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Risk management in the clinical laboratories-use of the Failure Modes and Effects Analysis (FMEA)

Katerina Tosheska-Trajkovska[1], Gordana Bosilkova[1], Irena Kostovska[1], Danica Labudovic[1], Julijana Brezovska[1], Svetlana Cekovska[1], Jasna Bogdanska[1], Marija Krstevska[1], Natasa Toseska-Spasova[2], Goran Nikolov[3], Sefedin Biljali[3], Sonja Topuzovska[1]

[1] Department of Medical and Experimental Biochemistry, Medical Faculty, "University St Cyril and Methodius", Skopje, Republic of North Macedonia

[2] Faculty of Dentistry, "University St Cyril and Methodius", Skopje, Republic of North Macedonia

[3] University Clinic of Clinical Biochemistry, Skopje, Republic of North Macedonia

Abstract:

Risk Management Process consists of a series of steps that, when undertaken in sequence, enable continual improvement in decision making. Failure Modes and Effects Analysis (FMEA) is systematic method of identifying and preventing product and process problems before they occur.

To present FMEA as a tool for risk managing and improvement in a public clinical laboratory.

We studied the failure modes that might occur in the total testing process (TTP) . Each failure mode was ranked on estimated frequency of occurrence (O), detection (D) and severity (S), each on a scale of 1–4. Failure risks were calculated by Risk Priority Numbers (RPNs) = O × D × S.

We used FMEA, including technical risks as well as risks related to human failure in assessment of analytical procedures. FMEA was applied in two stages: at the beginning of the project and after the implementation of the proposed measures. The analytical method was broken down into process steps and we identified possible failure modes for each step. Failure modes with the highest RPN scores were subjected to corrective actions.

We recommend risk analysis as an addition to the usual analytical validation, as the FMEA proved to be a reliable tool for detection of previously unidentified risks.

Key words: FMEA, risk management, clinical laboratory

Introduction

Quality in laboratory medicine should be defined as the guarantee that each and every step in the total testing process is correctly performed, thus ensuring valuable decision making and effective patient care (1).

Risk Management Process consists of a series of steps that, when undertaken in sequence, enable continual improvement in decision making (2).

Communication and consultation aims to identify who should be involved in assessment of risk (including identification, analysis and evaluation) and it should engage those who will be involved in the treatment, monitoring and review of risk (3).

Risk cannot be managed unless it is first identified. It should answer four questions:

1. What can go wrong?
2. How bad is it?
3. How often something goes wrong?
4. What should be done? (4).

Risk management is necessary because of the following basic concepts:

- Diagnostc devices are extremely diverse in their technology, design and function.
- Every test system is subject to hazards from the preanalytical, analytical and postanalytical stages of testing.
- The relative importance and likelihood of these failures varies with the device, the sample, the user and the environment.
- A high level of variability exists in terms of skills and knowledge level among end users.

- The number of potential failures is high, this makes it important to prioritize efforts to reduce risks. With the classification of severity of harm and probability of occurrence, one can prioritize the importance of events.

Laboratories should identify processes that most directly affect patient care and document this process for risk management (5-9).

Risk management process follows five basic steps:

1. Identification
2. Analyses
3. Evaluation
4. Treatment
5. Monitor and review (3,4).

Failure Modes and Effects Analysis (FMEA)

FMEA is a systematic method of identifying and preventing product and process problems before they occur (10). It involves identification of potential failure modes, determing the severity and effects of each failure and reviewing the control actions implemented to prevent or detect failure (Table 1).

Table 1. Elements of FMEA

Terms	
Failure	When a system performs in a way which was not intended
Effect	The impact the failure has on the process or end patient
Severity	How bad the effect is
Occurrence	How often will the cause happen
Detection	Ability to know that the failure has occurred

Aim of the study: The purpose of this analysis was identification of possible sources of failure applicable to a particular test system.

Methodology:

We used FMEA, including technical risks as well as risks related to human failure in assessment of analytical procedures. The analytical method was broken down into process steps and we identified possible failure modes for each step (Figure 1).

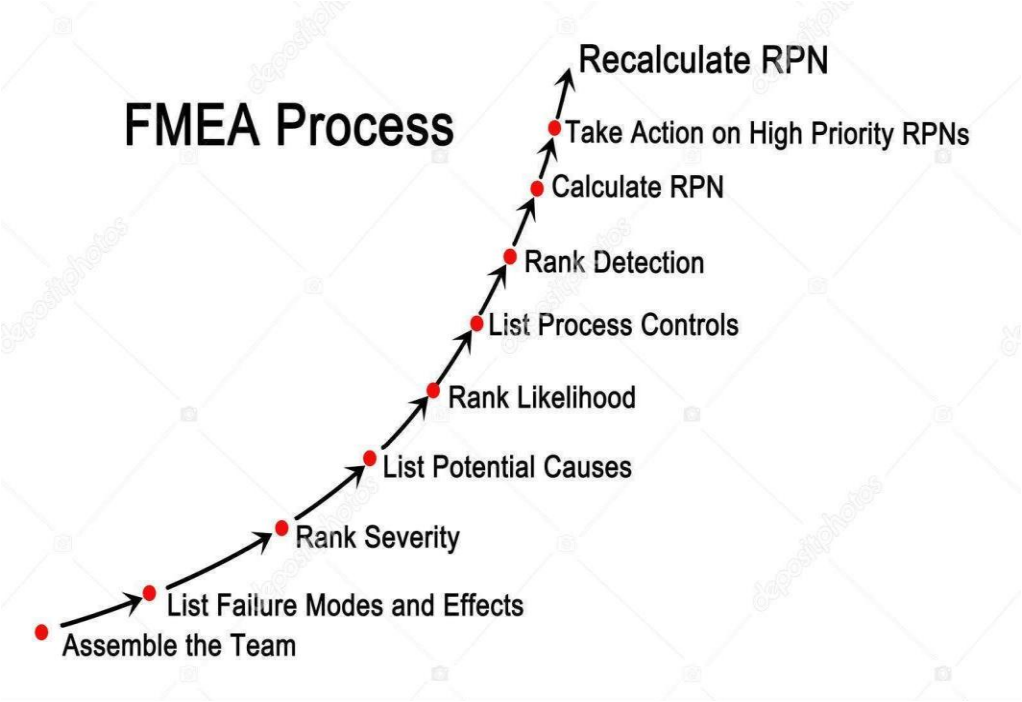

Figure 1. FMEA Process

The Severity is based on the effect of the failure event. We used a scale from 1 to 4, where 4 is the most severe event.
The probability of occurrence of the failure event was estimated. We used a scale from 1 to 4, where 4 is more than 1.
Criticality is the product of severity times the probability of occurrence (Table 2).
Criticality: Severity (S) x Probability of Occurrence **(S x O)**

Table 2. Calculation of criticality

Criticality				
Probability	**Severity**			
	Catastrophic (4)	Major (3)	Moderate (2)	Minor (1)
Frequent (4)	16	12	8	4
Occasional (3)	12	9	6	3
Uncommon (2)	8	6	4	2
Remote (1)	4	3	2	1

Failure risks were calculated by **Risk Priority Numbers (RPNs) = P × D × S**.
Detection – **(D)**
Failure modes with the highest RPN scores have been subjected to corrective actions.
Types of failure modes that can occur in the laboratory are presented in Table 3.

Table 3. Types of failure modes

Environmental	**Operator**	**Specimen**	**Analysis**
Temperature	Improper specimen preparation, handling	Bubbles	Calibration factor incorrect
Humidity	Incorrect test interpretation	Clots/hemolysis	Mechanical failure
Light intensity	Failure to follow test system instructions	Incorrect tube additive	Incorrect control

Many failure modes which are grouped into three main process categories are listed in Table 4.

Table 4. FMEA in clinical laboratory

Step in which failure occurs	Failure	Cause	Effect	Severity	Probability	Criticality	Prevention	Outcome measure
Operator	Debris in assay	Clot or particle from rubber stopper	Incorrect result	2	2	4	Check samples before placing in analyzer	Samples checked before analysis
Operator	Run stopped and restarted	Power failure	No result	2	1	2	Plug analyzer into backup power source	Monitor for frequencies of power failure
Operator	Too much sample	Sample overflow	Analyzer failure	1	2	2	Operator training	Audit operator training
Operator	Reagents added incorectly	Operator failure	No result	1	1	1	Operator training	Audit operator training
Environmental	Work area contaminated with analyte	Supplies (tubes, pippetes) contaminated with samples	Incorrect result	4	2	8	Clean work area regularly	Monitor for QC and proficiency failures
Environmental	Sample shipping/storage issues	Freezing or heating	Incorrect or no result	2	3	6	Monitor condition of samples on receipt and storage conditions in lab.	Audit that shipping and storage conditions are followed
Analytic	Reagents fail-poor or no reaction	Outdated	Incorrect result	3	2	6	Operator training to check dates	Audit that operators were trained
Analytic	Internal control fail	Reagent or analyzer	No result	1	1	1	Operator training	Audit that operators were trained
Analytic	Enzyme fails, possible inhibition	Sample drug or other inhibitor	Incorrect result	4	1	4	Operator training to recognize unusual results	Audit that operators were trained

Discussion:

The two standards of broad application in laboratories (EN ISO 15189: 2012 and EN ISO 9001:2015) are also involved in the risk management of the patient (1,11).

FMEA is a preventive technique already experimented with and applied in some areas of health organizations. FMEA has been recognized as a valuable instrument to for risk assessment for health products and processes (12,13). More generally, FMEA has been used as an instrument of risk assessment in the cases in which the human intervention is involved, considering that the phases in which the human intervention is involved are the riskiest points of a process (14).

FMEA technique can be applied to the processes of a medical laboratory, even if of small dimensions, and offers a high potential of improvement. Nevertheless, such activity needs a thorough planning because it is complex, even if the laboratory already operates an ISO EN 15189: 2012 System. Problems in its implementation are resoluble by a thorough planning and, if necessary, using a FMEA management software.
We found it interesting to carry out this study in all laboratory processes using FMEA tool because it is widely used in the clinical laboratories to highlight the need for implement risk management (15-21).
FMEA technique allows:
a) to identify process steps;
b) to identify where "undesirable" variation (failure mode) may occur;
c) for each identified failure mode to identify the effects on patient and how serious the effect is (criticality-severity and probability of occurrence);
d) for most critical items to conduct root cause analyses (fishbone);
e) to decide where to execute improvement actions, and
f) to measure the outcome of those reactions.

Benefits of FMEA are:

- Allows for a very structured analysis;
- Captures multiple causes and effects of failures;
- Link control (measures) plans within one analysis/planning document;
- Allows relative risk ranking for prioritisation.

FMEA has several limitations:

- Examination of human error is limited (traditional FMEA uses potentional equipment/system failures as the basis for the analysis;
- Analysis is for single fault error (misses intersctions between faults) and
- Often misses external influences
- The improvement potentially obtainable by FMEA in a clinical laboratory is high, and this fact should suggest further experiences in this field.

Conclusions:

We recommend using of FMEA when starting a new process to help uncover potential problem areas in the process.
Once a source of failure is identified, its risk can be assessed.
For important failures control measures can be implemented to reduce the risk of failures.
We recommend focusing on the highest risk items (determined by RPN).
The improvement potentially obtainable by FMEA in a clinical laboratory is high, and this fact should suggest further experiences in this field.

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