

# Chapter 11

## The Use of Information Systems in a Modern Cytopathology Laboratory

Stavros Archondakis  
Military Hospital of Athens, Greece

### ABSTRACT

*Over the last decade, cytopathology laboratories wishing to achieve an automated and seamless workflow process, to diminish turnaround times, and to improve their diagnostic accuracy have successfully adopted information technologies and automation. New types of cameras and microscopes connected to computers made possible image capture and transmission (telecytology). New innovative information technologies, including e-health and telemedical applications, constitute a valuable tool for interlaboratory collaboration and quality improvement. New applications are expected to enhance the opportunities for improvement in the field of cytological data management and sharing. In this chapter, the authors emphasize 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).*

### INTRODUCTION

During the last decades, medical data deriving from the analysis of patient samples was stored in medical laboratories and was provided to physicians manually (Brerider-Jr-McNai, 1996). The absence of an integrated laboratory information system was making medical data transfer extremely slow and potentially ineffective, while results correction and quality control were proved time and money consuming process (Kubono, 2004).

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Over the last decade, the wide implementation of laboratory information systems became a necessity dictated by the need of real-time results and the increasing role of laboratory medicine in therapeutic decisions (Georgiou & Westbrook, 2007).

Laboratory information systems have been implemented in many medical laboratories wishing to improve their quality standards. A laboratory information system (LIS) is a valuable tool for medical professionals in order to achieve

regulatory compliance, manage interlaboratory or intra laboratory collaboration, deliver detailed reports, and develop the laboratory networking capabilities. The result is better data management and sharing between the laboratory and its customers (either laboratories or clinicians) (Brerider-Jr-McNai, 1996).

Cytopathology laboratory services are crucial to patient care and have to meet the scientific or regulatory requirements concerning examination requests, patient preparation, patient identification, samples collection and handling (transportation, storage and processing), specimen's evaluation, clinical interpretation and reporting, as well as personnel's working safety (Okada, 2002).

The main cytological examination, the well-known Papanicolaou test consists a widely applied, cost-effective screening method for the early detection of cervical dysplasia and cancer. Well-written and well-implemented LIS software can implement emerging technologies aiming to improve the diagnostic accuracy of the method. Pap smears screening, and cytological diagnosis provision for the large majority of the female population requires a large number of skilled cytotechnologists and cytopathologists. Since the number of these professionals is still inadequate, the development of automated laboratory instruments and screening systems may give practical and satisfactory solutions. Laboratory informatics consists nowadays an essential tool of laboratory's quality assurance and improvement by playing a key role in the preanalytical, analytical and post analytical, diagnostic phases. A well-written and well-implemented LIS software can use medical data for the documentation of quality control (QC) measures (Okada, 2002).

In the past, manual methods of data storage in cytopathology laboratories were including logs and card files organized by patient name, date, specimen number or interpretation. During the last ten years, information technology has dramatically influenced the clinical laboratory practice, due to laboratory management information systems

wide implementation. A laboratory management information system (LMIS) implementation in the routine laboratory workflow has to overcome serious problems concerning medical data and laboratory hardware and software protection. The medical laboratory has to take measures against laboratory's information system improper or unauthorized use.

LMIS can also monitor all available indicators of the laboratory reports accuracy, completeness and timeliness. LMIS can also monitor effectively all available telemedical or e-health applications, especially when used for quality management purposes (Okada, 2002).

The management of laboratory information systems has nowadays to meet the requirements of relevant quality standards, applied for accreditation purposes. Accreditation is the process by which a certified organization or agency recognizes that a facility or service meets specific pre-established standards (Pantanowitz et al., 2009). ISO 15189:2012 is an international quality standard, mainly used by medical laboratories. ISO 15189:2012 can diminish significantly unexpected errors or problems. ISO 15189:2012 requirements for laboratory information systems suggest the implementation of specific measures concerning environmental conditions, system security, data entry control, medical reports, data retrieval and storage, and finally system's hardware and software maintenance (Kubono, 2004).

During the last decade, there is an ongoing demand by regulators, laboratory accreditation bodies and customers for implementation of more effective measures that could increase confidence in cytological laboratories performance. ISO 15189:2012 specific requirements improve the cytopathology laboratories' capacity to store, organize, process, and retrieve large amounts of information, to monitor turnaround times and other crucial quality assurance parameters. ISO 15189:2012 requirements include the implementation of specific measures concerning documentation, protection from unauthorized access,

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