DAILY INTERNAL QUALITY CONTROL IN CLINICAL BIOCHEMISTRY LABORATORY: APPROPRIATE DURATION OF QUALITY CONTROL SERA TESTING FOR DERIVATION OF ITS MEAN AND STANDARD DEVIATION

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ABSTRACT

BACKGROUND
As a part of Internal Quality Assessment, it is a usual practice in Clinical Biochemistry Laboratories to run Internal Quality Control (IQC) sera and check the results for any violation of Westgard rules. A mean and standard deviation (SD) of minimum 20 values of IQC results is taken for plotting Levey-Jennings (LJ) chart, but results of extended period (60 or 90 days) can also be used to calculate mean and SD.

AIMS
- To derive mean and SD of IQC results for a period of 20 days and 90 days.
- To monitor daily IQC results for violation of Westgard rules using mean and SD of 20 days and 90 days.
- To compare frequency of violation of Westgard rules and EQAS performance while using these two means and SDs.

METHODOLOGY
This study was conducted in the Clinical Biochemistry Laboratory of S.S.G. Hospital and Medical College, Vadodara, where two levels of IQC sera are run twice daily. When a new lot of IQC sera was put into use, means and SDs were derived using 20 days (Protocol-I) and 90 days (Protocol-II) results. Both were used for daily monitoring of IQC for 3 months. We compared frequency of violation of Westgard rules (13s, 23s, R4s, 10x) and EQAS Standard Deviation Index (SDI) for 10 different biochemical parameters while using these two protocols.

RESULTS
The Westgard rules were violated for a total of 48 times while using Protocol-I as compared to only 5 times while Protocol-II was used. No significant difference was found in EQAS results in terms of SDI.

CONCLUSION
From the current study, it is concluded that for IQC daily monitoring, if mean and SD are derived from longer period (90 days) results of IQC sera, there are fewer incidences of violations of Westgard rules without any compromising effect on EQAS results. Hence, by using more number of values over a longer period, one can reduce unnecessary rejections of run, re-run of IQC and repeated calibration of test parameters, thereby reducing the overall cost of testing and improving the turn-around time (TAT).

KEYWORDS
Internal Quality Control, Mean, Standard Deviation, Westgard Rules, Levey-Jennings Chart.

MESHTERMS
Quality Control.

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INTRODUCTION: The principles of quality management, assurance, and control have become the foundation by which clinical laboratories are managed and operated.1 Quality is defined as conformance with the requirements of users or customers. Quality improvement reduces waste and leads to improved productivity, which in turn reduces costs and provides a competitive advantage.1 In the routine operation of clinical laboratories worldwide, the performance of analytical methods is routinely monitored by analysing specimens whose concentrations or activities are known, followed by comparing observed values with known values.1 Specimens that are analysed for QC purposes are called control materials. They need to be stable, available in aliquots or vials and amenable to analysis periodically over a longtime.1 The control material preferably should have the same matrix as the test specimens of interest. In practice, clinical laboratories purchase materials from one of several...
companies that manufacture control sera that are supplied as liquid, frozen or lyophilised materials. The later ones are reconstituted by adding water or a specific diluent solution.\(^1\)

Two or three different materials should be selected to provide concentrations that monitor performance at different medical decision levels.\(^1\)

As a part of internal quality assessment, it is a usual practice in clinical biochemistry laboratories to run internal quality control (IQC) sera and check the results for any violation of Westgard rules.\(^2\) Following are the most commonly used Westgard rules for interpreting the control data:\(^2\)

- \(1_{3s}\) refers to a control rule where a run is rejected when a single control measurement exceeds mean+3SD limits.
- \(2_{2s}\) refers to the control rule where a run is rejected when two consecutive control measurements exceed the same mean+2SD limit.
- \(R_{4x}\) refers to a control rule where a run is rejected when one control measurement in a group exceeds the mean+2SD limit and another exceeds the mean−2SD limit.
- \(10x\) is a rule where a run is rejected when 10 consecutive measurements fall on one side of the mean.

The most common method of comparing the values observed for control materials with their known values is the use of control charts, in which the observed values are plotted versus the time when the observations were made.\(^1\)

A mean and standard deviation (SD) of minimum 20 values of IQC results is taken for plotting Levey-Jennings (LJ) chart, but results of extended period (60 or 90 days) can also be used to calculate mean and SD.\(^2,3\)

The IQC procedures are focused on the monitoring of a single laboratory. For comparison of performance of different laboratories, several external quality assurance schemes (EQAS) are available. The two are complementary activities, IQC being necessary for the daily monitoring of precision and accuracy of the analytical method, and external quality assessment being important for maintaining longterm accuracy of the analytical methods.\(^1\)

**AIMS:**

1. To derive mean and SD of IQC results for a period of 20 days and 90 days.
2. To monitor daily IQC results for violation of Westgard rules using mean and SD of 20 days and 90 days.
3. To compare frequency of violation of Westgard rules and EQAS performance while using these two means and SDs.

**METHODOLOGY:** The study was carried out at Clinical Biochemistry Laboratory, Medical College and Sir Sayajirao General (S.S.G.) Hospital, Vadodara.

Two levels of IQC sera are run twice daily. When a new lot of IQC sera was put into use, means and SDs were derived using 20 days (PROTOCOL-I) and 90 days (PROTOCOL-II) results. Both were used for daily monitoring of IQC for 3 months (Protocol-I during Jan-Mar, 2015 & Protocol-II during Apr-Jun, 2015).

We compared frequency of violation of Westgard Rules \((1_{3s}, 2_{2s}, R_{4x}, 10x)\) and EQAS standard deviation index (SDI) while using these two protocols.

Various parameters for which the two protocols were compared and the methods employed for their measurement are as follows:

1. Plasma Glucose: Hexokinase method.\(^4,5\)
2. Serum Urea: Glutamate Dehydrogenase (GLDH) – Urease fixed time method.\(^6,7\)
3. Serum Creatinine: Jaffe’s method.\(^8,9\)
4. Serum Glutamate Pyruvate Transaminase (Serum ALT): Modified IFCC kinetic method.\(^10,11\)
5. Serum Glutamate Oxaalocetate Transaminase (Serum AST): Modified IFCC kinetic method.\(^12,13\)
6. Serum Alkaline Phosphatase (ALP): IFCC kinetic method.\(^14\)
7. Serum Uric acid: Uricase – Peroxidase (Uricase – PAP) method.\(^15,16\)
8. Serum Cholesterol: Cholesterol Oxidase – Peroxidase method.\(^17,18\)
9. Serum Total Protein: Biuret method.\(^19\)
10. Serum Albumin: Bromocresol green method.\(^20\)

We used commercially available quality control sera for testing various biochemical parameters in this study. No patient specimen was tested in the present study.

**RESULTS & ANALYSIS:** As defined in material and methods, 10 parameters done in the Clinical Biochemistry Laboratory were included in the study. Their means and SDs were derived according to two protocols as mentioned below:

**Protocol I:** Means and SDs derived using 20 days results and used during January to March 2015.

**Protocol II:** Means and SDs derived using 90 days results and used during April to June 2015.

The two protocols were then compared on the basis of violation of Westgard rules and EQAS SDI.

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

1. **Mean (SD):** Table 1 shows means and standard deviations (SDs) of various parameters obtained while using the two protocols.
Table 1: Mean(SD) of Different Parameters in Protocol I & II

Table 1 shows that the means obtained using protocols I & II were more or less same while the SDs obtained using protocol II were broad for most of the parameters as compared to those obtained using protocol I.

2. No. of Violations of Westgard Rules: Table 2 shows the number of violations of Westgard rules while using the two protocols.

Table 2: No. of Violations of Westgard Rules

In present study, the Westgard rules were violated for a total of 48 times while using PROTOCOL-I as compared to only 5 times while PROTOCOL-II was used.

3. Percentage of Rejections: Table 3 and figure 1 show the rejections of runs while using the two protocols.

Table 3: Rejection of IQC runs while using Protocol I & II
Table 3 and figure 1 show that the rejection rate was 2.67% (48 out of 1800 runs) for Protocol I while it was only 0.28% (5 out of 1800 runs) for Protocol II.

So, the rate of rejection of IQC run was much less while using the Protocol II.

<table>
<thead>
<tr>
<th>PARAMETERS</th>
<th>PROTOCOL-I</th>
<th>PROTOCOL-II</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>January</td>
<td>February</td>
</tr>
<tr>
<td>Plasma Glucose</td>
<td>-0.19</td>
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</tr>
<tr>
<td>Serum Urea</td>
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<td>Serum ALT</td>
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<td>Serum AST</td>
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<tr>
<td>Serum ALP</td>
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<td>-1.19</td>
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<tr>
<td>Serum Cholesterol</td>
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<td>-0.25</td>
</tr>
<tr>
<td>Serum Uric Acid</td>
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<td>-0.58</td>
</tr>
<tr>
<td>Serum Total Protein</td>
<td>-0.22</td>
<td>-0.52</td>
</tr>
<tr>
<td>Serum Albumin</td>
<td>-0.03</td>
<td>-0.87</td>
</tr>
</tbody>
</table>

Table 4: EQAS SDI for different Parameters while using Protocol I & II

Table 4 shows that the EQAS SDI obtained while using both the protocols were within acceptable limits. So, there is no difference in the EQAS results obtained by using two different protocols.

DISCUSSION: This study was carried out to compare and evaluate two different protocols for derivation of mean and SD of IQC sera. The study was done over a period of 6 months, out of which both the protocols were used for a period of 3 months each.

In this study we found that the rejection rate for IQC runs was 2.67% (48 out of 1800 runs) for Protocol I while it was only 0.28% (5 out of 1800 runs) for Protocol II.

EQAS SDI for all the parameters included in the study was within acceptable limits while using both protocols.

So, for daily IQC monitoring, if mean and SD derived from longer period (90 days), i.e. Protocol II, results of IQC sera are used, there are fewer incidences of violations of Westgard rules without any compromising effect on EQAS results.

The limitation of the present study was that we used the two protocols in different time periods and so, there might be some confounding factors, other than mean and SD, leading to variation of results and thereby rejection of runs.

Further study needs to be carried out to find out which types of error could be deduced and which ones remain unaffected by changing protocols.

CONCLUSION: From the current study, it is concluded that for IQC daily monitoring, if mean and SD are derived from longer period (90 days) results of IQC sera, there are fewer incidences of violations of Westgard rules without any compromising effect on EQAS results. Hence, by using more number of values over a longer period, one can reduce unnecessary rejections of run, re-run of IQC, and repeated calibration of test parameters, thereby reducing the overall cost of testing and improving the turn-around time (TAT).

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REFERENCES