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Original Research Article

Evaluation of Short-term vs. Cumulative IQC Statistics for Reducing False Rejections in a High-Volume Laboratory

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Abstract:

Background and Objectives: Internal Quality Control (IQC) serves as a fundamental safeguard in clinical laboratories, ensuring that every test result meets the necessary standards for precision and reliability. IQC protocols require the use of control materials with established target ranges for all diagnostic parameters to validate the laboratory's clinical output. The term "IQC strategy" encompasses the total design of the quality control process, specifically identifying the control materials, testing intervals, concentration levels, and statistical rules required to maintain analytical quality. An effective IQC strategy ensures that lab tests remain reliable enough for their specific medical purpose, protecting patients from the consequences of undetected errors. Despite established international IQC recommendations, a significant gap remains between theory and everyday laboratory practice. The current study aims to determine the Lab mean and Standard deviation (SD), and compare the bias using Lab means derived from 20 days (Scheme I) and a long-term 90-day period (Scheme II) IQC results, respectively.

Materials and Methods: The study was carried out at the Clinical Biochemistry Laboratory, East Point College of Medical Sciences & Research Center (EPCMS&RC), Bangalore. In the Clinical Biochemistry section of EPCMS&RC Central laboratory, IQC is run daily at 8-hourly intervals on the Vitros 4600 Chemistry analyzer. Lab mean and SD for a new QC lot 89760 were derived using 20-day (Short term-I) and 90-day (Long term-II) IQC results for six biochemical parameters: Glucose, urea, creatinine, sodium, potassium, and chloride. Daily monitoring of IQC for 6 months was done using control charts of two schemes. (Scheme-I during Jan-Mar, 2025 & Scheme-II during Apr-Jun, 2025).

Results: Analysis of IQC data using the Westgard rules shows that the total number of QC outliers was 43 with Scheme-I control chart limits, as compared to only 7 times with Scheme-II control chart limits. There is a significant difference in the EQAS results obtained under two different schemes. Average bias is greater with scheme I than with scheme 2 for Chloride, Potassium, Creatinine, and urea, suggesting that scheme II QC control limits will be more appropriate than scheme I for defining IQC limits.

Conclusion: Using a 90-day Lab mean and SD for daily IQC monitoring reduces Westgard rule violations without compromising EQAS performance. Utilizing a larger data set over an extended period minimizes unnecessary run rejections and recalibrations, ultimately lowering operational costs and improving turnaround times.

Keywords: Westgard Rules, Clinical Laboratories, EQAS, IQC Monitoring.

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Introduction

Quality is defined as conformance to end users' requirements. [1] Quality is assessed in terms of accuracy, precision, sensitivity, and specificity.[2] IQC is a systematic daily monitoring process that ensures lab results are accurate and reliable. Using tools such as Levey-Jennings charts and Westgard rules, labs can detect and correct analytical errors in real time before releasing patient reports.[3] Most labs typically schedule their daily IQC frequency and volume to align with accreditation standards. Yet, under good laboratory practice, each laboratory is required to develop a unique “Individual Quality Control Plan”. By doing this, unnecessary, repeated IQC runs that cause waste are avoided, lowering the institution’s operational costs.[4]

IQC strategy defines whether a rule acts as a "stop" or a "caution" sign, and these can change depending on the specific test. A rejection rule calls for ceasing the testing process and fixing the problem

immediately. A warning rule is an early heads-up; you don't have to stop testing yet, but it's a signal to check for potential issues before they worsen. [5] Past research consistently emphasizes that robust IQC systems are essential for maintaining standards in clinical laboratories. After defining an IQC strategy, it shouldn't be left on autopilot. A cycle of continuous improvement is essential to keep the program effective. Regularly re-evaluating IQC helps the lab catch real analytical errors more reliably while reducing the noise of false alarms.[6]

IQC rules aren't foolproof. They sometimes miss real analytical errors (false negatives) or, on the flip side, trigger an alarm when nothing is actually wrong (false positives). Even using a combination of rules won't give 100% certainty. Probability of Error Detection (Ped) and the Probability of False Rejection (Pfr) are used to measure how often IQC rules fail. Ideal IQC rules would catch every single error (Ped = 100%) and never trigger a false alarm (Pfr = 0%). [7]

Strict rules will not ensure how well a test actually performs; they make the system more sensitive to small shifts. While this helps catch minor errors, it also triggers more false alarms, leading to constant troubleshooting, repeated tests, and delayed patient results. This extra work makes the lab less efficient and more expensive to run. Crucially, Sigma metric is based on the Total Allowable Error (TEa) and the test's inherent precision—it won't change just because of Westgard rules—5,6A fixed mean stays constant over time, giving a steady target for your IQC. A floating (or cumulative) mean updates with every new result, constantly shifting as a moving average. The gap between the lab's mean and the material's "true" value is the bias, which indicates how much systematic error or inaccuracy is creeping into the process. The current study aims to determine and compare bias using Lab means derived from short-term (Scheme I) and long-term (Scheme II) IQC results, respectively.[7] The study aimed to derive the laboratory mean and standard deviation (SD) of internal quality control (IQC) results over both short-term (20-day) and long-term (90-day) periods. It further sought to evaluate IQC compliance by auditing daily results against Westgard criteria using these two statistical benchmarks. Additionally, the study aimed to assess the correlation between IQC Westgard rule violations and external quality assurance scheme (EQAS) performance when applying 20-day versus 90-day SD values.

Materials and Method

The study was carried out at the Clinical Biochemistry Laboratory, East Point College of Medical Sciences & Research Center (EPCMS&RC), Bangalore. In the Clinical Biochemistry section of EPCMS&RC Central laboratory, IQC is run daily at 8-hourly intervals on the Vitros 4600 Chemistry analyzer. As per our Laboratory protocol, when a new lot of IQC sera is to be put into use, the means and SDs should be established. Lab mean and SD for a new QC lot 89760 were derived using 20 days (Short term-I) and 90 days (Long term-II) results. Daily monitoring of IQC for 6 months was done using control charts of two schemes. (Scheme I during Jan-Mar, 2025 & Scheme II during Apr-Jun, 2025).

The frequency of violations of the Westgard Rules and the EQAS standard deviation index (SDI) were compared when using these two schemes. Six parameters were chosen for comparison, and the methods employed for their measurement are as follows:

1. Plasma Glucose: GOD-POD method. [8,9,10]
2. Serum Urea: Urease method. [8,9,10]
3. Serum Creatinine: Creatinine amidohydrolase method. [8,9,10]
4. Serum Sodium: ISE Direct [8,9,10
5. Serum Potassium; ISE Direct [8,9,10]
6. Serum Potassium; ISE Direct [8,9,10]

Commercially available quality-control sera were used to test the biochemical parameters mentioned above in this study. Patient specimens were not used in the present study.

Results

The performance of 6 parameters tested in the Clinical Biochemistry Laboratory was included in the study. Their means and SDs were derived according to two schemes as mentioned below:

Scheme I: Means and SDs derived using 20-day results and used during January to March 2025.

Scheme II: Means and SDs derived using 90-day results and used during April to June 2025.

The two schemes were then compared with respect to violations of Westgard rules, acceptance limits, and EQAS SDI.

The rules to follow are as follows: Reject QC when 2-level QC is used:

1) Either QC values are outside 3 SD ($1_{3}s$)
2) Both QC values are outside 2 SD on the same side, but within 3 SD ($2_{2}s$)
3) Difference between both QC values is >4 SD i.e. one level QC is > 2 SD and other level QC is <2SD (R4s).
4) Ten consecutive values of the same level QC are >/< the mean, but within 2 SD (10x).
5) Five consecutive values of one level QC and five consecutive values of the other level QC are >/< the mean but within 2 SD (10x) [11]

Westgard Procedure Flowchart:

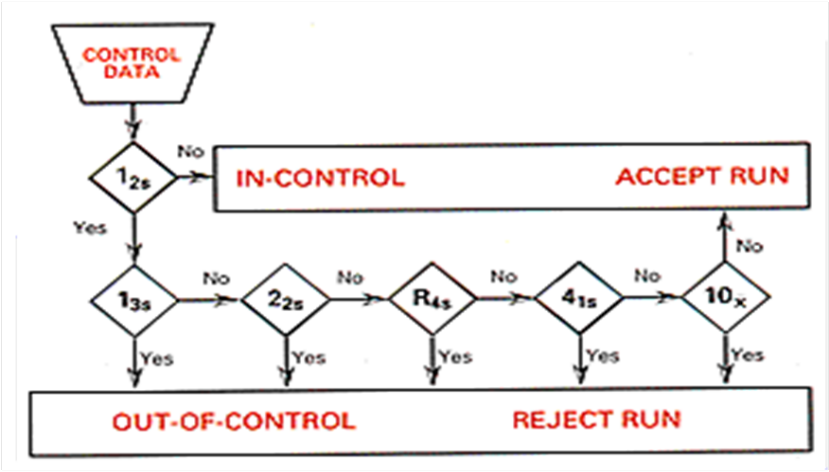

Figure 1: Westgard procedure flow chart

The observations made with respect to various aspects of the study are as follows:

1. Evaluation of QC data:

Appropriate corrective actions were taken for QC outliers, and a thorough review of QC data, per manufacturer ranges, using 2 SD acceptance limits, was conducted. An LJ chart is generated by the concerned technical staff and signed off by the Section Head, who provides their review comments confirming that Manufacturer QC ranges are applied. [12]

After obtaining the desired 20 data points, the manufacturer's fixed ranges are replaced by the lab defined ranges. After collecting 90 data points, cumulative lab-defined ranges were derived.

A Levey Jennings chart is generated and reviewed, stating that Lab-defined ranges have been established. A shift in the mean of more than 15% in lab-defined ranges relative to the manufacturer-provided ranges requires review/clarification from the manufacturer or peer group data.[13]

Table 1: Comparison of Lab Mean and SD of IQC results between Scheme I & II

Parameter	Mean (SD) Level 1		Mean (SD) Level 2	
	Scheme-I	Scheme-II	Scheme-I	Scheme-II
Glucose	85.3(4.5) mg/dL	85(5) mg/dL	276.5(13.75) mg/dL	279(14) mg/dL
Urea	33(1.4) mg/dL	31.3(2) mg/dL	96(2.99) mg/dL	93(5) mg/dL
Creatinine	1.69(0.11) mg/dL	1.72(0.11) mg/dL	5.09(0.26) mg/dL	5.03(0.265) mg/dL
Sodium	142.3(3) mmol/L	144.1(2.5) mmol/L	127(3) mmol/L	128.3(2.6) mmol/L
Potassium	3.84(0.15) mmol/L	3.92(0.12) mmol/L	6.15(0.16) mmol/L	6.16(0.14) mmol/L
Chloride	94(3.75) mmol/L	93(3.75) mmol/L	81.6(3.75) mmol/L	82(3.75) mmol/L

Analysis of IQC data using the Westgard rules shows that the total number of QC outliers was 43 with Scheme-I control chart limits, as compared to only 7 times with Scheme-II control chart limits.

2. Number of Violations of Westgard Rules:

Table 2 shows the number of violations of Westgard rules while using the two schemes

Parameter	1_{3s}		2_{2s}		R_{4S}		10_X	
	Scheme I	Scheme II	Scheme I	Scheme II	Scheme I	Scheme II	Scheme I	Scheme II
Glucose	2	1	3	0	2	0	1	0
Urea	4	0	0	0	1	0	2	1
Creatinine	1	0	4	0	1	1	1	0
Sodium	2	0	1	0	2	0	1	0
Potassium	2	0	1	0	4	0	1	0
Chloride	1	0	2	0	1	0	3	0

3. Percentage of Rejections:

Table 3 and Figure 1 show the run rejections for schemes I & II.

	Scheme I		Scheme II	
	Number	**%**	**Number**	**%**
Total runs	1800	100	1800	100
Rejected	43	2.38	7	0.38

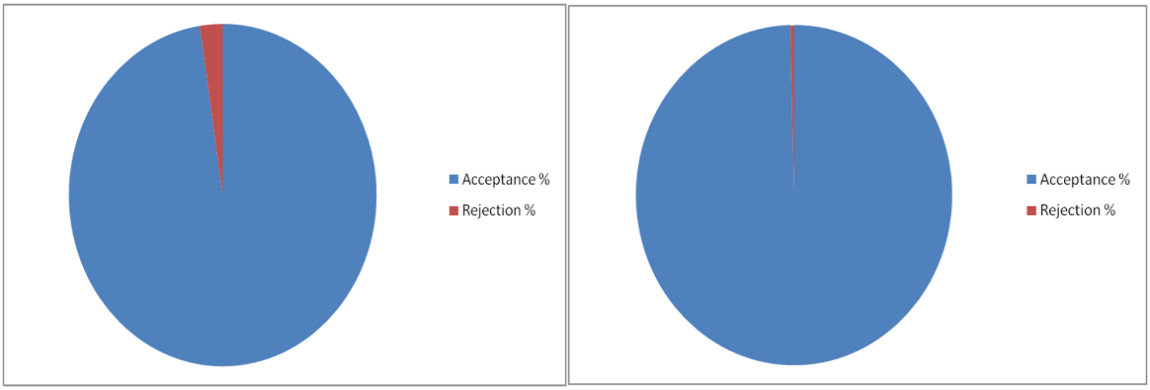

Figure 2: Showing Acceptence and rejection data

Table 4: Comparison of EQAS SDI obtained while using both schemes.

Parameter	Scheme I				Scheme II			
	January	**February**	**March**	**Average**	**April**	**May**	**June**	**Average**
Glucose	1.06	1.09	1.62	1.25	1.04	1.23	1.62	1.29
Urea	1.87	1.65	1.83	1.78	0.29	1.17	1.98	1.14
Creatinine	0.33	1.05	1.30	0.89	0.53	0.06	0.24	0.27
Sodium	1.35	0.64	1.58	1.19	1.35	1.53	1.33	1.40
Potassium	0.35	0.22	1.57	0.71	0.34	1.24	0.31	0.63
Chloride	0.99	1.71	0.95	1.21	0.57	1.53	1.09	1.06

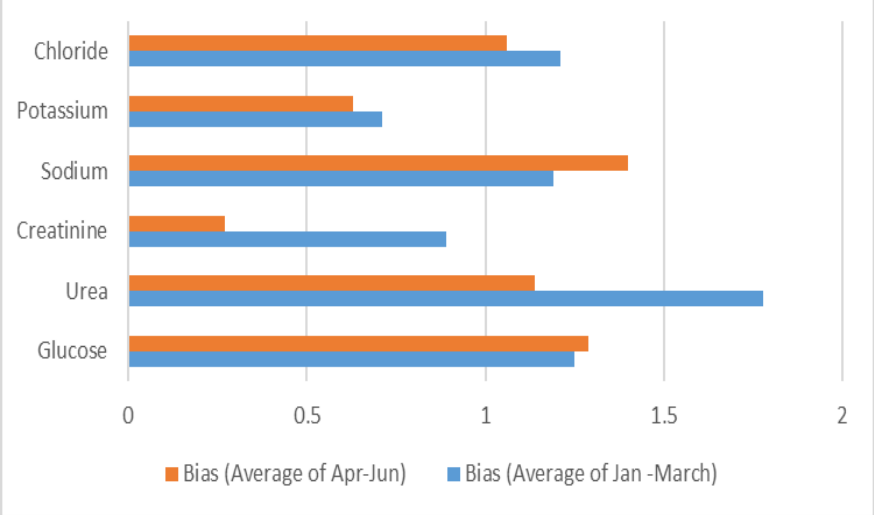

Figure 3: EQAS Bias Comparison between Scheme I and Scheme II

There is a significant difference in the EQAS results obtained under two different schemes. Average bias is greater with scheme I than with scheme 2 for Chloride, Potassium, Creatinine, and urea, suggesting that scheme II QC control limits will be more appropriate than scheme I for defining IQC limits.

Discussion

Internal Quality Control (IQC) results are evaluated against the procedure's own capabilities. [14] The goal is to confirm that the test is performing as consistently as expected. [15] This study compared and evaluated two schemes for calculating the Laboratory mean and standard deviation (SD) of internal quality control (IQC) sera. The results demonstrate that using Scheme II—derived control limits from a longer 90-day period IQC reduces Westgard rule violations during daily monitoring without compromising EQAS performance. However, a limitation of this study is that the protocols were implemented across different time

periods; this may have introduced confounding factors beyond the mean and SD that influenced variation in results and run rejections. Chasing down "false" errors adds extra work, lowers efficiency, and drives up costs. Further studies are needed to distinguish between protocol-dependent and protocol-independent errors. [15,16,17]

Conclusion

Labs should procure enough stable, uniform control material to last at least a year. [18,19] Sticking with the same batch for a long time makes it much easier to set reliable targets and cuts down on the constant work of validating new lot numbers. [20,21] Application of stringent Westgard rules doesn't actually make the test more accurate; it just makes the "alarm" more sensitive. [22] While strict criteria catch smaller errors, they also trigger more false alarms, leading to constant troubleshooting and slower results for patients. [23] This study concludes that using a 90-day Lab mean and SD for daily IQC monitoring reduces Westgard rule violations without compromising EQAS performance. Utilizing a larger data set over an extended period minimizes unnecessary run rejections and recalibrations, ultimately lowering operational costs and improving turnaround times. [24,25]

Acknowledgments

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