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Research Article

Patient based real time quality control using average of normal approach

Sarvatnida Shaikh[1], Shilpa Jain[2], Sarika Baku[3]

[1]Department of Biochemistry, Dharmsinh Desai University, Dr. N.D. Desai Faculty of Medical Science and Research, Nadiad, India
[2]Department of Biochemistry, All India Institute of Medical Sciences (AIIMS), Bhatinda, India
[3]Department of Biochemistry, GMERS Medical College, Junagadh, India

Abstract

Objectives: The limitation of internal quality control (IQC) based on daily running of commercially available QC material is that it is non-commutable and errors cannot be detected in between the scheduled runs. This study was carried out with the objective of finding the utility of patient based real time quality control (PBRTQC) in overcoming these limitations.

Methods: This observational descriptive study was carried out in the clinical chemistry laboratory of a tertiary care hospital between July 2023 to December 2023. PBRTQC was initiated in the laboratory by using Average of Normal (AoN) approach for serum sodium and potassium. Patients' sample-based reference mean (RP_M) and standard deviation (RP_{SD}) were calculated from the previous six months' data using reference intervals as truncation limits. For the next 2000 samples, the mean was calculated for each block of 20 samples ($\bar{x}$) and designated as $\bar{x}1$, $\bar{x}2$, $\bar{x}3$... These block means were plotted on the LJ chart and alarms were raised on the violation of predefined control rules. These alarms were investigated and necessary corrective measures were implied in the laboratory.

Results: $RP_M \pm RP_{SD}$ for sodium was 139.23±3.72 mEq/L and potassium was 4.26±0.45 mEq/L. The scheduled IQC was within range during the study. Alarms were raised for $\bar{x}13$, $\bar{x}28$, $\bar{x}29$, $\bar{x}30$, $\bar{x}35$, $\bar{x}36$, $\bar{x}55$, $\bar{x}74$ and $\bar{x}96$. The workup of these alarms revealed instrument calibration error in most of the cases. However, analysis of $\bar{x}35$ and $\bar{x}36$ revealed delayed transport, improper temperature maintenance and partial hemolysis. All responsible personnel were given training regarding sample transport procedure. Using real time monitoring, we were able to detect errors which would have otherwise gone unnoticed by conventional IQC.

Conclusion: PBRTQC permits stringent quality control in analytical as well as pre-analytical phase of testing procedure, even during the intervals between scheduled IQC runs. Successful implementation of PBRTQC will provide additional confidence in reporting laboratory results.

Keywords: Average of normal, quality control, real-time QC, serum potassium, serum sodium, reference mean (RP_M), reference mean standard deviation (RP_{SD})

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Conventional internal quality control (IQC) analysis strategies employed by laboratories involve periodic testing of QC sera. However, this strategy can detect only analytical errors at the scheduled QC run and there is no way to detect errors in the intervals between the run time. Further, preanalytical factors which affect patient's results are not reflected during IQC analysis. So, periodic IQC analysis delays error detection and is not useful for real time monitoring of results [1, 2].

Address for correspondence: Sarvatnida Shaikh, MD. Department of Biochemistry, Dharmsinh Desai University, Dr. N.D. Desai Faculty of Medical Science and Research, Nadiad, India
Phone: 9898350352 **E-mail:** sarvatnida@gmail.com **ORCID:** 0000-0002-4762-7770
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To augment existing QC strategies, various laboratories have tried different techniques, including inter-laboratory comparison, proficiency testing, patient based real time quality control (PBRTQC), six sigma metrics, etc. PBRTQC was introduced as a technique of quality control early in the 1960s [3]. The earliest method was called 'Average of Normal' strategy (AoN) [4]. It was largely based on a patient-centric approach and used the results generated by the laboratory over a defined number of patients' results to calculate the central tendency (mean/median) of an analyte. Subsequent patient results are then monitored in real time for any unusual deviation from this central tendency. This real time analysis will immediately detect any error which shift the patients' results in one direction. This could be analytical errors like calibration failure, instrument malfunction, etc., or even pre-analytical errors like hemolysis, delayed sample transport, sample processing errors, etc. So, PBRTQC strengthens and complements traditional IQC and so is a useful tool for quality assurance [5, 6].

With time, many strategies for PBRTQC were developed, like moving average, Bull's algorithm, moving SD, moving percentiles, exponentially weighted moving averages, etc. [7]. However, PBRTQC programs are still not widely implemented in clinical chemistry laboratories because of complex procedures and calculations, lack of any standard protocol for implementation, limited software support and a deficit of trained personnel to analyze and interpret the vast stream of data.

As a step towards continual improvement, we planned to initiate PBRTQC program in our clinical chemistry laboratory for critically important parameters like serum sodium and serum potassium using AoN approach.

Materials and Methods

This observational descriptive study was carried out in Clinical Chemistry Laboratory of a tertiary care hospital between July 2023 and December 2023. We planned to initiate PBRTQC program by AoN approach for serum sodium and serum potassium. All samples for electrolyte analysis are tested on Microlab 'MICROLYTE ANALYZER' in our laboratory. The instrument undergoes scheduled calibration every twelve hours. We validate this calibration by analyzing IQC sample. So, we perform two levels of Internal Quality Control (IQC) testing every 12 hours, in line with the Clinical Laboratory Standards Institute (CLSI) guidelines, which recommend running at least two levels of QC once daily. Further, we follow Westgard's rule of 1^{3S} and 2_{2S} for rejecting the QC run [8]. 1_{3S} rule rejects the run when a single control measurement exceeds the mean plus 3SD or the mean minus 3SD control limit. 2_{2s} rule rejects the run when two consecutive control measurements exceed the same mean plus 2SD or the same mean minus 2SD control limit [8].

To initiate AoN approach, we selected serum electrolytes based on two criteria. The first criterion was the daily number of performed tests. Serum electrolytes were representatives of high-frequency tests in our laboratory. Secondly, electrolytes have low biological variation (less than 1%) and by applying narrow truncation limits, we can get normal distribution of data [9]. We calculated a reference mean for serum sodium and serum potassium from previous six months' data (January to June 2023) of patients' results (n=8990). These results included all inpatient and outpatient departments representative of the general hospital population. The results were anonymized and exported from the laboratory information system(LIS) to excel sheets. The reference intervals of serum sodium (135–145 mEq/L) and serum potassium (3.5–5.5 mEq/L) were used as truncation limits to exclude 528 values from 8990 values. The remaining values (n=8462) were used for computing reference mean, i.e., patients' sample-based reference mean (RP_M) and reference standard deviation (RP_{SD}).

The subsequent samples were tested in blocks of 20 samples each. The samples were tested in blocks of 20, based on the recommendation by Li et al. [10], who proposed using a block size between 20 and 50. This block size facilitates quick error detection while minimizing the risk of false rejections. We excluded any value outside of $RP_M \pm 3\ RP_{SD}$ from these blocks. On applying Shapiro Wilk test, we found the blocks had normal distribution of data. A block mean ($\bar{x}$) for 20 samples was calculated and designated as $\bar{x}1$, $\bar{x}2$, $\bar{x}3$ ... $\bar{x}n$. We then plotted Levey Jennings (LJ) chart using RP_M and action/control limits were applied at ±2% and ±3% of RP_M. These narrower action limits were chosen rather than RP_{SD} as action limit as electrolytes have low biological variation (less than 1%) and it would increase sensitivity of analysis [9]. Any patient value crossing these action limit would alert the analyst.

All block means were being continuously plotted and analyzed for violation of following rules:

Rule I: One of the block means crosses ±3% action limit or

Rule II: Three consecutive block means crossing ±2% action limit.

The block means which violated any of the above rules were investigated to identify whether it is an analytical error or pre-analytical error. The workup of alarm raised was done according to the algorithm as shown in Figure 1. The error was rectified and necessary corrective measures were implemented in the laboratory.

Results

The RP_M derived from 8462 patient samples for serum sodium was 139.23 mEq/L and for serum potassium was 4.26 mEq/L. The action limits calculated from 2% of RP_M and 3% of RP_M are shown in Table 1. The subsequent patient results were being continuously divided into blocks of 20 values. The block means for 100 such blocks is shown in Table 2. These block means were being continuously plotted on LJ chart having RP_M and action limits (Figs. 2, 3).

During monitoring the 100 block means, we found that most of the block means were within ±1SD for both serum sodium and serum potassium. The PBQRTC alarm was raised seven times during our study. The routine twelve hourly IQC was

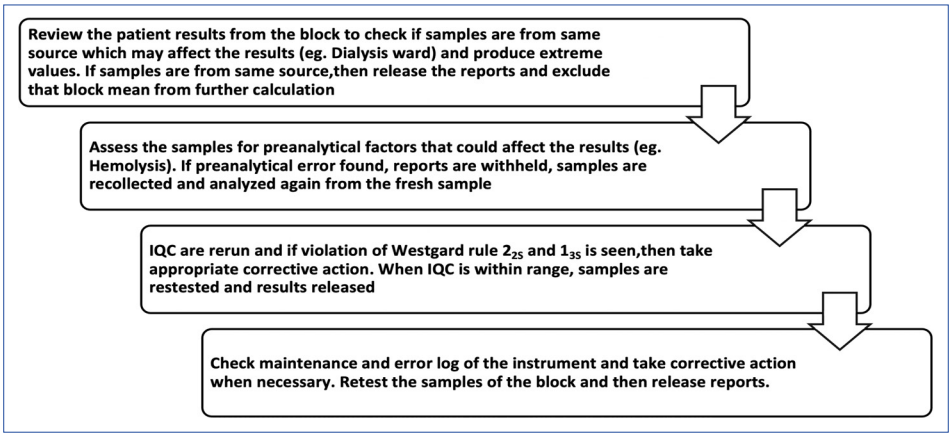

Figure 1. Figure shows sequential steps in the workup of alarm.

IQC: Internal quality control.

Table 1. Table shows the patients based reference mean (RPM), reference standard deviation (RPSD), 2% and 3% action limits for 8462 samples

Parameter	Serum sodium (mEq/L)	Serum potassium (mEq/L)
RPM	139.23	4.26
RPSD	3.72	0.45
RPM + 2% of RPM	142.01	4.34
RPM - 2% of RPM	136.45	4.18
RPM + 3% of RPM	143.40	4.38
RPM - 3% of RPM	135.09	4.14

within range during the study. The analysis and corrective action of the alarms raised are explained below:

- Rule I was violated by x̄28, x̄29, x̄30 for both serum sodium and potassium. For sodium, these three block means were below the 2% action limit, whereas for potassium, these block means were above the 2% action limit. The workup for these alarms is shown in Table 3. We found that there was no analytical error, as the IQC was retested and found to be within range and no instrument malfunction had occurred during the analysis. We suspected these samples to be hemolyzed but no apparent hemolysis was visible on inspection. On investigating the records for the time of

Table 2. Table shows block means (x̄) for serum sodium (Sod.) and serum potassium (Pot.). Each block represents an average of twenty samples

Block no.	Block mean sod. mEq/L	Block mean pot. mEq/L	Block no.	Block mean sod. mEq/L	Block mean pot. mEq/L	Block no.	Block mean sod. mEq/L	Block mean pot. mEq/L	Block no.	Block mean sod. mEq/L	Block mean pot. mEq/L	Block no.	Block mean sod. mEq/L	Block mean pot. mEq/L
1	138.70	4.21	21	137.20	4.21	41	140.23	4.32	61	140.05	4.19	81	139.31	4.20
2	141.10	4.28	22	136.42	4.24	42	140.76	4.27	62	137.70	4.25	82	140.94	4.19
3	135.78	4.21	23	138.66	4.18	43	140.73	4.29	63	138.55	4.16	83	139.20	4.24
4	136.16	4.24	24	139.78	4.19	44	139.57	4.25	64	138.15	4.2	84	142.05	4.3
5	137.78	4.27	25	138.64	4.21	45	137.16	4.29	65	139.50	4.25	85	142.16	4.22
6	139.30	4.25	26	138.30	4.22	46	136.52	4.22	66	136.80	4.21	86	138.15	4.24
7	139.00	4.21	27	137.17	4.29	47	135.95	4.24	67	135.65	4.31	87	141.00	4.3
8	137.00	4.27	28	135.20	4.15	48	136.75	4.29	68	138.52	4.24	88	141.10	4.36
9	141.20	4.28	29	135.60	4.16	49	137.20	4.29	69	139.20	4.27	89	137.00	4.25
10	138.88	4.34	30	135.30	4.15	50	139.10	4.23	70	136.40	4.25	90	138.85	4.29
11	136.60	4.23	31	138.17	4.32	51	140.33	4.32	71	139.15	4.31	91	137.31	4.32
12	137.25	4.2	32	138.00	4.22	52	140.23	4.29	72	139.15	4.22	92	137.75	4.2
13	134.95	3.9	33	136.00	4.23	53	136.63	4.19	73	136.26	4.31	93	138.27	4.3
14	140.20	4.27	34	138.00	4.25	54	138.94	4.21	74	134.80	4.04	94	142.00	4.23
15	137.42	4.27	35	131.85	5.12	55	134.75	3.95	75	136.36	4.22	95	139.50	4.21
16	139.73	4.24	36	132.35	4.93	56	139.55	4.22	76	138.41	4.3	96	134.65	4.03
17	137.55	4.2	37	138.35	4.25	57	138.42	4.28	77	136.94	4.33	97	136.52	4.32
18	139.23	4.2	38	139.83	4.27	58	140.70	4.24	78	141.05	4.22	98	142.35	4.26
19	138.82	4.24	39	140.38	4.17	59	137.30	4.26	79	136.47	4.29	99	140.50	4.26
20	139.75	4.25	40	137.70	4.21	60	138.27	4.24	80	138.95	4.21	100	138.42	4.28

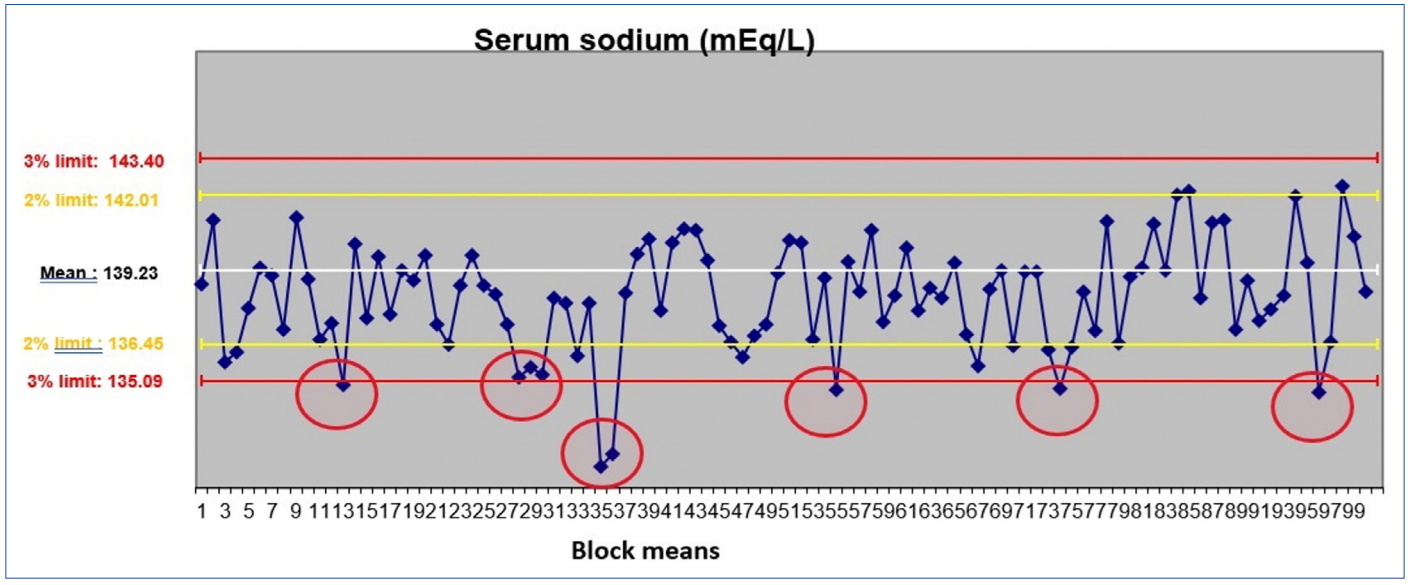

Figure 2. Shows LJ chart for serum sodium; White line indicates RP_M:139.23 mEq/L; Yellow line indicates 2% action limit:142.01 mEq/L and 136.45 mEq/L; Red line indicates 3% action limit:143.04 mEq/L and 135.09 mEq/L; Circle indicates alarm raised.

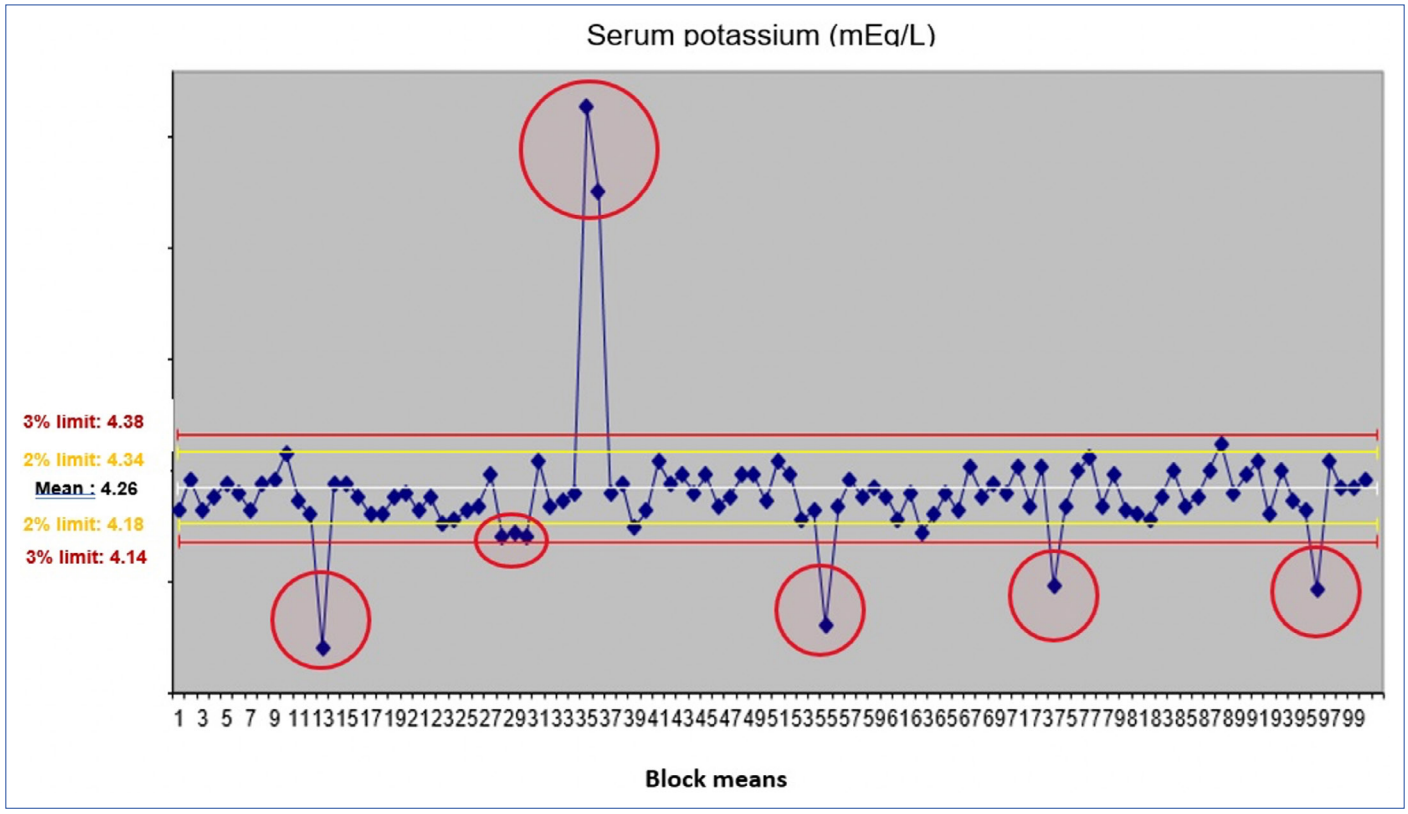

Figure 3. Shows LJ chart for serum potassium; White line indicates RP_M:4.26 mEq/L; Yellow line indicates 2% action limit:4.34 mEq/L and 4.18 mEq/L; Red line indicates 3% action limit:4.38 mEq/L and 4.14 mEq/L; Circle indicates alarm raised.

sample collection, transport and sample receipt in the laboratory. It was found that the transport of these samples from OPD was delayed. Transport boxes were inspected and it was found samples were transported without proper temperature maintenance. These could be the possible causes of partial hemolysis of these samples and hence outliers were seen on PBRTQC charts. These preanalytical errors could be detected by only PBRTQC monitoring and traditional IQC alone could have missed it. As a corrective action, all OPD personnel were trained regarding proper storage and transport of samples and they were instructed to recollect and retest all the affected samples.

Table 3. Table shows workup and corrective action for alarms raised

		PBRTQC alarm workup				
Block mean	**Rule violated**	**Review of patients results**	**Observed preanalytical problem**	**IQC testing (2 levels)**	**Maintenance and error log review**	**Corrective action performed**
x̄13	Block mean crossing ±3% action limit	Samples not from same source	No	Out of range	No error found	Recalibration done and patient samples retested and new results issued
x̄35	Block mean crossing ±3% action limit	Samples not from same source	No	Out of range	No error found	Recalibration done and patient samples retested and new results issued
x̄36	Block mean crossing ±3% action limit	Samples not from same source	No	Out of range	No error found	Recalibration done and patient samples retested and new results issued
x̄55	Block mean crossing ±3% action limit	Samples not from same source	No	Out of range	No error found	Recalibration done and patient samples retested and new results issued
x̄74	Block mean crossing ±3% action limit	Samples not from same source	No	Out of range	No error found	Recalibration done and patient samples retested and new results issued
x̄96	Block mean crossing ±3% action limit	Samples not from same source	No	Out of range	No error found	Recalibration done and patient samples retested and new results issued
x̄28, x̄29, x̄30	Three consecutive block means crossing ±2% action limit	Samples are not from same source	Delayed transportation could have caused partial hemolysis	Within range	No error found	Recalibration done and patient samples retested and new results issued

PBRTQC: Patient based real time quality control; IQC: Internal quality control; x̄: Block mean.

- Rule II was violated by x̄13, x̄35, x̄36, x̄55, x̄74, x̄96 as these block means crossed ±3% action limit. The workup of these alarms is shown in Table 3. It revealed that IQC was out of range during that time of testing these samples. So, as a corrective action, the instrument was calibrated and then IQC was retested which came within range. For these blocks, patient reports were released only after retesting and a new block mean was obtained. So, we found that even though the analyzer went out of calibration at some point of time, but the conventional IQC done at scheduled intervals failed to detect it.

Continuing the PBRTQC monitoring

For continuous monitoring, we revised the RP_M value after obtaining 100 block means within $RP_M \pm 3\ RP_{SD}$. The revised value (RP_{M1}) is calculated using average of previous RP_M and 100 block means. This revised RP_M is then used for further real time monitoring of patients' results.

Discussion

Successful implementation of PBRTQC programs provide an exciting opportunity for clinical laboratories to strengthen their existing quality control procedures. This paper presents the steps in establishment of the most fundamental AoN strategy for real time monitoring of patient results in a tertiary care hospital.

AoN strategy was the earliest version for PBRTQC, described by Hoffman et al. [4] in 1965. In this approach, selected patient's result that falls within the reference range is used in the calculation of a stable mean and 95% confidence interval was used as control limits [11]. After that, the average of selected consecutive patient results should fall within the control limits established for that population. According to Badrick T et al. [1], the control limits for PBRTQC can be defined by the user according to the quality goal desired. In this study, control limits were designed according to method of Korpman and Bull [12]. We chose serum electrolytes for initiating PBRTQC in our laboratory because they have low biological variation, thus simplifying the monitoring process [13, 14].

The procedure was initiated by calculating an RP_M and RP_{SD} from two months of data of electrolytes and using the reference interval as the truncation limits. These truncation limits would exclude values above or below a defined threshold, which could unduly shift the mean value. The use of reference range for truncation limits was proposed by Hoffman et al. [4] If narrower truncation limits are used, it would hinder error detection and exclude all results affected by bias [5]. In addition to truncation limits, other criteria can also be used to exclude certain patient groups (e.g., based on specific department, age, patient on dialysis) which would shift the mean on one side [1, 15].

After calculating RP_M and RP_{SD}, we used PBRTQC operated in batch mode. The number of results included in one batch is

called block size. A smaller block size will detect large errors earlier [1, 10]. So, we divided the subsequent samples into blocks of 20 and block means ($\bar{x}$) were calculated and plotted on LJ and analyzed for any violation of the predefined control limits. Whenever a block mean crossed the control limits, an alarm was generated in real time to ensure proper notification of personnel.

The workup of our alarms was designed according to the recommendations given by many authors [7,16–18]. These guidelines were adapted and modified according to the practical applicability for our laboratory. Since most errors occur during pre-analytical phase, it was justified to initially review patient results and samples as recommended by Badrick et al. [7] This was followed by analysis of internal quality control and reviewing maintenance logs to evaluate the alarm [17] . As we had only one electrolyte analyzer, we could not perform repeat testing of the sample on another analyzer, which should have been an integral part of alarm workup.

In our study, total of eight alarms were raised for 100 blocks analyzed (2000 samples). The frequency of alarm occurrence was in agreement with the results of other authors [16–20]. The workup of these alarms was manageable by the existing laboratory staff and the frequency of alarms did not cause alarm fatigue [21]. Our laboratory runs IQC every twelve hours but we noted IQC violations in most cases when PBRTQC alarm was raised. This indicated that PBRTQC is helpful in detecting errors even between the IQC runs. We performed recalibration of equipment in most of these violations. We need to further examine if more frequent recalibration of the electrolyte analyzer could reduce the frequency of occurrence of such alarms [22].

Seven out of eight alarms raised in this study were due to analytical errors, which were corrected by instrument recalibration and retesting of patient samples. Hence, PBRTQC is useful for detecting analytical errors which could not be detected by traditional IQC. This is in agreement with studies done by various authors [14, 19, 23–25].

Further, in our study one preanalytical error was detected in the form of delayed transport of samples to the laboratory. This could have caused partial hemolysis and led to erroneous results. This error couldn't be detected by traditional IQC, thus signifying the utility of PBRTQC in detecting pre-analytical errors. This use of PBRTQC has been explored by some authors, like Westgard et al. [26] who implemented PBRTQC for blood gas analysis samples and reported that 1.91% of the total errors were due to preanalytical factors, mainly due to micro-clots caused by improper mixing or improper anticoagulant. Lorde et al. [27] implemented machine learning algorithms on PBRTQC procedures for detecting pre-analytical errors like contamination of samples with intravenous fluid, delayed sample analysis and incorrect vacutainer errors [27]. However, there is limited research on the use of PBRTQC for detecting pre-analytical errors, which may stem from the extensive workup needed, adding on to the already complex and burdensome process of implementing PBRTQC.

Overall, our results demonstrated that the introduction of PQRTQC in laboratory should be done in a phased manner and supported by LIS to ease the implementation and evaluation of alarms. Commencing PBRTQC in a laboratory could have its own hurdles, but in the long run, it will provide additional confidence in reporting laboratory results. We also agree that PBRTQC cannot replace the existing internal quality control programs, but it can supplement and strengthen it.

The major limitation of our study is the fact that we performed PBRTQC on only serum sodium and potassium, who have low biological variation and hence, the best bias detection capabilities. However, the Clinical and Laboratory Standards Institute guidelines suggest that selection of tests for implementation of PBRTQC should be based on a risk-based quality control assessment for all parameters [28]. In our study, most of the calculations were done from Microsoft Excel and LIS support. However, as software support continues to improve, complex PBRTQC procedures will become easier to implement and more accessible for use in clinical chemistry laboratories.

Conclusion

This paper demonstrates that it is possible to effectively implement a simple PBRTQC procedure in a laboratory, even with limited software support. Each laboratory must assess the available PBRTQC strategies and tailor the techniques to meet their specific needs. Future research should concentrate on integrating the PBRTQC procedure outlined here with existing traditional control tools to develop a laboratory quality control plan grounded on risk assessment.

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