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Risk management culture in healthcare: ISO 7101:2023 requirements and advantages of the HFMEA method

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Abstract: The importance of clauses 6.1.2 and 6.1.3 of the ISO 7101:2023 standard and the HFMEA method in shaping the risk management process in the healthcare system has been studied. Differences in risk assessment criteria, patient safety orientation, and monitoring between classical FMEA and HFMEA in ISO 9001:2015 are analyzed. The classical 5-step HFMEA model was compared with the requirements of ISO 7101:2023. The new 8-step HFMEA model based on PDSA and the improved decision tree are substantiated as effective solutions in terms of clinical management, patient safety, and continuous improvement.

Keywords: HFMEA, ISO 9001:2015, ISO 7101:2023, quality managment, FMEA

1. Introduction

Clause 6.1 of the ISO 9001:2015 standard focuses on measures to address risks and opportunities[3]. Clauses 6.1.2 and 6.1.3 of the ISO 7101:2023 standard establish requirements for risk culture and risk management processes.

The term “risk” is defined in clause 3.7 of the ISO 7101:2023 terminology section as “Effects of Uncertainty.”[1]

The term risk assessment is defined in clause 3.36 of the ISO 7101:2023 Terms section as “A general process consisting of risk identification, risk analysis, and risk assessment.”[1]

The term risk management is defined in clause 3.37 of the ISO 7101:2023 terminology section as “the systematic application of management policies, processes, and practices to the tasks of risk analysis, assessment, control, and monitoring.” [1]

2. Research methodology

This study is based on analytical and comparative approaches. The requirements of ISO 7101:2023 and ISO 9001:2015 standards, the WHO risk management strategy, and scientific sources on FMEA and HFMEA were thoroughly studied. A structural comparison was made between the classic 5-step HFMEA model and the 8-step HFMEA model based on PDSA proposed by the authors, and the experience of its implementation in risk identification, assessment, personnel training, and risk registry maintenance processes was studied.

The “Risk Management Strategy” developed by the WHO to reduce uncertainty regarding the achievement of goals and outcomes, aims to manage risks and ultimately achieve risk awareness for everyone.

The ISO 7101:2023 standard provides general guidelines for risk management, but does not specify the criteria or formula for risk management.

Paragraphs 6.1.2 and 6.1.3 of the standard are dedicated to risk culture and risk management processes.

According to it:

(6.1.2) Risk culture - Knowledge, attitudes, and concepts about risk must be shared by everyone.[1]

(6.1.3) Risk management processes - The organization should have a documented system to identify risks and opportunities in its clinical and non-clinical activities.[1]

3. Results and discussion

Risk management processes and outcomes should be documented and reported.

The main layer, which utilizes the ISO 9001:2015 standard for risk assessment and management, utilizes the FMEA (Failure Mode and Effects Analysis) method. This method is calculated using the RPN- (Risk Priority Number) evaluation formula.

$$RPN = S \times P \times D$$

In medicine, the HFMEA (Healthcare Failure Mode and Effect Analysis) method is used to assess and manage risk.

And here

Risk Score = $S \times P$

Here:

- S - severity of the outcome (1-4 points).
- P - probability of occurrence (1-4 points).

Table 1

Example of HFMEA risk matrix.

Consequence / Probability	Small (1)	Average (2)	Serious (3)	Deadly (4)
Frequent (4)	4.	8.	12	16

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Occasionally (3)	3.	6.	9.	12
Rarely (2)	2.	4.	6.	8.
Very few (1)	1.	2.	3.	4.

The HFMEA method is recommended by the "VA National Center for Patient Safety (NCPS)." The NCPS is the U.S. Department of Veterans Affairs' national center for patient safety, leading patient safety programs for the healthcare system.[5]

Discussion

Although these two methods are somewhat similar in appearance and name, they have the following differences:

Table 2

Disadvantages of FMEA in medicine and advantages of HFMEA

No	Difference between FMEA and HFMEA in medicine	
1.	**Industry adjustment**	
	Traditional FMEA was originally developed for the automotive and manufacturing industries, so it is more suited to technical processes and equipment, and does not fully cover healthcare features such as the human factor, clinical decisions, a multidisciplinary team, and direct patient interaction. Consequently, there are limitations in fully modeling clinical processes and identifying hidden factors that affect patient safety.	The HFMEA was specifically adapted for the healthcare system by the VA National Center for Patient Safety, taking into account the interaction between clinical processes, patient safety events, and medical personnel. Therefore, it yields results closer to real working conditions at the clinic, department, and process levels.
2.	**According to the valuation method**	
	FMEA typically assesses risk through RPN. Since this indicator is based on the product of three subjective scores, there is a risk that different combinations will give the same RPN and lead to incorrect prioritization; for example, a very severe but rare event may be clinically misidentified with a mild but frequent event, resulting in the same RPN.	HFMEA uses hazard scoring, probability-weight matrix, and decision tree instead of RPN multiplier. This approach helps to more accurately set clinical priorities by separately considering the probability of harm to the patient and the severity of the outcome, and increases clinical sensitivity instead of a "mathematical score on paper."
3.	**Patient safety orientation**	
	Classical FMEA focuses more on product or process failures and does not interpret patient safety indicators or events in a separate structure. As a result, clinical risks such as medical errors, incorrect medication, and patient misidentification may not be sufficiently prioritized.	At the heart of the HFMEA methodology is patient safety: the patient corridor, clinical decision points, and safety events are considered separately during the analysis process. This directly links the risk assessment to the probability of clinical harm and complies with the patient safety requirements of ISO 7101:2023.
4.	**Team participation**	
	In many places, FMEA is done behind the desk by technical or quality department specialists; if clinicians, nurses, pharmacists, and other front-line staff are not sufficiently involved, the identified risks are disconnected from the real workflow. In practice, this can become a "just-for-the-document analysis."	At the very first stages of HFMEA, the condition is to create a multidisciplinary team: clinicians, nurses, pharmacists, managers, the quality department, and others will jointly map the process and identify risk points. This approach reduces subjectivity, uncovers hidden errors, and strengthens a risk culture among employees.
5.	**Results and monitoring**	
	Traditional FMEA often ends with a list of risks and RPN; corrective measures and indicators to measure their effectiveness may not be clearly expressed. Therefore, over time, it becomes more difficult to systematically monitor which measures worked and which did not.	Stage 5 of the HFMEA, along with specific measures, requires the establishment of indicators of safety, quality, and efficiency. These indicators are then monitored and risk reduction measures are re-evaluated; this ensures continuous improvement in accordance with the PDCA cycle and the requirements of ISO 9001:2015 and ISO 7101:2023.

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In the HFMEA model, the risk assessment consists of 5 stages, which are presented in Figure 1.

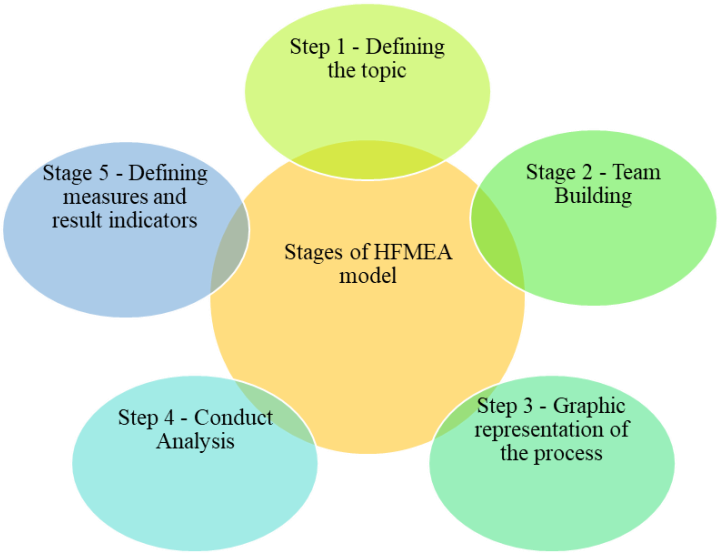


Fig. 1. 5 stages of traditional HFMEA conduction[5]

The traditional 5-step model of the HFMEA model is shown in Figure 4, which is a model for identifying healthcare risks. However, it has several disadvantages for fulfilling the requirements of the ISO 7101:2023 risk identification and control standard. The main shortcomings are the introduction of public awareness and training after identifying risks, and the lack of continuous monitoring of the risk registry[6].

Together with our team of medical and standardization specialists, we proposed the "PDSA-based 8 steps for conducting HFMEA" in Figure 6 and implemented risk identification, assessment, training of risk officials, and maintaining a continuous risk registry for these steps. Our proposed model is an 8-step HFMEA model based on PDSA. At the same time, it combines the stages of risk identification, response development, practical testing, result study, and refinement into a single cycle; therefore, it is evaluated as a scientifically and practically superior model in terms of clinical management, patient safety, and compliance with ISO 7101:2023 requirements.

The traditional HFMEA decision tree used to identify potential failures in healthcare processes is shown in Figure 5. The methodological significance of this decision tree lies in the fact that it combines the detection and severity indicators of traditional FMEA into a single decision tree rather than as independent mathematical expressions, thereby serving as a practical selection mechanism for clinical processes.

Risks rated at 8 points in this decision tree are considered risks that require serious attention. Risk levels below it require additional assessment based on factors such as the presence of a unique weakness in the process, the effectiveness of existing controls, and the ability to detect malfunctions early.

However, the scientific literature also indicates some limitations of traditional HFMEA decision trees[7]. In particular, because decisions such as "available effective management tools" or "identification" are often based on the subjective assessment of expert groups, different expert groups may reach different conclusions regarding the same clinical situation[7]. Furthermore, this model is primarily focused on risk identification and classification and lacks a mechanism for re-evaluating the effectiveness of subsequently implemented measures.

According to the ISO 7101:2023 standard, the HFMEA decision tree, shown in Figure 7, can be considered a logical extension of the classical decision tree, combining elements such as risk identification, assessment, control, monitoring, and continuous improvement into a single management system. The scientific novelty of this model lies in considering HFMEA not only as a tool for proactive risk analysis but also as a means of continuous quality improvement and the creation of a risk management culture within healthcare organizations.

ISO 7101:2023 lists risk management culture, documented risk management, monitoring, and continuous improvement as the primary requirements for healthcare organizations. Therefore, from a management perspective, the scope of decisions in Figure 7 is more complex than in the traditional HFMEA model. In particular, risk decisions within this framework can be re-evaluated based on the PDSA cycle in subsequent stages, making it a dynamic model rather than a static one.

Therefore, Figure 5 primarily illustrates the diagnostic algorithm for identifying and prioritizing hazardous failures, while Figure 7 illustrates it as a comprehensive control algorithm designed for managing, monitoring, and improving these failures. In this regard, the model in Figure 7 better meets the requirements of ISO 7101:2023, specifically the principles of risk management culture, patient safety, and continuous improvement, and can be considered a preferred approach for modern healthcare institutions in terms of both scientific rigor and practical application.

4. Conclusion

The results of the study showed that the classical FMEA and HFMEA approaches are insufficient for forming a risk management culture in healthcare organizations. It showed

the need to integrate them with the requirements of ISO 7101:2023. The 8-stage HFMEA model, based on the PDSA cycle, integrated risk identification, assessment, management, and monitoring into a single system. It has also proven to be a more effective approach in ensuring patient safety and continuous improvement. The HFMEA decision tree, adapted to ISO 7101:2023, reduces subjectivity in risk prioritization, increases the risk sensitivity of clinical teams, and allows for the systematic maintenance of a risk registry.

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