International Journal of Healthcare Management

ISSN: 2047-9700 (Print) 2047-9719 (Online) Journal homepage: www.tandfonline.com/journals/yjhm20

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To cite this article: Paula Machado Santos, Carminda Morais & Pilar Baylina (11 Jun 2024): Translation and cultural adaptation of the HFMEA into European Portuguese, International Journal of Healthcare Management, DOI: 10.1080/20479700.2024.2362026

To link to this article: https://doi.org/10.1080/20479700.2024.2362026

Published online: 11 Jun 2024.

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INTERNATIONAL JOURNAL OF HEALTHCARE MANAGEMENT
https://doi.org/10.1080/20479700.2024.2362026

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Translation and cultural adaptation of the HFMEA into European Portuguese

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ABSTRACT

Introduction: Health organizations are faced with daily challenges, requiring them to provide a quality service, ensuring effectiveness and efficiency. Risk management is one of the conditioning factors to achieve this purpose, ensuring preventive actions for all processes, promoting the identification of risk to the mitigation of its consequences for the patient, professionals, or organization. Patient safety is a priority and healthcare organizations should be concerned with the implementation of methodologies and tools to promote risk management, such as Healthcare Failure Mode and Effects Analysis (HFMEA). HFMEA has a high potential for risk management in healthcare organizations, with a proactive, prospective, and continuous approach to improvement.

Objective: Translation and adaptation of the HFMEA instrument into European Portuguese.

Materials and methods: A methodological study was carried out based on the proposal presented by Beaton and followed the recommendations of the International Test Commission and World Health Organization.

Results: The HFMEA 2021 was linguistically translated and culturally adapted to the new context ensuring reliability, content validity was assured by a group of experts, which ensured semantic, idiomatic, experimental, and conceptual equivalence between the original instrument and the translation.

Conclusions: HFMEA 2021 was successfully translated and adapted to European Portuguese, allowing its application.

ARTICLE HISTORY
Received 12 October 2023
Accepted 27 May 2024

KEYWORDS
Translation and cultural adaptation; risk management; quality management; HFMEA; Improvement

Introduction

Healthcare activities and processes are highly complex due to several issues such as science advance, new technologies, customer, and other interested parties' demands, and pressure to reduce costs. Faced with this scenario, risk management reveals the important role in achieving effectiveness of care, protecting the professionals' health, as well as protecting and better managing equipment and infrastructures.

According to the Portuguese Directorate-General of Health, risk management can be understood as a set of activities (planning, organization, management, implementation, and evaluation) aimed at reducing the occurrence of risks of harm to patients and professionals and reducing damage to property or losses in healthcare units [1]. This is in line with the integrative approach to risk management in healthcare, which can affect the safety and integrity of the patient, the professionals, the environment, and the institutional image [2,3].

In most cases, risk cannot be eliminated. So, the best way is to avoid it, by preventing the occurrence (or reoccurrence) of errors, identifying their causes and then acting to eliminate or minimise them [4]. This can be done through the implementation of risk management methodologies which, once adopted, promote the development and implementation of a risk management process that contributes to the detection and consequent reduction and/or elimination of errors. In the case of healthcare organizations, these can have serious implications for the well-being of the patients and families, as well as for the professionals [5]. The goal of any risk management process is to, analyse, assess, and treat risks to an acceptable level [6].

Risk management can be done in a reactive way (for example, incident notification, root cause analysis and action/improvement plan establishment, so the incident does not reoccur, or the risk is reduced to an acceptable level) or it can be done in a proactive way (preventive) anticipating the possible occurrence of risks, thus leading to changes that prevent this occurrence.

Background

Risk management methodologies should be part of any organisation interested in higher quality standards. They allow defining, organising, measuring, analysing, and understanding the organisation, and can be extremely important to support decision-making. Quality

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tools assume great relevance in complementing more complex methodologies, as is the case of Healthcare Failure Mode and Effects Analysis (HFMEA). This tool is an adaptation of the Failure Mode and Effect Analysis (FMEA) developed by USA military department in 1949, and based on a systematic process to help identify product and process problems before they occur [7].

The Veterans Affairs National Center for Patient Safety (VA NCPS) adopted and modified the FMEA for healthcare applications in 2001, incorporating concepts from other quality and safety tools (e.g. Root Cause Analysis (RCA), Hazard Analysis and Critical Control Point (HACCP)). HFMEA streamlines the hazard analysis steps of the traditional FMEA process by combining the detectability and criticality steps into an algorithm presented as a Decision Tree.

The HFMEA is uniquely suited for proactive risk assessment in healthcare and is one of several tools available to help organisations conduct proactive risk assessment [4,8–10].

The choice of this tool for implementing the risk management process recommended by ISO 31000 is due to its high potential and adherence in the contexts of healthcare organizations, which helps to meet challenges related to risk management, quality, efficiency, and effectiveness of processes and operations.

The HFMEA has been used in healthcare settings in some studies in Portugal, however, the use of free translation of an instrument or method built in another language and, consequently, in another culture may contribute to errors in the understanding of the process and concepts.

Considering the potential of this instrument described in several studies and assuming the need and relevance of the use of a risk management instrument valid for the Portuguese population, this study was designed with the purpose of performing the translation and cultural adaptation of the HFMEA 2021 into European Portuguese.

Material and methods

Type of study

This translation and cultural adaptation study followed the procedures established for the translation and validation of instruments, according to Beaton [11] and followed the recommendations of the International Test Commission [12] and World Health Organization [13].

The HFMEA 2021 instrument consists of set of worksheets which systematise the implementation of risk assessment process based on 5 steps: topic definition, team assemble, process description, analysis conduction, actions, and outcome measures identification. The application of this set of worksheets is supported by a guidebook that explains, step-by-step how to implement the risk assessment process [9,14].

Procedures

The translation and cultural adaptation of the original version of the HFMEA 2021 into European Portuguese was started after obtaining the formal authorisation from authors and the confirmation that there was no HFMEA 2021 translated into European Portuguese [14].

After permission was obtained, the translation process began, following the scientific methodology proposed by Beaton et al. and the recommendations of the ICT and WHO [11–13].

The translation process comprises a set of stages, as shown in Figure 1.

Based on this process, six distinct stages were conducted: Translation of the original version into Portuguese; Consensus version (reconciliation); Back-translation; Validation by a group of experts; Pretest; Submission of the documents for assessment by the authors of the instrument.

Ethical and legal considerations

The study was authorized by the Board of Directors, following a favourable opinion from the Ethics Committee and the Local Information Protection and Security Committee (LIPSC), as well as approvals and favourable assessment from the research group of Primary Care Center Group (PCCG). Authorization was also obtained from the coordinators of the Community Care Unit (CCU) where the study was conducted. The procedures only began after obtaining institutional approvals. Obtaining free and informed consent from all participants was a prerequisite, ensuring data confidentiality throughout the study, in accordance with the Helsinki Declaration.

Results

Stage I: Initial translation

This process involved the translation of the instrument and respective guidebook, which were in the original language (English), into the target language (European Portuguese). For these 2 translators were chosen, both bilinguals whose mother tongue was European Portuguese and who were independent from each other. Translator 1 was a health professional, with knowledge about the type of concepts used in the instrument, which allowed the translation to be performed from a clinical perspective, producing a better equivalence to the original terms. Translator 2 was an English teacher, had no knowledge or information about the concepts referred to in the

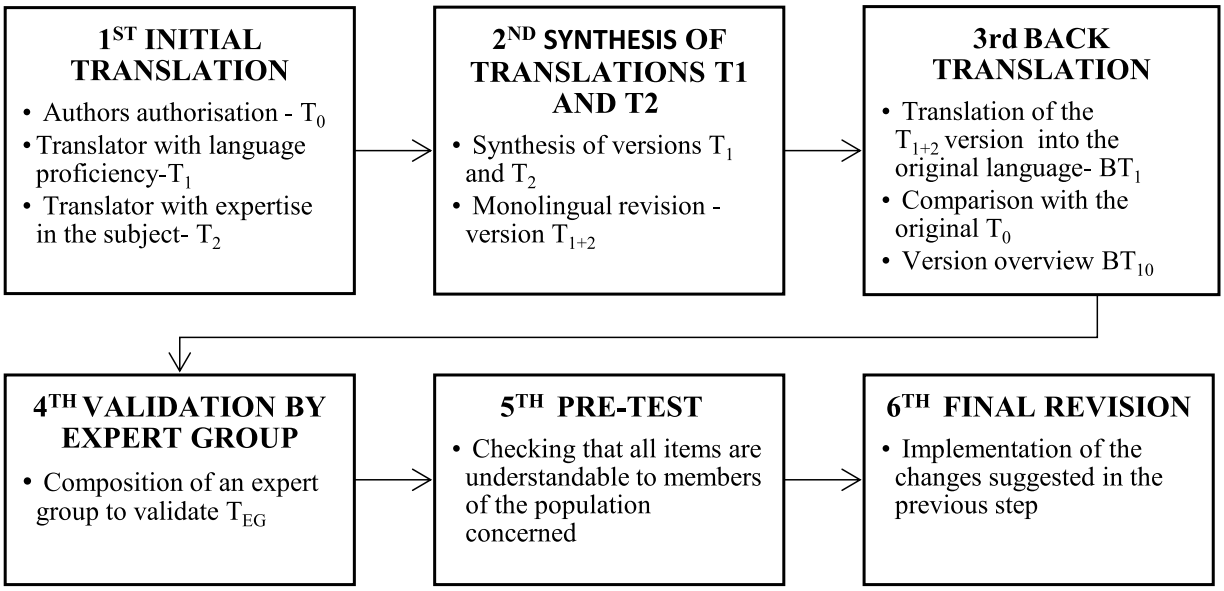

Figure 1. Translation process stages.

instrument and had no medical/clinical training, thus allowing the translation to reflect the language of the Portuguese population [11]. After acceptance, the first two versions of the HFMEA translation into European Portuguese were obtained T_1 and T_2.

Stage II: Synthesis of the translations

In this stage, for the preparation of consensus version (reconciliation), a collective review was adopted, developed by a reviewers' group, where the inclusion criteria were speaking English and having more than 3 years of professional experience. The group was composed of two nurses, one physician, one risk management engineer and another professional in the linguistic area ($n = 5$). The translated instrument – T1+2 was compared to the original one in English, adapting the expressions of the tool to professional terms.

It was found that both translations were quite similar, with the presence of some synonymous words and different distributions of words within the sentence but having the same idea, these were minor issues that were resolved through consensus. It was decided which sentences, expressions and synonymous words made the statements simpler and more comprehensible. At this stage, the greatest difficulty arose in translating the following expressions:

- 'Step' which was translated in version 1 to '*Etapa*' and in version 2 to '*Passo*'. The review team considered the expression 'Etapa' since NP ISO 31000 [15], uses this expression in the risk management process;
- 'Severity' which was translated in version 1 as 'Severidade' and in version 2 as '*Gravidade*'. The review team considered the expression '*Gravidade*', because although the two terms are used in the risk matrices it is the expression used in the Portuguese translation of the FMEA [16]. A consensus version or synthesis version was thus constituted – $T_{1+2.}$

Stage III: Back translation

After the Portuguese consensus version (T_{1+2}) was ready, the research team recruited a linguist for the back translation from Portuguese into English – version BT_1.

The translator's criterion was to be fluent in both languages, whose native language was the original language of the instrument (English), without any knowledge regarding the original version and/or concepts explored in the instrument.

The back-translation was compared with the original document and summarised in a single version by the researchers, the BT_{1+0} Version.

Stage IV: Expert group (content validity)

The back-translated version (BT_1) showed very satisfactory proximity with the original version of the instrument, resulting in some linguistic discrepancies which were referred to the reviewers' group for validation. As recommended by Beaton et al. [17], the Expert Group (EG) was composed of bilingual experts, a total of 9 professionals with knowledge in the areas of quality of care, patient safety culture, accreditation, linguistics, and experience in the translation, cultural adaptation, and validation of instruments.

For the translation analysis, the items of the instrument were numbered, and a Microsoft Form was created. The experts were intentionally invited to analyse the translations following Breslin's recommendations [18], and each item in both versions was assessed

using the following scale: Different meanings; Almost the same meaning; Exactly the same meaning.

In this stage, content validity was obtained with at least 90.0% of the expert group members agreement regarding each of the items of the instrument [11], a general validation index (GVI) of the instrument was then calculated, based on the formula:

General Validation Index (GVI) = number of experts who attributed the same meaning/total number of experts × 100.

No item was classified as 'Different meanings in each of the versions', items 1-9, 11-13, 14.1-16, 20, had a concordance rate of 100.0% and no modification was necessary. The remaining items were discussed and resolved by consensus of the Expert Group in a videoconference meeting, and their resolution is listed in Table 1.

Once this process was completed, the preliminary European Portuguese version (T_{EG}) was obtained for the pre-test.

Step V: Pre-test

The final draft version of the HFMEA (TEG) was applied to a sample of professionals from another Community Care Unit – Primary Care, to check whether the instrument translated was easy to understand and to apply. Five nurses, one physician and one physiotherapist participated (all professionals consented and accepted to participate in the pre-test). The care process chosen for risk assessment was the 'Clear identification of the patient in care planning at home'. After applying the instrument, the professionals were questioned about the comprehension, relevance of the questions, and if it was 'user friendly', allowing assessing whether the terms used were easily understood and acceptable. The final instrument should be understandable by the equivalent of a 12-year-old child (approximately a sixth-grade reading level, as this is the recommended general reading level for questionnaires) [17].

After this pre-test, the conclusion was that the instrument was culturally adapted, as the participants understood all the questions and did not raise any doubts regarding the format and content. The pre-final version didn't need to be reformulated, thus being designated as the final version in Portuguese '*HFMEA_PT: Análise de Modos de Falha e Efeitos nos Cuidados de Saúde*'. (Appendix A)

Stage VI: Submission of the instrument for authors consideration

The final stage was the submission of all translations, back-translations, expert reports, and annotations to the authors of the original instrument. The documents resulting from the various stages of this methodological process were sent by email to the VA NCPS, which accepted the final version of the instrument, with the remark to put the 'Completion date' instead of 'Date to be completed' because it has the wrong context. The translation makes it look like the user will enter a date in the future when the project is expected to be completed, which is not the intent of the instrument. The suggestion has been included in the final translation. They emphasize that the rows in the table are used for different purposes. The first row is used for the failure mode. The remaining rows are used for the causes. This is a significant part of the sequence of completing an HFMEA project. Once this stage was completed, the process of translation and cultural adaptation of the instrument was successfully concluded.

Table 1. Validation of translation by Expert Group.

Item (AR)	Reviewers' comments	Translation after reviewers' validation T_{EG}
Title (77,78%)	It was decided to translate into Portuguese the name of the instrument and to keep the acronym in English HFMEA, bearing in mind that this instrument is thus known in the international scientific universe. Changed Care for context as the FMEA can be applied in various contexts Failure Mode and Effect Analysis in Health Context (HFMEA™)	*Análise de Modo de Falha e Efeito no Contexto da Saúde (HFMEA™)* *Processos – Etapa 1 e 2* 'Healthcare Failure Mode and Effect Analysis (HFMEA) Process Step 1 and 2'
10 (66,67%)	Keep the term draw up as it is a term used in the quality framework	*Quem irá redigir a ata e manter os registos?* 'Who will draw up the minutes and maintain records?'
14 (88,89%)	Semantic and idiomatic equivalence Scoring	*Pontuação* 'Scoring'
17 (77,78%)	Idiomatic equivalence	*Tipo de ação* 'Action Type'
18 (44,44%)	The difference between rationale and reason is that rationale is an explanation of reason, fundamental basis that justifies action with rationale for something while reason is generally a cause or reason that generally does not require explanation	*Ações ou fundamentação para parar* 'Actions or rationale for stopping'
19 (88,89%)	Result is what you want to achieve, while outcome is more related to the key objectives, which you hope to achieve. As outcome does not have an explicit translation, it is decided to keep the English	*Resultados de medida (Outcome)* 'Measuring Results (Outcome)'
21 (44,44%)	The approval is generally done at the end of the document, in this phase the agreement is sought Management Concurrence	*Concordância da Gestão* 'Management Concurrence'

Discussion

The translation and cultural adaptation of an instrument for use in a new country, culture, and/or language requires a specific methodology approach, to achieve equivalence between the original (source version) and the target version. In the case of cross-cultural translation and adaptation, there are several guidelines, but no consensus that leads to a single reference standard [19]. Recommendations proposed in the 1990s and updated in 2000 are the most widespread in the international literature. Items should be translated linguistically, as well as, culturally adapted to maintain the validity of the psychometric properties of the instrument and allow for data sharing and comparisons at national and international levels [11–13,17].

Before any translation work is initiated, permission must be obtained from the authors of the original instrument. The first contact has two purposes: to ascertain whether someone else has not already started a similar translation and to discuss with the author the requirements for a translation agreement.

The use of at least two independent translators reduces the likelihood of errors, divergent interpretations, and ambiguous items in relation to the original [11]. Once the synthesis version was obtained, the back translation was performed, considered a fundamental resource that enhances the quality of the final version. This procedure should be carried out by back-translators who are fluent in the source and target languages, do not know the test and are native speakers of the source language [17], as was the case in this study. A linguist was hired for the reverse translation from European Portuguese into English, given the difficulty in finding professionals who met the criteria described by Beaton et al, [17]. The comparison between the translated version and the original version showed Equivalence between both versions.

To improve the validation process, the inclusion of experts from several professions was ensured to incorporate several opinions and experiences. The discussions generated due to the discrepancies and the search for consensual solutions proved to be essential for the entire process that ensured content validity [20].

The present study included 9 experts for the validation process. The literature presents controversies about the number of participants in this process but a minimum of five and a maximum of ten professionals are referred [20]. Also, having all translators present in the expert group was an advantage because discrepancies or wording changes could be made immediately [17].

The pre-test stage allowed assessing the so-called apparent (or face) validity of the instrument [17], it was found that the translated instrument does not present problematic terms or items, ambiguous concepts or difficult to understand concepts. While this stage provides useful information about how an individual person interprets the instrument items, it does not address construct validity, reliability or item response patterns which are also critical to describe a successful cross-cultural adaptation. Beaton et al. [17], recommend additional testing for the retention of the psychometric properties of the instrument, although it is not necessary for the approval of the translated version.

The submission of the entire process to the authors of the HFMEA and their opinion finalised the translation and cultural adaptation procedures, which proved to be successful, ensuring that the European Portuguese version kept the meaning and intention of the original items. The acronym designation (HFMEA) was adopted due to the international scientific universe recognition.

The content validity of the instrument was ensured through the analysis by a panel of experts and the preliminary study, and no changes were needed to the initial translation of the items after the preliminary study, maintaining, according to the experts' assessment, a semantic equivalence to the original version.

The criterion validity was not assessed since there is no instrument available in the Portuguese population that assesses the same domains.

All requirements of the scientific methodology proposed by Beaton et al. [11] were met and the recommendations of the ICT and WHO [11–13] for the process of cultural adaptation of the HFMEA were followed.

However, this study has some limitations, including the consumption of time and human resources required by the methodology. Important to highlight the importance of board leadership in all the processes to ensure the motivation and awareness promotion of all professionals involved. Further research is needed to explore the application of the outcome of this work, and the team is planning further research in the coming months. Opportunities for continuous quality improvement have been created for conducting additional studies.

Conclusions

This study provides a valuable contribution to proactive risk management implementation in Portugal. All the work was conducted with accuracy, focused on the usefulness it may have in the context of quality and safety in health. By determining the consolidation of a risk management instrument for the Portuguese population, we contribute to the legitimacy and development of this field of research. This is an important milestone for the progress of science in Portugal, which has implications in the field of practice, teaching, research, and care management. Using this instrument, it is possible to contribute to the construction of safer working environments, minimise risks and promote an even more proactive and reliable performance towards excellence.

To ensure that its application reaches its full potential in contributing to improving healthcare in Portugal, we suggest that further research studies should be conducted and disseminated using the HFMEA in various healthcare settings. The validation of this risk management tool in different care processes may support the planning of actions, procedures, processes, and services, with the purpose of reducing/eliminating risks that can impact in the effectiveness of care.

Practical applications

By translating and culturally adapting this tool, it is possible to expand the scope of the HFMEA application and contribute to the scientific community and the quality of healthcare by creating safer environments for patients and professionals. It also makes it possible to compare patient safety data between national and international organizations, identify patterns, trends, and differences in relation to the phenomenon studied, contributing to the advancement of knowledge and best practices.

The translation and validation of this tool allow its implementation in different care processes by healthcare professionals, researchers and students interested in proactive risk assessment and risk management studies, using a validated and reliable tool for teaching, for management, and for healthcare quality improvement.

Acknowledgments

The authors thank all members of the Expert Group. Our gratitude and thanks to *Unidade Local de Saúde de Matosinhos* who allowed the primary researcher the time to conduct the study and their willingness to support this research and provide clarification and context to our analysis.

Disclosure statement

No potential conflict of interest was reported by the authors.

Funding

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors. this research and provide clarification and context to our analysis.

Declaration of generative AI and AI-assisted technology in the writing process

The authors declare no use of AI and AI-assisted technology in the writing process of this work.

Contributions

This paper is the result of a research team of three authors with different roles: Paula Machado Santos (study conception, methodology, research and investigation process and manuscript preparation), Pilar Baylina (study conception, methodology, research and investigation process and manuscript preparation), Carminda Morais (manuscript revision). All members of the group named as authors read and approved the final manuscript.

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Appendix. HFMEA_PT (VA National Center for Patient Safety, 2021)

HFMEA_PT: Análise de Modos de Falha e Efeitos nos Cuidados de Saúde

Processos - Etapa 1 e 2

ETAPA 1. Selecionar o processo que pretende examinar

Definir o âmbito (Seja específico e inclua uma definição clara do processo ou produto a ser estudado).

Esta HFMEA está centrada na _____

_____

_____

_____

ETAPA 2. Reunir a equipa

HFMEA Número_____

Data de Início _____ Data de Conclusão_____

Membros da equipa:

1. _____
2. _____
3. _____
3. _____
4. _____
5. _____

Líder da Equipa _____

Estão representadas todas as áreas afetadas? ___SIM ___NÃO

Diferentes níveis e tipos de conhecimentos estão representados na equipa? ___SIM ___NÃO

Quem irá redigir a ata e manter os registos? _____

HFMEA Sub-processo Etapa Título e Número																
HFMEA Etapa 4 - Análise de Perigos											**HFMEA Etapa 5 - Identificar Ações e Resultados**					
Modo de falha: Primeiro analisar o modo de falha antes de determinar as causas potenciais		**Causas potenciais**		**Pontuação**			**Análise da Árvore de Decisão**				**Tipo de Acão** (Controlar Aceitar Eliminar)	**Ações ou fundamentação para parar**	**Resultados de medida** ***(Outcome)***	**Pessoa responsável**	**Concordância da Gestão**
				Gravidade	Probabilidade	**Pontuação de Perigo**	Fraqueza de Ponto Único	Existem medidas de controlo	Detetabilidade?	**Proceder?**					
		→													