Chapter

Control of Clinical Laboratory Errors by FMEA Model

Hoda Sabati, Amin Mohsenzadeh and Nooshin Khelghati

Abstract

Patient safety is an aim for clinical applications and is a fundamental principle of healthcare and quality management. The main global health organizations have incorporated patient safety in their review of work practices. The data provided by the medical laboratories have a direct impact on patient safety and a fault in any of processes such as strategic, operational and support, could affect it. To provide appreciate and reliable data to the physicians, it is important to emphasize the need to design risk management plan in the laboratory. Failure Mode and Effect Analysis (FMEA) is an efficient technique for error detection and reduction. Technical Committee of the International Organization for Standardization (ISO) licensed a technical specification for medical laboratories suggesting FMEA as a method for prospective risk analysis of high-risk processes. FMEA model helps to identify quality failures, their effects and risks with their reduction/elimination, which depends on severity, probability and detection. Applying FMEA in clinical approaches can lead to a significant reduction of the risk priority number (RPN).

Keywords: Patient Safety, Medical Laboratory, Risks, Failure Modes, Processes

1. Introduction

All medical cares, including clinical laboratories, carries an intrinsic risk of errors that can result in harm, disability, and even death so today their activities have seen a significant increase in monitoring [1]. In the past, laboratory processes performed in clinical laboratories focused only on results, while today, they focus on issues related to reliability, safety and effectiveness. It is very important in health world, being aware of the error rate attributable to health system that has great impact on patients [2]. Currently, some strategies are proposed to analyze and to see how you can decline the rate of preventable errors. In order to guarantee reliable results and improved data consistency, while operating with reduced funding, laboratories need to acquire a new culture of management, more tools and specific training [3]. Research management founded on a quality approach is emerging as an essential tool to ensure valuable, vigorous and dependable consequences, within a framework of the best practice. Risk management has been disseminated in clinical laboratories only for the last years, although it has been applied in healthcare since the 80s. That was partly due to constant inspections during the cycle of laboratory examination, rework, removal of any defects and adjustment after the identification of possible causes of flaws or errors. One of the instruments used in risk management is the analysis of failure modes and effects analysis (FMEA). The FMEA model has been applied in various medical fields, including clinical laboratory activities to improve

patient safety before serious harm to their health. By reducing/eliminating errors, the FMEA model helps to prevent and control failures and their risks in clinical approaches [4].

2. Failure mode and effect analysis: background and description

Failure mode and effect analysis (FMEA) which was first developed in the 1940s is a systematic technique for identifying all possible errors in a system or process. Adoption of this analysis by National Aeronautics and Space Administration (NASA) in relation with aerospace missions in mid-1960s made its practical application possible. Since then, this analysis has been widely used in diverse industries such as oil and gas, food and automotive and electronics systems. In recent years FMEA has been also successfully applied in the health system as an effective tool for improving patient safety and performance in hospitals. Today, The FMEA is emerging as a tool for assessing the risk of clinical trial processes and clinical analytical methods. However, there are still too few reports about this last use and even fewer data are available on the application of the methodology in clinical laboratories [5–8]. The risk assessment in this technique involves identification of potential errors, determining the severity (S), occurrence (O) and effects of each error and reviewing the control actions implemented to prevent or detect (D) errors [9] (**Figure 1**). In the traditional FMEA, to measure these criteria, a numeric scale of 1 to 10 is used (**Table 1**). Thus, each failure mode is been ranked by a scale called Risk Priority Number (RPN) characterized by multiplying the numbers of three criteria (S, O, D) together. Therefore, the higher the RPN value, the more important the error is and its correction has more priority. So, RPN is so beneficial to identify high risk failures modes requiring priority functions [10, 11].

Prevention, reducing or excluding of errors and their risk is an essential requirement in clinical analytical tests which is been established by the laboratory according to RPN limit. The laboratory decided the assessing scale of frequency, the severity and errors detection which is being different for each test. There are three main categories of errors [12, 13]:

I. Critical errors – Mainly through request for analysis, if not identified and corrected early, have serious consequences for the patient's health

II. Major errors – resulting from the inappropriate application of the sampling method

III. Minor errors – considered so, because of the low probability of occurrence, the high probability of detection or low/absent severity. These errors are taken into account only with the purpose to review the method and the technical instruction

Classification of potential errors occurred in the clinical laboratory processes which are subjected to the samples shown in **Table 2** (The following items only examples of errors and do and does not include all clinical laboratory failure modes) [14, 15].

In clinical laboratories all errors should be controlled by quality indicators. To monitor and assess periodically laboratories' involvement in patients' care the implementation of quality indicators is necessary. ISO/TS 22367 supports the non-conformities, errors and incidents identifying in the clinical laboratory, with an emphasis on the pre-analytical and post-analytical processes. These processes are

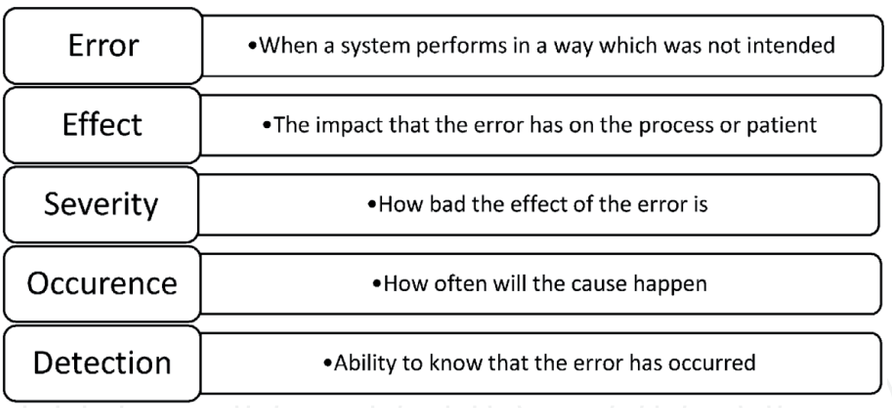

Figure 1.
FMEA elements.

Severity scale (scale 1 [least severe] to 10 [most severe] for each effect)					
Minor (1)	**Low (2,3)**	**Moderate (4-6)**	**High (7,8)**	**Very high (9,10)**	
The minor nature of this failure will not have a significant effect on the patient or the choice of treatment	Because of this failure, the patient experiences only a minor injury or a minor discomfort	Failure can lead to patient dissatisfaction, which may include discomfort or failure	Dissatisfaction with the nature of the failure leads to serious disruption and risk to the patient's health	This failure affects safety or increases mortality. This may endanger the patient's life	
(I)					
Probability scale (scale 1 [least frequent] to 10 [most frequent] for the occurrence)					
Remote (1)	**Very low (2)**	**Low (3,4,5)**	**Moderate (6,7)**	**High (8,9)**	**Very high (10)**
Failure is unlikely; This failure was never observed	Only a few separates failures have ever been observed or reported	Isolated failures have been encountered	Occasional minor failures have been encountered	Failure is often encountered	Failure is almost inevitable
(II)					
Detection scale for occurrence (scale 1 [always detected] to 10 [never detected] for each occurrence)					
Very high (1,2)	**High (3,4)**	**Moderate (5,6)**	**Low (7,8)**	**Very low (9)**	**No detection (10)**
It is almost certain to detect the failure mode	There is a good chance of detecting the failure mode	One may detect the existence of the failure mode	There is a poor chance of detecting the existence of the failure mode	One probably will not detect the existence of the failure mode	The existence of the failure mode will not or cannot be detected
(III)					

Table 1.
Failure Modes and Effects Analysis Scale for Severity, Probability, and Detection. (I): Severity score (S): 1 to 10 scales from least to most severe (II) Probability score (P): 1 to 10 scales from least to most probable (III) Detectability score (D): 1 to 10 scales from most to least detectable.

Pre-analytical	Analytical	Post-analytical
Incorrect identification of the patient	Procedural non-conformity	Incorrect result
Mislabeling of samples	Errors of equipment or reagents	Result sent to a different patient
Incorrect tube for sampling or incorrect storage	Discrepancies in the results of the internal control	Introducing incorrectly the results in the system
Improper or prolonged transport conditions	Delay in analyzing the samples	Lack of information about the limits concerning the results' interpretation

Table 2.
Potential errors occurred in the clinical laboratory processes.

the most critical and the most difficult ones to control due to involving of various specialists, sections and centers [16]. Clinical laboratory process map is shown in **Figure 2**. The processes map together with the risk map can give us an overview of the failures distribution in each of the processes [3].

Like any analytical method, FMEA should be thoroughly understood prior to being introduced in laboratory practice. There are five stages in its implementation which will be explained in more detail in the methodology [17–19].

FMEA assessment 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;
- change in the probability of certain risks when the selection process for new employees was initiated;
- sharing the risk with other staff members when the clinical emergency staff was involved in the potential problem.

FMEA contributed to quality planning, allowing the evaluation of interconnected activities designed to generate products and assisting in the identification of controls.

2.1 FMEA in clinical laboratory activities and patient' safety

Errors in the laboratory activities can lead to consequences in patients' safety. That's why these errors should be identified, controlled and reduced. Effective patient treatment can be improved by prevention and detection of the errors at the time of occurrence which in turn ensures the patient' safety. Currently, the tendency to move from the traditional technical adopted like internal quality control (IQC) and external quality assessment (EQA) to risk management is seen in all quality systems of clinical laboratories. It is conclusive the need for risk management in clinical laboratories and monitoring them within the quality plan, a fact that would lead to an increase on patient safety. Studies have revealed that FMEA is useful for detecting errors and improving patients' safety and it can yield benefits, for failures management and general process improvement, within a laboratory system where

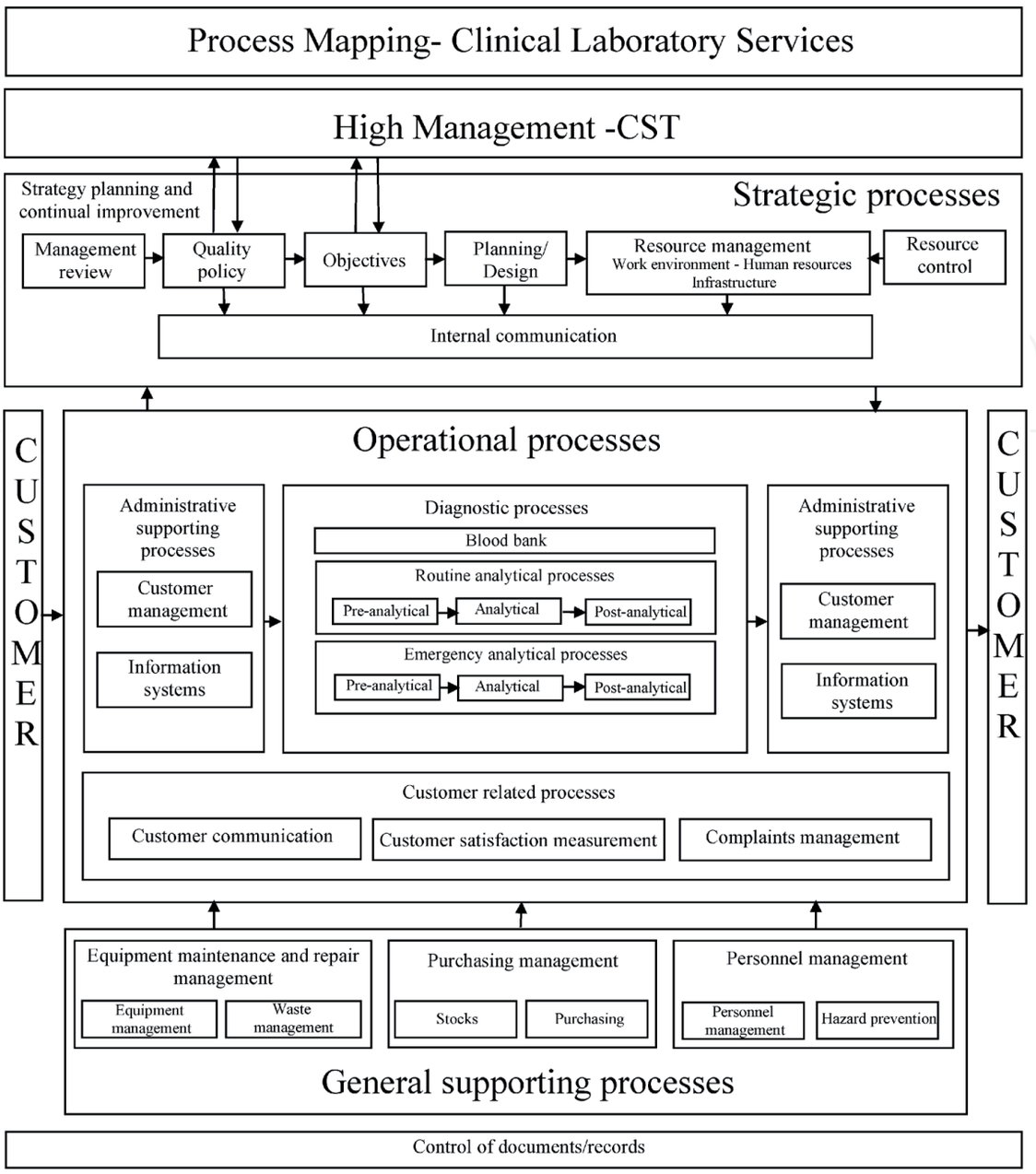

Figure 2.
Processes map of clinical laboratory.

time and team input is limited, and within a process that was considered to have few obstacles [1–4]. Former study showed that FMEA can effectively reduce errors in clinical chemistry laboratories [20].

Woodhouse et al. showed applying FMEA for identified processes in a hemotherapy service, can reduced the possibility of error occurrence and increased the probability of detection [21]. Momenizadeh et al. concluded that implementing FMEA can significantly reduce laboratory errors [22]. Molavi-Taleghani et al. argued that FMEA method is very effective in identifying the possible failure of treatment procedures, determining the cause of each failure mode, and proposing improvement strategies [23]. Applying the FMEA risk assessment tool to laboratory processes can increase effectiveness, efficiency and reproducibility of the results [24]. Risk management in the clinical laboratory by FMEA can decrease the possibility of errors occurrence and ensures the accuracy of results and patient's safety. Risk management guidelines recommended that the clinical laboratories must have a proactive and individualized role in reducing the potential errors by developing an appreciate Quality

Control Plan (QCP). The laboratories must create their own analytic process to identify the weakness of each testing stage. As errors and their risks were identified, the laboratories select the appropriate control processes to detect and to prevent the occurrence of errors. All errors and control processes are mentioned in the QCP [25].

2.2 FMEA benefits and barriers

The Benefits of implementing FMEA approach in clinical laboratories include enhancing patients' safety, improving quality of tests, reducing the chances of repeating the same failure, cost and time and encouragement for teamwork and effective communication between functions – collaboration [26]. In comparison with other quality improvement tools FMEA can be fairly compared, its risk can be assessed, and a score can be assigned.

FMEA also has some barriers such as limits of human error analysis (traditional FMEA uses potential equipment/system failures) and missing interactions between faults and external influences. The reproducibility and generalizability of FMEA in clinical laboratory approaches are factors of concern but since this method is based on hypothetical possibilities uncertainty is still likely to remain [27]. Previous study showed that using FMEA is more time-consuming than other hazard analysis that identifies failure modes but the improvement potentially obtainable by FMEA in a clinical laboratory is high, and this fact should suggest further experiences in this field. Despite the barriers, FMEA represents an appreciate, comprehensive, and organized approach to known potential patient safety failure modes in clinical laboratory [28–30]. processes. According to the *risk-based thinking* introduced by new ISO 9001:2015 standard, FMEA is an appropriate approach errors analysis of operational processes under an ISO-certified Quality Management System [31].

3. Methodology

Analytical methodology of FMEA is very effective in maintaining patient safety. Laboratory staffs trained in FMEA methodology can greatly reduce time requirements and guarantee that all activities involved are coordinated increasing the accuracy of laboratory results [17–19].

The FMEA process including 5 steps as follow:

1. Selecting a process for study;
2. Assembling a multidisciplinary team;
3. Collecting and organizing data about the selected process;
4. Analysis of hazards;
5. Developing and implementing appropriate actions and measuring the outcomes;

3.1 Selecting a process for study

The intricacy of laboratory processes increases the probability of undesirable errors. The more steps in the process and the greater their dependency, the greater the chance of error. In this step the laboratory identifies the critical processes based on the severity of possible harmful errors and the potentially dangerous impact on patient safety [17–19].

3.2 Assembling a multidisciplinary team

Gathering specialists with different levels and types of training, with specific knowledge and experience of the selected process. A team head can lead team members through the process, and can help ensure that team members complete each step and record the results of FMEA [17–19].

3.3 Collecting and organizing data about the selected process

In this step the assembled team creates an accurate diagram of potential failure modes of each listed activity using focus laboratory staff activities and reaching a common conclusion and recording it on FMEA form (**Table 3**) [17–19].

3.4 Analysis of hazards

This step including identifying failure modes in each step, determining the potential effect of each failure mode, ranking the severity of failure mode effects, ranking the probability and detectability of each failure mode and identifying the critical failure modes [17–19].

3.5 Developing and implementing appropriate actions and measuring the outcomes

Identifying the root causes of critical failures is an important step in developing an appropriate action plan. Traditional root cause analysis methods are used to

Project: **Product:** **System:**					**Date:** **Prepared by:**					**FMEA number:** **Reference documents:**	
System Component Function	Potential failure mode	Potential consequences/effects of failure	Severity	Critical	Potential causes of failure	Probability	Current design controls	Detection	RPN	Recommended actions	Responsibility And completion date

Table 3.
FMEA form.

determine the underlying cause of each critical failure so that appropriate actions can be taken. Once the root causes of critical failures have been identified, the team's aim is to eliminate the risk of failures, reduce the likelihood of failure or mitigate the effects of failure should it affect the patient [17–19].

4. Discussion

Clinical laboratories processes tend to errors due to human interactions and instrumental mistakes. Therefore, it is essential to design plans to make errors preventable. In the clinical laboratory, most errors are in the pre-analytical phase. The criteria for risk assessment designing plans for preventive errors were defined in the laboratory. There is no standard for developing and implementing of these plans in the laboratory, impediment the comparison between pairs and application of best practices. Some of the staff laboratory features, namely the ability to think analytical and simultaneously to establish standard policies and strict adherence to protocols, helped in the prevention of the potential errors. These plans for risk assessment can help reduce the occurrence of adverse errors. FMEA may become the common standard for measurement and comparison, particularly in clinical laboratories. In fact, the total testing process is intricate, consisting of numerous steps that are not always taken under the control of laboratory experts. Current evidence on the stratification of errors in clinical laboratory strongly supports the introduction of FMEA for further reducing error rates, particularly in the extra-analytical steps. While the first aim of FMEA is to promote an approach to ensuring the safety of laboratory processes, total cost reduction should be simultaneously achieved when considering the entire process of patient safety [13–16].

Mascia et al. shows that the FMEA risk management approach as applied to a scientific processes is in line with the current needs of management models to raise effectiveness and efficiency, to enhance reproducibility, and to facilitate a rapid industrialization of obtained results [24]. In order to achieve reliable results in long run of clinical laboratory approaches Momenizadeh et al. suggested that the managers of the laboratories of Markazi province (Iran) should focus on the implementation of the FMEA [22]. Sudhakar et al. reported that FMEA is a beneficial technique to decrease quality failures in clinical biochemistry laboratories. As compared to other prospective risk analysis approaches, FMEA prevent and solve high risk failure modes in clinical laboratories [32]. Previous study stated the efficiency of FMEA risk assessment to detect and to adjust the quality control procedures in order to improve the analytical performance of clinical chemistry laboratories [33].

In all clinical laboratories a risk assessment approach is required according to ISO 17025:2017 standard dedicated to laboratories measurement, in order to improve uncertainty and thus the reliability and reproducibility of results. Performing FMEA to processes in the laboratory facilitates evaluation high-risk processes tend to failure before an error happen. By assuming and compensating for less-than-perfect human performance, FMEA promotes error prevention through identification of valuable and consensually accepted quality indicators in all steps of the testing process [34].

5. Conclusion

Clinical laboratories are inseparable part of health care system as they help in appropriate diagnosis of patient's health. Their working process is a complex

procedure which may associate with certain errors. Improvement of the patients' safety by reducing the errors and their risks in clinical laboratories is a great challenge. High-quality clinical laboratories ensure that they perform standard tasks, monitor, and improve their performance, creating a culture of transparency, defining responsibilities, and optimizing patients' safety. FMEA is very effective and successful technique in preventing errors, improving quality and safety of tests, identifying potential errors, and prioritizing clinical laboratory improvement strategies. FMEA had a multidisciplinary approach and its complex configuration processes involvement facilitated the management of errors. As compared to other prospective risk analysis methods, FMEA analysis provides a good solution for high risk failure modes in clinical laboratories. Therefore, FMEA is a suitable and efficient tool to identify most clinical laboratory errors to improving the quality of laboratory processes and ensuring the accuracy of obtained results and maintaining patient health and safety. The overall purpose of this paper is to encourage clinical laboratories to assess and monitor their own. In addition, it should be possible to identify and monitor error rates to improve upon the process on the basis of objective and desirable quality specifications.

Conflict of interests

The authors declare that they have no conflicts of interest.

Author contributions

All authors contributed equally to this manuscript, and approved the final version of manuscripts.

Ethical declarations

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