of level II, 33% (3 of 9 analyzers) of level III; Na^+ in 11% (1 of 9 analyzers) of level I, 33.3% (3 of 9 analyzers) of level II, and 66.7% (6 of 9 analyzers) of level III; Cl^- in 11.1% (1 of 9 analyzers) of level I; and glucose in 50.0% (2 of 4 analyzers) of level III.

Both C_p and C_{pk} were at or above 1.33 in 80.7% (150 of 186 groups). pH, K^+, and iCa^{++} showed both C_p and C_{pk} at or above 1.33 in all 3 levels of 9 analyzers.

3. Comparison between Cp levels of the fixed QC range of the manufacturer and that of AMC internal QC

(Table 4)

C_p levels of AMC were lower than those of the manufacturers in level III of pH; level I and level III of pCO_2; level I and level II of pO_2; level I, level II, and level III of Na^+; level I of K^+; level I, level II, and level III of iCa^{++}

Table 3. Acceptability of fixed QC range

$C_p \geq 1.33$ and $C_{pk} \geq 1.33$	80.7% (150 of 186 groups)	Acceptable by the quality criteria of all the other groups except CLIA '88 unacceptable groups
$C_p \geq 1.33$ and $C_{pk} < 1.33$	4.8% (9 of 186 groups)	Unacceptable by systematic error pCO_2-level 2-PICU, pCO_2-level 2-CSICU pO_2-level 3-NICU, pO_2-level 3-PICU, pO_2-level 3-CSICU Cl-level 1-ORF, Cl-level 1-C4, Na-level 2-CSICU, Na-level 3-F4
$C_p < 1.33$	14.5% (27 of 186 groups)	Unacceptable by random error with or without systematic error Glucose-level 3-C4, ORF pCO_2-level 1-MICU, CSICU, C4, NICU, ER, OR, PICU, F4 pCO_2-level 2-NICU, C4, OR pCO_2-level 3-MICU, ORF, OR Cl-level 1-OR Na-level 1-PICU Na-level 2-PICU, OR, ER Na-level 3-CSICU, OR, PICU, NICU, C4, ER

Table 4. Comparison of C_p level of fixed control limits between manufacturer's SD and averages of SD of internal QC results of 9 networked POCT gas analyzers over 5 months

Test item	QC materials	Target value	SD established by manufactures	SD of QC results of this hospitals	Fixed control limits	C_p* by SD of manufactures	C_p† by SD of QC results of this hospital	Difference of C_p between SD of manufactures and SD of QC results of this hospital
pH	level 1	7.1500	0.005	0.00390	0.02	1.3	1.7	0.4
	level 2	7.3500	0.005	0.00450	0.02	1.3	1.5	0.1
	level 3	7.5500	0.005	0.00650	0.02	1.3	1.0	-0.3
pCO_2	level 1	70.00	0.83	1.973	6.4	2.6	1.1	-1.5
	level 2	40.00	1.09	0.898	5	1.5	1.9	0.3
	level 3	20.00	0.52	0.759	3	1.9	1.3	-0.6
pO_2	level 1	150.00	1.62	1.966	11	2.3	2.0	-0.4
	level 2	100.00	0.81	1.778	7.8	3.2	1.5	-1.7
	level 3	65.00	1.61	1.436	9.2	1.9	2.1	0.2
Na	level 1	115.00	0.64	0.812	5	2.6	2.1	-0.6
	level 2	135.00	0.96	0.984	5	1.7	1.7	0.0
	level 3	155.00	0.85	1.315	7	2.7	1.8	-1.0
K	level 1	3.00	0.01	0.011	0.3	10.0	8.8	-1.3
	level 2	5.00	0.03	0.019	0.3	3.3	5.4	2.1
	level 3	7.00	0.04	0.031	0.3	2.5	3.2	0.7
Cl	level 1	80.00	0.74	0.636	6	2.7	3.1	0.4
	level 2	100.00	0.83	0.508	6	2.4	3.9	1.5
	level 3	120.00	0.76	0.580	6	2.6	3.4	0.8
Glucose	level 1	200.00	1.65	2.585	14	2.8	1.8	-1.0
	level 2	100.00	1.24	1.373	10	2.7	2.4	-0.3
	level 3	50.00	1.07	1.408	10	3.1	2.4	-0.7
Ca	level 1	1.60	0.01	0.018	0.1	4.0	2.2	-1.8
	level 2	1.20	0.01	0.013	0.1	3.3	2.6	-0.7
	level 3	0.80	0.01	0.012	0.1	3.3	2.8	-0.5

*, fixed control limits / 3 SD established by manufactures; †, fixed control limits/3 SD of QC results of this hospitals.
Abbreviations: See Table 2.

and level I, level II, and level III of glucose. Among those, the difference between C_p levels of AMC and those of the manufacturer was at or above 1.00 C_p in level I of pCO_2, level II of pO_2, level III of Na^+, level I of K^+, level I of iCa^{++}, and level I of glucose and it was below 1.00 C_p in level III of pH, level III of pCO_2, level I of pO_2, level I of Na^+, level II and level III of glucose, and level II and III of Ca^{++}. But C_p levels of AMC were higher than those of the manufacturer in level I and level II of pH, level II of pCO_2, level III of pO_2, level III of K^+, and level III of Cl^-.

DISCUSSION

As arterial blood gas and electrolyte test results affect greatly the prognosis and the treatment of patients, a strict and efficient QCan of POCT arterial blood gas and electrolyte tests is absolutely essential[1, 2].

According to the established QC principles and guidelines of CAP laboratory accreditation, each laboratory should set or establish an allowable range of limit of each lot of QC material in house. But Bayer Rapidpoint 400 POCT analyzers use cartridges for QC and reagents, which makes it impossible to set a new allowable range when there is a change in the lot number. Even if there are lot changes in QC materials, they use fixed quality control range[5].

Authors analyzed internal QC data generated by 9 Rapidpoint 400 analyzers over 5 months from May to September 2004 with Six Sigma metirics for objective quality assessment. We set 4 sigma mandated by CLIA '88 as precision criteria, which is 1.33 C_{pk}.

Among 39 groups out of 186 (19.3%) with C_{pk} below 1.33, 27 groups (14.5%) also had C_p below 1.33. Thus it was inappropriate to fix QC range considering random errors even if we disregarded systematic errors.

The QC material or group in which C_p and C_{pk} were both below 1.33 in most analyzers was pCO_2 level I (88.9 %, 8 of 9 analyzers), and that in second most was Na^+

level III (66.7%, 6 of 9 analyzers). The target value of pCO_2 level I was 70 mmHg and the number of change of QC material lot number was 8. The averages of measurements of QC material was 72.1 (63.8-81.6) and the bias from target value was 2.1. The mean (range) and CV, respectively, of each lot number (no.) were as follows: 73.3 (63.8-79.5) and 2.9% for lot no. 1, 71.4 (68.4-78.1) and 1.9% for lot no. 4, 71.7 (65.7-78.0) and 3.0% for lot no. 7, 72.9 (64.1-78.5) and 3.4% for lot no. 10, 73.2 (67.1-81.6) and 3.4% for lot no. 15, those of lot number 26, 70.4 (64.3-75.7) and 2.8% for lot no. 26, 70.9 (64.7-74.5) and 2.3% for lot no. 31, and 72.6 (66.8-80.0) and 3.2% for lot no. 36. Total CV of all the QC results of pCO_2 level I was 3.2%, the average of intra-lot CV was 2.9% (1.9-3.4), and inter-lot CV calculated by $\sqrt{(total\ CV)^2-(intra\text{-}lot\ CV)^2}$ was 1.4%. Out of total CV, intra-lot CV comprised 82% ($2.9^2/3.2^2\times100$), and inter-lot CV 18% ($1.4^2/3.2^2\times100$).

The target value of Na^+ level III was 155 mmol/L and the number of change of QC material lot no. was 6. The mean of measurements of QC material was 154.2 (145.2-162.7) and the bias from target value was 0.8. The mean (range) and CV of each lot no. were as follows: 154.4 (151.3-158.5) and 0.8% for lot no. 3, 154.2 (151.6-157.1) and 0.8% for lot no 9, 154.8 (151.7-159.8) and 0.8% for lot no. 12,153.4 (150.2-160.2) and 1.0% for lot no. 28, 152.9 (145.2-158.5) and 1.3% for lot no. 33, and 155.7 (153.2-162.7) and 1.0% for lot no. 38. Total CV of all QC results of Na^+ level III was 1.1%, and the mean of intra-lot CV was 1.0% (0.8-1.3). And inter-lot CV calculated by $\sqrt{(total\ CV)^2-(intra\text{-}lot\ CV)^2}$ was 0.5%. Out of total CV, intra-lot CV comprised 83% ($1.0^2/1.1^2\times100$) and inter-lot CV 17% ($0.5^2/1.1^2\times100$).

In 4.8% of the cases with C_{pk} below1.33 and C_p at or above 1.33, it was inappropriate to fix quality QC due to systematic errors.

pO_2 level III showed C_{pk} below1.33 and C_p at or above 1.33 in 33.3% (3 of 9 analyzers). The target value of pO_2 level III was 65 mmHg and QC materials from three lots were used in this investigation. The mean of measurements of QC material was 62.8 (58.9-68.5) and the bias from target value was 2.2. The mean (range) and CV, respectively, of each lot number were as follows: 63.9 (61.0-67.7) and 2.3% for lot no. 9, 63.0 (59.7-66.0), and 2.0% for lot no. 33, and 61.4 (58.9-68.5), and 2.1% for lot no. 38. Total CV of all QC results of pO_2 level III was 2.7% and the mean of intra-lot CV was 2.1%. And inter-lot CV calculated by $\sqrt{(total\ CV)^2-(intra\text{-}lot\ CV)^2}$ was 1.7%. Out of total CV, intra-lot CV comprised 60% ($2.1^2/2.7^2\times100$) and inter-lot CV 40% ($1.7^2/2.7^2\times100$).

Of the 186 groups, 150 (80.7%) showed both C_p and C_{pk} at or above 1.33, actually C_{pk} at or above 3, and it was appropriate and reasonable to fix QC range.

Authors evaluated the validity of fixed QC range of POCT Rapidpoint 400 by the manufacturer: 19.3% (36 of 186 groups) could not satisfy or meet the criteria mandated by CLIA '88. Random error accounted for 14.5% (27 of 186 groups) and systematic error 4.8% (9 of 186 groups). To cut down or reduce the random errors such as intra-lot variability, more strict maintenance procedures of the analyzer and control of sample quality would be needed on the operator side. Likewise, to reduce the systematic errors such as inter-lot variability, more strict quality control and improvement procedures would be needed on the manufacturer side.

In conclusion, we may use a fixed QC range for Rapidpoint 400 blood gas analyzer for more than 80% of QC materials, but the remaining ones require more strict maintenance of the instrument and handling of QC material by the operator and quality improvement by the manufacturer.

요 약

서론 : 현장검사용 Bayer Rapidpoint 400 장비는 정도관리물질 카트리지의 제품번호가 변경되더라도 정도관리물질 검사값의 허용범위를 고정하여 사용한다. 제조사에 의해 권장된 고정정도관리범위를 평가하기 위하여, 9대의 Rapidpoint 400 현장검사장비 내부정도관리결과를 Six Sigma metrics를 가지고 분석하였다.

방법 : 저자들은 2004년 5월부터 9월까지 5개월동안 본원 Rapidpoint 400 현장검사장비 9대에서 시행된 8항목(pH, pCO_2, pO_2, Na^+, K^+, iCa^{++}, Cl^-, glucose)의 내부정도관리결과에 대하여 조사하였다. Capability index (C_p, Total allowable error (TEa)/3 standard deviation (SD)) 및 Capability index considering bias (C_{pk}, (TEa-bias)/3 SD)를 가지고 186군의 내부정도관리결과를 분석하였다. 고정정도관리범위의 적절성은 CLIA '88의 질 기준인 4 시그마에 해당하는 1.33 C_{pk}를 가지고 평가하였다.

결과 : 80.7% (150군/186군)에서 C_p 및 C_{pk} 모두 1.33 이상이어서 고정정도관리범위의 사용이 적절하였다. C_{pk}가 1.33 미만이어서 고정정도관리범위의 사용이 부적절한 경우가 19.3% (36군/186군)이었는데, 이중 C_p도 1.33 미만이어서 오차의 주요인이 무

작위적이라 사료된 것은 14.5% (27군/186군)이었고, C_p는 1.33 이상이어서 오차의 주요인이 계통적이라 사료된 것은 4.8% (9군/186군)이었다.

결론 : Rapidpoint 400 장비 제조사가 제공하는 고정정도관리범위를 CLIA '88의 질 기준을 가지고 평가한 결과, 약 80%의 연구군에서 고정정도관리범위의 사용이 적절하였고, 약 20%에서는, 검사자측의 더욱 엄격한 장비 및 검체관리와 제조사측의 정도관리물질 제조공정의 질 향상이 요구되었다.

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