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Cross-cultural adaptation and content validity of the Adverse Events Associated with Nursing Practices instrument

Adaptação transcultural e validade de conteúdo do instrumento Eventos Adversos Associados às Práticas de Enfermagem

Adaptación intercultural y validez del contenido del instrumento Eventos Adversos Asociados a las Prácticas de Enfermería

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ABSTRACT

Objective: To conduct the cross-cultural adaptation and evaluate the evidence of content validity of the Adverse Events Associated with Nursing Practices instrument in the Brazilian context.

Method: Psychometric study, conducted between June 2021 and February 2023, following the stages of the Patient-Reported Outcomes Measurement Information System protocol. Semantic, idiomatic, experimental and conceptual equivalences were evaluated, along with content validity evidence, considering Content Validity Ratio (CVR) parameters, with the participation of 25 experts.

Results: A Brazilian version with 55 items was obtained, demonstrating good linguistic equivalence to the original version (agreement rate=99.2%), and adjustments in the items writing. CVR values remained above 0.60. Cognitive testing indicated good understanding, confirmed by the 31 participants in this stage, with a short application time (average = 17 minutes).

Conclusion: The final version of the instrument showed good linguistic equivalence, strong evidence of content validity and a good response process in the Brazilian context.

Descriptors: Drug-related side effects and adverse reactions. Nursing care. Nursing, team. Patient safety. Psychometrics. Validation study.

RESUMO

Objetivo: Realizar a adaptação transcultural e avaliar as evidências de validade de conteúdo do instrumento Eventos Adversos Associados às Práticas de Enfermagem no contexto brasileiro.

Método: Estudo psicométrico, realizado entre junho de 2021 e fevereiro de 2023, de acordo com as etapas do protocolo *Patient-Reported Outcomes Measurement Information System*. Avaliadas as equivalências semântica, idiomática, experimental e conceitual, além das evidências de validade de conteúdo, considerando parâmetros de *Content Validity Ratio* (CVR), com participação de 25 especialistas.

Resultados: Obteve-se versão brasileira com 55 itens, boa equivalência linguística à versão original (taxa de concordância=99,2%), e ajustes na redação dos itens. Os valores de CVR mantiveram-se acima de 0,60. A testagem cognitiva indicou boa compreensão, confirmada pelos 31 participantes dessa etapa, com curto tempo de aplicação (média = 17 minutos).

Conclusão: A versão final do instrumento apresentou boa equivalência linguística, fortes evidências de validade de conteúdo e bom processo de resposta no contexto brasileiro.

Descritores: Efeitos colaterais e reações adversas relacionados a medicamentos. Cuidados de enfermagem. Equipe de enfermagem. Segurança do paciente. Psicometria. Estudo de validação.

RESUMEN

Objetivo: Realizar la adaptación transcultural y evaluar las evidencias de validez de contenido del instrumento Eventos Adversos Asociados a las Prácticas de Enfermería en el contexto brasileño.

Método: Estudio psicométrico, realizado entre junio de 2021 y febrero de 2023, según los pasos del protocolo del *Patient-Reported Outcomes Measurement Information System*. Se evaluaron equivalencias semánticas, idiomáticas, experimentales y conceptuales, además de evidencias de validez de contenido, considerando parámetros de Relación de Validez de Contenido (RCV), con 25 participaciones de especialistas.

Resultados: Se obtuvo una versión brasileña con 55 ítems, buena equivalencia lingüística a la versión original (tasa de acuerdo=99,2%), y ajustes en la redacción de los ítems. Los valores de RCV se mantuvieron por encima de 0,60. Las pruebas cognitivas indicaron una buena comprensión, confirmada por los 31 participantes en este paso de la investigación, con un tiempo de aplicación corto (promedio = 17 minutos).

Conclusión: La versión final del instrumento mostró buena equivalencia lingüística, fuerte evidencia de validez de contenido y buen proceso de respuesta en el contexto brasileño.

Descriptores: Efectos colaterales y reacciones adversas relacionados con medicamentos. Atención de enfermería. Grupo de enfermería. Seguridad del paciente. Psicometría. Estudio de validación.

INTRODUCTION

Adverse events are defined as any incident arising from intentional or unintentional actions, which result in harm or injury to the patient⁽¹⁾. In Brazil and worldwide, people who

use healthcare services can be victims of harm during health care in different scenarios, as a result of unsafe practices within healthcare services^(2,3).

Before the Covid-19 pandemic period, they represented the third leading cause of death in the United States, behind only heart disease and cancer. Currently, adverse events are the main cause of death, with exponential growth, not only in the USA, but throughout the world, with 2.6 million related deaths in emerging countries⁽⁴⁾.

In Brazil, over 290,000 incidents were reported in 2022. It is essential to associate this data with relevant prevention measures, outlining the causality of the events, proposing safe practices to reduce risks and promoting the return of information to notifiers⁽⁵⁾.

Although it is recognized that all healthcare professionals are susceptible to adverse events during care, the care activities provided by the nursing team are considered one of the main sources of care and support for patients and their families in the most vulnerable moments of their lives^(6,7). With the direction of skills, competencies, and scientific and technological knowledge, they aim to provide care that prioritizes patient well-being and integrity, focusing on quality of care, preserving safety in healthcare, and resolving the occurrence of failures in patient care^(8,9).

Achieving safer nursing care requires an organizational alliance, enabling surveillance strategies to be aimed at interrupting failures and latent conditions, leading nurses to an increasingly qualified, safe and high-quality practice⁽¹⁰⁾.

To improve understanding of the magnitude and diversity of adverse events, it is necessary to identify and evaluate, in a valid and reliable way, possible latent failures in the diverse stages of the care process, understanding that health AE are, in essence, linked to human factors and aspects of the structure and process inherent to the healthcare services themselves, reinforcing the existing weaknesses of the system. This goal can be accomplished through the use of instruments with strong evidence of validity and reliability, subjected to appropriate techniques and testing⁽¹¹⁾, essential for clinical practice, envisioning improvements in the quality of care.

The instrument “Adverse Events Associated with Nursing Practices (*Eventos Adversos Associados às Práticas de Enfermagem* - EAAPE)” is a technological innovation and self-administered tool, developed with adequate specificity to identify nurses’ perception about the occurrence/risks of adverse events in the hospitals settings in Portugal. It consists of a seven items scale developed to identify nurses' perception regarding the risk/occurrence of AEs and, simultaneously, evaluate the frequency of processes and practices that may be associated with

patient safety, from the perspective of preventive practices and the occurrence of failures in the care process⁽¹²⁾.

However, no studies on cross-cultural adaptation or evaluation of the validity evidence of the instrument for its use in the Brazilian context were identified. It is believed that this instrument can be a relevant tool to assist professionals and leaders in identifying risks and the occurrence of adverse events in nursing practices, thus enabling the development of strategies to promote greater safety in the context of nursing care^(7,10).

The objective of the study was to conduct a cross-cultural adaptation and evaluate the evidence of content validity of the Adverse Events Associated with Nursing Practices instrument in the Brazilian context.

METHOD

Ethical aspects

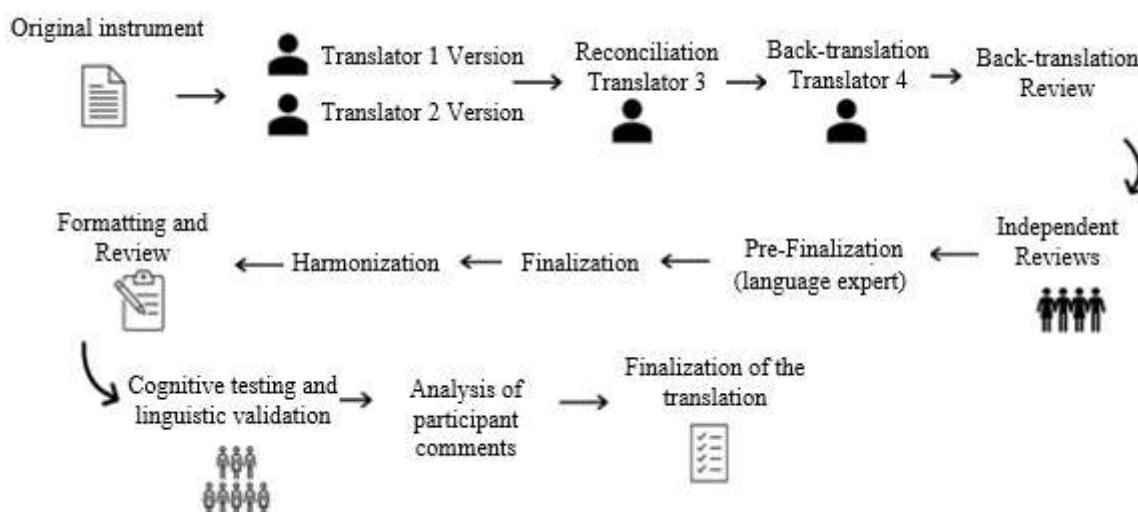
Authorization for the cross-cultural adaptation of the questionnaire to the Brazilian context was obtained from the author who developed the tool and preceded the execution of the study phases.

The study protocol was approved by the Research Ethics Committee of the proposing institution (CAAE nº 54090421.4.0000.5259 and Opinions: 5.189.974 and 5.655.953). All participants were informed about the objectives of the study and signed the Informed Consent Form, as required by Resolution 466/2012.

Study design and methodological stages

This is a psychometric study, cross-cultural adaptation of the EAAPE to the Brazilian context, conducted between June 2021 and February 2023. The protocol adopted to perform the cross-cultural adaptation process complied with the recommendations of the Patient-Reported Outcomes Measurement Information System (PROMIS)⁽¹³⁾, as shown in Figure 1.

Figure 1 - Methodological stages for cross-cultural adaptation. Rio de Janeiro, Rio de Janeiro, Brazil, 2022



Source: Adapted⁽¹⁴⁾ for PROMIS.

The stages of the cross-cultural adaptation process, according to the PROMIS protocol⁽¹³⁾, include: (1) Initial translation, carried out independently by two native Brazilian and bilingual translators, one of whom has knowledge in the health area; (2) Reconciliation, with selection of the most appropriate version of the instrument components by a third Brazilian and bilingual translator; (3) Back-translation, with back-translation of the reconciled version by a Portuguese translator fluent in Brazilian Portuguese, without knowledge of the original version and the initial translations of the instrument; (4) Review of the back-translation, comparing it with the original version to assess discrepancies; (5) Independent reviews, with review of all previous stages by bilingual professionals, experts in the healthcare area and/or method used, following methodological recommendations⁽¹³⁾. The experts selected the translation they deemed most appropriate for each item or produced alternative translations when the previous ones were unacceptable. During this stage, the procedures for linguistic equivalence analysis were applied, and at the end, content validity evidence analysis was conducted.

The analysis of linguistic equivalence was employed to evaluate the quality of the translations, including a group of five bilingual experts, one in languages/literatures and four nurses with doctoral degrees, with research and development areas in patient safety and adverse events. Participant selection considered the analysis of the Lattes electronic curriculum, examining the research area and development areas of the professional, which should be related to the theme of the study, in addition to being a professional with a

bachelor's degree and a degree in languages (Portuguese) and a post-doctorate at the Faculty of Languages, from Portugal.

The entire instrument was analyzed, with semantic, idiomatic, conceptual and experimental equivalences assessed, considering the intercultural context⁽¹⁵⁾. They were requested to indicate whether or not the item remained; if not, a suggestion for adaptation described and the agreement rate can then be calculated⁽¹⁶⁾.

The analysis of content validity evidence was conducted by a panel with 20 bilingual experts, in the fields of patient safety and/or psychometrics, and from different areas of healthcare disciplines⁽¹⁵⁾. The selection of the group considered the area of expertise and/or research, which should be related to the study theme (patient safety/adverse events in health and nursing), as well as professionals with vast knowledge and experience in Psychometrics, identified through a search using the Curriculum Lattes platform.

Each instruction/item was evaluated according to the following indicators: clarity (the way the sentence is written, understandable and appropriate to the concept), practical relevance (or even representativeness in the items of the underlying construct)⁽¹⁷⁾, theoretical relevance (the content of the item is or not indispensable in the target culture) and dimensionality (checks whether a given item is capable of measuring the proposed construct as a quality or attribute)⁽¹⁸⁾. Based on this expert analysis, it was possible to calculate the Content Validity Ratio (CVR)⁽¹⁹⁾.

Following the PROMIS proposal, (6) Pre-finalization was conducted, when the main researcher evaluated the relevance of the reviewers' comments, based on the theoretical foundation of the instrument, with the aim of identifying potential problems in the translations; (7) Finalization, when a language expert, native of the target language (Brazilian Portuguese), determined the final translation by reviewing all information in the item history and addressing the main researcher's comments; (8) Harmonization, with another thorough evaluation and equivalence of the final version conducted by the team of researchers, in addition to checking all material, aiming to guarantee the quality of the entire process; (9) Formatting and review, with review and formatting of the entire instrument in the appropriate model to be presented to participants in the next phase; (10) Cognitive testing and linguistic validation, aimed at verifying the understanding of the instrument by the target population, as well as verify the applicability of its final version in Portuguese spoken in Brazil.

A total of 31 nurses with healthcare activities in a public and university hospital in the State of Rio de Janeiro – RJ, Brazil participated in the cognitive testing (pre-testing). Professionals of both genders were included, with healthcare activities in inpatient services in

the clinical, surgical, and intensive care units and with experience equal to or greater than six months. Those who were on vacation or leave of any nature were excluded.

All participants filled out the instrument independently using an electronic tool (tablet). Afterwards, they were invited to participate in an individual in-person interview, in order to remove any doubts about their understanding or any item in the instrument.

The formulation of the interview content was prepared according to Bandalos⁽²⁰⁾, who innovates in his speech about the psychometrics field and provides guidelines for writing cognitive and affective items and conducting an updated item analysis, and included the questions: How did you feel when responding to the instrument? Do you believe that it can assist in the investigation/determination of care process indicators and outcomes in Adverse Events Associated with Nursing Practices? Consecutively, for each item, the following question was asked: Please read item 1. How do you feel when reading this statement? Regarding the statement in item 1, what do you understand from it? [...].

The content of the interviews was recorded on digital media, after signing the voice authorization form and after that all content was fully transcribed and checked by two researchers independently.

Finally, the stage (11) the analysis of participant comments and finalizing the translation took place, when the research team gathered the participants' comments and the suggested improvements for better understanding that had been proposed.

Analysis of results and statistics

In the evaluation of linguistic equivalence, items with an agreement rate of less than 80% were reviewed⁽¹⁶⁾ and sent back to the group of experts for new evaluation. To analyze the evidence of content validity, for each indicator evaluated, the CVR was calculated⁽¹⁹⁾.

The CVR calculation is a linear transformation of a proportional level of agreement between experts⁽²¹⁾. The proposed CVR critical values (CVR critical) mathematically proves that the level of agreement exceeds chance, determining how many members of a panel need to agree with an essential item so that it can be included or discarded from the final instrument⁽²²⁾. With the participation of 20 experts respondents at this stage, a critical CVR of 0.50 was determined.

In the cognitive testing phase, or pre-test, the participants' comments were analyzed by the researchers to consolidate the Brazilian version of the EAAPE.

RESULTS

The initial translations performed by the two independent translators (T1 and T2) were similar. There was a discrepancy related to dimension four, with a suggestion to use the term “Pressure ulcers” in T1 and “Pressure injury” in T2. In the item of the original version “Nurses assume themselves as true advocates of the interests of the patient and family.”, T1 indicated the continued use of the term “advocates”, while T2 opted to use the nomenclature “defenders”. Both translators chose to use the nomenclature “patient” in all items in which it was presented, different from the original which uses the term “ill”.

In the reconciliation stage, a third translator (T3) presented the version called “pre-final”, which included the incorporation of the terms “pressure injury” and “defenders”, in the contexts mentioned above.

The “pre-final” version was back-translated and evaluated by a fourth translator, native to the original language of the instrument. At this stage, no discrepancies with the original instrument were found, and there were no suggestions for changes to this version. To review the back-translation, a comparative table was created to identify discrepancies in the translations and provide support to reviewers in the following stages. No relevant discrepancies requiring changes to the items were identified.

In the first stage of independent reviews, questions 10 and 21 presented a semantic evaluation of 80%. Item 17 - “At the beginning of hospitalization, an overall clinical assessment is performed (degree of mobility, urinary/fecal incontinence, sensory changes, changes in the state of consciousness, vascular disease, nutritional status)”, presented a result below what was expected for equivalence semantics (agreement rate =0.60). The title and other instructions and response options obtained 100% in the evaluation of all equivalences. The researchers decided to revisit all items that presented any equivalence less than 100% to in order to propose improvements to the writing of the items.

A group of 20 experts was responsible for analyzing the content validity evidence, unanimously consisted of nurses, 18 women, 12 researchers in the area of patient safety and adverse events, four experts in the subject of the study and four psychometricians. As for the locations of activity, 15 were in the state of Rio de Janeiro, two in São Paulo, one in Espírito Santo, one in Piauí and one in Maranhão, representing 90% of participants from the southeast region and 10% from the northeast of Brazil.

The clarity indicator presented low CVR values for items 1 – “Patients are adequately monitored” and 23 – “Repositioning is adjusted to needs”, and indicated for modification. However, items 5 – “Nurses assume themselves as true defenders of the interests of patients

and families” and 41 – “There are failures in monitoring perfusion rates” presented CVR at the exact value of 0.50 (value defined as cutoff). All these items were reviewed to propose improvements. In the other aspects, pertinence and relevance, all items presented a critical CVR above the established value. All items were recognized as belonging to one of the suggested dimensions.

After the adjustments, the first consensus version was obtained, consisting of 55 items, as well as the original version, evaluated by the same panel of experts. CVR values were once again calculated to analyze the content validity evidence. The results of the reevaluation of CVR values for the Brazilian version are presented in Table 1.

Table 1 - Reevaluation of Content Validity Ratio values for the preliminary Brazilian version of the “Adverse Events Associated with Nursing Practices (EAAPE)” Instrument. Rio de Janeiro, Rio de Janeiro, Brazil, 2022

Questions	Clarity	Pertinence	Relevance	Related dimensionality?	Average CVR
Title: Adverse events associated with nursing practices (EAAPE)	1.00	1.00	1.00	na	1.00
Instructions: Consider service/work unit the service or department of the hospital where you usually work. Read the statements carefully and for each one, mark only one point on the scale by filling in the circle. Thank you very much for your collaboration.	1.00	1.00	1.00	na	1.00
Item 1: Patients are adequately monitored.	1.00	1.00	1.00	1.00	1.00
Item 2: Changes in clinical status are detected in a timely manner.	0.60	1.00	1.00	1.00	0.90
Item 3: There is a risk of worsening/complications of the patient’s condition due to surveillance deficits.	0.80	1.00	1.00	1.00	1.00
Item 4: There is a risk of worsening/complications of the patient’s condition due to inadequate clinical judgment.	0.60	0.90	0.90	1.00	0.85
Item 5: Nurses assume the role of true defenders of the interests of the patient and family.	1.00	1.00	1.00	1.00	1.00
Item 6: Nurses question the practice of other professionals when it involves the patient’s interest.	0.70	0.90	1.00	1.00	0.90
Item 7: Nurses respect patient privacy.	0.90	0.90	0.90	1.00	0.92
Item 8: Nurses respect patient confidentiality.	0.80	0.80	0.90	1.00	0.97
Item 9: Nurses delegate their nursing tasks to other less prepared professionals.	0.60	0.80	0.70	1.00	0.77
Item 10: There is a risk of worsening/complications in the patient’s condition due to failures to defend their interests.	0.80	0.90	0.90	1.00	0.90
Item 11: There is a risk of worsening/complications in the patient’s condition due to delegation of nursing tasks to less prepared personnel.	0.60	0.70	0.80	1.00	0.77
Item 12: The risk of falls is assessed for all patients according to the institutional protocol.	0.80	0.90	0.90	1.00	0.90
Item 13: Fall prevention procedures are adjusted based on the risk assessment.	0.90	1.00	0.90	1.00	0.95
Item 14: Patient surveillance is adjusted to the assessed risk.	0.70	0.80	0.80	1.00	0.82

Item 15: There is a risk of patient falls.	0.80	0.80	0.80	1.00	0.85
Item 16: Patient falls occur.	0.70	1.00	0.90	1.00	0.90
Item 17: An overall clinical assessment is conducted at the beginning of the hospitalization (degree of mobility, urinary/fecal incontinence, changes in consciousness, vascular disease, nutritional status)	0.90	1.00	1.00	1.00	1.00
Item 18: Periodic skin inspection is conducted in areas at risk or with previous injuries.	0.80	1.00	1.00	1.00	0.95
Item 19: Risk stratification scales (Braden and/or Norton scales) are used.	1.00	1.00	1.00	1.00	1.00
Item 20: Preventive measures adjusted to risk factors are implemented.	0.60	1.00	0.90	1.00	0.87
Item 21: General skin care is appropriate to identified needs.	0.60	1.00	1.00	1.00	0.90
Item 22: Nutritional support is adjusted to needs.	0.60	1.00	1.00	1.00	0.90
Item 23: Changes in decubitus/positions are adjusted to the patient needs.	1.00	1.00	1.00	1.00	1.00
Item 24: There is a risk of pressure injuries	0.80	0.80	0.80	1.00	0.85
Item 25: Pressure injuries occur.	0.80	0.90	0.90	1.00	0.90
Item 26: There is a risk of medication errors occurring.	0.70	1.00	1.00	1.00	0.92
Item 27: Medication errors occur.	0.70	0.90	0.90	1.00	0.87
Item 28: There are medicines with similar labels and packaging.	0.80	1.00	1.00	1.00	0.95
Item 29: There are many medications at the same scheduling time.	0.70	1.00	1.00	1.00	0.92
Item 30: The pharmacy sends the wrong medication.	0.90	1.00	1.00	1.00	0.97
Item 31: The medication is not available in a timely manner.	1.00	1.00	1.00	1.00	1.00
Item 32: Nurses are interrupted during their tasks.	0.60	0.80	0.80	1.00	0.80
Item 33: Nurse distraction.	0.80	0.60	0.70	1.00	0.77
Item 34: Failures in communicating changes in patient accommodation (bed transfer).	1.00	0.90	1.00	1.00	0.97
Item 35: Failures in physician/nurse communication regarding changes in medical prescriptions.	1.00	1.00	1.00	1.00	1.00
Item 36: Communication failures (oral or telephone medical prescription).	1.00	1.00	1.00	1.00	1.00
Item 37: Communication failures (lack of previous administration record).	1.00	1.00	1.00	1.00	0.92
Item 38: Incorrect identification of the prepared medication.	0.90	1.00	1.00	1.00	0.97
Item 39: Failure to comply with patient identification procedures.	1.00	1.00	1.00	1.00	1.00

Item 40: Failures in the execution of the administration technique.	1.00	1.00	1.00	1.00	1.00
Item 41: Failures in monitoring infusion rates.	1.00	0.90	1.00	1.00	1.00
Item 42: Failures in monitoring the effects of medication.	0.80	1.00	1.00	1.00	0.95
Item 43: here is a risk of infections (HAIs).	0.80	0.90	0.90	1.00	0.90
Item 44: Infections occur (HAIs).	0.80	0.90	0.90	1.00	0.90
Item 45: Hand hygiene is performed: Before and after contact with patient.	1.00	1.00	1.00	1.00	1.00
Item 46: Hand hygiene is performed: Before procedures that require antisepsis.	1.00	1.00	1.00	1.00	1.00
Item 47: Hand hygiene is performed: After contact with blood and body fluids.	1.00	1.00	1.00	1.00	1.00
Item 48: Personal protective equipment (PPE) is selected and adjusted for the procedures to be performed.	0.70	1.00	1.00	1.00	0.92
Item 49: When handling sharp material, inappropriate procedures such as bending or recapping needles after use are avoided.	0.90	1.00	1.00	1.00	0.97
Item 50: Sharp objects (needles, scalpel blades, etc.) are stored in rigid containers, located near to the procedure.	0.70	1.00	1.00	1.00	0.92
Item 51: Patient accommodation is based according to the patient's immunological susceptibility and clinical condition (e.g., isolation according to needs).	0.70	0.90	0.90	1.00	0.90
Item 52: Hospital waste is appropriately treated, according to the group to which it belongs.	1.00	0.90	1.00	1.00	0.97
Item 53: Dirty laundry is separated according to its place of origin, packed in a special bag, and transported to the laundry in a closed vehicle.	0.90	0.90	0.90	1.00	0.92
Item 54: The occurrence of adverse events associated with nursing practices compromises patient safety.	0.70	0.70	0.90	1.00	0.82
Item 55: Adverse events associated with nursing practices could have been avoided.	0.90	1.00	1.00	1.00	0.97

Source: The authors, 2022.

na: not applicable.

With the implementation of the results obtained, the final structure was an instrument with strong content validity evidence, thus consisting, like the original instrument, of 55 questions distributed across seven dimensions.

Among the 31 nurses who participated in the cognitive testing, 18 worked in clinical wards (58.1%), eight in surgical wards (25.8%) and five in intensive care units (16.1%). Among them, 27 were female (87.1%), with ages ranging between 23 and 51 years (average=44 years).

After the research proposal presentation, all participants filled out the instrument and took on average 17 minutes to complete it. Upon completion, they were invited to participate in an individual in-person interview with the main researcher, in a place designated for this purpose. The average interview duration was 28 minutes. All participants reported excellent understanding of the Brazilian version of the EAAPE, without questions or doubts.

After analyzing the comments and observing a high understanding of the instrument adapted for the Brazilian context, it was not necessary to adjust the questionnaire. Thus, the final Brazilian version of the instrument “Adverse Events Associated with Nursing Practices (EAAPE)” was consolidated, with 55 items distributed in seven dimensions (Figure 2).

Figure 2 - Brazilian version of the instrument “Adverse Events Associated with Nursing Practices (EAAPE)”. Rio de Janeiro, Rio de Janeiro, Brazil, 2022

Eventos adversos associados às práticas de enfermagem (EAAPE)					
<p>Considere serviço/unidade de trabalho o serviço ou departamento do hospital onde trabalha habitualmente. Leia atentamente os enunciados e em cada um assinala apenas um ponto da escala, preenchendo o círculo. Muito Obrigada pela colaboração. Um evento adverso é definido como qualquer tipo de engano, incidente, acidente, erro ou desvio da norma, susceptível de causar dano ao paciente. A segurança do paciente é definida como a prevenção de danos ou eventos adversos resultantes da prestação de cuidados de saúde Indique, por favor, a frequência em que acontece cada uma das situações: No meu serviço/ unidade...</p>					
Itens	Dimensões				
1-Vigilância/Julgamento clínico					
1. Os pacientes são adequadamente vigiados.	Nunca	Raramente	Algumas vezes	Frequentemente	Sempre
2. As alterações do estado clínico são oportunamente detectadas.	Nunca	Raramente	Algumas vezes	Frequentemente	Sempre
3. Existe risco de agravamento/complicações do estado do paciente por déficit de vigilância.	Nunca	Raramente	Algumas vezes	Frequentemente	Sempre
4. Existe risco de agravamento/complicações do estado do paciente por julgamento clínico inadequado.	Nunca	Raramente	Algumas vezes	Frequentemente	Sempre
2. Advocacia					
5. Os enfermeiros assumem papel de verdadeiros defensores dos interesses do paciente e família.	Nunca	Raramente	Algumas vezes	Frequentemente	Sempre
6. Os enfermeiros questionam a prática de outros profissionais quando está envolvido o interesse do paciente.	Nunca	Raramente	Algumas vezes	Frequentemente	Sempre
7. Os enfermeiros respeitam a privacidade do paciente.	Nunca	Raramente	Algumas vezes	Frequentemente	Sempre
8. Os enfermeiros respeitam a confidencialidade do paciente.	Nunca	Raramente	Algumas vezes	Frequentemente	Sempre
9. Os enfermeiros delegam suas funções de enfermagem a outros profissionais menos preparados.	Nunca	Raramente	Algumas vezes	Frequentemente	Sempre
10. Existe risco de agravamento/complicações no estado do paciente por falhas na defesa dos seus interesses.	Nunca	Raramente	Algumas vezes	Frequentemente	Sempre
11. Existe risco de agravamento/complicações no estado do paciente por delegação de funções de enfermagem a pessoal menos preparado.	Nunca	Raramente	Algumas vezes	Frequentemente	Sempre
3. Quedas					
12. O risco de quedas é avaliado para todos os pacientes, de acordo com o protocolo institucional.	Nunca	Raramente	Algumas vezes	Frequentemente	Sempre
13. Os procedimentos de prevenção de quedas são ajustados levando-se em consideração a avaliação do risco.	Nunca	Raramente	Algumas vezes	Frequentemente	Sempre
14. A vigilância do paciente é ajustada ao risco avaliado.	Nunca	Raramente	Algumas vezes	Frequentemente	Sempre
15. Existe risco de ocorrência de quedas dos pacientes.	Nunca	Raramente	Algumas vezes	Frequentemente	Sempre
16. Ocorrem quedas de pacientes.	Nunca	Raramente	Algumas vezes	Frequentemente	Sempre
4. Lesão por pressão					
17. No início da internação é realizada uma avaliação clínica global (grau de mobilidade, incontinência urinária/fecal, alterações do estado de consciência, doença vascular, estado nutricional).	Nunca	Raramente	Algumas vezes	Frequentemente	Sempre
18. É realizada a inspeção periódica da pele em áreas de risco ou de lesões prévias.	Nunca	Raramente	Algumas vezes	Frequentemente	Sempre
19. São utilizadas escalas de estratificação de risco (ex: escalas de Braden e/ou Norton).	Nunca	Raramente	Algumas vezes	Frequentemente	Sempre
20. São implementadas medidas preventivas ajustadas aos fatores de risco.	Nunca	Raramente	Algumas vezes	Frequentemente	Sempre
21. Os cuidados gerais com a pele são adequados às necessidades identificadas.	Nunca	Raramente	Algumas vezes	Frequentemente	Sempre
22. O suporte nutricional é ajustado às necessidades.	Nunca	Raramente	Algumas vezes	Frequentemente	Sempre
23. As mudanças de decúbito/posições são ajustadas às necessidades dos pacientes.	Nunca	Raramente	Algumas vezes	Frequentemente	Sempre
24. Existe risco de ocorrência de lesões por pressão.	Nunca	Raramente	Algumas vezes	Frequentemente	Sempre
25. Ocorrem lesões por pressão.	Nunca	Raramente	Algumas vezes	Frequentemente	Sempre
5. Medicação					
26. Existe o risco de ocorrência de erros de medicação.	Nunca	Raramente	Algumas vezes	Frequentemente	Sempre
27. Ocorrem erros de medicação.	Nunca	Raramente	Algumas vezes	Frequentemente	Sempre
5A. Ocorrem erros na preparação da medicação por:					
28. Existem medicamentos com rótulo e embalagem semelhantes.	Nunca	Raramente	Algumas vezes	Frequentemente	Sempre
29. Existem muitos medicamentos no mesmo horário de aprazamento.	Nunca	Raramente	Algumas vezes	Frequentemente	Sempre
30. A farmácia envia o medicamento errado.	Nunca	Raramente	Algumas vezes	Frequentemente	Sempre
31. O medicamento não está disponível em tempo.	Nunca	Raramente	Algumas vezes	Frequentemente	Sempre
32. O enfermeiro é interrompido durante a atividade.	Nunca	Raramente	Algumas vezes	Frequentemente	Sempre
33. Distração do enfermeiro.	Nunca	Raramente	Algumas vezes	Frequentemente	Sempre
5B. Ocorrem erros na administração da medicação por:					
34. Falhas na comunicação sobre mudanças na acomodação dos pacientes (troca de leito).	Nunca	Raramente	Algumas vezes	Frequentemente	Sempre
35. Falhas na comunicação médico/enfermeiro acerca das alterações na prescrição médica.	Nunca	Raramente	Algumas vezes	Frequentemente	Sempre
36. Falhas na comunicação (prescrição médica oral ou por telefone).	Nunca	Raramente	Algumas vezes	Frequentemente	Sempre
37. Falhas na comunicação (ausência de registro da administração anterior).	Nunca	Raramente	Algumas vezes	Frequentemente	Sempre
38. Identificação incorreta do medicamento preparado.	Nunca	Raramente	Algumas vezes	Frequentemente	Sempre
39. Não cumprimento dos procedimentos de identificação do paciente.	Nunca	Raramente	Algumas vezes	Frequentemente	Sempre
40. Falhas na execução da técnica de administração.	Nunca	Raramente	Algumas vezes	Frequentemente	Sempre
5C. Vigilância da medicação					
41. Ocorrem falhas na vigilância das velocidades de	Nunca	Raramente	Algumas vezes	Frequentemente	Sempre
42. Ocorrem falhas na vigilância dos efeitos da medicação.	Nunca	Raramente	Algumas vezes	Frequentemente	Sempre

6. Infecção relacionada à assistência à saúde (IRAS)					
43. Existe risco de ocorrerem infecções (IRAS).	Nunca	Raramente	Algumas vezes	Frequentemente	Sempre
44. Ocorrem infecções (IRAS)	Nunca	Raramente	Algumas vezes	Frequentemente	Sempre
A higienização das mãos realiza-se:					
45. Antes e após o contato com o paciente.	Nunca	Raramente	Algumas vezes	Frequentemente	Sempre
46. Antes de procedimentos que exijam antisepsia.	Nunca	Raramente	Algumas vezes	Frequentemente	Sempre
47. Após o contato com sangue e fluidos corporais.	Nunca	Raramente	Algumas vezes	Frequentemente	Sempre
48. Os equipamentos de proteção individual (EPI) são selecionados e ajustados aos procedimentos a serem realizados.	Nunca	Raramente	Algumas vezes	Frequentemente	Sempre
49. Na manipulação de material perfuro-cortante são evitados procedimentos inadequados como dobrar ou reencapar agulhas, após a sua utilização.	Nunca	Raramente	Algumas vezes	Frequentemente	Sempre
50. Os objetos perfuro-cortantes (agulhas, lâminas de bisturi etc.) são acondicionados em recipientes rígidos, localizados próximo da realização do procedimento.	Nunca	Raramente	Algumas vezes	Frequentemente	Sempre
51. A acomodação dos pacientes realiza-se de acordo com a susceptibilidade imunológica e condição clínica do paciente (ex. isolamento de acordo com as necessidades).	Nunca	Raramente	Algumas vezes	Frequentemente	Sempre
52. Os resíduos hospitalares são tratados apropriadamente, de acordo com o grupo a que pertencem.	Nunca	Raramente	Algumas vezes	Frequentemente	Sempre
53. A roupa suja é separada conforme o local de procedência, acondicionada em saco próprio e transportada para a lavanderia em carro fechado.	Nunca	Raramente	Algumas vezes	Frequentemente	Sempre
7. Percepção Geral (no meu serviço)					
54. A ocorrência de eventos adversos associados às práticas de enfermagem compromete a segurança do paciente.	Nunca	Raramente	Algumas vezes	Frequentemente	Sempre
55. Os eventos adversos associados às práticas de enfermagem podiam ser evitados.	Nunca	Raramente	Algumas vezes	Frequentemente	Sempre

Source: Adapted from the original instrument Adverse Events Associated with nursing practices, by the authors, 2022.

DICUSSION

The results showed that, after the cross-cultural adaptation process, the Brazilian version of the Adverse Events Associated with Nursing Practices instrument presents good quality in the translation process and robustness related to content validity to be used by nurses. No issues were detected in its cognitive testing, following a trend of stability of good validity evidence of observed in the Portuguese hospital context⁽¹²⁾, with potential for adaptations in new countries.

The studied instrument has the potential to enable nursing, a healthcare professional category that remains with patients 24 hours a day and that has been at forefront of health care, to develop prevention and intervention actions capable of producing benefits in provision of care that enables to identify the risk of unfavorable clinical outcomes and potential adverse events⁽⁶⁾.

Furthermore, it can provide excellent support to managers to identify weak points and define improvement strategies, especially at a time when concerns about workloads, complexity of care, time pressure and limited resources are growing, which may increase the frequency of adverse events that threaten patient safety.

It is reiterated that the use of validated instruments cannot be replaced by the empirical assessment of phenomena that are not directly measurable. Only through contemporary validation techniques can one determine the degree to which theory and evidence enable the

interpretation of the scores obtained on the latent variable evaluated, thus providing potential support for routine care⁽²³⁾.

Cross-cultural adaptation is a complex and methodologically rigorous procedure, aimed at ensuring the maintenance of the theoretical content and its psychometric characteristics, or the results of the study cannot be considered valid. It is noteworthy that simple translation does not provide a valid measure for the new culture, and may result in the development of an instrument that is not linguistically equivalent to the original questionnaire⁽²⁴⁾.

Researchers from different areas, in the Brazilian and international context, have made efforts to develop studies that enable technological advances and evaluation of the health conditions of populations using international parameters. To make this possible, contemporary recommendations for translation, adaptation and validation of tools within this context are used as a basis^(11,25).

The adoption of PROMIS, an internationally recognized and accepted methodological framework, developed at Northwestern University (United States), enabled the successful process of cross-cultural adaptation (CCA) of the EAAPE to Brazil, which increases the quality and methodological rigor of this type of research, when compared to previously established protocols^(15,26).

Regarding the semantic and cultural criteria, both must be considered in the CCA process. In this study, in the translation phase, some adjustments presented were related to the difference in spelling that resides between American and European Portuguese, semantically, there is no change, as it is a spelling issue. It is noteworthy that the original study uses the term “ill” to refer to the person who uses the healthcare service, however, for the Brazilian version of the instrument, the term “patient” was used, which was presented as the most appropriate in Brazilian context, besides being the term adopted by current legislation⁽²⁷⁾.

Regarding back-translation, despite not being unanimous among the guidelines for CCA, it is recommended as an indicator of psychometric evidence⁽¹³⁾. When compared to the original version, the Brazilian version showed no discrepancies, although Portuguese from Portugal and Brazilian are languages with different characteristics, influenced by historical, social and oral roots⁽²⁸⁾, this observation may be related to their common origin.

The back-translation review confirmed that the reconciled version did not present misinterpretations of the items. Subsequently, the independent review stage allowed adjustments to the instrument’s content to ensure good understanding and refinement of the instrument to a version closer to the original.

It is a critical and complex stage in the process of developing health measurement instruments, which have complex and not directly observable constructs, when seeking to verify that the set of items are theoretically appropriate to measure the proposed construct. It provides evidence about the degree to which the elements of an evaluation instrument are relevant and representative of the target construct for a specific evaluation purpose^(23,29).

It can be stated that the characteristics of the group of experts involved in this stage allowed to contemplate a consistent and heterogeneous population capable of interpreting the content with theoretical, methodological observations and the practice scenario involved with the latent variable. However, it is understood that, regarding the location of practice, it was not possible to cover the entire national territory, which can still be addressed with future testing, with an expansion of the sample in the evaluation of the internal structure of the EAAPE.

Initially, the suggestions from the experts were accepted and the items were modified. In the second stage, the changes were validated. It is worth noting that regarding item 1, it was decided to maintain the term “monitored”, as it is understood that the use of the term surveillance would be the most appropriate in this context, as it encompasses a broader meaning than monitoring or observation.

It is important to highlight that the use of valid instruments can be an additional strategy in health surveillance in the field of patient safety, minimizing failures, preventing adverse events and, thus, reducing patient morbidity and mortality⁽¹⁰⁾.

In view of the results of this study, stands out the importance of following the recommendations regarding the development and evaluation of appropriate instrument testing techniques and practices, as instruments without strong evidence of validity may negatively impact clinical practice or for whatever its purpose, since its measurement, as well as the interpreted results, can compromise decision-making based on its applications^(11,29,30).

It is important to emphasize that there was no need to remove or add items to the instrument, and adjustments were made to the writing of items where issues were identified. Writing the items is one of the most important stages in the instrument development process, as they can affect the understanding of the question and the responses of participants^(20,31).

Regarding the sampling of the cognitive test, the recommendations of the international literature were met⁽¹⁵⁾, and the Brazilian version of the EAAPE was well understood by all participants, guaranteeing the applicability of its final version in Brazilian Portuguese in its target audience.

The concerning estimates regarding occurrence of unsafe care processes in healthcare services, and their respective repercussions for patients, reinforce the need to broaden the discussion on the topic and the adoption of safer nursing practices^(4,5,32,33).

To address the frequency and magnitude of this issue, investments, resources and practices aimed at disseminating a safety culture in healthcare services must be guaranteed. In addition to normative issues, the construction of a safety culture as a structural component of healthcare services should favor the implementation of safe practices that aim to improve organizational processes to improve the quality of service and reduce the incidence of adverse events, and promote continuous improvements that will result in better outcomes^(26,34).

At the end of the cross-cultural adaptation process, it is possible to verify an instrument linguistically equivalent to the original version, ensuring strong evidence that all theoretical content has been accurately expressed in the use of the tool.

Considering that conducting the cognitive testing stage in only one scenario limits cultural variability in countries like Brazil, it is essential to recognize that the diversity of units may have the potential to capture different perceptions about the phenomenon evaluated, in order to represent the Brazilian population in the study, ensuring the integrity of the instrument evaluated.

This limitation can be overcome in a future stage by expanding the sample of participants, independent variables, such as region of residence/work, gender, time working in the profession, levels of qualification, type of institution and employment relationships, among others. Thus, it will be possible to analyze the evidence of validity of the internal structure and relationship with other variables, which can more reliably determine the elements that interfere in the perception of the phenomenon evaluated, as well as its application in the nursing practice in Brazilian hospitals.

CONCLUSION

At the end of the cross-cultural adaptation process, the questionnaire “Adverse Events Associated with Nursing Practices (EAAPE)” was obtained, adapted to Brazilian Portuguese, maintaining the semantic, idiomatic, conceptual, and experimental equivalences, according to the original version. Regarding content validity, the evidence presented was considered satisfactory and ensures clear, relevant and pertinent content to the Brazilian context, confirming its easy understanding by the target audience to which it was applied.

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