Original Article

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Effect of Internal Quality Planning using Sigma Metrics in Lean Management of a Clinical Chemistry Laboratory: An Analytical Study

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ABSTRACT

Introduction: Across the globe, quality control systems serve as the foundation for providing accurate and precise results, and also immediate error detection. However, many laboratories adhere to uniform Quality Control (QC) rules for all parameters, which may result in unnecessary overspending. The present study aimed to establish individual control rules and determine the number of control measurements for each of the 10 parameters using Westgard EZ Rules 3 software. The cost-effectiveness and benefits of applying these new rules were evaluated, alongside the lot-to-date, lot-to-lot, and company-to-company Coefficient of Variation (CV) for quality control materials.

Aim: To assess the impact of sigma-metrics-based internal quality planning on lean management in a clinical chemistry laboratory.

Materials and Methods: This cost-effective analysis study was conducted using commercially available quality control materials. It was done in the Department of Biochemistry in the Super Specialty Block (SSB) Biochemistry laboratory at Jawaharlal Institute of Postgraduate Medical Education and Research (JIPMER), Puducherry, India, from June 2020 to June 2022. Initially, the existing practices were scored. Using Westgard EZ Rules 3 software, OPSpecs charts and power function graphs were plotted using Westgard EZ Rules 3 software, and control rules and the number of control measurements for 10 parameters (Urea, Creatinine, Calcium, Phosphorus, Magnesium, Uric acid, Aspartate Transaminase (AST), Alanine Transaminase (ALT), Alkaline Phosphatase (ALP), and Total protein) were determined. Cost-effective and cost-benefit analyses were conducted using quality cost worksheets. A comparison of lot-to-date (month to month), lot-to-lot, and company-to-company CV was performed using Statistical Package for Social Sciences (SPSS) Software version 19.0.

Results: In the present study, it was found that ALP, calcium, and magnesium followed the 1_{3S} rule, whereas the remaining 7 parameters followed the $1_{3S}/2_{2S}/R_{4S}/4_{1S}/10_{X}$ rule with two control materials. The study revealed a decrease in cost by 95.8%, 92.3%, and 81.5% for ALT, AST, and creatinine, respectively, and by 71.1%, 68.8%, 59.8%, and 54.9% for uric acid, phosphorus, total protein, and urea, respectively, if the new control rules were followed instead of the existing ones. ALP, magnesium, and calcium showed no cost difference, indicating that the current control rules were similar to the newly framed ones. Furthermore, there was no significant difference in lot-to-date (month to month), lot-to-lot, and company-to-company CV on QC rules for most parameters despite changing reagent lots.

Conclusion: In conclusion, the study demonstrated that the control rules for each of the 10 parameters (Urea, Creatinine, Calcium, phosphorus, magnesium, uric acid, AST, ALT, ALP, and total protein), as well as the comparison of QC material CV, proved to be cost-effective.

Keywords: Analysis of variance, Bias, Calcium, Cost-effectiveness analysis

INTRODUCTION

Quality control systems across the globe serve as the foundation for providing accurate, precise results and immediate error detection [1]. Six Sigma uses a structured strategy referred to as Define, Measure, Analyse, Improve, and Control (DMAIC) to enhance process quality and minimise the defects [2]. Lean comprises principles and techniques for planning, refining, and leading processes, thereby minimising waste and improving productivity [3].

A power function graph is a tool for detecting the chance of rejection versus error size for a Statistical Quality Control (SQC) procedure. In practice, values less than 0.05 or 0.01 (5% or 1%) for false rejections and more than 0.90 or 90% for error detection can be utilised. The critical systematic error (Δ SEcrit) denotes the error size that systematically results in a medically important error [4].

Westgard rules ensure that laboratory quality control is within the range before reporting the results. The primary objective of Westgard rule selection is to achieve 90% or above error detection and 5% or less false rejection with the assistance of the power function graph and OPSpecs chart [5].

Quality Assurance (QA) for biochemical parameters cannot be achieved solely with Internal Quality Control (IQC) and External Quality Control (EQC) as they cannot detect the exact number of defects or errors in the laboratory [6]. Most laboratories follow the same QC rules to all parameters, which may not be necessary and can lead to overspending. The concept of refining the quality of reported results, with the goal of achieving zero defects, depends on a system that integrates accuracy and process improvement like the Six Sigma management methodology [7]. There is a need to use Lean and Six Sigma together as appropriate tools to provide accurate and precise results in a cost-effective manner.

In the present study, individual control rules and the number of control measurements for each of the 10 parameters were established using Westgard EZ Rules 3 software. Cost reduction in the laboratory was done by applying these newly established rules in place of existing practices. A comparison was done between the effect of the lot-to-date (month-to-month) CV of Biorad QC material, a lot-to-lot CV of Biorad QC material, and company (Randox)-to-company (Biorad) CV of QC material for both normal and pathological levels.

MATERIALS AND METHODS

It was a cost-effective analysis study in quality management conducted using commercially available quality control materials.

The study took place in the Department of Biochemistry at SSB Biochemistry Laboratory, Jawaharlal Institute of Postgraduate Medical Education and Research (JIPMER), Puducherry, India, from June 2020 to June 2022. The study obtained approval from the Post Graduate Research Monitoring Committee (PGRMC) approval Institute Ethics Committee Review exemption certificate (Ref no. JIP/IEC/2020/090).

Study Procedure

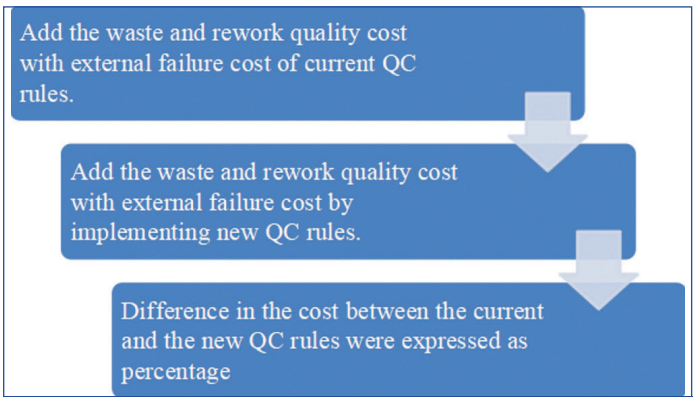
First, the scoring of existing practices was completed based on a 15-step proforma. Biorad QC with lot numbers 26470 (26471 for normal level and 26472 for pathological level) and 26490 (26491 for normal level and 26492 for pathological level), as well as Randox QC with lot number 1392UN for normal level and 1174UE for pathological level, were used. A total of 12 vials from each of the aforementioned QC lots were reconstituted as per standard QC preparation guidelines and aliquoted as 250 microlitres each. The stability of reconstituted QC material in aliquots is confirmed for one week when stored at -20°C (the range for QC material storage after reconstitution is -18°C to -24°C) [8]. Once all the aliquots prepared from the vial were used, the next QC vial was aliquoted and stored as mentioned above. These aliquoted QC materials were run as patient samples three times a day (morning, afternoon, and night) for 10 parameters, namely, urea, creatinine, calcium, magnesium, phosphorus, uric acid, AST, ALT, ALP, and total protein in the Beckman Coulter AU5800 autoanalyser for three months, and data were collected. In each run, one normal level and one pathological level QC material aliquot from both lots of Biorad and Randox were run.

With the available data, the CV was calculated for every 20 runs using the online Westgard CV calculator. Bias was calculated using the External Quality Assurance Scheme (EQAS) report from CMC Vellore. Total allowable Error (TEa) data were obtained from CLIA guidelines 2019 [9-12]. Medical decision limit data were obtained from the Westgard Website [13,14]. OPSpec chart and power function graph were plotted using Westgard EZ Rules 3 software, and control rules and the number of controls for each parameter were designed [4]. Cost-effective analysis were done using quality cost worksheets [15].

STATISTICAL ANALYSIS

Comparison between lot-to-date (month-to-month), lot-to-lot, and company-to-company CV was conducted using SPSS Software Version 19.0. All continuous variables were checked for normality using the one-sample Kolmogorov-Smirnov test. The data were expressed as mean±Standard Deviation (SD). Comparison between two groups was done using independent samples t-test, and comparison between three groups was done using one-way Analysis of Variance (ANOVA) repeated measures.

Cost reduction percentage calculation: The steps involved in calculating the cost reduction percentage by calculating the percentage difference between the new and current QC rules using the Westgard Quality cost worksheets are shown in [Table/Fig-1] [15].



[Table/Fig-1]: Flowchart for cost-reduction percentage calculation [15].

RESULTS

The existing practice score was 21 out of 75, as determined using the proforma mentioned in [Annexure I]. The AST has the maximum CV, creatinine has the maximum Bias%, and ALP has the maximum total allowable error% as shown in [Table/Fig-2,3], while calcium has the minimum CV and Bias%, and total protein has the minimum total allowable error%. The medical decision level for all 10 parameters is mentioned in [Table/Fig-2,3].

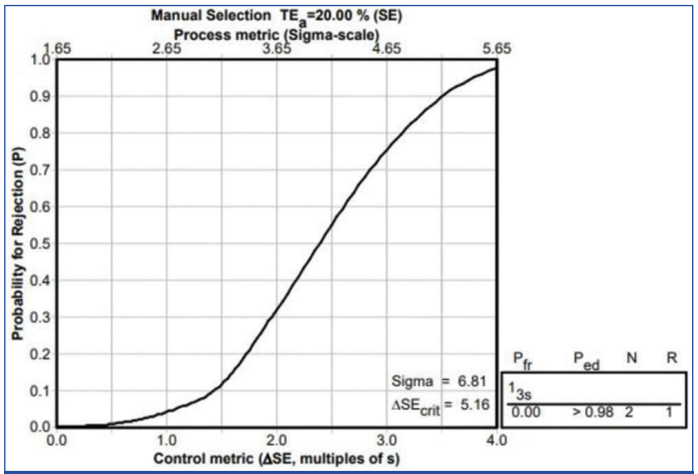
Parameters	CV%	Bias%	TEa%	Medical decision level
Urea	2.27	1.85	9	55.6 mg/dL
Creatinine	2.02	2.58	10	0.60 mg/dL
Calcium	1.89	0.84	11	7 mg/dL
Phosphorus	2.67	1.69	10	2.5 mg/dL
Magnesium	2.43	0.90	15	2 mg/dL
Uric acid	2.28	1.83	10	2 mg/dL
AST	3.15	2.36	15	60 IU/L
ALT	3.12	1.88	15	60 IU/L
ALP	2.89	1.96	20	150 IU/L
Total protein	2.25	0.90	8	6 g/dL

[Table/Fig-2]: CV%, Bias%, TEa% and medical decision level for the normal level Biorad QC material for the above 10 parameters.

Parameters	CV%	Bias%	TEa%	Medical decision level
Urea	2.31	1.85	9	107 mg/dL
Creatinine	2.14	2.58	10	1.60 mg/dL
Calcium	1.93	0.84	11	13.5 mg/dL
Phosphorus	2.26	1.69	10	5 mg/dL
Magnesium	2.38	0.90	15	6 mg/dL
Uric acid	2.14	1.83	10	8 mg/dL
AST	2.88	2.36	15	300 IU/L
ALT	2.74	1.88	15	300 IU/L
ALP	2.65	1.96	20	400 IU/L
Total protein	2.22	0.90	8	4.50 g/dL

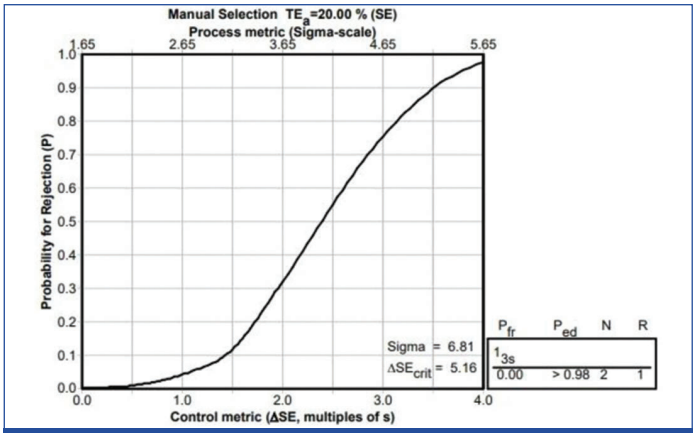
[Table/Fig-3]: CV%, Bias%, TEa% and medical decision level for the pathological level Biorad QC material for the above 10 parameters.

OPSpecs chart and power-function graph, which are helpful in selecting the control rule for ALP and could be used for other parameters as well are shown in [Table/Fig-4,5].



[Table/Fig-4]: OPSpecs for ALP for pathological level Biorad QC chart with an operating point and the line just above can be taken as a rule to be followed. Similarly, OPSpecs charts are used for other parameters also.

The ALP has a maximum sigma-metric value of 6, followed by a sigma-metric value of 5 for magnesium and calcium, a value of 4 for ALT and AST, and a value of 3 for creatinine, uric acid, phosphorus, total protein, and urea as shown in [Table/Fig-6]. As the sigma-metric values decrease from 6 to 3, the control rule changes from a



[Table/Fig-5]: The power function graph for ALP for pathological level Biorad QC for selecting the control rule as mentioned in a box. Probability of error detection on the y-axis vs size of systematic error (lower x-axis) and sigma quality (upper x-axis). Power curves represent Statistical Quality Control (SQC) procedure [14]. Similarly, a power function graph was used for other parameters.

single control rule of 1_{3S} to multicontrol rules of $1_{3S}/2_{2S}/R_{4S}/4_{1S}/10_X$. ALP, magnesium, calcium, ALT, AST, creatinine (normal level QC), uric acid (pathological level QC), and phosphorus (pathological level QC) showed more than 90% probability of error detection, while the remaining parameters showed less than 90% error detection when the above quality control rules were applied. All 10 parameters showed less than 10% probability of false rejection when the above rules were applied.

Parameters	Ped	Pfr	Sigma-metric	Rules to be followed
ALP (N)	>0.98	0	6.24	1_{3S}
ALP (P)	>0.98	0	6.81	1_{3S}
Magnesium (N)	>0.98	0	5.80	1_{3S}
Magnesium (P)	>0.98	0	5.92	1_{3S}
Calcium (N)	0.94	0	5.38	1_{3S}
Calcium (P)	0.92	0	5.26	1_{3S}
ALT (N)	0.98	0.01	4.21	$1_{3s}/2_{2s}/R_{4S}/4_{1S}/10_X$
ALT (P)	1	0.01	4.79	$1_{3s}/2_{2s}/R_{4S}/4_{1S}/10_X$
AST (N)	0.96	0.01	4.01	$1_{3s}/2_{2s}/R_{4S}/4_{1S}/10_X$
AST (P)	0.99	0.01	4.39	$1_{3s}/2_{2s}/R_{4S}/4_{1S}/10_X$
Creatinine (N)	0.91	0.01	3.67	$1_{3s}/2_{2s}/R_{4S}/4_{1S}/10_X$
Creatinine (P)	0.84	0.01	3.47	$1_{3s}/2_{2s}/R_{4S}/4_{1S}/10_X$
Uric acid (N)	0.89	0.01	3.58	$1_{3s}/2_{2s}/R_{4S}/4_{1S}/10_X$
Uric acid (P)	0.94	0.01	3.82	$1_{3s}/2_{2s}/R_{4S}/4_{1S}/10_X$
Phosphorus (N)	0.62	0.01	3.11	$1_{3s}/2_{2s}/R_{4S}/4_{1S}/10_X$
Phosphorus (P)	0.91	0.01	3.68	$1_{3s}/2_{2s}/R_{4S}/4_{1S}/10_X$
Total protein (N)	0.64	0.01	3.16	$1_{3s}/2_{2s}/R_{4S}/4_{1S}/10_X$
Total protein (P)	0.67	0.01	3.20	$1_{3s}/2_{2s}/R_{4S}/4_{1S}/10_X$
Urea (N)	0.64	0.01	3.15	$1_{3s}/2_{2s}/R_{4S}/4_{1S}/10_X$
Urea (P)	0.60	0.01	3.10	$1_{3s}/2_{2s}/R_{4S}/4_{1S}/10_X$

[Table/Fig-6]: Control rules for Normal (N) and Pathological level (P) Biorad QC material to be followed for the above 10 parameters when two levels of control material are used.

Cost-reduction percentage, which is maximum for ALT and minimum for ALP, calcium, and magnesium is shown in [Table/Fig-7]. It indicates that the current control rules that were followed were similar to the control rules to be followed for ALP, calcium, and magnesium. For the rest of the parameters, new control rules were to be followed for cost reduction.

Parameters	Cost-reduction percentage
ALT	95.8
AST	92.3
Creatinine	81.5
Uric acid	71.1
Phosphorus	68.8
Total protein	59.8
Urea	54.9
ALP	0.9
Calcium	0
Magnesium	0

[Table/Fig-7]: Cost-reduction percentage calculated using quality cost worksheet for waste and rework and for external failure cost.

Except for phosphorus (pathological level QC), all other parameters do not show any significant difference in the month-to-month CV of QC materials for three months as shown in [Table/Fig-8].

Parameters (CV)	Month	Normal level			Pathological level		
		Mean	SD	p-value	Mean	SD	p-value
Urea	1	4.81	1.76	0.97	3.93	0.90	0.98
	2	5.28	1.03		4.05	3.80	
	3	5.16	4.82		4.21	1.44	
Creatinine	1	5.59	0.93	0.98	4.42	1.69	0.45
	2	3.93	1.52		2.98	1.05	
	3	4.60	2.20		4	1.24	
Calcium	1	2.76	1.20	0.46	2.99	0.43	0.09
	2	2.16	0.47		2.12	0.64	
	3	1,95	0.72		1.89	0.41	
Phosphorus	1	4.74	1.88	0.14	3.49	0.73	0.03
	2	2.70	0.47		2.07	0.48	
	3	4.95	1.15		4.47	1.29	
Magnesium	1	4.27	1.13	0.19	4	1.32	0.23
	2	2.87	1.12		1.82	0.78	
	3	3.32	0.87		3.85	2.02	
Uric acid	1	3.78	1.69	0.19	2.87	0.57	0.48
	2	2.14	0.36		1.76	0.34	
	3	4.27	1.10		4.04	1.45	
AST	1	5.80	2.21	0.14	4.32	1.81	0.38
	2	2.88	0.52		4.25	1.02	
	3	6.25	1.73		5.58	0.65	
ALT	1	5.41	1.40	0.05	4.08	1.79	0.20
	2	2.96	0.64		2.24	0.55	
	3	5.76	1.76		4.61	1.89	
ALP	1	7.50	5.70	0.29	5.16	3.06	0.20
	2	2.96	0.78		2.06	0.40	
	3	5.40	1.31		4.95	2.12	
Total protein	1	3.90	1.85	0.16	6.15	6.32	0.37
	2	2.39	0.57		1.95	0.27	
	3	4.68	1.29		3.92	1.14	

[Table/Fig-8]: Comparison of the CV of normal and pathological level Biorad QC material month-wise for three months.*
*Comparison is done by one-way ANOVA with repeated measures. p-value <0.05 is considered significant

[Table/Fig-9] shows that except for uric acid (normal level QC) and AST (pathological level QC), there was no significant difference in the lot-to-lot CV of QC materials.

[Table/Fig-10] shows that except for magnesium (normal level QC) and AST (pathological level QC), there was no significant difference in the company-to-company CV of QC materials.

DISCUSSION

The sigma-metric-based QC rules appear to be helpful in selecting appropriate control rules for each parameter and also in reducing the overall cost expenditure in the laboratory.

Parameters CV	Lot	Normal level			Pathological level		
		Mean	SD	p-value	Mean	SD	p-value
Urea	1	3.57	0.96	0.08	3.61	1.15	0.53
	2	5.08	2.74		4.06	2.17	
Creatinine	1	4.37	1.42	0.59	3.60	1.31	0.71
	2	4.70	1.64		3.80	1.38	
Calcium	1	2.77	1.87	0.42	2.65	2.40	0.66
	2	2.29	0.85		2.33	0.67	
Phosphorus	1	3.11	0.82	0.06	2.90	1.07	0.49
	2	4.13	1.59		3.25	1.33	
Magnesium	1	2.91	0.92	0.18	2.95	1.13	0.64
	2	3.49	1.12		3.22	1.68	
Uric acid	1	2.34	0.77	0.03	2.44	0.64	0.28
	2	3.39	1.43		2.89	1.27	
AST	1	4.06	0.93	0.19	3.28	0.83	0.04
	2	4.98	2.15		4.72	1.30	
ALT	1	4.10	1.22	0.33	2.96	0.57	0.21
	2	4.71	1.78		3.64	1.75	
ALP	1	3.59	0.84	0.13	2.93	0.49	0.13
	2	5.28	0.64		4.06	2.44	
Total protein	1	2.75	0.82	0.09	3.07	0.92	0.41
	2	3.66	1.57		4.01	3.80	

[Table/Fig-9]: Comparison of the CV of normal and pathological QC material between lot 1 and lot 2 of Biorad.*
*Comparison is done by independent-samples t-test. p-value <0.05 is considered significant

Parameters (CV)	Company	Normal level			Pathological level		
		Mean	SD	p-value	Mean	SD	p-value
Urea	Randox	3.85	1.35	0.17	4.10	1.47	0.17
	Biorad	5.08	2.74		4.06	2.17	
Creatinine	Randox	4.82	1.20	0.85	4.26	1.04	0.85
	Biorad	4.71	1.64		3.80	1.38	
Calcium	Randox	2.62	0.70	0.31	2.26	0.49	0.76
	Biorad	2.29	0.85		2.33	0.67	
Phosphorus	Randox	3.66	0.97	0.39	3.81	0.83	0.30
	Biorad	4.13	1.59		3.34	1.31	
Magnesium	Randox	2.70	0.57	0.04	2.85	0.55	0.46
	Biorad	3.49	1.12		3.22	1.68	
Uric acid	Randox	3.24	0.87	0.76	3.56	0.95	0.16
	Biorad	3.39	1.43		2.89	1.27	
AST	Randox	4.37	1.34	0.41	3.69	0.77	0.02
	Biorad	4.98	2.15		4.72	1.30	
ALT	Randox	4.06	0.95	0.27	3.86	0.95	0.70
	Biorad	4.71	1.78		3.64	1.75	
ALP	Randox	4.10	0.91	0.28	3.80	0.81	0.73
	Biorad	5.28	3.64		4.06	2.44	
Total protein	Randox	3.55	0.67	0.83	3.60	0.83	0.71
	Biorad	3.66	1.57		4.01	3.80	

[Table/Fig-10]: Comparison of the CV of normal and pathological level QC material between Randox and Biorad companies.*
*Comparison is done by independent-samples t-test. p-value <0.05 is considered significant

In the present study, among the 10 parameters, ALP had a sigma-metric value >6. Calcium and magnesium had sigma-metric values between 5 and 6. AST and ALT had sigma-metric values between 4 and 5. Urea, creatinine, phosphorus, uric acid, and total protein had sigma-metric values between 3 and 4. When compared with the study by Mao X et al., ALP, magnesium, and urea had similar sigma-metric values of >6, 5-6, and 3-4, respectively. AST, ALT, creatinine, uric acid, and total protein in the present study had low sigma-metric values when compared to Mao X et al., study, which reported a sigma-metric value of >6 for AST, ALT, creatinine, and uric acid, and a sigma-metric value of 5-6 for total protein. The sigma-metric value for calcium and magnesium was not calculated in Mao X et al., study [6].

The difference in the sigma-metric values might also be due to differences in the analyser, reagents, methods and environmental conditions used between this study and Mao X et al., study.

As a result, in the present study, ALP, calcium, and magnesium will follow the 1_{3S} rule, whereas the remaining seven parameters will follow the $1_{3S}/2_{2S}/R_{4S}/4_{1S}/10_X$ rule with two levels of control materials. These rules were framed with the idea of low false rejection of less than 5% and high error detection of more than 90%. Thus, the present study provides additional support to previous study findings of high sigma-metrics reducing the number of control rules and vice versa [16].

With the help of waste and rework and the external failure cost worksheet, it has been found that there would be a decrease in cost for seven parameters if the new control rules were followed instead of the existing control rules, and for the remaining three parameters, no cost reduction was noted, indicating that the current control rules were similar to the new control rules framed. Thus, the present study proves that running two levels of control five times a day for low sigma-metric QC parameters is still cost-effective and beneficial compared to running two levels of control material twice a day using waste and rework and external failure cost worksheets. Similarly, for high sigma-metric QC parameters, running two levels of QC single time a day also proves to be cost-effective.

There was no significant difference in lot-to-date (month-to-month), lot-to-lot, and company-to-company CV on QC rules for most of the parameters despite changing the reagent lot in between. As a result, the number of calibration usages can be reduced, enabling cost reduction.

Limitation(s)

Studies using different company QCs can further strengthen the present study. Studies using at least six or more QC lots can also provide sufficient evidence for the findings in the present study.

CONCLUSION(S)

It is recommended that each clinical chemistry laboratory establish its own control rules using sigma-metric-based QC rules, aiming to reduce the cost. Having prior knowledge about lot-to-date (month-to-month), lot-to-lot, and company-to-company CV on QC can also reduce costs. By reducing costs and simultaneously improving the quality of test results, the present study provides an idea for managing the laboratory cost-effectively, and the reduced cost can be utilised for further improvements in the laboratory.

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"To my parents, to science, to humanity"

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[ANNEXURE I]

Scoring of existing practices proforma

15 steps involved in performance-driven quality control (scoring the existing practices)	Score for each step, where a value of "0.0" is similar to the following examples	Score for each step, where a value of "5.0" is similar to the following examples	Rating
When selecting an analytical process, compare claims of accuracy and precision. These claims form an important component of the selection process.	We do not include accuracy and precision on our criteria list.	Accuracy and precision are the most important items on our criteria list.	1
Define performance standards for each analyte that state "if a sample has a true value of x units, reported results must be within y units or z% of that value".	Never. We do not have performance standards or TEa limits defined for any analyte. "This is a good laboratory. We are good people. Our methods are all good."	We set performance standards for all tests.	2
Ensure performance standards are met before reporting any results.	Never.	Always.	2
Select QC samples with analyte levels that monitor clinical decision points.	No. We just accept what the manufacturer provides.	Yes. If necessary, we purchase separate controls or make samples.	0
Verify that QC samples react the same way as patient samples (i.e., changes in accuracy or precision of patient results are reflected by proportional changes in accuracy or precision in QC sample results).	No. We never verify changes in QC patient samples or monitor patient values. We don't check for this when purchasing new controls.	Yes. We verify changes in QC with patient samples andmonitor patient values or moving averages. We check new QC samples for this before purchasing.	0
Periodically calculate the mean of a defined set of QC points as an indicator of accuracy.	No. We use a running mean. We don't examine or assess mean values on a regular basis.	Yes. We calculate and examine and assess mean values on a regular basis.	0
Periodically calculate the SD or cv of a defined set of QC points as an indicator of imprecision.	No. We use a running SD. We don't examine or assess SDs or CVs on a regular basis.	Yes. We calculate and examine and assess SDs or CVs on a regular basis.	0
Assign the current calculated mean and SD on the QC chart.	No. We assign a mean from the history or the package insert or whatever, and/or…"The SD assigned on the chart is not the actualmethod SD; it comes from PT limits or package inserts or we just multiply it a few times so we don't get false QC flags".	Yes. We always assign the current calculated mean and SD on the QC chart. We rely on our QC strategy to alert us to change. When a shift in the mean occurs, we update the mean on the QC chart (after making sure the system still meets performance standards).	0
Periodically calculate the margin for error or critical systematic error (SEc) for each QC sample.	Never.	Regularly.	0
Select appropriate control strategies (frequency of testing, QC rules, and processes to create and examine QC charts) for each QC sample on each analyte based on margin for error (SEc). Choose a QC strategy that will detect changes that would cause resultsto fail to meet the performance standards defined for each QC sample.	No. We use whatever QC software comes with our instrument or LIS or QCsamples. We never compare QC results to performance standards. Or...Someone (who cannot be questioned) decided to use a 1-2s or 1-3s rule for all controls on all tests.	Yes. We proactively select QC strategies and implement performance-driven quality control. We regularly compare QC results to performance standards and adjustthe QC process if the method performance changes (as noted by a change in mean or SD of a new data set).	0
Plot all results on QC charts.	Never. We don't plot results.	Always. All values.	5
Apply rules, examine charts and report patient results only if there are no QC flags.	No. We report results and then someone examines QC later.Or, we report all results - QC flags don't make us stop reporting. The doctors need the results.	Yes. We always check QC before reporting patients. We never report results on runs with QC rejects until the cause of the flag has been determined and we are sure the method still meets performance standards.	5
If QC flags indicate that the accuracy or precision of themethod has changed, compare the mean and SD of the current data population to performance standards.	If we start getting a new mean, then that must be what the control should be now. Or... "change is OK if the supervisor says so". Or... "If you can explain the change", it's OK. Or.. "If the change is not too big", it's OK.	If we start getting a new mean or SD, then we calculate Total Error and SEc to make sure the method is within allowable error.	0
If the changed analytical process still produces results within allowable limits of the correct/true value, adjust the QC process and carry on.	Sort of. We change the values on the chart whenever we start getting a new mean or SD. Then the chart looks better. Or... No. Whenever there is a change, we call for technical support. "All change is bad. It must be eliminated."	If the method is within TEa, we change the mean or SD on the QC chart and, if advisable, adjust the QC rules and process.We realise change can be for the better- change is not always bad.	1
If the method no longer meets performance standards, then stop reporting results while you make sure the numbers are correct and corrective action if indicated.	No. We never stop reporting results. The doctors need the results.	Yes. We never release results that may be wrong and therefore lead the clinician to the wrong decision and subsequent action, thus harming the patient.	5
		Total score	21