Preface

Medical laboratory services are essential to patient care and include arrangements for examination requests, patient preparation, patient identification, collection of samples, transportation, storage, processing and evaluation of clinical samples, together with subsequent interpretation, reporting and advice, and safety in the medical laboratory work. ISO 15189:2012 is an international standard that can be used by medical laboratories wishing to improve their quality standards. Its requirements contain a number of general guidelines that help each laboratory to build and expand its own quality system.

Laboratory automation can offer greater productivity, lower cost, and easier integration with modern instrumental equipment. Moreover, laboratory information systems permit the laboratories to achieve maximum efficiency and significantly increase cooperation among physicians and reduce human errors. Information technology systems also provide reliable, standardized procedures for the assessment of medical laboratories (Vacata, et al., 2007).

Proper implementation of a Laboratory Management Information System (LMIS), according to the ISO 15189:2012 requirements, enhances the capacity of medical laboratories to store, organize, process, and retrieve prodigious amounts of information. In this context, the LMIS continuously improves and monitors the quality of services, monitors turnaround times and other crucial quality assurance parameters, assists research and teaching, and reduces the cost of services. Furthermore, telemedicine and e-health services shape or are affected by the ISO 15189:2012 requirements. However, there are formidable difficulties during the implementation of standards for medical laboratories, as well as ISO 15189:2012, because standards include general guidelines concerning the use of laboratory information systems with respect to electronic medical records, which require further elaboration.

During the last decade, information technology has dramatically changed the practice of clinical laboratory professionals, due to the implementation of laboratory management information systems. A Laboratory Management Information System (LMIS) is a valuable tool for medical professionals wishing to manage complex processes, ensure regulatory compliance, promote collaboration between departments of the same or independent laboratories, and generate detailed reports.

LMIS implementation in the routine laboratory workflow may present problems concerning medical data storage, security, and retrieval, as well as proper use of laboratory hardware and software by authorized and trained personnel. Medical information stored in computer systems may be lost or changed by unauthorized personnel. As a result, the laboratory has to follow strict rules in order to protect its information system from improper or unauthorized use and solve all possible problems that may be encountered.
LMIS implementation in the traditional medical laboratory workflow should also ensure continuous monitoring of prospective or retrospective, qualitative or quantitative indicators regarding the accuracy of the laboratory reports and their completeness and timeliness. LMIS should also monitor all potential telemedical or e-health medical laboratory applications, especially if they are used for quality management purposes.

ISO 15189:2012 is a powerful tool for diminishing unexpected errors or problems. The requirements of the standard for the laboratory information management include the implementation of specific measures concerning validation, documentation, protection from unauthorized access, safeguard from tampering or loss, and integrity of data. Furthermore, telemedicine procedures should follow ISO 15189:2012 requirements for quality and expertise in order to provide validated laboratory medical information. Finally, e-health services or telemedicine may help laboratories wishing to apply external quality control programs, especially in the field of proficiency testing or periodical interlaboratory comparisons.

**THE CHALLENGES**

The effective implementation of ISO 15189:2012 in medical laboratories demands an adequate understanding of the existing challenges. Such challenges can be classified into seven main categories:

- Development of well-written and well-implemented LIS software that can use medical data for the documentation of Quality Control (QC) measures.
- Formulation of effective security policies and procedures against the laboratory’s information system improper or unauthorized use.
- Enactment of policies and procedures that will effectively monitor all available indicators regarding the accuracy of the laboratory reports, their completeness, and timeliness.
- Endowment of effective policies and procedures that will monitor all available telemedical or e-health applications.
- Establishment of effective policies and procedures that will comply with relevant regulations and guidelines edited by national or international regulatory bodies.
- Inclusion of effective policies and procedures for implementation of proper internal/external quality control measures.
- Manifestation of effective policies and procedures for the validation and verification of proper methods.

A medical laboratory should keep up quality control measures in order to detect, reduce, and correct deficiencies in laboratory diagnoses, and perform a set of procedures in order to ensure that the preparation, interpretation, and reporting of laboratory specimens meets specific quality standards. Moreover, quality assurance policy is used by a medical laboratory as a retrospective tool measuring the success of pre-, post-, and analytical methods. As a result, the laboratory should implement an effective quality control program designed to monitor and evaluate the quality of its testing methods. The quality control program implemented by a medical laboratory should be able to guarantee the accuracy, reliability, and timeliness of diagnoses.
Moreover, the laboratory may introduce electronic monitoring in order to perform quality control measures. Electronic data can be extracted and manipulated in a convenient and simple way, not demanding computer-specialists as end users. In an accredited medical laboratory, quality assurance methodologies are designed and used in order to continually improve the diagnostic accuracy and eliminate false negative diagnostic rates (Okada, 2002).

Finally, an accredited medical laboratory should electronically track QC/QA indicators, which will be computed either within the LIS and/or by exporting data from the LIS (by using common spreadsheet software).

A medical laboratory information system should monitor laboratory requisition completeness, problems documented by the accession, occurrences, and trends with any particular clinician office sending specimens to the laboratory. Identification of such problems could prompt the redesign of requisition forms while specimen rejection incidents and labeling errors should also be electronically documented, and specimen rejection frequency should be regularly reported to the offices of the physicians. Comments entered within available QA fields should be included in the final report (Okada, 2002).

Moreover, a medical laboratory information system should also monitor electronic data integrity and take all available security measures, which may include regular back up of data, password protection, data encryption, use of antiviral software, firewalls, and audit trails. It should also assign different privileges to users and allow only certain individuals to finalize and sign out abnormal medical diagnoses.

Additionally, a laboratory information system should ensure the integrity of finalized reports. Changes, where applicable, should be incorporated in the form of an addendum to the existing report. It should also use standardized diagnostic terminology and coded comments in order to ensure uniformity of the reporting language. Such coded comments allow quick data entry and rapid result reporting to the clinician. Laboratory reports using standardized language make up an efficient means to extract data, enabling calculations of diagnostic reproducibility (Okada, 2002).

Similarly, a modern medical laboratory’s information system should possess the ability for remote log-in and access to ordering and reporting systems via a secure Web browser, allowing laboratories to access the LIS from distant locations. It should also allow reliable electronic signatures for data authentication. Regarding test ordering, a medical laboratory’s information system should be able to provide immediate feedback to all users (Okada, 2002).

A modern medical laboratory’s information system should also possess a user-friendly display of the test catalog with available alternative groupings. The laboratory’s administration should periodically monitor menu consistency and complete or update them according to patient needs (Okada, 2002).

Finally, the laboratory’s information system should be able to relay orders to different interfaced systems without manual intervention, so that tests ordered in one facility can enable specimens to be collected and accessioned at another location or institution.

A modern medical laboratory’s information system should contain functionalities to optimize specimen collection and processing (Okada, 2002) and interface with laboratory automation management software to ensure that all the pre-analytical conditions stipulated in the ordering process are transmitted to the specimen-processing system. Likewise, the laboratory’s information system should hold functionalities to optimize the analytical phase, the result entry and validation, result reporting, notification management, data mining and cross-sectional reports, method validation, and quality management by using a module supporting accreditation requirements (Okada, 2002).
SEARCHING FOR A SOLUTION

The net of accredited laboratories is globally expanding (Kubono, 2007). Many more countries will incorporate ISO 15189 requirements in their national or local regulations. Medical laboratories that will develop the most innovative and up-to-date procedures for electronic medical reporting and storage will become referral laboratories for their countries or regions (Kubono, 2007).

On the other hand, all laboratories’ notices concerning the implementation of the ISO 15189:2012 are collected by an international working group, which is responsible for the revision of the standards when necessary. Problems that might be reported to this international working group are examined, and suitable solutions will be incorporated in the standard’s future editions or specific guidelines (Kubono, 2007).

The ISO 15189 requirements for quality and competence concerning the electronic medical data comprise a set of general guidelines that will help each laboratory to establish and develop its quality system. However, the procedures that will eventually be performed by each laboratory during the development of an acceptable quality system may differ according to its specific needs and limitations (Kubono, 2004, 2007).

Meanwhile, the efforts of the medical community continuously aim at the creation of a secure electronic environment for medical data management, storage, retrieval, and updating, as well as decision support and quality control mechanisms (Kubono, 2004, 2007).

Procedural requirements for the implementation of high-quality electronic medical databases include the acquisition of an electronic procedure manual available to all computer users and the implementation of specific procedures aiming at the protection of electronic data from any damage caused by hardware or software failure.

System electronic security from unauthorized alterations is of paramount importance and has to be ensured by implementing strict policies concerning authorization for entering, changing, or editing electronic medical records. As a result, medical data integrity must be continuously monitored for any errors during transmission and storage processes. Specific procedures for reviewing all automatic calculations as well as the data entered in the laboratory information system must be performed in order to ensure medical data’s integrity (Okada, 2002).

Specific procedures must ensure that electronic medical data will be easily retrievable by all authorized personnel. Parameters such as footnotes, interpretative comments, and uncertainty of a given measurement must be easily reproducible as part of the electronic medical report, offering the clinician the chance to interpret, with precision, laboratory medical data.

Hardware and software requirements for the implementation of high-quality electronic medical databases include the acquisition of a complete record of all preventive actions concerning computer maintenance (Vacata, et al., 2007).

Every back up must be followed by systematic verification of the software integrity. All mistakes detected during back up have to be documented, and corrective action must restore the system’s proper function. Authorized personnel must verify that all programs run properly after first installation or any documented modification, and all serious computer malfunctions must be reported to an authorized laboratory’s member responsible for the proper use of the medical laboratory’s electronic records. System maintenance must be scheduled in such a way that it will not interrupt the patient-care service. Documented procedures for handling computer shutdown and restart will ensure medical data’s integrity (Vacata, et al., 2007; Kubono, 2007).
Cooperation between the laboratory and hospital information system will be improved by the implementation of specific procedures concerning data replacement, recovery, and updating (Okada, 2002). All computer problems, such as unexpected shutdown, downtime, or breakdown, must be fully documented, and corrective action must be taken in order to avoid these problems in the future (Vacata, et al., 2007; Kubono, 2007).

The use of the electronic signature in medical reports may diminish bureaucratic problems but, on the other hand, makes the laboratory information system more vulnerable. The laboratory management has to implement specific policies that will protect medical data from unauthorized access but will not endanger the cooperation between medical and laboratory information systems (Vacata, et al., 2007).

Laboratory personnel training in informatics is necessary for ensuring the efficient function of the laboratory information system. The laboratory management has to plan personnel training in such a way that the laboratory main function will not be put in danger. Poor hardware maintenance or improper use by inadequately trained personnel may cause a laboratory information system failure. Laboratory reports may be lost or deteriorated due to malignant software (virus programs), while LIS hardware may be damaged by adverse environmental conditions, such as heat, humidity, or a possible fire, due to the vulnerability of wires and cables to unfavorable environmental conditions. Finally, medical data stored only in electronic mediums may be easily lost due to a system’s unexpected failure (Vacata, et al., 2007). All these potential threats of a laboratory information system require the implementation of specific measures and policies that may have considerable economic impact, or may even prove unaffordable. The laboratory management is responsible for making an economic plan after taking into account the particular laboratory resources and needs (Okada, 2002).

Before new software or hardware is introduced in a laboratory, the risk connected with such an introduction should be assessed. The risk assessment should include identification of possible events, which may result in non-compliance, estimation of their likelihood, identification of their consequences, and ways of avoiding them, costs, drawbacks, and benefits (Vacata, et al., 2007). Good knowledge of computer software and hardware details is also essential for the maintenance, troubleshooting, and update. Medical laboratory personnel have to be periodically trained to use new computer facilities and new software products. Their training may be extremely difficult. Therefore, the laboratory director has to encourage these training sessions and continuously motivate its personnel.

Moreover, we have to take into account that computer facilities maintenance is of paramount importance in the workflow of a medical laboratory. Therefore, the laboratory personnel should take specific measures for protecting the hardware. The hardware should also be fully protected from any actual damages, and especially fire (Vacata, et al., 2007).

The provision of an uninterruptible power supply will protect the computer from crashing during power outages or from low and high voltage occurrences (Vacata, et al., 2007). A UPS is much better than a surge protector and can save the laboratory computer facilities from virtually any type of power failure (Okada, 2002).

Finally, the laboratory should also obtain a complete record of all preventive actions concerning computer maintenance (Vacata, et al., 2007), as hardware preventive maintenance is the best way to dramatically reduce all factors threatening or shortening computer life (Okada, 2002). Software preventive maintenance can be achieved by using anti-virus applications, defragmentation software, and testing utility programs (Vacata, et al., 2007).
ORGANIZATION OF THE BOOK

In Chapter 1, Kijpokin Kasemsap introduces the role of Total Quality Management (TQM) practices, thus explaining the introduction of Quality Management (QM) systems, the significance of TQM, the concept of TQM practices, the utilization of QM practices, and the relationship between TQM practices and quality performance. In addition, 17 TQM practices associated with quality performance (i.e., top management commitment, customer focus, training and education, continuous improvement and innovation, supplier quality management, employee involvement, information and analysis, process management, quality systems, benchmarking, quality culture, Human Resource Management [HRM], strategic planning, employee encouragement, teamwork, communication, and product and service design) are explained. This chapter serves as a valuable guideline for both researchers and practitioners to review their TQM programs in order to improve quality performance.

In Chapter 2, Vincent Šoltés, Antonio José Balloni, Beáta Gavurová, and Michal Šoltés argue that there are significant disparities among the health needs of citizens and the financial resources of the healthcare system. Limitations of the inputs to growth of the health systems are primarily due to fiscal constraints, the demographic crisis, the degree of competitiveness of the EU, as well as the willingness of citizens to bear some degree of the tax burden. The costs of providing healthcare can be reduced by the proper implementation of eHealth project, as is evidenced by the analysis of the costs and benefits of successful implementation abroad. The aim of this chapter is to evaluate the use of Information and Communication Technologies (ICT) in medical institutions, in Slovakia, as the basis of effective strategic management, influencing the positive and negative changes in their external environment. In addition, the chapter focuses on investments in technological innovation, its determinants, and specification of the effects of the use of IS and IT in healthcare facilities. Finally, it reflects the partial outputs of the first international research GESITY/Hospitals 2011-2012 conducted in partnership with Slovakia and Brazil, in connection with the objectives of the implementation of an eHealth program in Slovakia.

In Chapter 3, Andrew Georgiou reviews what is currently known about the effect of the Electronic Medical Records (EMRs) on aspects of laboratory test ordering, their impact on laboratory efficiency, and the contribution this makes to the quality of patient care. The EMR can be defined as a functioning electronic database within a given organisation that contains patient information. Although laboratory services are expected to gain from the introduction of the EMRs, the evidence to date has highlighted many challenges associated with the implementation of EMRs, including their potential to cause major shifts in responsibilities, work processes, and practices. The chapter outlines an organisational communication framework that has been derived from empirical evidence. This framework considers the interplay between communication, temporal, and organisational factors, as a way to help health information technology designers, clinicians, and hospital and laboratory professionals meet the important challenges associated with EMR design, implementation, and sustainability.

In Chapter 4, Viroj Wiwanitkit realizes that the LIMS can be useful in all steps of the laboratory cycle (pre-, intra-, and post-analytical phases). There are many LIMSs at present, and those LIMSs are used worldwide. The present concern is on the standardization of the existing system. In this context, international collaboration to set the standards is required. In addition, the multidisciplinary approach to add up the advantage and application of the technology is promising. With the more advanced computational and wireless information technology, the next step of LIMS will be big wireless LIMS networks that extend from medical laboratories and wards within the hospital to outside units as well as patient homes. The point-of-care LIMSs are the actual future perspectives.
In Chapter 5, Po-Hsun Cheng contends that instrument calibration is an important process within the laboratory activities. Many mobile medical devices are widely and routinely utilized for monitoring people’s physiological data by home-care users. However, it is necessary to let these test data be as effective as laboratory reports, so physicians can recognize as well as refer to them. The chapter proposes a Medical Instrument Calibration (MIC) process to let all connected instruments share and store their current calibration information in a global MIC’s Database (MICDB). The MICDB is based on the ISO 15189:2012 standard and provides cloud-based functions via Web Services. It also shares collaborated information that is provided by other medical instruments and vendors. A MIC process for calibrating the instrument is not only required for the laboratory, but it can also be adapted for mobile medical devices and home-care instruments.

In Chapter 6, Edison Fontes and Antonio José Balloni provide a structured definition to develop, implement, and keep the needed regulatory rules or principles for an Information System Security (ISS). In addition, the reader finds how to ensure the right use of this ISS, as well as in authorization and protection against disaster situations such as an effective system protection when accessing, storing, using, and retrieving the information in normal or contingency situations. This compound is the structure of information security policy that is based on a set of controls as described in NBR ISO/IEC 27002. The definition of this structure for the information security policy is important because the Norm ABNT does not indicate nor define—nor explain—how the structure of this policy should be (i.e., which are the fundamental elements and functions, which are the standards of rules for the controls and other practical issues) so that the policy could be effective for the organization. The structure shown in this chapter represents a practical and useful architecture regarding the elements of the information security policy of the organization.

In Chapter 7, Güney Gürsel gives evidence that medical laboratories are the key departments for healthcare. It does not matter if they are independent or part of the health center; they use an information management system. This system has to communicate and exchange data with many different organizations for many different reasons. Interoperability is the ability of two or more systems to exchange data and to use the exchanged data as their own. As always in health information technologies, this is easy to say and hard to perform. It has some challenges. To conquer interoperability, we need standard vocabularies, protocols, nomenclatures, classifications, etc. In this chapter, laboratory management information system-related interoperability issues are examined.

In Chapter 8, Kyriacos C. Tsimillis and Sappho Michael deal with issues of quality management and quality assurance in medical laboratories. Basic terms and their role in quality assurance in laboratory examinations are analyzed and discussed. Clarifications on certification and accreditation are given with a comprehensive analysis of the procedures they refer to and their implementation for particular tasks. The implementation of the international standard ISO 15189 is presented with reference to some recent developments. The chapter has been prepared to help medical laboratories in an introductory understanding of quality assurance issues and encourage them to proceed with the implementation of the standard ISO 15189 and not as a detailed guide. Some practical considerations rising from the experience of a small country such as Cyprus are also discussed.
In Chapter 9, Petros Karkalousos argues that ISO 15189:2012 is more specific to clinical laboratories as compared to the old one. The present chapter emphasizes in the most important changes between the two versions of the standard, especially in those that reveal the “spirit” of the new version. Some of these refer to ethics, quality management system, encouragement of the staff, risk management, evaluation of staff performance, purchase and withdraw of equipment, laboratory facilities, reagents and consumables, communication between the laboratory and its stakeholders, verification of the results by trained personnel, procedures of reporting the results, metrological procedures and traceability, function of laboratory information system, and responsibilities of laboratory director.

In Chapter 10, Fikriye Uras provides support that the accreditation standard of ISO 15189, a guidance document, provides validation that a laboratory is competent to deliver accurate and reliable test results. This international standard has been evolving since 2003. Following the second publication (2007), the standard was released as a revised and updated version in 2012 (Medical laboratories – Requirements for quality and competence). The text of ISO 15189:2012 has been approved as EN ISO15189:2012. European Union members and associate countries agreed to accord it the status of a national standard by May 2013. Any conflicting national standards need to be withdrawn by November 2015 at the latest. The purpose of this chapter is to mark the differences between the two versions of the standards and to highlight the changes and additions that have been incorporated into ISO 15189:2012. A practical approach will be helpful for laboratories to make a smooth transition to the updated standard when revising their quality and technical documentation to meet the new requirements.

In Chapter 11, Stavros Archondakis emphasizes quality management concepts applied to cytopathology laboratories and the application of innovative information technologies in a modern cytopathology laboratory wishing to establish an effective quality management system and meet all current requirements concerning all aspects of its routine workflow (personnel, premises, environmental conditions, equipment, information systems and materials, pre-examination processes, examination processes, and the post-examination phase).

In Chapter 12, Naeem A. Mahoto, Faisal K. Shaikh, and B. S. Chowdhry propose an innovative architecture for the laboratory management information system to enhance the quality and management issues. The proposed architecture integrates two major fields, namely wireless technology and data mining. The wireless technology enables the collection of data easily and wirelessly, and data mining ensures meaningful and novel knowledge discovery from the collected data. In particular, the architecture helps management in three different ways: (1) prevention of risks/errors using technological solutions, (2) an environment to respond rapidly to adverse events, and (3) construction of knowledge base for future guidelines.

In Chapter 13, Alessandro Fiori, Alberto Grand, Piero Alberto, Emanuele Geda, Francesco Gavino Brundu, Domenico Schioppa, and Andrea Bertotti clarify that research laboratories produce a huge amount of complex and heterogeneous data typically managed by Laboratory Information Management Systems (LIMSSs). Although many LIMSSs are available, it is often difficult to identify a product that covers all the requirements and peculiarities of a specific institution. To deal with this lack, the Candido Cancer Institute decided to start a project, named the Laboratory Assistant Suite (LAS), with the aim of developing a new software platform that assists researchers throughout diverse laboratory activities. The proposed system can track laboratory experiments even in problematic environments, support the integration of heterogeneous biomedical data, and help in decision-making tasks. In this chapter, the authors present the current architecture of the system, some real-use cases, as well as statistics about stored data and user feedback in order to provide an overview of the functionalities and show the effectiveness of the platform in supporting research in the molecular oncology field.
In Chapter 14, Donovan McGrowder and Romeo Bishop seek to find out information on the functionalities of the laboratory information systems available in medical laboratories in Jamaica and their ease of use and the overall performance and satisfaction of medical technologists using them. A cross-sectional descriptive survey involving the use of a 48-item questionnaire was conducted among medical laboratories with a LIS. There were a total of 14 completed questionnaires out of 15, giving a response rate of 93.3%. The findings reveal that the majority of the laboratories have a LIS that provides multi-level security, allows password protection at different levels, maintains a patient database, and generates records. The majority of the medical technologists agree or strongly agree that it is easy to use the LIS and experience improved overall performance on the job. The medical technologists clearly understand the existing features and functionality of the LIS. Additional functional features of the LIS should be customized, and adequate funding is needed, especially for hospital-based laboratories.

In Chapter 15, Patrizia Colangeli, Fabrizio De Massis, Francesca Cito, Maria Teresa Mercante, and Lucilla Ricci assert that the Laboratory Information Management System (LIMS) is recognized as a powerful tool to improve laboratory data management and to report human health as well as veterinary public health. LIMS plays an essential role in public health surveillance, outbreak investigations, and pandemic preparedness. The chapter aims is to provide an overview of LIMS use in veterinary fields as well as to report 20 years of experience of a Veterinary Public Institute in working with LIMS, illustrating the features of the LIMS currently in use in the institute and highlighting the different aspects that should be considered when evaluating, choosing, and implementing a LIMS. In depth, the chapter illustrates how LIMS simplifies the accreditation path according to ISO IEC 17025 and the role in the epidemiology and veterinary public health. For this aspect, it is very important to collect clear data, and for this reason, a LIMS has to activate formal checks and controls on business rules. To facilitate this issue, an interconnection between LIMS and other applications (internal or external to laboratory) could be improved to allow automatic data exchange. At the same time, the unique data encoding at national/international level should be used.

Conclusively, Laboratory Management Information Systems: Current Requirements and Future Perspectives introduces the role of total quality management practices, reviews what is known about the effect of the electronic medical record on aspects of laboratory test ordering, argues that the present concern is on the standardization of the existing systems, proposes a calibration process, provides rules for information security, examines interoperability issues related to the laboratory management information system, provides support for the accreditation standard of ISO 15189:2012, proposes an innovative architecture for the laboratory management information system, and emphasizes quality management concepts applied to cytopathology laboratories.

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