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Healthcare Safety Management: The Model of Fmea/Fmeca in Anatomic Pathology Service

Ianni A[1]*, Virgili R[2], Piredda M[3], De Marinis MG[3] and **Petitti T[1]**

[1]*Research Unit in Hygiene, Statistics and Public Health (Dir. Prof. T. Petitti), Campus Bio-Medico University, Rome, Italy*
[2]*Anatomic and Surgical Pathology Service and Unit, Campus Bio-Medico University Hospital, Rome, Italy*
[3]*Nursing Research Unit (Dir. Prof. M.G. De Marinis), Campus Bio-Medico University Medical School, Rome, Italy*

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***Corresponding author:**
Ianni Andrea
Research Unit member, Hygiene, Statistics and Public Health (Dir. Prof. T. Petitti), Campus Bio-Medico University, Rome
Italy
E-mail: a.ianni@unicampus.it

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Abstract

Safety is a universal concern in healthcare service management. In this context, patient safety can be defined as the absence of avoidable harm, because all health care activities bring inherent risk of adverse events (AE).

Documenting and analyzing potential risks proactively is essential for improving patient safety. Accomplishing this goal requires an effective method to identify risks and an easily understood approach to manage them. Because of its complex nature, surgical pathology practice is inherently error prone: currently, pressure is done to reduce errors in several fields of healthcare, including pathology.

This paper presents the failure mode and effects analysis (FMEA) tool applied to the whole set of activities in an Anatomic and Surgical Pathology Service of a University Hospital. After a wide search of scientific literature, a model was prepared to review main factors that contribute to error in this type of service. The use of a simulation method is also suggested, to increase results and obtain a more objective, comprehensive, and systematic panel to identify potential system risks. The model has been developed to conduct a FMEA as part of a wider strategy of risk reduction, based on a measure-analyze-implement-control methodology to improve the process of a surgical pathology laboratory and service.

Failures were then analyzed for likelihood, severity, and discoverability of occurrence using the FMEA methodology and a high fidelity simulation was developed by creating scenarios based on actual sentinel events. Finally, attention has been paid to the preparatory steps of FMEA team assembly, given that FMEA successful completion is judged to be highly dependent on the team members' aptitude and on their commitment to hold regular, productive meetings.

The developed model confirms to be a useful addition to the tool kit available to health professionals for assessing and improving the safety of health care processes.

Abbreviations: FMEA: Failure Mode and Effect Analysis; FMECA: Failure Modes, Effects and Criticality Analysis; AE: Adverse Events

Keywords: surgical pathology; error reduction; FMEA/FMECA; hospital management

Introduction

Error in healthcare can be defined as the failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim [1]. Determining the deep causes of error is an important step in failure prevention mainly through system re-design. A problem in error reduction is that most errors are secondary to multiple

causes and difficult to target with a single initiative. Quality in health care activities is another key aspect of healthcare management and it appears strictly related both to safety and risk control [2]. Quality appears as a comprehensive and multifaceted concept whose dimensions vary in importance depending on the situation: technical competence, accessibility, effectiveness, interpersonal relationship, efficiency, continuity, safety and adequate facilities [3, 4]. Risks are no longer thought in a negative sense but can be perceived as a tool to identify opportunities for improving the outcome of health care services [5]. Risk management is a process consisting of several main phases, as risk identification, estimation and control, and should hence embrace all its phases to achieve its goal, that is ensuring patient safety [6]. Clinical and pathology laboratory medicine has seen the dissemination of risk management philosophy and technique in the last years, with a set of actions to recognize or identify risks, assess the probability of something happening in case of hazard and evaluate the severity of their consequences [7].

One of the main instruments used in this field is the Failure Mode and Effects Analysis (FMEA). Companies and institutions that properly use that method not only save resources but also maintain high levels of customer satisfaction [8]. FMEA is a proactive risk assessment tool used to identify potential vulnerabilities in complex, high-risk processes and to generate remedial actions to counteract them before they result in adverse events [6, 9]. Although developed by engineers and originally employed in high-risk industries such as aviation and nuclear power, FMEA is now increasingly used to proactively assess and improve the safety of complex health care processes, including intravenous drug administration, blood transfusion, sterilization of surgical instruments and a wide variety of organizational processes [2, 10].

The method of FMEA is useful and can be applied valuably for obtaining new improvement goals and deep changes of an already existing product or process, to ensure more reliability and analyze causes of flaws in already established flows, and finally as a tool for organizational learning [5].This systematic method is based on team work for identification, evaluation, prevention, control or the elimination of the causes and effects of potential risks in a system before a final product is delivered to a final user [5, 8]. Main goal is to discover latent conditions and active failures and to prioritize these based on the potential severity of risks associated with them.

Among health care errors, studies have demonstrated that diagnostic errors are associated with poor patient outcomes [7, 11, 12]. When errors occur in pathology medicine, they have the capacity to generate profound diagnostic confusion. These errors can take a variety of forms in different subspecialties of pathology. Errors in pathology laboratory and unit can occur at any point from specimen retrieval through specimen analysis; they are classified broadly as pre-analytic phase, analytic phase, and post-analytic phase errors [4, 13, 14]. Errors in anatomical pathology may occur in a variety of settings and might involve reporting an incorrect diagnosis or the absence of a correct diagnosis on a submitted tissue specimen [15, 16].

This paper attempts to review main aspects of risk management process applied to anatomic pathology laboratory and unit in a University Hospital and discusses a practical application of FMEA/FMECA in that field, by elaborating a model of process analysis joined with a simulation trial and a proposed guide for an effective team formation.

Methods

In the present study main available databases were systematically investigated, with a two-steps selection of most relevant articles. Several terms were used for collecting papers, in order to cover the wide field of interest regarding safety and errors in anatomic pathology. A wide literature review was performed to identify main types of error in anatomic and surgical pathology units, as well as factors that contribute to errors in that specialty and most effective error-reduction strategies applied to pathology.

A failure mode and effects analysis (FMEA) tool was applied to the whole set of activities in an Anatomic and Surgical Pathology Service of a University Hospital. Analysis of steps in anatomic pathology sample flow was performed and risk analysis was applied to each critical point. A model was prepared to identify potential vulnerabilities in a complex set of processes as those performed in an anatomic pathology laboratory, in order to generate remedial actions effective in counteracting risks before they can result in adverse events. Main classical stages (phase 1 to 5) were performed during the introduction of FMEA model into anatomic pathology practice. An experienced and multi-disciplinary team was built at the beginning of the present study, so that phase 1 and 2 (first preparation and acknowledgment of the potential values of that method) were performed in a short time. The following stages (phase 3 to 5) were directed to collect a detailed list of potential active and latent failures and prepare action plans, adapting work processes and involving other hospital areas, beyond the anatomic pathology unit. Finally, next efforts were done to calculate a risk priority number (RPN) for each potential failure mode. An RPN is the quantitative estimate of the risk associated with each failure mode.

A simulation was added to the developed FMEA model, in order to obtain a better understanding of events by creating similar conditions and studying the team performance to perceive the vulnerabilities and the failure modes. The use of simulation, in conjunction with the developed FMEA model, was performed to elicit interdisciplinary expertise within the team and organizational analysis, in an attempt to improve team work and communication.

Finally, on the basis of the perception that success of FMEA could partially depend on appropriate participants identification and availability, attention was applied to the preceding preparatory steps of FMEA team assembly and meeting scheduling, as well as to evaluate the aptitude and commitment of team members.

Results and Discussion

Anatomic pathology error detection articles were searched to discuss what is meant by error in pathology, to suggest definitions that could be useful in risk analysis and to discuss where errors in anatomic pathology occur in relation to the classical laboratory test cycle. Literature review confirmed the point of view that risk management methods appears as an actual requirement applied to medical laboratories accreditation, underlining the well-known change in healthcare professional culture, from error detection to management of risk throughout all steps of laboratory medicine.

Another result of the first part of this study is the observation that clinical risk analysis is one of the essential tasks of hospital managers worldwide. Risk reduction enhances the healthcare service quality and effective relationship between hospital staff and patients; moreover, it limits lawsuits for malpractice events. An effective multi-disciplinary strategy is recognized to be based on the ability to identify the existing factors for risk on the one hand, and risk analysis and appropriate strategy selection for controlling and eliminating risk itself on the other hand. Under that perspective, quality of clinical services can be viewed from different perspectives, such as safety, acceptability and reliability. Literature review showed that providing quality in patient care has become more and more crucial in today's highly competitive, highly cost-conscious healthcare systems.

In the second part of this study, health care failure mode and effect analysis (FMEA) confirmed to be an effective technique for assessing risk of patient injury by prospectively identifying and prioritizing potential system failures. The model developed followed classical structure and stages, including the following main aspects: forming a team of experts, determining the process and identifying conditions, failure modes and their effects, determining the probability of failure occurrence, severity of effects, and probability of potentials for both failure and effects before the patients or the staff are harmed. Repeatability, severity and identification probability received a score between1 to 10, and at the end, a Risk Priority Number (RPN) was determined (FMECA); the score was then re-calculated after the implementation of corrective strategies, in order to determine the effectiveness of the model.

Quality in healthcare appears as strictly connected to risk management principles. On the basis of this assumption, the developed model helped in obtain that full implementation of risk management and quality management systems should not be regarded as separate activities, but should be integrated within everyday practice of anatomic pathology laboratory professionals. Thus, moving from a focus on human failures (e.g., by systematically applying risk management principles and implementing evidence-based practice to tackling system failures) and improving the quality of care showed to be the best solution to improve patient safety.

The developed model resulted in actions to address the root causes, determining the following situations: risk reduction through the development of a preventive action plan to promote process improvement; immediate removal of the risk source when the pieces of equipment were increased; sharing the risk with other staff members when the clinical emergency staff was involved in the potential problem (simulation). The proposed FMEA model contributed to quality planning, allowing the evaluation of interconnected activities designed to generate products and assisting in the identification of controls. The developed model confirmed to be a useful addition to the tool kit available to health professionals for assessing and improving the safety of anatomic pathology processes.

Simulation - that joined and completed the model - allowed to analyze and prevent medical errors in the anatomic pathology setting, through identifying errors and their systemic causes, then learning from them and finally alerting the system to prevent their reoccurrence. In this regard, the developed model represents, as expected, a prospective risk analysis technique, to be involved in a wider risk management and analysis plan.

Finally, attention in creating the multi-disciplinary team revealed to add value to the proposed FMEA model as well as to simulation phase, increasing skills, experience and knowledge represented in the team and involved in effective work meetings. A subsequent study has been planned to confirm and extend these preliminary results in anatomic pathology unit.

Conclusions

The issue of error in healthcare has acquired over the years a growing relevance [1, 17]. Process analysis, error handling and assessment of programs for risk reduction are considered an important part of corporate policies for quality built on the concept of "patient at the centre" [2]. Recommendations and guidelines dealing with themes such as patient safety goals and error reduction have been widely published and released in the last twenty years [3, 5, 13]. Although there has been heavy emphasis on medication errors and hospital care in the whole period, scrutiny has been more recently applied to different fields of health care and to the work of clinical and pathology laboratories [7, 12]. Anatomic and surgical pathology errors have been reported to occur in a wide range, depending on the involved methods of detection and error definition [12-14]. When measuring anatomic pathology discrepancies, based on a multi-institutional survey, a median rate of 5.1% was observed [16], with a striking variability across Centers and laboratories (percentile distribution: 25^{th}=10.0%; 75^{th}=1.0%).

In this context, patient safety, defined by the Institute of Medicine (IOM) as "the prevention of harm to patients" [1], can be considered the ultimate goal of medical laboratory services. Risk management principles should therefore be regarded as integral part of anatomic pathology laboratory in assuring quality and safety [7], so that they have become actual requirements of international standard for accreditation [3].

The use of a locally adapted FMEA/FMECA model, a widely used technique for assessing risk of patient injury, in anatomic pathology setting can allow to prospectively identify the primary failure modes and events, creating risk priority categories as well. The model developed in the present study can contribute to increase our understanding of how errors occur and prepare an interdisciplinary strategy of risk reduction in anatomic pathology units.

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