ABSTRACT

During the last decade, there is a stringent and ongoing requirement by regulatory bodies, and often enforced by law, for the implementation of measures increasing the confidence of cytological laboratories (expressed as requirement for accreditation via ISO 15189 or 17025). In this study, we present a quality control and assurance (QC&QA) method and results based on Cytology-Histology (C-H) and Cytology-Cytology (C-C) comparisons, on the basis of real data related to cervical cancer. The proposed QC&QA methodology allows the assessment of laboratory performance over time and the assessment of the laboratory as a facility and individual personnel as well. Moreover, we propose a high-level design for a Laboratory Information System capable of supporting the proposed methodology. The usual methodology to regularly control laboratory performance (once or twice per year), is not nowadays efficient. LIS implementation following the proposed scheme can support instant QC&QA, thus ensuring laboratories confidence and timely initiation of corrective actions.

Keywords: Cervical Cancer, Cloud Computing, Cytology, Cytopathology, E-Health, ISO 15189, Laboratory Information Systems, Liquid Based Cytology, Pap Test, Quality Control and Assurance, Software, Systems Architecture

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INTRODUCTION

There are many aspects related to the quality in cytology and how to control and assess. One of the fundamental methods is the correlation of the cytologic and histologic answers (Clary et al., 2002; Izadi-Mood et al., 2013). Furthermore, estimation of agreement between cytopathologists and review of the cytologic slides offers the possibility to investigate laboratory performance. The concept is to evaluate the discrepancies, determine why occurred, to identify sampling and interpretive errors, re-examine diagnostic criteria, improve the diagnostic accuracy of the laboratory and to ensure the appropriate patient care. The way cytologic and histologic (C-H) correlation as well as the correlation between cytological diagnoses (C-C) (Raab et al., 2006) is performed, has changed over time. Years ago, it was just to collect all cases every few months and go through them. This is not anymore an acceptable method because patients would not like to learn about a mistake a few months after it, especially, if this could have been corrected (Renshaw, 2011). The improvement of information systems and LIS in most cytologic and histologic laboratories, allows such correlations to be performed just immediately after the release of the examination results. Additionally, data mining either on-line or in a later stage may produce valuable knowledge for trends and problematic areas in the processes and therefore to initiate corrective actions for quality improvement.

During the last decade, there is a stringent and ongoing requirement by regulatory bodies, often enforced by law, for the implementation of additional measures in order to increase the confidence of cytological laboratories. This is expressed as a requirement to apply ISO 15189:2012, entitled: “Medical laboratories — Requirements for quality and competence” (ISO, 2014b) and to additionally obtain accreditation by an organization regulated by the government. ISO 15189 was created by the International Organization for Standardization (ISO) (ISO, 2014a), the first version of the standard was issued in 2003, nowadays the most recent and applicable version of this standard is ISO 15189:2012.

This standard must be implemented by all medical laboratories that handle human biological material irrelevant of their legal status (private or public), their size or geographical distribution, the number of employees and the types of examinations performed. This becomes more important as laboratory examinations on the patient, directly influence the care and handling by a percentage as high as 70%.

ISO 15189 is composed by two parts chapter 4 describes the requirements related to the management. This chapter is practically the adaptation of ISO 9001:2008 and the family 9000 standards (ISO, 2009) in the environment of medical laboratories. The second part of the standard (chapter 5) focuses on technical requirements. The general aspects and the components of this management system are briefly highlighted in Figure 1.

This standard poses requirements, among others, for the implementation of specific measures concerning internal and external quality control and assurance. Accreditation (the process by which a certified organization or agency recognizes that a facility or service meets specific pre-established standards) is strongly influenced by both types of quality control because these can diminish significantly unexpected errors or problems (Mourtzikou et al., 2013).

Laboratory information systems (LIS) nowadays are used to supervise many varieties of inpatient and outpatient medical tests. The primary features that laboratory information systems have included involve: management of sample check in, order entry, specimen processing, result entry and patient demographics, as well as medical history. A LIS tracks and stores all the information related to the patient from patient arrival (and for cytopathology laboratories from examination ordering and sample arrival) until he/she leaves and stores the data for future retrieval. LISs also produce reports for the tests that handle and statistics related to various aspects of the laboratory such as time for execution of examinations, sample volumes,
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