Information systems as a quality management tool in clinical laboratories

Vanessa Schmitz and Marta Rosecler Bez el Boukhari  
Centro Universitário Feevale, Novo Hamburgo/RS - Brasil  
e-mail: vanessa.schmitz@gmail.com, martabez@feevale.br

Abstract – This article describes information systems as a quality management tool in clinical laboratories. The quality of laboratory analyses is of fundamental importance for health professionals in aiding appropriate diagnosis and treatment. Information systems allow the automation of internal quality management processes, using standard sample tests, Levey-Jennings charts and Westgard multirule analysis. This simplifies evaluation and interpretation of quality tests and reduces the possibility of human error. This study proposes the development of an information system with appropriate functions and costs for the automation of internal quality control in small and medium-sized clinical laboratories. To this end, it evaluates the functions and usability of two commercial software products designed for this purpose, identifying the positive features of each, so that these can be taken into account during the development of the proposed system.

Keywords – information systems, biomedicine, clinical laboratory, quality management

1. Introduction
Clinical laboratories carry out a range of tests and clinical analyses with the aim of diagnosing the presence of diseases, offering relevant data for health professionals and making patient treatment faster, more accurate and more effective. The quality of laboratory results is of fundamental importance, as incorrect information could lead to misdiagnosis and inappropriate treatment. Quality is ensured through internal controls, which verify the functioning of test processes and the validity of their results, and external controls, which compare the results returned by different laboratories. Internal controls are essential in ensuring the quality of results, and are carried out by the laboratory itself, based on tests of standard samples, control charts and multirule procedures.

As a result of the volume of data to be processed and the importance of access to accurate information at the appropriate time, information systems have a crucial role in the medical field. An appropriate information system is, therefore, a valuable tool in quality management in clinical laboratories, allowing swift, simple analysis of quality tests, avoiding problems related to the calculation and interpretation of test results, and identifying problems in the processes, thereby ensuring delivery of results within specified quality standards.
The present study seeks to determine specifications for an internal quality management system for small to medium-sized laboratories on the basis of the perceived needs of the Biomedicine laboratory at Centro Universitário Feevale.

2. Quality management in the clinical laboratory

In order to carry out their activities in a competitive environment, clinical laboratories should adopt a management model that focuses on the needs and wishes of the client while optimizing processes and performance. Quality management aims to meet these demands through procedures and policies that satisfy clients by ensuring and improving the service performance of the laboratory as a whole [5].

Clinical laboratories are responsible for supplying test results that are accurate and relevant for the diagnosis of the patient. The aim of quality management is, therefore, to ensure the value and clinical precision of the analyses, while preventing errors by evaluating the quality of the material utilized, the validity of the method and the performance of the procedures, reagents, techniques, instruments and personnel involved in the tests. It is also responsible for evaluating the quality of the test results [1].

Laboratory tests require strict control of analytical variables in order to ensure precise results. Sample type, reagent stability, water quality, cleanliness of glassware and equipment calibration are examples of the variables that can influence the quality of laboratory results. During a quality test, if measures are detected that fall outside the established limits, the relevant variables should be reexamined. Quality management tests are carried out regularly and should include all tests undertaken at the laboratory in order to ensure reliable results. These results should be stored in such a way as to allow the evaluation of their precision and accuracy and the observation of trends over time [3].

Effective quality management procedures to ensure the reliability of evaluations were developed and put into practice in order to meet the need for reliability in clinical test results. Reliability in the precision of results allows physicians to make important decisions on the basis of laboratory tests, as inaccurate results could lead to irreparable harm to the patient [5].

A quality management program has the benefit of reducing the need to repeat tests, thereby increasing the value of the service provided, the number of satisfied clients and laboratory’s income.

Quality management tests include internal control systems, which determine whether the laboratory is operating within pre-established standards that ensure valid and reliable results, and external control systems, which verify the precision of the tests by means of comparison with other laboratories. With these methods, including frequent monitoring of tests, clinical laboratories seek ongoing improvements in their quality and ensure reliable results for their clients [5].

Initial quality evaluation of clinical laboratories is carried out using control samples with known values. This indicates whether the laboratory test is producing accurate, reliable results, which can be represented using a quality management graph known as a Levey-Jennings chart [5], [9-11]. Test results which fall outside the established control limits indicate that the test process is not functioning correctly.

3. Information systems for quality management in the clinical laboratory

As a result of the continual increase in the quantity of data, information and knowledge, information systems have become an important tool for the adequate performance of professional activities in the biomedical field. Use of such tools has helped to improve quality management in clinical laboratories, offering faster, more reliable access to information and automating processes, which results in increased quality in the services offered to clients [7], [8].

The use of information systems in clinical laboratories offers the possibility of automating routines, reducing process execution times and costs and allowing more uniform analyses, which are less subject to variations resulting from human intervention. Information systems also include all the laboratory’s operating and support processes, offering an appropriate way to store, consult and administer data, integrating the concepts of efficiency, effectiveness, promptness and quality [6].

An information system aids in the control of the quality, processing, visualization and interpretation of results, by allowing the relevant information to be stored and managed [3].
4. Proposal for an information system for quality management in the clinical laboratory at Centro Universitário Feevale

The clinical laboratory of the Biomedicine Faculty at Centro Universitário Feevale currently carries out its quality management on a manual basis. Information is entered manually by filling out forms, making the process laborious and subject to error. In view of this deficiency, the present study proposes to analyze and model the future implementation of an information system to meet the quality management needs of this and other small laboratories. Such establishments do not have the resources to invest in expensive commercial software, highlighting the need for an efficient, accessible system developed to meet their specific needs.

This study works towards the integration of the areas of biomedicine and information technology, through an exchange of experience that favors the cooperative construction of knowledge.

5. Comparative analysis of software for internal quality management in clinical laboratories: Qualichart and MultiQC

In order to compare the main functions offered by commercial software for quality management in clinical laboratories, an evaluation was carried out of Qualichart, from Biosoft Informática Ltda. [2], and MultiQC, from Marquis-Soft [4]. The evaluation used suppliers’ demonstration versions and included three items seen as essential for internal quality management in clinical laboratories: administration of control materials, daily data control and definition of analytes.

5.1. Administration of control materials

This section compares and evaluates the above-cited software products in terms of the functions they offer the user for administration of control materials.

Figure 1. Qualichart – Control materials screen [2].

Figure 2. MultiQC – Control materials screen [4].
As shown in figure 1, Qualichart has the advantage of registering control materials and entering analyte control values on the same screen, together with lot validity date, while MultiQC utilizes two screens for the same process, as shown in figures 2 and 3. MultiQC’s screens are friendlier, clearer and more objective. Qualichart lists all the registered analytes in spreadsheet form, simplifying the entry of control values, but the method used to activate the fields complicates the process.

5.2. Entry of daily data
Entry of daily data is the second point of comparison.
For the entry of daily data, Qualichart uses a spreadsheet with values for each control level for a given analyte, as shown in Figure 4. This screen is practical, but fails to protect against human error, because the lines are identified only by sequential numbering, and information can only be visualized by double clicking on the cell.

This same screen offers a Levey-Jennings chart and a control data table, which shows the reference mean and standard deviation values supplied by the manufacturer of the control material, together with the mean and standard deviation calculated from the daily samples. It also offers functions for verification and documentation of violation of Westgard rules and a list of error types, classified as random or systematic.

MultiQC offers a specific dialog box for entry of data for each analyte, as shown in Figure 5. A Levey-Jennings chart is plotted for each control level for the analyte, showing material, mean and coefficient of variation. As shown in figure 6, these charts are clear and detailed, and up to three can be visualized on the same screen. They include symbols to indicate changes of reagent, calibrations and other events, facilitating identification of possible abnormalities.

This software does not offer verification using Westgard rules. Instead, it uses an evaluation based on EWMA (Exponentially Weighted Moving Average) and EWMV (Exponentially Weighted Moving Variance).

MultiQC also presents value, EWMA and date and time of entry of daily data when the mouse is positioned over a point on the chart. A double click presents the values in a table, as shown in figure 7.
5.3. Definition of analytes

This section deals with the comparative analysis of the definition of analytes using the two programs.

![Figure 8. Qualichart – Analyte definition screen [2].](image)

As shown in figure 8 Qualichart allows analytes to be entered and edited, but not excluded from the system. MultiQC allows all three operations, as shown in figure 9. Both programs allow for configuration of quality verification rules. Qualichart offers the option of verification using Westgard multirules. MultiQC allows for adjustment of EWMA and EWMV thresholds.

Qualichart uses the same screen to register both reagents and analytes, which may cause confusion for the user. This system offers up to three levels of control, whereas MultiQC offers up to six.

6. Conclusions

Clinical laboratories should guarantee the quality of the tests and analyses they carry out, so as to allow precise diagnosis and appropriate treatment of patients. The quality of the results can be verified by carrying out tests and procedures in the laboratory itself, and information systems can be introduced as a tool for processing control sample test data, performing mathematical and statistical calculations and customizing rules for error verification. This allows for the swift visualization of test results by means of charts and tables, aiding the interpretation of results and simplifying the identification and solution of any problems that may arise.

Although the tests in this study were carried out on demonstration versions of the commercial software products, it was possible to evaluate their main characteristics and gain an impression on the advantages each version offers for clinical laboratories. Both systems satisfy requirements in terms of the three items evaluated in this study, with each one offering certain advantages in relation to the other. For this reason, there is a chance for the development of a system to meet the specific needs of the clinical laboratory at Centro Universitário Feevale, incorporating the positive features of each approach.
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