

Management of Internal Quality Control (IQC) data in a clinical biochemistry laboratory using spreadsheet software

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Abstract

Background: In a clinical biochemistry laboratory the large quantity of numerical data generated due to implementation of an Internal Quality Control (IQC) protocol needs to be managed effectively to monitor the quality of the analytical phase of testing. Such data management procedure needs to be simple and cost effective to facilitate the implementation of the IQC protocol. **Aims and objectives:** The objective of this study was to develop a simple and cost effective procedure for management of IQC data in a clinical biochemistry laboratory. **Materials and Methods:** A method of organizing IQC data into files and folders was defined. The popular spreadsheet software, Microsoft Excel (version 2007), was used to design a proforma comprising tabular and graphical components to handle IQC data. This proforma was used to record values of control sera (run as a part of IQC protocol), convert them into z scores and represent them on a Levy-Jennings (LJ) chart for ease of interpretation. Other methods of IQC data management were reviewed and a comparison was drawn between all methods regarding their advantages and limitations. **Results and conclusion:** IQC data could be effectively managed using the Microsoft Excel software due to its ability perform calculations and represent data graphically. A review of various methods of managing IQC data revealed that this method described by the authors was most suitable for laboratories using multiple instruments, multiple levels of controls and not wanting to procure expensive tailor-made software from commercial vendors..

Keywords

Quality, IQC, spreadsheet, software, z score.

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Introduction

The primary role of a clinical biochemistry laboratory is to perform various analyses on body fluids and to report results to clinicians for better patient management. The analytical performance of the laboratory is usually monitored by adopting standard internal quality control (IQC) and external quality assurance (EQA) protocols. The IQC protocols have to be implemented on a daily basis and generate large amount of numerical data. Such data from multiple instruments needs to be amalgamated, documented, processed, interpreted and reviewed effectively to bring about continuous improvement in quality. This data management procedure needs to be simple and cost effective to encourage its voluntary implementation by all laboratories despite absence of local regulatory compulsion, as it would ultimately improve the quality of healthcare services offered.

The objective of this project was to develop a simple and cost effective procedure for IQC data management.

Material and Methods

To achieve the objective mentioned above the popular spreadsheet software Microsoft Excel (version 2007) was used.

Step 1: Preparing folders, files and sheets (Refer to figure 1)

A separate folder labeled 'IQC data' was created in the hard disc drive of a computer installed in the laboratory. Within this folder separate sub folders were created each pertaining to one calendar year. Within each sub folder twelve different excel files were created, one for every month of that

year. Within one excel file separate excel sheets were used to record data pertaining to every analyte. All folders, files, and sheets were labeled appropriately. Thus one Excel sheet represented IQC data for one particular analyte for a period of one month. The sheet was divided into two parts, the z score table and the Levy-Jennings (LJ) chart as shown in figure 2.

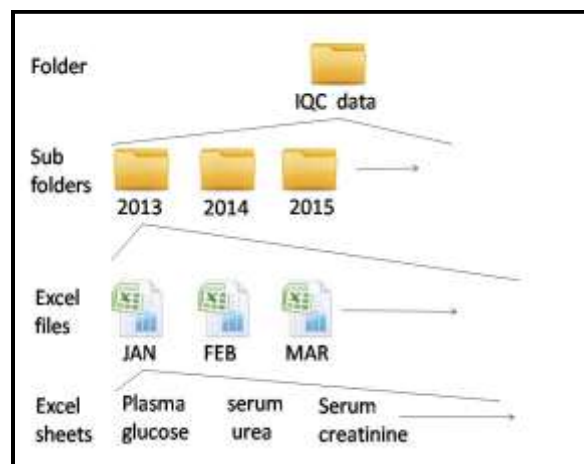


Figure 1: Organization of folders, subfolders, excel files, and excel sheets to store IQC data

Step 2: Generating the z score table (Refer to figure 2)

Commercially available control serum (labeled as L1) was procured, divided into aliquots, stored at -20° C and used for the experiment. Alternatively pooled sera prepared in the laboratory itself can be used to save on cost of commercially available control sera. The procedure for preparing pooled sera can be found in literature.¹ The IQC data management protocol described below was implemented for all routine biochemistry tests performed by the laboratory like plasma glucose, serum urea serum creatinine, and serum lipid profile. As

an example, IQC data management of plasma glucose values for twenty runs is considered here. Glucose concentration was determined in aliquots of the L1 control serum on twenty different occasions and the intra-laboratory mean and intra-laboratory standard deviation (SD) were calculated. After this the control serum was analyzed on each day at least once (and if required more number of times) and values of glucose concentration were entered date-wise and run-wise in the z score table in the column marked 'L1 value'. The z score is the value obtained by subtracting the intra-laboratory mean from the control value of that run and then dividing it by the intra-laboratory standard deviation.² To calculate the L1 z score for run number 1 the following formula was entered in cell D4 of figure 2 :
 =IF (C4>0,(C4-81.38)/5.14,0)

In this formula C4 refers to the cell in which L1 glucose concentration of run no. 1 is entered, 81.38 is the intra-laboratory mean and 5.14 is the intra-laboratory standard deviation as mentioned above. This formula was dragged downwards so as to apply it to respective runs. Due to this as L1 glucose concentrations for each run were entered in column C in the sheet their respective z scores automatically appeared in column D. Advantage of using z score over absolute value is that even if there is a change in lot number of the control serum within the month (implying a change in concentration) the same graph can be continuously used by entering corresponding mean and SD values of the new lot in the formula mentioned above from that run number onwards.

Step 3: Plotting the Levy Jennings (LJ) chart (refer to figure 2)

The z scores in the table were represented in the form of LJ chart with run number on the x axis and z scores on y axis. A separate chart was prepared for every ten runs to prevent overcrowding of data. The chart was placed alongside the corresponding tabular data for convenient viewing as shown in figure 2. Table 1 summarizes the characteristics used to plot the LJ chart.

Type of graph: Scatter with straight lines and markers		
	X axis	Yaxis
Data represented	Run number	z scores
Minimum value	Least value of run number	-3
Maximum value	Highest value of run number	+3
Major unit	1	1
Minor unit	1	1
Axis crosses at	Y axis crosses X axis at minimum run number	0.00 (X axis crosses Y axis at 0.00

Table 1: Characteristics used to plot the LJ chart in the excel sheet

Thus, as glucose values of L1 control serum were entered for each run in the z score table, the z scores would automatically appear in the table as well as be plotted on the LJ chart.

Since depending on the sample number some analytes may require two levels of controls to be run twice daily a similar excel sheet is shown in figure 3 with hypothetical values of glucose concentrations for two levels of control sera (L1 and L2) for twenty runs. The z scores for both L1 and L2 control sera can be shown graphically in the same LJ chart as two different data series (L1 and L2). The characteristics used to plot the charts were the same as mentioned in Table 1.

Step 4: Interpretation

Based on the LJ chart and by applying various Westgard rules the run numbers which violated the rules were identified. The various Westgard rules used were 1_{2s} , 1_{3s} , 2_{2s} , R_{4s} , 4_{1s} , 10_x .¹ The rule violated was entered against the corresponding run number in the column of the z score table marked 'rule violated'. Based on the rule that was violated the cause of the violation was identified, and the

necessary corrective and preventive action was taken.

Results

Figure 1 shows the arrangement of folders, subfolders, excel files and excel sheets as described in step 1 above. Figure 2 shows the excel sheet containing z score table and LJ chart for L1 control values of glucose generated from our experiment where only one level control was used once a day (and on more occasions only if required). Figure 3 shows the excel sheet generated out of hypothetical values of glucose obtained from two levels of control sera (L1 and L2) run at least twice daily.

The last column of the z score table shows the Westgard rules violated against the respective runs (Eg. Run nos 3, 5, 13, 17 in figure 2). If more than one run was considered for interpreting the rules, the rule violated was entered against the last of the runs considered (eg. Run no. 6 and 7 in figure 3 violated the 2_{2s} rule for L1 control). If a rejection rule is violated the necessary corrective and preventive action should be taken and the control should be run once more to demonstrate that it is within allowable limits. (eg. Run nos. 7 and 11 in figure 3).

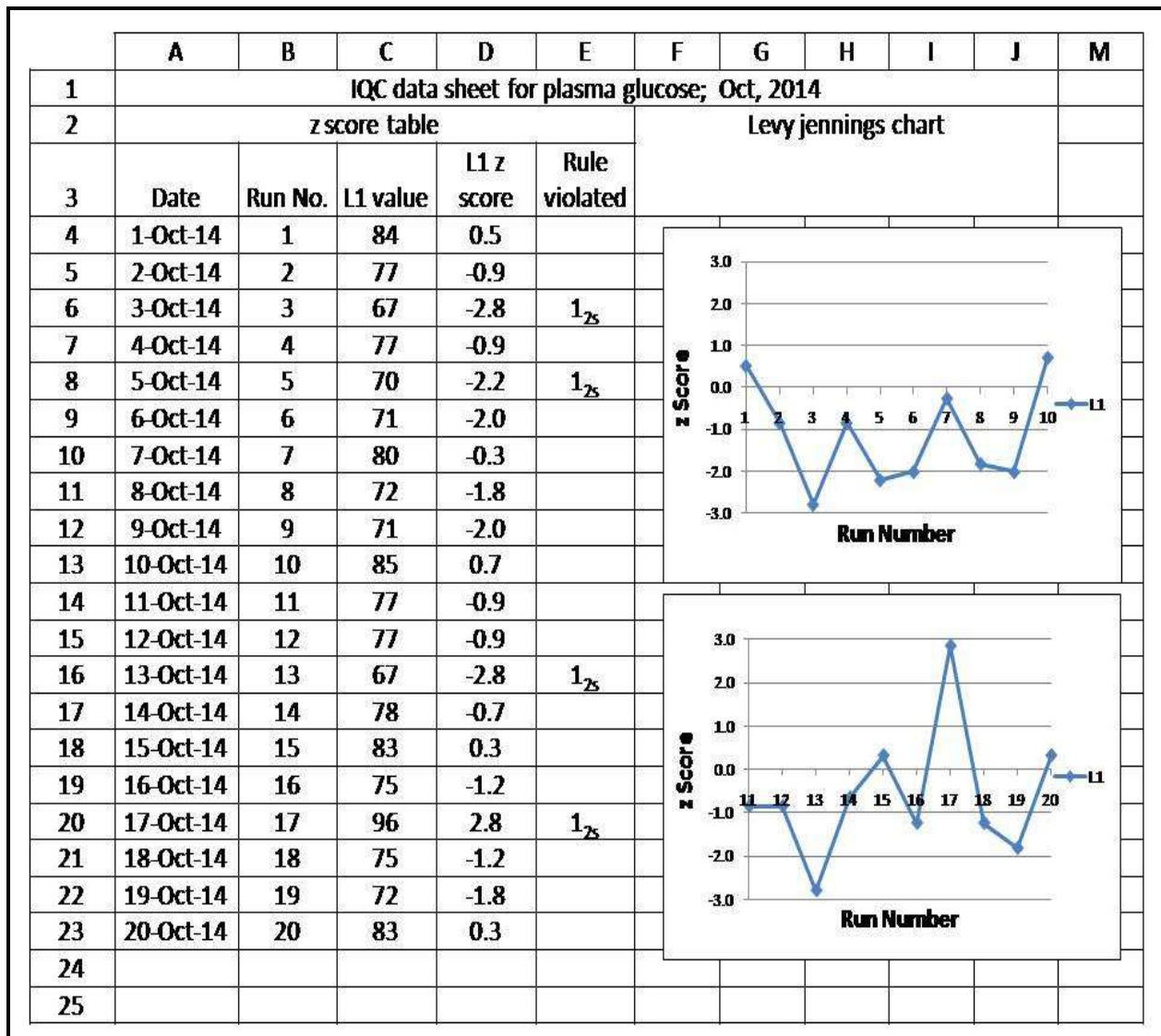


Figure 2: Excel sheet generated from the procedure adopted by the authors as explained in step 2 and step 3

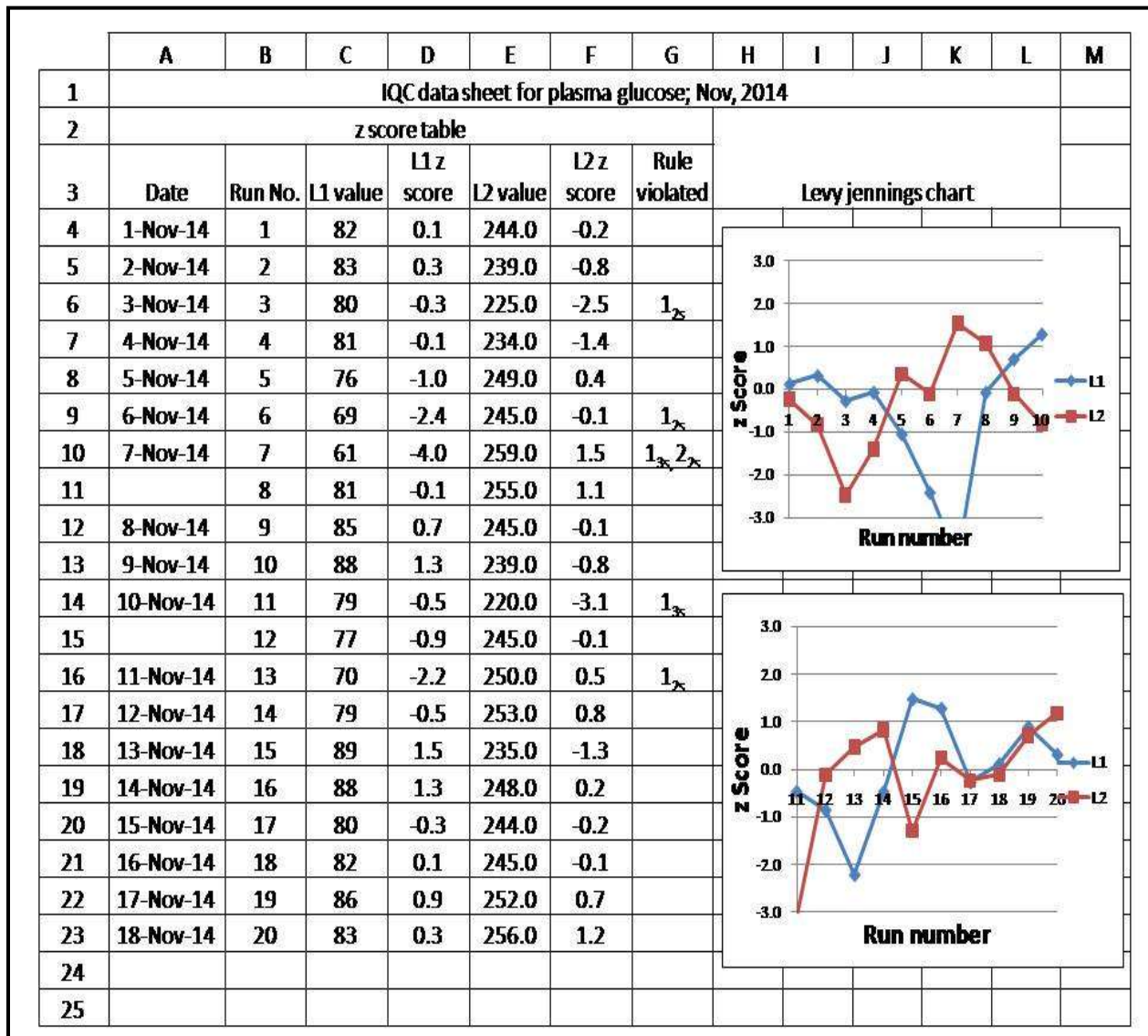


Figure 3: Excel sheet with hypothetical values of plasma glucose as explained in step 3

Discussion

In a clinical biochemistry laboratory the quality of the analytical phase of testing can be monitored on a daily basis by implementing an IQC protocol. This involves the following steps:

1. Initial replicate measurements (at least 20) of quality control sera under different conditions (different instruments, different technical staff, etc.) and calculation of the intra

laboratory mean and SD using these values.

2. Plotting a LJ chart using these mean and SD values.
3. Analyzing the control sera daily along with patient samples, and recording their values,
4. Plotting the values on the LJ charts
5. Applying various Westgard rules to the LJ charts to know if any rule is violated and recording it.

The authors have converted the absolute value of control sera to z scores and plotted z scores on the LJ chart for reasons mentioned above in step 2. Based on the rule violated the cause of the error can be identified and rectified. Thus the IQC protocol involves large scale data management including recording of raw data, calculation of statistical parameters, graphical representation of these parameters, and interpretation of the graph. This can be done using one of the following methods available.^{3,4}

1. A completely manual method

2. Built in IQC modules in semi or fully automated analyzers
3. A tailor-made laboratory software or Laboratory information system (LIS) installed in the laboratory
4. Online QC service providers
5. A spreadsheet software like Microsoft Excel as described here.

Table 2a and 2b show a comparison of advantages and limitations of these methods. The information regarding various other modes of IQC data management along with their merits and limitations was obtained from colleagues working in clinical biochemistry laboratories at other centers.

Manual method	Built in IQC mode in analyzers	LIS	Online QC service providers	Spreadsheet software
1.Can combine data from different instruments in the same LJ chart 2.Can combine data from different levels of control sera in the same LJ chart 3.Least expensive	1.No manual transposition of data required reducing errors. 2.Records can be stored as soft copies reducing storage space	1. No manual transposition of data required reducing errors if used with bidirectional interfacing of instruments. 2. Can club data from several instruments and control sera in the same LJ chart. 3. Records can be stored as soft copies reducing storage space	1.No manual transposition of data required if interfacing with various instruments is done reducing errors. 2.Records can be stored as soft copies reducing storage space 3.May be less expensive than LIS.	1. Errors during calculation and plotting of graph are avoided due to automation. 2. Can club data from several instruments and controls in the same LJ chart. 3. Records can be stored as soft copies reducing storage space. 4. Inexpensive as the software is easily available

Table 2a: Advantages of various methods of IQC data management

Manual method	Built in IQC mode in analyzers	LIS	Online QC service providers	Spreadsheet software
1. Time consuming and may delay reporting of results. 2. Occurrence of errors during recording, calculations and graph plotting 3. Large data storage required to store hard copies of records. 4. Extensive training of technical staff required.	1. Cannot club data from several instruments in the same LJ chart. 2. Cannot club data from different concentrations or control sera in the same LJ chart.	1. Can be expensive as it has to be procured from commercial software vendors 2. Training of technical staff required to use tailor-made software	1. Cannot operate without internet connection 2. Requires entry of Laboratory IQC data on a third party website which may raise security concerns. 3. More expensive compared to using spreadsheet software	1. Errors can occur while transposing data manually from the instrument to the spreadsheet software.

Table 2b: Limitations of various methods of IQC data management

It indicates that due to its speed and accuracy an LIS would be the most preferred method for a high end laboratory (that can bear its cost) specially using bidirectional interfacing between the LIS and all the instruments. The built in IQC module would be the preferred option for laboratories using a single instrument and a single level of control serum. However for small to medium sized laboratories using more than one instrument and more than one level of control sera the method using spreadsheet software like Microsoft excel mentioned above may be most suitable due

to ease and simplicity of implementation and cost effectiveness.

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