

GUEST EDITORIAL PREFACE

Special Issue on Quality in Cytopathology Laboratories

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INTRODUCTION

Nowadays the examinations performed by clinical laboratories are vital for patient management and subsequent treatment, as they directly influence the care and handling by a percentage as high as 70%. In order to ensure the quality of examination results, various countries are forcing the adoption of quality standards, such as ISO 15189:2012 (ISO, 2014a) or ISO 17025:2005 (ISO, 2014b). The most popular standard is ISO 15189:2012, entitled: “Medical laboratories - Particular requirements for quality and competence”. This is especially designed for medical laboratories handling human biological material; it is synthesized of two major components: chapter 4: related to the management requirements and chapter 5: focusing on technical requirements. The application of such standards is now obligatory in several countries, for example in France all medical laboratories are required to adopt ISO 15189:2012 for all the examination types performed by 2016.

The modern cytopathology laboratory is continuously changing, due to scientific innovations and advances. Consequently, cytopathology laboratories become complex organizations having numerous branches. For example, their structure includes units for diagnostic, functional, analytical and quantitative cytopathology as well as cytogenetics of the interphase. More advanced laboratories may have units for molecular cytopathology and telecytology. Today, the cytopathology laboratory becomes complicated and involves highly skilled personnel and specialized medical devices, orchestrated to perform several hundreds of different examination types.

Hopefully, despite this complexity, modern cytopathology laboratories are very well structured and have typical and standardized workflow. These structures and the repetitive work tasks are ideal for the adoption of quality standards; however in order to ensure efficiency, efficacy and smooth operation, it is necessary to establish information technology tools. Today the role e-Health for the assurance of quality

and consequently the role of journal such as “*International Journal of Reliable and Quality E-Healthcare*” is highlighted and becomes more and more important.

INSIDE THIS ISSUE

This special issue related to “Quality in Cytopathology Laboratories” includes four contributions to the discussion of the topics, challenges, opportunities, ideas, implementations and developments addressing the quality requirements for cytopathology laboratories.

The first paper entitled “*A Quality Control Study of Liquid Based Cytology Test Papanicolaou: Design and Implementation Aspects of Laboratory Information Systems for Continuous Quality Control*” (Margari et al., 2014), addresses a quality control and assurance method based on Cytology-Histology and Cytology-Cytology comparisons. The authors present results based of real data related to cervical cancer collected from a cytopathology laboratory and the relevant histological outcomes. The proposed methodology suggests the assessment of laboratory performance over time and the assessment of the laboratory as a system as well as an assessment of individual laboratory personnel. Complementary the authors propose a high-level design for a Laboratory Information System capable of supporting the proposed methodology. This paper addresses internal quality control, as there is no certified third party that qualifies the accuracy of results. The advantage of this methodology through the coupling with the proposed LIS is the capability to have in hand quality metrics almost instantly and thus to ensure laboratory confidence and timely initiation of corrective actions.

The second paper is entitled “*The Implementation of Cloud-based Telemedical Applications for External Quality Control Purposes in the Field of Cytopathology*” (Archondakis et al., 2014). In contrast to the previous paper, that to my opinion is categorized as internal quality control, this article deals with external quality control. Specifically analyzes the details of the

implementation of an accredited proficiency testing scheme by cytopathology laboratories according to ISO 15189:2012. The innovation of this article is that the proposed scheme is based on cloud-based telemedical applications, is relatively simple to implement and has low cost. During this effort, the authors involved six cytopathology laboratories and used fifty pap smears with histological confirmation. The study had a large number (20) of the board-certified cytopathologists that reviewed the smears and provided responses related to a) the diagnostic categories and b) smear quality. The costs of participating in external quality assessment schemes is not negligible, especially for small size cytopathology laboratories, this paper provides an easy and inexpensive to implement a methodology for quality control based on cloud computing services.

The other two papers are complementary and written on the basis of ISO 15189:2012. The first is entitled “*ISO 15189:2012 Management Requirements for Cytopathology Laboratory Information Systems*” (Pouliakis et al., 2014a). This paper introduces the idea of an enhanced Laboratory Information System (eLIS), being capable to facilitate the everyday routine of the modern cytopathology laboratory workflow and demystifies the entities required to augment a LIS in a way to support the management requirement posed by the standard (chapter 4) (ISO, 2014a). It is worth noting that despite the standard does not force the use of LISs, nowadays it is difficult (if not impossible) for a cytopathology laboratory to operate efficiently without an LIS. According to the authors the proposed eLIS has an added value; because the addition of new quality related entities coupled with the appropriate logic; allows instant, better and more frequent monitoring of management operations as these are posed by the standard requirements. Alternatively without a dedicated and specialized LIS it would be time-consuming processes with increased bureaucracy (a disadvantage of the ISO standard often used against it).

The complementing paper has a similar title: “*ISO 15189:2012 Technical Requirements for Cytopathology Laboratory Information Systems*” (Pouliakis et al., 2014b). In this paper, the authors analyze all sections of ISO 15189:2012 technical requirements (chapter 5). Specifically address: personnel, workplace, equipment, pre-analytical procedures, analysis, quality assurance of examinations, post-analytical procedures, reporting of results and LIS requirements. The authors took the standard’s sections one by one and propose solution for the design of the eLIS and the required entities and subsystems that can be used to address the construction of a real system that could support the implementation and monitoring of the standard requirements. The last two papers to my opinion are of interest not only to the modern cytopathology laboratory but to other types of medical laboratories as well.

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