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Transition to ISO 15189 : 2012 for Cytopathology Laboratories Part 3:
Risk Analysis and Management

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ABSTRACT

Modern cytopathology has advanced from the point when conventional Pap testing was adequate enough for medical diagnosis thanks to the implementation of the latest Laboratory Diagnostics. No matter how well-structured a cytopathology laboratory may be, it is still subjected to potential risks that could dramatically affect its services. Risk identification, evaluation and management via a Quality Control Plan can become a powerful tool for cytopathology laboratories wishing to maintain or/and enhance the quality of their diagnostic services. The authors present their experience on the implementation of such a risk analysis and control system covering all the necessary parameters and issues that should be addressed. Also, a hypothetical structure for a risk analysis is presented with useful guidance associated with cytological laboratories conducting morphological and molecular examinations. Finally, a mobile health solution is proposed that, if designed properly, could further optimize and harmonize risk management strategies globally.

KEYWORDS

ISO 15189:2012, Management Strategies, Quality Control Plan, Quality Management, Risk Analysis, Risk Assessment, Risk Frequency, Risk Identification, Risk Monitoring & Review, Risk Severity

INTRODUCTION

Risk is a word with a wide range of definitions. Usually the term "risk" is used to define the possibility of a harm, a danger or a hazard and the likelihood of their occurrence in a stated timescale (Alberg, Hatfield, & Huxley, 1996). Risk analysis or risk assessment is defined as the process of evaluating the potential dangers and possible errors that could happen as a result of an unexpected adverse event. It is an analytic report that aims to numerically determine the consequences and influence of any potential risk related to a specific enterprise taking into consideration its likelihood and frequency of occurrence as well as the severity of the possible outcomes. It is a process that involves collection, categorization

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and evaluation of information and data from numerous different sources in order to assess the degree and likelihood of a particular identified risk or hazard and the patterns of circumstances in which risk-associated parameters may arise (Kohn, Corrigan & Donaldson, 2000; Morgan, 2000).

It is a powerful tool that has been extensively used in various sectors and fields such as Industrial and Banking Management for decades since it provides valuable information in the process of crucial decision-making that affects the worldwide economy. It is a process of high significance since its final findings could play a major role in the developing of a better understanding of the parameters that regulate a well-defined field or system.

Risk analysis could be easily applied in any particular sector or enterprise that is subjected to possible dangers and as an outcome all the medical diagnostic laboratories could act as promising enterprises of that kind. One outstanding example of such a laboratory is the modern cytopathology laboratory that offers valuable services to patients such as arrangements for examination requests and preparation of patients, collection, transportation, storage, analysis and diagnostic evaluation of clinical samples, as well as interpretation, reporting and advice (Archondakis, 2015). The main cytological examination, the well-known Papanicolaou test is a widely applied, cost effective screening method for the early detection of cervical dysplasia and cancer. A well-written and well-implemented risk analysis and management system could improve the diagnostic accuracy of this examination by ensuring that all the potential hazards that could occur would be efficiently managed by the laboratory personnel who at the same time would constantly try to eliminate the recurrence possibility of each one of these events.

Nowadays, it is very obvious that cytological laboratories, due to the clinical importance of the evaluations they perform, are constantly trying to improve even further the quality of the services they provide. The most efficient way to achieve this, is through the application of well-designed and well-implemented Quality Control (QC) and Quality Assurance (QA) processes and standard operating procedures (SOP) from the laboratory in terms of an established Quality Management System (QMS) covering all stages of laboratory activity. QC defines service's quality, imparting to it the credibility needed for its intended purpose, while QA activities measure the degree to which desired outcomes are successful (Archondakis, 2015; Archondakis, Vavoulidis, & Nasioutziki, 2016).

The most popular procedure through which the cytological laboratories can ensure or even maximize their levels of QC and QA is through the implementation of the International Standard ISO 15189 specific requirements concerning every aspect and activity within a medical diagnostic laboratory. The most recent version of this International Standard, published in 2012, introduces the use of the risk analysis and management in medical laboratories. More specifically, in the Section 4.14.6, it is clearly mentioned that the medical laboratories should try to estimate the potential impact that all their activities, processes and possible errors would have on the final diagnostic results that refer to patients and should use the findings of these risk evaluations so as to design and carry out proper corrective and/or preventive plans in order to successfully eliminate the probability these adverse events should re-occur (International Organization for Standardization, 2012).

The purpose of this article is to present our experience on the application of a risk analysis and management system to cytopathology laboratories wishing to establish a QMS in agreement with the ISO 15189:2012 specific requirements or aiming to a successful transition of their already applied QMS from the ISO 15189:2007 to ISO 15189:2012 specific requirements. Furthermore, we describe in detail the aspects and parameters that a well-designed risk analysis should include. In addition, we propose a hypothetical concept of how such a risk analysis should be structured providing analytic guidance associated with various aspects while performing the evaluation of possible hazards that could take place and affect the overall performance of a modern cytological laboratory that carries out both morphological and molecular cytological diagnostic examinations. Finally, we describe a

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