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SCHOOL OF DOCTORAL STUDIES IN MEDICINE AND PHARMACY

Doctoral Thesis
Summary

Solutions to be implemented in medical laboratories practice of risk management

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Introduction

Laboratory tests are necessary to establish the diagnosis and the treatment of patients. The best way to guarantee the patients and the doctors that the results of the tests released by the medical laboratory are relevant for the patients' health or diseases assessment is medical laboratories accreditations according to ISO 15189, a process of evaluation and recognition of its specific competency to test, by experts in the field of laboratory medicine. The last version of the standard ISO 15189:2013 contains a section dedicated to risk management (section 4.14.6).

The laboratory's activity is virtually divided into three phases: pre-analytical, analytical and post-analytical. From these ones, pre-analytical phase was analysed less comparatively with the other phases by the health responsible, reaching the point to which up to 65% of the errors of the testing process to be associated with this phase. Occurrence of pre-analytical errors can affect patient's safety due to delay in clinical and therapeutical decisions because of the venous blood need of recollection.

Objectives

A first objective of the studies was to analyze and manage the risks associated with the pre-analytical process to raise efficiency in quality management in a medical analysis laboratory. We also set out to develop a guide on how to use the tools and techniques selected in risk management analysis, and an algorithm for approaching the risk management process adapted to medical laboratories. Another objective was to increase the quality of medical services provided by a medical laboratory by decreasing the number of non-conformities of the pre-analytical process, in the period 2015-2018, and to outline a data collection protocol adapted to the infrastructure and accreditation requirements for medical laboratories in Romania.

Personal contribution

The personal contribution was presented in four studies that allowed the achievement of the proposed objectives. The first two studies refer to the risk management analysis that was based on the application of tools and techniques available to identify the root cause and opportunities for improvement in the medical laboratory. The third study is an inter-laboratory study that was the basis for establishing the current performance of the participating medical laboratories, as well as the desired performance. The fourth study focuses on establishing an algorithm for selecting and monitoring quality indicators, as a way to assess the effectiveness of measures taken following the risk management analysis for the pre-analytical process.

Study 1. Research on risk analysis according to the tools and techniques available to identify the root cause and opportunities for improvement in the clinical laboratory

One of the stages of risk management analysis is to identify possible nonconforming events (risks) for the process of interest. Before starting the activity of improving the pre-analytical process, it is necessary to understand its importance and contribution to achieving the proposed objectives. The SIPOC diagram (Suppliers-Inputs-Process-Outputs-Customers) is a method that provides an overview of the process, the direction of information flow, and the beneficiaries of the process. A practical approach was to identify the main stages or activities of the pre-analytical process and then arrange them in the order in which they take place over time, thus drawing up the process map. Subsequently, each stage or activity was evaluated to identify possible nonconforming events, most often during brainstorming sessions. The result of the brainstorming was the drawing up of a list of potential nonconforming events, which can be grouped and represented graphically in the form of the Ishikawa diagram or the "fish bone" diagram. The FMEA (Failure Modes and Effects Analysis) / FMECA (Failure Modes, Effects and Criticality Analysis) technique prioritizes possible nonconforming events, taking into account the probability of their occurrence and the impact they may have on the achievement of the initial objectives. Once possible nonconforming events were identified, the risk associated with them was assessed. For nonconforming events at the top of the Pareto chart, with a high impact on the achievement of the initial objectives, the measures implemented aimed at reducing the risk to an acceptable level according to the risk matrix. After drawing up the list of possible nonconforming events and prioritizing them based on PRN (Priority Risk Number), the stage for identifying opportunities for improvement follows. Choosing and implementing appropriate measures to reduce the likelihood / frequency of occurrence or impact of nonconforming events depends on identifying and understanding their root causes using the tools: "Five Whys?" and/or FTA (Fault Tree Analysis). The first study demonstrates the need to apply risk management analysis tools and identify opportunities for improvement in laboratory medicine, and to develop a customized methodology to be widely used in our field.

Study 2. Managing risk in a clinical laboratory for the pre-analytical process

The second study aimed at applying the risk management methodology developed in a medical laboratory to prevent the risks associated with the activities of the pre-analytical process, constituting an element of originality of the thesis. The risk management analysis had the following objectives: early warning of potential nonconforming events (risks) by using risk and/or quality indicators that detect changes in the pre-analytical process; mitigating the effect / impact of risks by taking preventive action, taking into account the future consequences of the decisions now taken and developing risk response strategies for cases where risks occur. In this study, we opted for the risk management model recommended by SR ISO 31000: 2018, which divides the risk management process into stages (sub-processes) that we have developed as suggestively as possible. The risk management analysis addressed the pre-analytical process for the Departments of Biochemistry, Hematology and Coagulation, being carried out with the participation of all laboratory staff from the mentioned departments and managed by the management of the clinical laboratory. The study group consisted of all the nonconformities of the pre-analytical process registered in our laboratory between 01.01.2015-31.12.2018. In our study, for the analysis of the risk management process, we followed the stages of the PDCA (Plan-Do-Check-Act) cycle that reflect the experimental scientific method of formulating a hypothesis, collecting data to test the hypothesis, analyzing the data and interpreting the results: planning the risk management process; identifying risks; risk analysis; elaboration of the risk response plan; risk monitoring and control. We concluded that although risk management is a requirement for accreditation of medical laboratories, due to the need for time and staff resources with competence in quality and risk management, the process of implementing risk management in medical laboratories is still in its beginning.

Study 3. Pre-analytical risk components in four branches of a medical laboratory in Romania

The third study is an inter-laboratory study that was the basis for establishing the current performance of the participating medical laboratories, as well as the desired performance. This study was conducted in four branches of a national laboratory between January 2015 and March 2015 and aimed to identify, define, analyze and estimate pre-analytical quality indicators selected for risk management assessment, grouping errors according to their criticality and effects on patient health and safety. Our study emphasizes the importance of standardized definitions and best practice guidelines for medical laboratories in making strategic decisions to improve the health and safety of patients, thus meeting accreditation requirements.

Study 4. Use of quality indicators in the process of monitoring and improving quality in a clinical laboratory

The fourth study aimed to prepare a guide for the selection and use of quality / performance indicators for the pre-analytical process in our laboratory and to monitor their evolution between 2015 and 2018, the study being prospective. The first part of the study (pilot study) took place between 01.01.2015 - 31.12.2015, when we selected IQ / KPI for the pre-analytical process using FMEA and FRACAS techniques, risk analysis respectively. In the FMEA, PRN (Priority Risk Number) was calculated for each potential nonconformity (risk), so we were able to pay attention to the risks that needed improvement. Using the FRACAS table, all observed nonconformities were recorded in the "Record Notebook - Nonconforming Evidence" form, internal audit reports and nonconforming event reports. In order to have an efficient management, the laboratory has implemented a set of indicators that bring information about quality / performance (QI / KPI), risk (KRI) or control (KCI). The criteria for selecting nonconformities that may become quality indicators for the pre-analytical process are the following: to be able to be measured accurately and exactly; be of significant predictive value; high impact of a nonconforming event on the patient's health and safety even if the frequency of occurrence is low; high frequency even if the impact on health is small. Once the quality indicators were selected, in the second stage of the study we prepared the "Quality Indicator Guide" taking into account the stages of the PDCA (Plan-Do-Check-Act) cycle. The four stages of the PDCA cycle can be considered the stages of a scientific study by formulating the hypothesis, collecting data to verify the hypothesis, respectively analyzing and interpreting the results. Our study emphasizes the importance of good practice guidelines for medical laboratories for defining and using quality indicators, respectively, for risk management analysis for a process of interest, thus meeting the accreditation requirements.

Conclusions (general)

Nonconformities or errors occur in all medical specialties and can cause injury to patients. The venous blood collection is one of the most common medical procedures. Laboratory tests provide about 70% of medical decisions, so the time to release of results and their accuracy are critical to diagnosing and

administering treatment. In laboratory medicine, the frequency of errors is lower compared to the frequency of errors in other medical specialties. However, the large number of tests required means that even the low frequency can have a significant impact on patient safety. Nonconformities or pre-analytical errors cause repeated blood sampling and delayed release of results. In this context, the optimization of the pre-analytical process management is a possibility to obtain the decrease of the number of errors in the medical laboratory.

The originality of the thesis

We consider that the following contribute to the originality of the thesis: the studies published by us are among the very few studies in the literature in which, for the specialty of laboratory medicine, tools and methods of risk management used successfully in various industries have been applied, followed by an adapted and easy-to-apply methodology in the medical laboratory. To our knowledge, none of the studies published in the literature have evaluated the effectiveness of implementing the risk management process in the medical laboratory by selecting and using quality indicators, respectively the Six Sigma quality metric tool, expressing the degree of improvement of the pre-analytical process. For the first time in Romania, this thesis simultaneously analyzed the information regarding risk and quality. An innovative idea of the research carried out in this thesis is the elaboration of the user guide of the selected tools in risk management, the algorithm for approaching the risk management process, the data collection protocol, the selection guide and the use of quality indicators.