ARTICLE CASE STUDY

Implementation of HFMEA in a Primary Care Emergency Service of the Portuguese National Health System - A case study

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ABSTRACT

Background: One of the main priorities for healthcare institutions is to provide better and more advanced services that contribute to prolonging the lives of those who seek their care, as well as improving their quality of life as long as it lasts. Both their patients and the professionals who work in those institutions need to feel protected against adverse effects that may affect them physically, mentally, or socially. As such, both at national and international levels, healthcare governing bodies have made decisions and implemented measures aimed at reducing the risk of adverse effects for the patients who use their services.

Objectives: The main objective of this work was to develop and implement a risk management system based on HFMEA in a basic emergency service (primary care), to promote patient safety and the safety of healthcare professionals.

Methods: A prospective, explanatory, and descriptive case study was applied to a basic emergency service, using ISO 31000 – risk management in organisations, and the healthcare failure mode and effects analyses (HFMEA) support tool.

Results: There were identified 57 possible failures associated with 88 different effects, with risk magnitudes classified as severe (1 cases), very severe (18 cases), and intolerable (38 cases). Failures whose effects impact patients were mentioned 2,6 times more than those primarily affecting professionals.

Conclusion: The study allowed the identification of different failures in some of its work processes, for which corrective measures were determined to be carried out by the team and the governing entities of the service, to be implemented as soon as possible, ensuring greater safety in its services.

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What do we already know about this topic?
Proactive risk management tools like HFMEA are well-established in hospital settings, but their application in primary care remains limited. Patient and professional safety are interlinked, and systemic failures—not individual errors—are often the root of adverse events.
What is the main contribution to Evidence-Based Practice from this article?
This study demonstrates that HFMEA can be successfully adapted and implemented in a Basic Emergency Service within primary care. It identifies 57 failure modes and 88 associated effects, offering practical tools such as digital reporting systems and a customized risk matrix. It also emphasizes team engagement and interprofessional collaboration in risk analysis.
What are this research's implications towards health policy?
Theoretically, it reinforces the systemic nature of risk. Practically, it provides a replicable framework for risk mitigation in primary care. At the policy level, it supports the integration of structured risk management approaches like HFMEA into national patient safety strategies.
Authors' Contributions Statement:
José Mário Macedo (JMM): Investigation, writing—review and editing; Sara Sá (SS): Investigation, writing—review and editing; Álvaro Gestoso (AG): Investigation, writing—review and editing; Susana Ramalho (SR): Investigation, writing—review and editing. Daniela Martins-Mendes: (DMM) Investigation, writing—review and editing. Ana Cláudia Pereira (ACP): Investigation, writing—review and editing. Rúben Fernandes (RF): Investigation, conceptualization, software, writing, funding and resources, project administration. Pilar Baylina (PB): Investigation, conceptualization, writing—review and editing, funding and resources, project administration. All authors have read and agreed to the published version of the manuscript.

Introduction

Introduction

Adverse effects resulting from healthcare are among the leading causes of death or disability worldwide (World Health Organization, 2019b, 2019c). these adverse effects are caused by errors that usually come from the interaction of multiple factors rather than individual carelessness or misconduct. This is a worldwide concern and since 2000 patient safety gained special attention (Donaldson, 2002; Kohn et al., 2000) and several international projects focusing on patient safety have highlighted the importance of cause-and-effect relationship between healthcare workers safety and patient safety (Baylina & Moreira, 2011; Loeppke et al., 2017; Yassi & Hancock, 2005).

A prevention approach must be adopted to eliminate/minimize systemic errors along all healthcare. Proper risk management requires a prospective analysis that considers structures, processes, and outcomes systemically ("Medical Errors: Focusing More on What and Why, Less on Who," 2007; Washburn, 2001) and can be supported by several international good practices and standards, such as ISO

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31000 (International Organisation for Standardization, 2018), and tools such as Failure Mode and Effects Analysis (FMEA). The Veterans Affairs National Center for Patient Safety (NCPS) adapted FMEA for healthcare, creating the Healthcare Failure Mode and Effects Analysis (HFMEA) in line with ISO 31000 criteria. This tool enables the proactive implementation of measures to prevent risks (DeRosier et al., 2002; International Organisation for Standardization, 2018; Veteran Affairs & National Center for Patient Safety, 2014). These tools have been used more in hospital care and less in primary healthcare settings. Thus, the main goal of this work was to apply HFMEA to a primary healthcare setting from the Portuguese National Health Service.

Methods

This study was conducted at a Basic Emergency Service from the Portuguese national health service, which includes a clustering of Primary Healthcare Centers (PHCC). For better understand the problem a literature review was conducted using keywords such as "Patient

Safety," "Healthcare worker's Health and Safety," "Risk management," "Prevention," and "Primary care" in scientific databases such as B-On, PubMed, Google Scholar, and Science Direct.

The target population of this study included all Basic Emergency Service users and professionals, with 21 health professionals actively participating in the service from September 2021 to August 2022. Data collection was facilitated through meetings and the ZOOM platform, as well as email exchanges and survey created on the Google Forms® platform. Data was collected and analysed using Excel® and Word® files, with quick access links provided on all computers within the Basic Emergency Service work environment.

To ensure a comprehensive risk collection identified by the different professionals involved in the study and to facilitate the organisation, analysis, and interpretation of risk management, the HFMEA matrix was used. This matrix was adapted from the model provided by the Veterans Affairs National Center for Patient Safety (Veteran Affairs & National Center for Patient Safety, 2014; Veteran Health Administration - National Center for Patient Safety, 2021). Descriptive analysis was performed using the Microsoft Excel® program to support data analysis.

Results

The HFMEA criteria for probability of occurrence and severity for failure mode (FM) assessment were adapted to better adjust with the specific context of the health department. The following ratings were defined according with the risk assessment matrix presented in Table 1:

Table 1. Risk assessment Matrix.

		SEVERITY			
		4 – Catastrophic: Incidents involving irreversible errors or causing major permanent loss of function.	3 – Major: Incidents with reversible errors that can lead to long-term consequences or extensive damage, requiring prolonged healthcare needs.	2 – Moderate: Incidents involving errors that require support for resolution or result in superficial damage with short-term healthcare needs.	1 – Minor: Incidents with minor damage that can be easily eliminated/minimized or quickly controlled
PROBABILITY	4 – Very likely: it occurs always or almost always (more than 1 time/week)	**16**	**12**	**8**	**4**
	3 – Quite likely: occasional occurrence (5 times/year to 1 time/month)	**12**	**9**	**6**	**3**
	2 – Likely: rare occurrence (between 1 to 4 times/year)	**8**	**6**	**4**	**2**
	1 – Unlikely: very rare occurrence (less than 1 time/year – history)	**4**	**3**	**2**	**1**

For each failure mode (FM), using the scores of occurrence probability and severity, the hazard score value (HSV) was obtained. For each HSV a degree of acceptability was defined according to the following criteria:

•Acceptable (A) – magnitudes 1 and 2 – does not require specific action.

•Moderate (M) – magnitudes 3 and 4 – perform a cost-benefit analysis of the proposed solutions or control measures.

•Severe (S) – magnitudes 4 and 6 – establish a plan with measures to reduce the risk, determining the necessary actions, which must be implemented within a given period. If the risk is already associated with very serious consequences or death, further action will be required to establish the likelihood of the injury occurring to determine improved control measures.

•Very serious (VS) – magnitudes 8 and 9 – do

not restart work until the risk is reduced. If the FM corresponds to work in progress, the problem must be solved in less time than for a "severe" risk, and workers should be trained and informed about the risks they are exposed to.

•Intolerable (IN) – magnitudes 12 and 16 – work should not be restarted or continued until the risk is reduced. If it is not possible to reduce, even with unlimited resources, work should be prohibited.

Two tools were created using the Google Forms® application for reporting potential failures and assessing the probability of occurrence and severity of effects. These tools were available on the Basic Emergency Service computers' desktops and distributed via email to all professionals.

The first tool, called the "Phase 1 Survey" allowed participants to report potential failures in selected processes such as the pharmaceutical products administration (PPA), professional-user communication/interaction (PUCI), facilities and equipment (FE), complementary diagnostic and therapeutic means (CDTM), medical/nursing observation (MNO), user's transfer (UT), and other relevant processes (OP) not included in the previous categories, as suggested by professionals. For each of these processes, a flow diagram was design to better identify process/subprocess steps. FM were identified for the subprocess steps and out of the seventy reports obtained, sixty-five were considered after eliminating duplicates, incomplete entries, and poorly formulated reports. This demonstrated the importance attributed by each participant to potential failures modes and their effects.

These reports were then analysed, restructured, and organised, grouping together those that were similar or complementary. This led to the creation of the second tool, named "Phase 2 Survey."

The Phase 2 Survey focused on the FM that both users and professionals may face individually or jointly. It involved rating the probability of occurrence and severity for fifty-seven FM and assessing of their possible eighty-eight effects.

The "Phase 1 Survey" resulted in 65 valid responses, obtained from the participation of at least 21 professionals. Senior technicians in diagnosis and therapy (STDT) contributed with 33 reports, physicians (P) contributed with 19, nurses (N) contributed with 6, technical assistants (TA) contributed with 3, and operational assistants (OA) contributed with 4. The process with the highest number of reported FM was "Facilities and Equipment," with a total of 28 reports, mentioned by all professional groups. "Pharmaceutical Products Administration" received attention in three reports, exclusively submitted by physicians. "Professional-user communication/interaction" received nine reports and drew the attention of physicians, nurses, and STDT. OA only reported FM in the "Facilities and Equipment" process. The "User Transfer" process appeared in only two reports, by a TA and by a STDT.

In the "Other Process" (OP) category, there were four mentions, each related to a different sub-process: "Corpse Transfer," "Security Team," "Waste," and "No Quality Audits," with the participation of one TA, one P, and two STDT.

Based on the FM reported in the initial survey, the "Phase 2 Survey" was prepared, which identified 88 possible failure mode causes (FMC). Among these, 49 FMC could affect users, 21 FMC could affect professionals, and the remaining 18 FMC could impact both groups (Table 2).

Table 2. Distribution of causes (Phase 2 Survey) associated with failure modes identified in the Phase 1 Survey, categorized by magnitude and process, with emphasis on the target.

Magnitude	Targeted	Process							Totals
		pharmaceutical products administration	professional-user communication/interaction	facilities and equipment	complementary diagnostic and therapeutic means	medical/nursing observation	user's transfer	and other relevant processes	
6	Professional								
	User				1				1
	Professional+User								
8	Professional					1			1
	User				3	1			4
	Professional+User			1		1			2
9	Professional			3					3
	User		7	1	2	2	1	1	14
	Professional+User							3	3
12	Professional		2	12	2				16
	User	2	2	6	4	4		3	21
	Professional+User			10	1	1			12
16	Professional				1				1
	User	1			6		2		9
	Professional+User			1					1
Total		3	11	34	20	10	3	7	88

Only one of the FM was classified as severe, while the others were considered very serious or intolerable, with HSV predominantly being 9 and 12. The processes with the highest likelihood of FM occurring were "Facilities and Equipment" and "Complementary Diagnostic and Therapeutic Means". These processes also had FM with the lowest level of risk acceptability.

The obtained results guided the decision-making process regarding the definition and implementation of an action plan to reduce the risk, thereby ensuring a safer environment for both users and professionals at the Basic Emergency Service (Table 3).

Table 3. Action Plan

Failure Mode	Measures Implemented	Level
Poor support for users with disabilities	- Ensure appropriate follow-up for the user until a legitimate companion arrives. - Request referring entities to revise procedures and ensure users are not sent unaccompanied.	*IN
Wrong identification	- Use all available means to confirm the identity of the user during evaluation.	*IN
Poor user-professional communication	- Professionals must confirm mutual understanding in each interaction with the user.	*VS
Lower quality of service	- Adopt clinical guidelines appropriate to SUB practices. - Establish emergency action plans and protocols. - Implement internal quality audits.	*IN
Decreased user privacy	- Prohibit the constant presence of security personnel near sorting areas unless strictly necessary. - Restrict access of third-party professionals to treatment rooms.	*IN / *VS
Lower acuity in physical examination	- Reorganize furniture and equipment in consultation rooms to reduce distractions and improve examination conditions.	*VS
Psychological trauma	- Provide timely and clear information to families and companions, especially in case of transfer. - Relocate transfer routes to the morgue to areas not visible to others.	*VS
Tobacco smoke inhalation	- Prohibit smoking near the SUB entrance.	*IN
Microbiological risks	- Procure and provide appropriate ties for sealing contaminated waste bags until officially supplied by ARS.	*VS

Note: * Measure to adopt immediately; ** Measure to adopt immediately but it requires the involvement of external parties; IN Measure concerning intolerable risk; VS Measure concerning very serious risk.

The responsibility for implementing some of these measures lied internally with the Basic Emergency Service team of professionals within their competences, while others required the involvement of external parties such as the Regional Health Administration, Municipalities, or other relevant entities, who need to be informed for the implementation of these measures.

Discussion

The overall results of the study align with the recommendations of relevant organizations such as the World Health Organization (WHO) and the European Commission, which aim to

minimize avoidable adverse events and reduce potential harm to healthcare users and professionals (Council of Europe, 2006; Council of European Union, 2009; Direção Geral de Saúde, 2015; World Health Organization, 2020).

The study demonstrated the applicability of a risk management programme in a primary healthcare provider, although its implementation remains limited despite increasing recognition (Lawati et al., 2018; Verbakel et al., 2016). The project involved representatives from all professional functions, identified potential failures, their various effects, and potential victims. Through a detailed analysis, potential risks were identified, and an action plan was established, outlining relevant preventive and corrective measures for each risk, following the recommendations of the HFMEA methodology (DeRosier et al., 2019; Veteran Health Administration - National Center for Patient Safety, 2021). While this methodology is considered valuable and effective in reducing risks and improving service quality, some published works indicate that it may not always be fully implemented (Asgari Dastjerdi et al., 2017; Institute for Healthcare Improvement, 2017; Stalhandske et al., 2009).

The reported failures encompassed environmental, physical, toxicological, and psychosocial factors, posing significant challenges for occupational health research (European Commission, 2011; Giurgiu et al., 2015). The attention given by the BES team to a wide range of processes, including potential failures and potential victims, aligns with the concerns expressed in the National Plan for Patient Safety 2015-2020, which has been adapted and extended for the 2021-2026 period, emphasizing the importance of enhancing healthcare safety with a focus on patients and their caregivers (Ministério da Saúde, 2015; Ministério da Saúde & Sec. Estado da Saúde, 2021).

To effectively enhance healthcare safety, the implementation of risk management measures is necessary, as proposed by organizations responsible for this critical field and endorsed by the project team (Council of European Union, 2009; Direção Geral de Saúde, 2015; European Observatory on Health Systems, 2019; World Health Organization, 2017).

Most of potential failures were associated with "facilities and equipment" and "CDTM", followed by "professional-user communication/interaction" and "medical/nursing observation." There were fewer reports of potential failures in the processes of "pharmaceutical products administration," "user's transfer," and "other process." These areas overlap with those covered in other international studies that used this risk management tool (Asgari Dastjerdi et al., 2017).

With scores of 12 and 16 assigned to the magnitude of the reported risks, most of them were deemed intolerable and require prompt implementation of measures, as recommended by the VA National Center for Patient Safety for risks rated at magnitude 8 or higher. Except for one (an obsolete electrocardiograph), all reported failures were deemed unacceptable (Ministério da Saúde & Administração Regional da Saúde de Lisboa e Vale do Tejo, 2010; Veteran Affairs & National Center for Patient Safety, 2014; Veteran Health Administration - National Center for Patient Safety, 2021).

Conclusions

This study conducted at a Basic Emergency Service aimed to assess and manage risks in healthcare services using the HFMEA methodology. It involved 21 health professionals and employed several data collection methods and tools, such as literature

review, questionnaires, and the HFMEA matrix, with descriptive analysis.

Overall, the development of a HFMEA risk assessment tool in a Basic Emergency Service of a Primary Healthcare Centres Cluster successfully achieved its objectives despite facing various challenges, including the lack of a prevailing risk management culture, particularly in primary healthcare within the national context. This lack may have contributed to la ess engagement with the project in the beginning but it was successful outdated. Another challenge was the limited knowledge related to these issues for some professionals. To minimize this challenge, training sessions were implemented. Regardless, the team's engagement in this project was obtained, and the main objectives of this project were accomplished. Finally, it is important to highlight that this work served as a pioneering endeavour and a valuable learning experience for the team members actively involved in the Basic Emergency Service's professional activities.

Considering the limited research in this area and its critical implications for patient safety in primary care, further studies are strongly recommended.

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