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Cross-cultural adaptation, validation and reliability of the Medication Safety Thermometer tool for use in Brazil

Adaptação transcultural, validação e confiabilidade da ferramenta Medication Safety Thermometer para uso no Brasil

Adaptación transcultural, validez y confiabilidad de la herramienta Medication Safety Thermometer para uso en Brasil

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ABSTRACT

Objectives: to perform cross-cultural adaptation, face and content validation and reliability analysis of the Medication Safety Thermometer tool for use in Brazil. **Methods:** the process of cross-cultural adaptation and validation followed the stages of translation, synthesis of translations, back-translation, content validation performed by experts, and face validation through pre-testing. Reliability was determined by calculating the Kappa coefficient. **Results:** the two translated versions were synthesized into a single version, which was back-translated and showed no divergences. The expert committee judged the adapted tool as equivalent, reaching a Content Validity Index higher than 0.8. The mean global understanding was 1.82, demonstrating face validity. The assessed items had Kappa coefficient greater than 0.61, showing agreement between observers. **Conclusions:** the cross-cultural adaptation of the tool was performed following an established methodology. The adapted tool showed inter-rater reliability and validity for use in Brazil.

Descriptors: Medication Errors; Validation Study; Core Health Indicators; Patient Safety; Translation.

RESUMO

Objetivos: realizar adaptação transcultural, validação de face e conteúdo e análise da confiabilidade da ferramenta *Medication Safety Thermometer* para uso no Brasil. **Métodos:** o processo de adaptação transcultural e validação seguiu as etapas de tradução, síntese das traduções, retrotradução, validação de conteúdo realizada por especialistas e validação de face mediante o pré-teste. A confiabilidade foi determinada pelo cálculo do coeficiente de Kappa. **Resultados:** as duas versões traduzidas foram sintetizadas em uma única versão, que foi retrotraduzida e não demonstrou divergências. O comitê de experts julgou a ferramenta adaptada como equivalente, alcançando Índice de Validade de Conteúdo maior que 0,8. A média de compreensão global foi de 1,82, demonstrando validade de face. Os itens avaliados apresentaram coeficiente de Kappa maior que 0,61, evidenciando concordância entre observadores. **Conclusões:** a adaptação transcultural da ferramenta foi realizada seguindo metodologia estabelecida. A ferramenta adaptada mostrou confiabilidade entre observadores e validade para utilização no Brasil.

Descritores: Erros de Medicação; Estudo de Validação; Indicadores Básicos de Saúde; Segurança do Paciente; Tradução.

RESUMEN

Objetivos: realizar adaptación transcultural, validez facial y contenido y análisis de confiabilidad de la herramienta *Medication Safety Thermometer* para uso en Brasil. **Métodos:** el proceso de adaptación transcultural y validez siguió las etapas de traducción, síntesis de las traducciones, retro-traducción, validez de contenido realizada por especialistas *y* validez facial mediante el pretest. La confiabilidad fue determinada por el cálculo del coeficiente de Kappa. **Resultados:** las dos versiones traducidas fueron sintetizadas en una única versión, que fue retro-traducida y no demostró divergencias. El comité de expertos juzgó la herramienta adaptada como equivalente, alcanzando Índice de Validez de Contenido mayor que 0,8. La mediana de comprensión global fue de 1,82, demostrando validez facial. Los ítems evaluados presentaron coeficiente de Kappa mayor que 0,61, evidenciando concordancia entre observadores. **Conclusiones:** la adaptación transcultural de la herramienta fue realizada siguiendo metodología establecida. La herramienta adaptada mostró confiabilidad entre observadores y validez para utilización en Brasil.

Descriptores: Errores de Medicación; Estudio de Validación; Indicadores de Salud; Seguridad del Paciente; Traducción.

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INTRODUCTION

About 10% of patients suffer harm from health care. Among them, 18.3% are related to medication errors[1], and these are the greatest cause of preventable harm to patients[2-3]. The safe use of medicines is an important aspect of health care worldwide. This issue was highlighted by the World Health Organization (WHO) in 2017 through the declaration of the Third Patient Safety Challenge, which aims to reduce serious and preventable medication-related harms by 50% by 2022. To this end, it is essential to assess the nature and scope of preventable harm and strengthen monitoring systems for detection and tracking[4].

Voluntary incident reporting forms the database of medication safety in most institutions. These reports are important for learning, however, because it is a voluntary process, involving the exposure of the professional, this practice does not represent the real magnitude of the problem, detecting only a small fraction of the adverse events (AE), from 10% to 32%[5].

The use of the Global Trigger Tool (GTT) has emerged as the method of choice for measuring AEs in health care settings. However, because it is a retrospective technique, it limits immediate improvement interventions, is time consuming, requires a trained team skilled in identifying AEs; and results depend on the quality of information available[6]. In addition to these weaknesses, Silva et al. in a prospective study including 300 patients reported low accuracy of the GTT in detecting AE and suggest the need to adopt combined strategies to improve the effectiveness of the tool[7].

Measuring harm from medication-related errors is complex and requires steps to measure individual errors, signs of harm, and actual harm. In order to overcome these measurement difficulties, the National Health Service (NHS) in England created the Medication Safety Thermometer (MedST) tool in 2013, focusing on "measuring to improve". Through structured data collection in three stages, it is possible to measure process and outcome indicators, as well as determine the instantaneous prevalence of harm over time caused by potentially dangerous medications (anticoagulants, opioids, injectable sedatives, and insulin) and evaluate the impact of interventions aimed at improving the proportion of patients free of harm caused by medication-related AEs[8].

The need to reduce serious and avoidable drug-related harm, to measure and monitor the impact of improvement actions on medication safety and patient safety, and the lack of validated tools available in Brazil for this purpose, motivated this study.

OBJECTIVES

To perform the cross-cultural adaptation, face and content validation, and inter-rater reliability analysis of the Medication Safety Thermometer tool for use in Brazil.

METHODS

Ethical aspects

The process of cross-cultural adaptation of the tool was authorized by the authors. The study was conducted in accordance with Resolution 466/2012, referring to research involving human beings, and was approved by the Research Ethics Committees of the participating institutions. The professionals included in the study had the right to participate or not and to withdraw at any time, having signed the Free and Informed Consent Term (FICT).

Study design, time and place

Methodological type study for cross-cultural adaptation according to methodology described by Beaton et al[9]. The tool was validated at the content and face levels. These stages of the research were conducted in a public hospital and a private hospital, both located in Porto Alegre, state of Rio Grande do Sul (RS), during the period from January to April 2020. In the period from December 2020 to February 2021, the tool reliability analysis was conducted, with data collection in a private hospital in Porto Alegre.

Population, inclusion and exclusion criteria

For the pre-test stage, 35 healthcare professionals were selected by convenience. For the reliability analysis, two healthcare professionals were the evaluators. Inclusion criteria were: having graduated in Nursing or Pharmacy, and working in the institution for more than six months. Professionals who, at the time of the survey, were on vacation, maternity or medical leave were excluded. To analyze the tool's reliability, we included patients over 18 years old and hospitalized in the institution for more than 24 hours. Patients whose medical records were not available for consultation at the time of collection were excluded from the sample.

Study protocol

In the cross-cultural adaptation process, the following steps were performed: translation into Portuguese, overview of the translations, back-translation, evaluation by the expert committee, pre-test, and submission to the authors.

Translation into Portuguese

The tool was translated into Portuguese, independently, by two bilingual translators, both Brazilians and native speakers of the foreign language. Initially, each translator received a document with guidelines for the translation, including the need to record in a report the critical points identified in the translation; and the description of how the decision making process was carried out in these situations. In this phase, each translator produced a translation, resulting in documents T1 and T2.

Overview of translations

The researchers of the study unified the translations from the previous step (T1 and T2) into just one version (T1-2), considering the two versions of the translation, the original tool and the translators' critical point reports. The divergences were detailed in a report.

Back-translation

The third stage of this study comprised the back translation of the synthesized version (T1-2) into the original language of the tool. This step was carried out independently, by two bilingual translators, native of MedST's country of origin (United Kingdom), with no knowledge of the original version of the tool. This phase aimed to evaluate whether the translated versions maintained the same content as the original version and resulted in two back-translation documents (RT1 and RT2) and a critical points report from each of the translators.

Evaluation by the expert committee

This stage of the CTA process aimed to achieve cross-cultural equivalence and content validation of the tool through the evaluation of the equivalences by a committee of experts. The committee was composed of seven people, being health professionals and translators who participated in the previous stages. The group was composed of inter-professionals (pharmacists, physicians, nurses and bachelor's degree in literature and in English); they were residents in the South, Southeast and Center-West regions of the country. The experts evaluated all questions, using a Likert scale, in equivalence level in the following aspects: semantic, cultural idiomatic and conceptual. According to their expertise, each professional on the committee evaluated the tool individually and independently, corresponding to the qualitative analysis of this stage. The quantitative evaluation was done by calculating the Content Validity Index (CVI) for each of the items evaluated by each expert, in order to determine the tool's content validity. The work resulting from the work of the committee of experts was the elaboration of the pre-final version of the tool.

Pretest step

The objective was to perform the face validation of the pre-final version of the tool, to assess the verbal understanding of each of the items of this version by the target population of the tool. This step was performed in two hospitals, one public and one private, and the choice of institutions with different care profiles aimed to validate the tool in different settings and health contexts.

Thirty-five invited healthcare professionals participated in the pre-test stage[9]. Those who accepted and signed the FICT were given a form containing the tool, a three-point Likert scale to express understanding on each question, and a space for suggestions to improve understanding.

Submission to the authors

In the final stage, all the reports developed during the CTA process were submitted to the authors of the tool, showing that the process was carried out with methodological rigor and that the tool is adapted for use in another context.

Tool validation

The process of CTA and validation of the tool was carried out following the methodological rigor described by the authors on which this study was based[9-10]. The content validation of the tool was performed by means of qualitative and quantitative analysis of the experts' evaluations. The face validation, which evaluated the verbal understanding of each of the tool's items, was performed through the pre-test of the final version by the target population.

Reliability

Inter-observer reliability was evaluated by calculating the Kappa coefficient, which considered the responses issued for 90 patients by two raters, who filled out the tool simultaneously and without communicating. The Kappa coefficient measures the degree of agreement of the evaluations made by several evaluators for the same samples[11].

Analysis of results and statistics

The data resulting from the expert committee evaluation were compiled in Microsoft Excel®, version 2016 software. The quantitative analysis of the content validation was performed using the CVI. This method measures the proportion of judges in agreement about the items of a tool - this index is calculated for each of the items evaluated, following the formula:

$$CVI = \frac{\text{Number of experts with equivalent category score}}{\text{Total number of experts}}$$

For an item to be considered equivalent (score +1) by the expert, it was necessary to achieve semantic, idiomatic, cultural and conceptual equivalence. In situations where the item was considered not very equivalent (score 0) or not equivalent (score -1), the expert suggested adjustments to make it equivalent. In CTA studies in which the expert committee is composed of six or more experts, the recommended CVI for each of the items should not be less than 0.78. However, to verify the validity of new tools in general, a minimum agreement of 0.80 is recommended - the value adopted in this study[10].

The results of the face validation were compiled in Microsoft Excel®, version 2016 software. To analyze the understanding of the items, a three-point Likert scale was used: 0 = not understandable; 1 = not very understandable; and 2 = understandable. The analysis was performed by summing the points, mean and standard deviation for each of the items of the tool; and, at the end, the overall mean of understanding of all questions was calculated.

To calculate the Kappa coefficient, the answers obtained by the evaluators in each question were considered, in order to assess the agreement of evaluator 1 with the answers of evaluator 2 in each of the items assessed in the questionnaire. The database was unified so that the responses of the two evaluators for each patient were in the same database, and so that a comparison between the responses could be made. The coefficient was calculated using SPSS 20 software, and the reference values and interpretation of the measure were: 0 = poor; 0 to 0.20 = weak; 0.21 to 0.40 = likely; 0.41 to 0.60 = moderate; 0.61 to 0.80 = substantial; and 0.81 to 1.00 = almost perfect[11].

RESULTS

Initial translation steps, translation overview, and back translation

Two translators participated in the translation stage, one being a professor of English with extensive experience in research, teaching and health measurement tools, and who was informed about the objective of the research and of the tool. The second translator had experience with translations and participated in this step not knowing the tool and the research objective.

The divergences found during the synthesis of the translations were discussed and solved by consensus based on theoretical reference and considering the Brazilian hospital reality. Among the discussion points, the use of the term "medication management technician" was highlighted, which does not exist in Brazil, as well as the translation of the term trigger for trigger, which were considered in the synthesis phase for further debate with the expert committee. In this phase, the commercialization records in Brazil of the drugs cited in the tool were reviewed; the abbreviations were described in full in order to facilitate understanding; and the measurement units were reviewed and adapted to our context. In the back translation stage, no relevant disagreements with the original tool were observed.

Evaluation of equivalencies by the expert committee

The evaluation of the equivalences by the committee of experts comprised the content validation of the tool. The experts who made up the expert committee were chosen and invited to participate in the research. The group was composed of professionals with expertise in quality management, patient safety, safe use of medicines, adult health, epidemiology, research methodology, letters, teaching and hospital and clinical pharmacy; with a long trajectory in patient safety and safe use of medicines; and linked to committees, institutes and renowned societies in the area and involved in national discussions about improving health care, being considered qualified to adapt the tool to the Brazilian context. At this stage, of the 38 items of the tool evaluated by the committee, 20 were considered equivalent, with CVI ≥ 0.80. After compiling the experts' suggestions, the critical points and the items that did not reach equivalence were debated with the committee members by means of a videoconference, in order to resolve the discrepancies raised in this first phase. After discussion and consensus, the 18 items that did not reach equivalence were modified and sent again for the committee's analysis. Subsequently, all items evaluated presented CVI ≥ 0.80, being considered equivalent.

Evaluation of verbal comprehension of the tool by health professionals

Evaluation of verbal comprehension of the tool by health professionals comprised the face validation of the tool. The pre-final version of the tool was evaluated in terms of understanding by 35 professionals, 16 pharmacists and 19 nurses, working in inpatient units, emergency, intensive care units, operating room, care risk management, dispensing pharmacy and clinical pharmacy of two hospitals in Porto Alegre. The professionals included in the sample had a mean time working in the health area of 12 years; 85.7% (30/35) of them had post-graduation/specialization; and 37% (13/35) had master degree. Of the 35 professionals, 11 worked in the teaching field in addition to their care work.

The overall average verbal comprehension, considering all items of the version of the tool submitted to the pre-test, was 1.82 (maximum = 2.0). The average verbal comprehension scores for each of the items are described in Table 1.

Table 1 – Evaluation of verbal comprehension of the Medication Use Safety Thermometer, Porto Alegre, Rio Grande do Sul, Brazil, 2020

Item	Mean (Standard deviation)	Item	Mean (Standard deviation)
1	1.74 (0.41)	20	1.97 (0.06)
2	1.91 (0.16)	21	1.91 (0.16)
3	1.12 (0.73)	22	1.94 (0.11)
4	1.80 (0.35)	23	1.77 (0.38)
5	1.89 (0.20)	24	1.94 (0.11)
6	1.97 (0.06)	25	1.77 (0.38)
7	2.00 (0.00)	26	1.94 (0.11)
8	1.63 (0.49)	27	1.91 (0.16)
9	1.57 (0.54)	28	1.89 (0.20)
10	1.60 (0.53)	29	2.00 (0.00)
11	1.63 (0.47)	30	1.94 (0.11)
12	1.71 (0.42)	31	1.89 (0.21)
13	1.71 (0.42)	32	1.83 (0.29)
14	1.94 (0.11)	33	1.83 (0.29)
15	1.89 (0.20)	34	1.83 (0.29)
16	1.69 (0.43)	35	1.85 (0.26)
17	1.77 (0.35)	36	1.97 (0.06)
18	1.77 (0.35)	37	1.74 (0.38)
19	1.77 (0.35)	38	1.97 (0.06)

Submission to authors

The authors considered that the CTA process was carried out following all recommended steps, and the documentation reflects this process. Therefore, the conclusions were: cross-cultural adaptation was achieved; and the tool has psychometric properties suitable for use in Brazil.

Reliability

Inter-observer reliability was evaluated by calculating the Kappa coefficient for each of the instrument's variables, as described in Table 2.

Table 2 – Kappa coefficient calculated simultaneously for two raters (90 patients), Porto Alegre, Rio Grande do Sul, Brazil, 2021

Variable	Kappa Coefficient
Question 6	0.739
Question 7	0.955
Question 8	0.924
Question 9	0.961
Question 10	0.909
Question 11	0.986
Question 17	1
Question 18	0.662
Question 21	0.662
Question 22	0.656

In the previous table, it is possible to see that all variables of the tool showed at least substantial strength of agreement between the two raters. Questions 7, 8, 9, 10, 11 and 17 reached Kappa coefficient values between 0.81 and 1.0, reaching almost perfect agreement, concluding that these items are easy to understand and their operational definitions are well established. Questions 6, 18, 21, and 22 showed Kappa coefficient values between 0.61 and 0.80, denoting substantial agreement. Although discrepancies were found between raters on these items, the coefficient continues to show high magnitude. For questions 12, 13, 14, 15, 16, 19, and 20, it was not possible to obtain the Kappa coefficient, because at least one rater presented constant answers, without variations. For these items, the percentage of agreement between the two raters was calculated, which ranged between 98.9% and 100%, demonstrating the agreement between observers.

The final version of the tool, adapted and validated, is shown in Chart 1.

Chart 1 – Final version of the "Medication Use Safety Thermometer" tool, Porto Alegre, Rio Grande do Sul, Brazil, 2021

Medication Use Safety Thermometer - Data Collection Form			
SECTION 1 - Completion to be performed by nurses or pharmacists with information gathered from the patient's medical record, prescription, talking with the patient/caregiver and the care team. Section to be completed for ALL patients evaluated.			
Patient record number:			
Sector (unit) in which the patient is hospitalized at the time of the evaluation:			
1.1 Sex	( ) Female ( ) Male ( ) Other	**1.2 Age**	( ) Less than 18 ( ) 18-24 ( ) 25-44 ( ) 45-59 ( ) 60-79 ( ) 80 or more
1.3 Are there any reports of drug allergies described in the patient's chart? (including no known allergies)		( ) Yes ( ) No	
1.4 Was medication reconciliation[1] performed by the pharmacist within the first 24 hours of the patient's admission to this sector? *[1] Obtaining a complete and accurate list of the patient's usual medication use and then comparing it with the prescription at all transitions of care.*		( ) Yes ( ) No ( ) No – The patient is still within the 24-hour period at the time of evaluation	
1.5 How many drugs are prescribed for the patient in the current prescription? *Exclude "as needed", "at the physician's discretion" medications, attack doses, oxygen, dietary supplements, parenteral and enteral nutrition. Different doses of the same medication count as one medication.*		( ) 0 ( ) 1 to 4 ( ) 5 to 9 ( ) 10 to 15 ( ) 16 to 20 ( ) More than 20	

1.6a Check below which medications are prescribed for the patient: 1.6b If any of these prescribed medications have not been administered in the last 24 hours, check the reason (if so, check more than one reason):		**Reasons for omission**							
		Way not availabe	Patient refuseed	Absence of medication reconciliation	Medication unavailable	Valid clinical justification	Patient absent at the moment of administration	Motive not identified	Others
	Anticoagulant								
	Opioids								
	Insulin								
	Anti-infectives (antibiotics, antifungals, antivirals, and antimalarials)								
	Any other prescribed medications								

To be continued

Chart 1

Medication Use Safety Thermometer - Data Collection Form		
1.7 Has the patient received any of the following medications in the last 24 hours?	( ) Anticoagulants: heparin, low molecular weight heparin, warfarin, and direct oral anticoagulants (dabigatran, apixaban, rivaroxaban)	( ) Opioids
	( ) Intravenous or subcutaneous sedatives: midazolam, diazepam, propofol, fentanyl	( ) Insulin

If the answer is YES to question 1.7, proceed to Section 2. If the answer is NO, then you have finished filling out this form.

SECTION 2 - Only complete Section 2 if the patient has received any of the following medications: anticoagulant, opioid, intravenous or subcutaneous sedative, and/or insulin in the past 24 hours, as answered in question 1.7. Only answer questions related to the medication(s) received by the patient. The information can be collected by nurses or pharmacists.

2.1 Anticoagulants (heparin, low molecular weight heparin, warfarin, and direct oral anticoagulants)
Signal of Damage Investigation:

Did the patient present any kind of damage? ( ) Yes, bleeding ( ) Yes, venous thromboembolism ( ) No	Has the patient received administration of vitamin K, protamine, or clotting factors? ( ) Yes ( ) No	Does the patient have an International Normalized Ratio (INR) greater than 6 or an Activated Partial Thromboplastin Time (APTT) greater than 40 seconds? ( ) Yes, INR greater than 6 ( ) Yes, APTT greater than 40 seconds ( ) No

2.2 Opioids
Signal of Damage Investigation:

Has the patient received naloxone administration? ( ) Yes ( ) No	Is the patient's respiratory rate below 8 breaths per minute (rpm)? ( ) Yes ( ) No

2.3 Injectable sedatives (midazolam, diazepam, propofol, fentanyl)
Signal of Damage Investigation:

Did the patient receive administration of the reversal agent flumazenil? ( ) Yes ( ) No	Did the patient have common complications related to excessive sedation that included hypotension, delirium, respiratory depression, reduced Glasgow scale? ( ) Yes ( ) No

2.4 Insulin
Signal of Damage Investigation:

Does the patient have capillary blood glucose (< 70 mg/dL) or symptoms of hypoglycemia (anxiety, confusion, extreme hunger, fatigue, irritability, sweating, clammy skin, or hand tremors)? ( ) Yes, capillary blood glucose < 70 mg/dL ( ) Yes, symptoms of hypoglycemia ( ) No	Is the patient in diabetic ketoacidosis (DKA - a serious complication of diabetes that occurs when the body produces too many ketones) or hyperglycemic hyperosmolar state (HSS - a situation of severe hyperglycemia, increased plasma osmolality, and dehydration)? ( ) Yes, diabetic ketoacidosis ( ) Yes, hyperglycemic hyperosmolar state ( ) No	Did the patient receive administration of a reversal agent for hypoglycemia (glucose 10%-50% or intravenous glucagon 1 mg)? ( ) Yes ( ) No

If one of the answers was YES in Section 2, indicating a sign of harm, discuss the issue in an inter-professional meeting and decide on the level of harm, based on the World Health Organization's International Classification of Patient Safety. This meeting should include (at least) one nurse, one pharmacist and one physician.

SECTION 3 – Inter-professional meeting

Definitions of harm according to the International Classification of Patient Safety

No damage	When the patient has no symptoms and needs no intervention.
Light damage	Patient had mild symptoms, minimal or intermediate short-term damage without intervention or with minimal intervention (little treatment or observation).
Moderate damage	Patient required intervention (e.g., supplemental procedure or additional therapy), prolonged hospitalization, loss of function, permanent or long-term damage.
Severe damage	Patient required life-saving intervention, major medical/surgical intervention or major permanent or long-term damage, fetal disturbance/risk or congenital anomaly.
Death	When the adverse event causes patient death.

To be continued

Chart 1 (concluded)

Medication Use Safety Thermometer - Data Collection Form		
Interprofessional meeting - Professionals involved		
1. Name:	Role:	Involved in patient care? Y/N
2. Name:	Role:	Involved in patient care? Y/N
3. Name:	Role:	Involved in patient care? Y/N
4. Name:	Role:	Involved in patient care? Y/N
5. Name:	Role:	Involved in patient care? Y/N
Based on the outcome of the inter-professional meeting, describe the level of harm identified.		
Anticoagulants √		Learning after the inter-professional discussion:
No damage		
Light damage		
Moderate Damage		
Severe Damage		
Death		
Opioids √		Learning after the inter-professional discussion:
No damage		
Light damage		
Moderate Damage		
Severe Damage		
Death		
Injectable sedatives √		Learning after the inter-professional discussion:
No damage		
Light damage		
Moderate Damage		
Severe Damage		
Death		
Insulin √		Learning after the inter-professional discussion:
No damage		
Light damage		
Moderate Damage		
Severe Damage		
Death		
Outcome of the inter-professional meeting:		( ) Referral to the Superior Inter-professional Team meeting ( ) Incident Report Finalized Incident Report No. (if applicable)
General remarks:		

DISCUSSION

Among the changes made in the evaluation stage by the expert committee, the name of the tool, initially translated as "Medicine Safety Thermometer", was changed to "Medicine Use Safety Thermometer", because the medication chain is extensive, and the tool assesses safety only in the use process. The substitution of the term "pharmacy team" for "pharmacist", in item 1.4, was done, because the medication reconciliation process is an attribution of the pharmacist only. The function "technician in medication management" does not exist in Brazil; therefore, it was removed from the form. In item 2.4, the measurement unit of capillary blood glucose was converted to the usual Brazilian measurement (mg/dL). The English term "trigger", described throughout the tool, was translated literally as "*gatilho*". In the literature, it has been observed that most studies use the term

"trigger" to refer to a sign of an adverse event. In discussion with members of the expert committee of this research, several translation options were considered, such as signaler, tracker, trigger, and, based on the suggestion of a professional on the committee who has expertise in vocabulary and language, it was decided to use the term "*sinal*" (signal).

The appropriateness of the term "multidisciplinary" was discussed throughout the CTA process. In our country, the terms "multidisciplinary", "multi-professional", "interdisciplinary" and "inter-professional" are used as synonyms, making consensus difficult. According to the literature[12] and what is used by the World Health Organization, the most recent and correct term is "inter-professional", referring to the involvement of two or more professions or professional activities with a view to collaboration. In the initial evaluation of the expert committee, the translation from "multidisciplinary" to "inter-professional" did not meet the recommended CVI. After discussion of this point with the experts and presentation of evidence, the term was accepted and achieved CVI > 0.8, and this term was adopted[13]. The original tool employed the National Patient Safety Agency risk assessment scale for level of harm classification. The classification terms and definitions were adapted considering the nomenclature and definitions used in Brazil[14].

After the pre-test stage, some items were adjusted in view of the suggestions of the target population in order to make the tool more understandable and in accordance with the Brazilian context. Among the changes, the term "care professionals" was replaced by "pharmacists and nurses". The justification for this change lies in the fact that, in Brazil, these are the professionals involved in the activities of collecting information on safety in the use of medicines. The item related to "control number" showed the lowest average degree of verbal understanding by the target population, who did not understand what the information to be filled in this item was. Since in Brazil all patients have a medical chart/registration number, it was understood that through this information it is possible to identify the patient, so the term was adjusted. Regarding the gender identification, the option "Other" was included in order to contemplate patients who did not identify themselves with the existing alternatives. The age range 60-74 years was extended to 60-79 years aiming to include, in only one range, the longevous (80 years or more), allowing the monitoring of these patients who have multiple comorbidities and polypharmacy, factors that contribute to the occurrence of AEs[15].

Five of the 19 nurses who participated in the pre-test questioned the meaning of the term "reconciliation". In order to make the item clear, the concept of the term was described and adjusted to "conciliation", according to the denomination used in Brazil[16]. In the original version of the tool, to fill in item 1.5, related to the number of drugs prescribed to the patient, "intravenous therapy" was excluded. Knowing that the intravenous administration of drugs can cause AEs[17-19], it was decided not to exclude from the count the drugs administered by this route. The injectable sedatives lorazepam and clonazepam were excluded from item 2.3, since they were not registered for marketing in Brazil; and the drugs propofol and fentanyl were included. The term "dextrose", described in item 2.4, was replaced by "glucose"; and, for the adapted version of the tool, it was opted to classify the damage according to the National Health Surveillance Agency[20].

Study limitations

The impossibility of assessing the criterion validity of the tool in question is considered a limitation of this study, due to the inexistence of an instrument considered the gold standard in Brazil for measuring the variable studied.

Contributions to the field of nursing, health or public policy

The cross-cultural adaptation, validation and analysis of the reliability of this tool for use in Brazil allow measuring the panorama of AEs related to medications in our country. By measuring it, it becomes possible to identify the main offenders linked to AEs, which can direct improvement actions in institutions, seeking continuous improvement, increased quality of care and patient safety.

CONCLUSIONS

The Medication Safety Thermometer was cross-culturally adapted for use in Brazil. We performed content validation, face validation, and inter-rater reliability analysis of the cross-culturally adapted tool. It can be used in hospitals to measure indicators related to the safe use of medicines in these institutions.

SUPPLEMENTARY MATERIAL

Manuscript resulting from Thesis. Garzella, Priscila Martini Bernardi. Cross-cultural adaptation and validation of the Medication Safety Thermometer tool for use in Brazil. Postgraduate Program in Pharmaceutical Sciences, Federal University of Rio Grande do Sul. [Internet]. 2021. Available from: https://lume.ufrgs.br/handle/10183/230375

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