

Translation to Brazilian Portuguese and cultural adaptation of a questionnaire addressing high-alert medications

Tradução para português do Brasil e adaptação cultural de um questionário sobre medicamentos potencialmente perigosos

Traducción para el portugués de Brasil y adaptación cultural de un cuestionario sobre los medicamentos potencialmente peligrosos

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ABSTRACT

Objective: To describe the translation into Portuguese and cultural adaptation of a Questionnaire addressing High-Alert Medications to the Brazilian context.

Methods: Methodological study comprising the translation from Chinese to Brazilian Portuguese, synthesis of translations, back translation, panel of experts, and pretest to obtain the final version of the questionnaire.

Results: <inor lexical variations were resolved after obtaining consensus between the translators. The panel of experts concluded that the Portuguese version presented semantic, idiomatic, cultural and conceptual equivalence, though 50% of the items required adjustment. Thirty nurses from a teaching hospital participated in the pretest and considered the items to be understandable.

Conclusions: Satisfactory semantic, idiomatic, cultural and conceptual equivalence was obtained between the versions. The Portuguese version was also considered to be relevant to the Brazilian culture and easily understood. Nevertheless, its psychometric properties need to be assessed before making it available.

Keywords: Translating. Nursing. Patient safety. Medication errors.

RESUMO

Objetivo: Descrever os processos de tradução para a língua portuguesa e adaptação cultural do *Questionário de Medicamentos Potencialmente Perigosos* para o contexto brasileiro.

Métodos: Estudo metodológico compreendendo as etapas de tradução do chinês para o português brasileiro, síntese das traduções, retrotradução para a língua de origem, comitê de juízes e pré-teste, procedendo à versão final do questionário.

Resultados: No processo de tradução, variações vocabulares mínimas foram solucionadas após consenso entre os tradutores. O comitê de juízes considerou que a versão traduzida para o português apresentou equivalência semântica, idiomática, cultural e conceitual, mas 50% dos itens necessitaram de ajustes. No pré-teste 30 enfermeiros de um hospital de ensino avaliaram os itens como compreensíveis.

Conclusões: Houve equivalência semântica, idiomática, cultural e conceitual satisfatória entre as versões do questionário, o qual é pertinente à cultura brasileira e facilmente compreensível. Entretanto, para que se disponibilize o questionário adaptado, faz-se imprescindível avaliar suas propriedades psicométricas.

Palavras-chave: Tradução. Enfermagem. Segurança do paciente. Erros de medicação.

RESUMEN

Objetivo: Describir el proceso de traducción al portugués y adaptación cultural del Cuestionario de Medicamentos Potencialmente Peligrosos para el contexto brasileño.

Métodos: Estudio metodológico que abarca las etapas de traducción del chino al portugués de Brasil, síntesis de las traducciones, traducción a la lengua de origen, comité de expertos y prueba previa, procediéndose a la versión final del cuestionario.

Resultados: En el proceso de traducción, variaciones mínimas de vocabulario se resolvieron después del consenso entre los traductores. El comité de expertos llegó a la conclusión de que la versión traducida al portugués mostró equivalencia semántica, idiomática, cultural y conceptual, pero el 50% de los ítems demostró la necesidad de ajustes. En la prueba previa, 30 enfermeros de un hospital escuela evaluaron los ítems como comprensibles.

Conclusiones: Hubo equivalencia semántica, idiomática, cultural y conceptual satisfactorias entre las versiones del cuestionario, el cual es pertinente a la cultura brasileña y de fácil comprensión. Sin embargo, a fin de poner a disposición el cuestionario adaptado, es esencial evaluar sus propiedades psicométricas.

Palabras clave: Traducción. Enfermería. Seguridad del paciente. Errores de medicación.

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■ INTRODUCTION

Approximately 20 medications are known for their increased risk of significantly harming or even causing death if inappropriately used, accounting for 80% of deaths due to administration errors, which compromises patient safety. Due to the occurrence of errors in the administration of these components and consequent catastrophic clinical results, these drugs are identified as potentially dangerous drugs or high-alert medications, including antithrombotic, anti-diabetic, neuromuscular blocking, and anesthetic agents and agents for mild sedation, intravenous adrenergic agonists, intravenous beta-blockers, concentrated electrolytes, opioids, and chemotherapeutic agents, among others⁽¹⁻⁴⁾.

Therefore, it is essential to highlight the importance of high-alert medication lists to be used in hospital and outpatient settings worldwide. Note that such lists should be established in accordance with the context inherent to each health facility, considering that some therapeutic classes possess particularities, such as when all the drugs composing these classes can be classified as high-alert medications, while other classes include only one or some drugs considered to be high-alert medications in specific medication categories⁽³⁾.

Despite their increased potential risk, high-alert medications are components frequently used in hospital and outpatient facilities in the pharmacotherapy of various clinical conditions so that the establishment of continuing education provided to healthcare workers in combination with the implementation of a surveillance system is needed to prevent errors and harm caused by high-alert medications. Hence, high-alert medications should be a priority whenever a program designed to prevent medication errors is implemented⁽⁵⁻⁶⁾.

The improvement of the safety of medications has become one of healthcare workers' concerns, especially safety concerning high-alert medications. The level of knowledge of these professionals concerning how to avoid medication errors during processes involving high-alert medications is unclear. Observations and reports indicate that knowledge of this topic is often insufficient, hindering healthcare professionals from properly performing the administration of high-alert medications and related tasks⁽⁷⁾.

In the sphere of patient safety and quality of health-care workers' knowledge regarding medication-related processes, the issue of high-alert medications has received a remarkable contemporary approach after the National Program of Patient Safety was implemented⁽⁸⁾ and the Basic Protocols of Patient Safety were ratified, especially the

Prescription, Use and Drug Administration Safety Protocol in accordance with the publication of the Decree GM/MS No. 2.095/2013⁽⁹⁾.

In the context of nursing practice, the role of nursing professionals in preventing medication errors involving high-alert medications comprises the identification and communication of any errors and assessment of the performance of the nursing staff in promoting the safe administration and use of medications. In order to decrease administration errors, continuing education actions and the development of protocols concerning the preparation and administration of medication are crucial for the nursing staff to become aware of the risks posed when administering medication and recognize incompatibilities and specific attributes of pharmaceutical products, such as dosage, route of administration, dilution, storage, and adverse effects⁽¹⁰⁾.

In order to obtain an overview of the knowledge of nursing professionals and establish mechanisms for a future intervention, Chinese researchers⁽⁷⁾ developed and validated a questionnaire to measure the knowledge of Chinese nurses concerning high-alert medications.

Aware of the importance of adopting valid tools to measure workers' knowledge of high-alert medications in order to implement preventive measures to avoid adverse events related to these medications, this study's objective was to describe the translation of this questionnaire (titled in Portuguese: *Questionário de Medicamentos Potencialmente Perigosos*) to Portuguese and its cultural adaptation for the Brazilian context, verifying its applicability in the context of nurses by performing face and content validity analysis of the adapted version.

METHOD

This study originated from the thesis⁽¹¹⁾ "Patient safety and high-alert medications: cross-cultural adaptation of a questionnaire".

A bibliographical search on the topic concerning the knowledge of healthcare workers concerning high-alert medications identified a Chinese scientific paper reporting the development of an instrument to specifically measure the knowledge of nurses on high-alert medications⁽⁷⁾. Note that no other similar instruments were found and, for this reason, this Chinese questionnaire was selected for this study. Thus, after analyzing this scientific manuscript, the translation and cultural adaptation process of the questionnaire was initiated.

The Chinese self-reporting questionnaire is composed of 20 items with the following alternatives for answers:

"false", "true", and "I do not know," with a total score of 100 points; each correct answer is scored 5 points. The instrument is divided into two domains. The first is an assessment of nurses' knowledge of the clinical procedures related to the administration of these medications (10 items). This domain addresses the knowledge of nurses concerning particularities of medications, such as storage, prescription, dispensing, and administration of high-alert medications. The second domain comprises knowledge of nurses of clinical procedures concerning the administration of referenced drugs, especially routes of administration and dosages⁽⁷⁾.

The original instrument's validation process included face, content and construct validation. Additionally, the authors of the original version measured the instrument's internal consistency by using the reliability coefficient Kuder–Richardson Formula 20 (KR-20). Satisfactory reliability of $\alpha=0.74$ was achieved, which shows the scale is appropriate to be applied in the population of nurses under study(7). Note that the KR-20 coefficient is used to measure the reliability of instruments with dichotomous answers such as true or false, yes or no, agree or disagree(12).

This methodological study was based on the stages suggested by Beaton *et al.*⁽¹³⁾, whose methodological framework was adopted. It included translating the instrument into Portuguese, making a synthesis of translations, performing back translation, synthesis of back translations, assessment by a panel of experts, and pretesting. The cultural adaptation of a scale to be used in another country, different culture, or different language, requires a rigorous method because the instrument undergoes psychometric and validation tests after cultural adaptation⁽¹³⁾.

First, the original version was translated from Chinese into Brazilian Portuguese by two independent translators with proficiency in both languages. One of the translators, a professional in the health field and experienced in the translation of instruments, was aware of the study's objective and its underlying concepts, as well as having had clinical and therapeutic knowledge seeking to detect ambiguities and meanings of the original items. The other translator, not a professional from the health field, was not aware of the study's objectives, though also did have experience in the translation of instruments. At the end of this first stage we had two translated versions called T1 and T2.

The two translated versions (T1 and T2) were analyzed and compared so that a synthesis of translations was achieved. Both translations were compared and lexical variations found between versions were properly resolved through consultations between translators and researchers so that a single version called T12 was obtained by consensus.

Back translation was performed in the third stage of the translation and cultural adaptation process; that is, the synthesis of both versions (T-12) was translated back into the original language by two other bilingual translators with linguistic and cultural mastery of Chinese and Brazilian Portuguese. These professionals had not participated in the first translation process, as it was essential that they be unaware of the questionnaire's original version.

After this stage was concluded, two new versions of the questionnaire in Chinese were obtained, RT1 and RT2, and both were compared and divergences resolved through the reports of both translators to facilitate changes to be implemented in the Portuguese version (T-12). Considering that only one discrepancy regarding meaning was reported in the back translation and it was properly rectified, we concluded that the Portuguese synthesis version was appropriate to be sent to the panel of judges.

Intending to perform face and content validity and develop the pre-final version for pretest, we adopted a method based on the analysis of the T-12 version by a panel of five judges (two nurses, two pharmacologists, and one physician), who provide care, or teach and research or work in the field of patient safety and nursing, though they were not required to have proficiency in the Chinese language.

The number of five judges was established to minimize doubtful questions and avoid the risk of a tie⁽¹⁴⁾. The judges were selected by convenience from different regions of Brazil according to their availability and interest; they all signed free and informed consent forms. These experts received an instrument developed by the researchers in which they were supposed to report their assessment of each item of the questionnaire according to semantic, idiomatic, conceptual, and cultural equivalence and make suggestions whenever necessary. A minimum of 80% agreement among judges was necessary to accept and incorporate suggestions⁽¹⁴⁾.

The pretest was intended to verify whether the pre-final version could be easily answered and truly understood by the target audience, composed of 50 nurses from a university hospital in the interior of the state of São Paulo. This population was intentionally chosen; note that the literature recommends from 30 to 50 individuals be in a sample(13,15). These professionals were active in the care delivery field, agreed to sign free and informed consent forms, worked full time in the study setting for at least six months, with a workload of at least 36 weekly hours.

The participants received an envelop with the Portuguese version and an instrument to assess criteria including clarity of the redaction of items and relevance between the scale's items and the context of nurses working in

Brazil. At this same point in time, the researcher provided instruction on how the nurses were to properly fill in the questionnaire and the assessment instrument, establishing a maximum period of five days to return the questionnaire, properly answered and assessed. At the end of this stage, 20 nurses were excluded, as they did not answer at least 70% of the assessment instrument, resulting in a total of 30 valid responses. The assessment instruments completed by each of the respondents were analyzed to verify level of understanding and the need to change items.

The Statistical Package for the Social Science (SPSS), version 17.0, was used to compile and descriptively analyze data concerning the application of the questionnaire in the pretest.

After the pretest and after a final version was established, all the documents generated during all the stages of the translation and cultural adaptation process of the questionnaire to enable it to be used in Brazil were submitted to the authors of the original version.

The study was approved by the Institutional Review Board at the University of São Paulo at Ribeirão Preto on March 26th 2014 (No. CAAE 11835713.5.0000.5393).

RESULTS

No discrepancies in words or expressions were found during the translation process, though minor lexical variations were observed between the independent versions, which were clarified and resolved after discussion and consensus was obtained between the translators.

Over the cultural adaptation process, the only mandatory change occurred at the end of the back translation and concerned the need to conform alternatives for answers of the questionnaire's items after orientation provided by the authors of the original version. The answer options were translated in versions T1 and T2 as "agree", "disagree" and "I do not know" and were kept this way in the back translation. The authors, however, recommended replacing these words with "true", "false" and "I do not know;" the recommended change was implemented.

The panel of experts considered the Portuguese version to present semantic, idiomatic, cultural and conceptual equivalence, while 50% of the items (items 2, 4, 5 and 6, linked to the domain "Drug administration"; and items 1, 2, 6, 7, 8 and 10 from the domain "Clinical procedures") obtained a percentage of agreement lower than 80% among the judges (14) and required adjustments to be considered to have been successfully culturally adapted. All the suggestions were analyzed by the researchers and accepted, so that a pre-final version was obtained.

The main changes recommended by the judges for the items reported concerned medications that were mentioned as examples of some items and some concentrations. Suggestions to change the medications and concentrations were justified by the context of the practice of Brazilian nurses and standardization of medications existing in Brazilian health facilities. Hence, medications and concentration of medications of the items under study were replaced by those more frequently found in Brazilian health facilities, so that heparin was replaced by warfarin sodium, potassium chloride at 15% was replaced by potassium chloride at 19.1%, calcium chloride at 10% by calcium gluconate at 10%, and, finally, sodium chloride at 3% was replaced by sodium chloride at 20%.

In regard to the pre-test, it is important to highlight that the individuals were responding to an instrument with dichotomous answer options of the type "yes" or "no" in regard to clarity of redaction and relevance of items, in addition to the possibility of recommending changes. Therefore, considering aspects associated with the clarity and relevance of items, we could deduce that among the nurses participating, more than 90% understood most of the items, with the exception of item 1, which belonged to "Drug administration," in which case 70% of the individuals reported understanding the item, and items 1 and 7 of the "Clinical procedures" domain, in which 83.3% and 86.7%, respectively, of the participants reported understanding the items.

At this point, the changes suggested by the participants in the pretest were verified by the researchers, understanding that after implementing the changes proposed, there was no need to adapt items from a semantic point of view and they would be kept in the instrument, since the expected level of comprehension had been achieved. We observed, though, that only 36.7% of the participants who reported a lack of clarity and/or lack of relevance in at least one of the items presented their doubts or indicated what changes would be necessary to improve understanding of the instrument's content.

Hence, after the translation and cultural adaptation, a final version was obtained, which is presented in the Charts 1 and 2. Note that none of the original items were excluded in the adaptation process.

DISCUSSION

The method through which the translation and cultural adaptation of the questionnaire on high-alert medications was implemented was a rigorous process. This is an important fact, considering the purpose of this study is to develop

Final Portuguese version translated to English				
Questionnaire on high-alert medications				
I – Drug administration				
1. It is recommended to decrease the use of units of measures that represent the dose by posological unit or the total dose of medication to avoid administration errors, while it is better to use the term ampoule or bottle. For instance: Ampicillin 2 bottles.				
·	□True	False	☐ I do not know	
2. It is recommended to use U to replace the word unit in medical prescriptions to reduce administration errors. For instance: Insulin Regular 6U.				
	True	□ False	☐ I do not know	
3. Heparin and insulin are high-alert drugs very frequently used during hospitalization and both present concentration in units. Hence, they should be stored side by side to facilitate use. True False I do not know				
4. The medications shou concentrations 1 mg, 2.5	ıld present different concentrat		e. For instance: Warfarin sodium at	
5. Considering the safety of patients who need to replace potassium, it is preferable to administer potassium orally				
(tablet or solution) rather than through intravenous administration of potassium chloride.				
	□True	False	☐ I do not know	
	19.1% solution belongs to the nospitalization, an alert label sh □True		nowever, because it is a drug in an easily accessible location. I do not know	
7. The dosage of pediatric medications should be prescribed in tablespoons to avoid administration errors.				
	□True	☐ False	☐ I do not know	
8. Analgesic fentanyl transdermal patches, used in cancer patients, belong to the group of special control drugs and, therefore, their use need to be controlled and recorded.				
	□True	☐ False	☐ I do not know	
9. Neuromuscular blockers used during anesthesia or intubation, such as Atracurium, should be stored in easily accessible places for emergency use.				
	□True	☐ False	☐ I do not know	
10. Drugs with similar names should be differentiated on labels. For instance, DOBUTamine and DOPamine should be used on labels to show the two distinct medications.				
	True	False	☐ I do not know	

Chart 1 – Final version of the domain "Drug administration" of the questionnaire on high-alert medications after performing all the translation and cultural adaptation process stages. Ribeirão Preto, SP, Brazil, 2014.

Source: (11)

a reliable, new and useful instrument to be implemented in the context of Brazilian nursing.

With regard to the questionnaire's functional structure, we opted to retain its configuration and appearance according to the model proposed in the original version, since no difficulties or misunderstandings were observed in its completion on the part of nurses.

No important discrepancies were found between the two translations, even though some words and expres-

sions chosen by the translator with knowledge in the health field were more coherent with the language used by the population to which the questionnaire is directed, which made it more intelligible. In contrast, another study⁽¹⁶⁾ verified that certain words were better chosen by the professional expert in linguistics, considering the translation was more appropriate to the understanding of a lay population, which was the target audience of the instrument under study, in that case.

Final Portuguese version translated to English				
Questionnaire on high-alert medications				
II – Clinical procedures				
1. In cases of mild allergic reactions with the appearance of erythema, it is necessary to rapidly administer intravenously 1 ampoule of 1 mL of epinephrine 1:1000 solution.				
True	☐ False	☐ I do not know		
2. In emergency situations, 10 mL of Calcium (□True	Gluconate at 10% can be ra □ False	pidly administered, within 1 to 2 minutes. □ I do not know		
3. Calcium gluconate at 10% and Calcium Chloride at 10%, even though produced by different manufacturers, correspond to the same drug and have the same concentration, therefore one can replace the other.				
□True	☐ False	☐ I do not know		
4. Routinely, the dosage expression of insulin i □True	s mL or cc, for instance: IR (□ False	Regular Insulin) 4 mL subcutaneous injection. ☐ I do not know		
5. To calculate the dosage of chemotherapy for True	adults weight is commonly □ False	, used while body surface is used for children. □ I do not know		
6. In some special cases or during an emergency such as in the occurrence of ventricular fibrillation, Potassium Chloride at 19.1% can be administered by intravenous bolus.				
□True	☐ False	☐ I do not know		
7. Ringer's solution does not contain potassium ions, however, if the patient's situation requires, 10mL of Potassium Chloride at 19.1% can be added to Ringer's solution and rapidly infused.				
□True	☐ False	☐ I do not know		
8. The insulin syringe, the 1 mL syringe and the tuberculin syringe have the same scale graduation. Therefore, one can replace the other.				
□True	☐ False	☐ I do not know		
9. In patients with low levels of sodium, 500 mL of Sodium Chloride at 20% can be rapidly infused.				
□True	☐ False	☐ I do not know		
10. After administering heparin, it is preferable to use the access for chemotherapy, such as the Port-a-Cath (totally				
implantable catheter), for blood collection and the administration of other medications.				
□True	☐ False	☐ I do not know		

Chart 2 – Final version of the "Clinical procedures" of the questionnaire on high-alert drugs, after performing all the stages of the translation and cultural adaptation process. Ribeirão Preto, SP, Brazil, 2014.

Source: (11)

The redaction undertaken during the stage of synthesis of translations sought to keep the questionnaire free of any influence in order to develop the consensual version T-12. No inconsistencies that could potentially interfere in the method's rigorousness or which were not in accordance with the Brazilian context, were observed during the back translation phase.

Other researchers also followed paths very similar to the one described in this study over the course of the first stages of the translation and cultural adaptation process, reaching satisfactory results regarding the maintenance of the instruments' conceptual equivalence⁽¹⁶⁾.

In the phase in which the questionnaire was assessed by a panel of judges who were experts on high-alert

medications, the adjustments considered essential by the judges involved in the investigation were suggested and then considered by the researchers according to their cultural relevance. Agreement among experts can be quantified by completing an assessment instrument, the basic scope of which was to convert content validity, which is an extremely subjective technique within an objective process.

Considering the barriers to understanding reported by the experts, the items that needed adjustment were later changed. Note that most of the changes concerned the medications mentioned as examples in the questionnaire and their respective concentrations, which diverged from those commonly used in Brazilian hospitals, and, therefore, did not apply to the context of Brazilian nursing.

Even though an acceptable result was achieved in regard to understanding of the items, the translation and adaptation procedures presented some complex issues over the course of the study, especially in regard to the decision to replace certain high-alert medications or concentrations that were part of the original version with medications of the same therapeutic class or different concentration that were, however, more frequently used in Brazilian hospitals. Hence, as reported by another cross-cultural adaptation study⁽¹⁷⁾, this study also verified the need for conceptual adjustments in certain lexical and idiomatic expressions, which negatively impacted semantic equivalence and, consequently, interfered in the understanding of the content of the original instrument.

In the pretest, a sample of 30 nurses answered the items of the questionnaire on high-alert medications and reported the extent to which they understood it, using concepts of clarity and relevance. The nurses were instructed to report any type of discrepancy in the understanding of items. Thus, it was appropriate to draw a parallel between the components of the original questionnaire and the extension of uses of high-alert medications in the context of the nursing service in Brazil, a particularity that favored the validity of the cultural adaptation process.

Even though this is a self-report instrument, ideally its pretest application should be performed in the presence of a researcher. The presence of a researcher is crucial because it enables clarifying ambiguities and verifying difficulties in interpretation respondents may have, in addition to enabling an estimate of the time necessary to complete the instrument⁽¹⁸⁾.

In summary, the aspects concerning comprehension, relevance, and clarity of each of the items were initially checked through the analysis and suggestions of experts and then through the participation of the target audience in the pre-test. The panel of experts and the target audience agreed that the components of the original questionnaire can be associated with the perspectives on the use of high-alert medications in Brazilian healthcare facilities.

Therefore, the final result from the translation and cultural adaptation process of the instrument under study was considered satisfactory in regard to clarity in the composition of the elements considered, according to the methodological framework adopted, presenting conceptual, semantic, cultural and idiomatic equivalence to the Portuguese language and the Brazilian hospital context.

It is important to stress that the translation and cultural adaptation of a given instrument is only one of the stages

of the whole process so that the subsequent phase, characterized by the assessment of psychometric properties that include reliability, sensitivity, and validity, is also necessary for it to be made available for application in the corresponding context⁽¹⁷⁾.

We consider this study to be an essential stage in the movement toward the availability of a valid questionnaire to measure the knowledge of nurses working in Brazilian hospitals regarding high-alert medications in Brazilian hospitals.

CONCLUSIONS

Based on the results presented here, we conclude that the translation and cultural adaptation retained the characteristics of the original version concerning understanding, agreement and relevance of the instrument's items, even after making necessary changes in the semantic and idiomatic equivalence. In summary, considering such parameters, we can assure there is satisfactory semantic, cultural, and conceptual equivalence between the original and translated versions. The Portuguese version is relevant to the Brazilian culture and is easily understood.

We believe that the language of the original instrument was one of the main limitations observed in this study, especially in the stage related to the assessment of the questionnaire by a panel of judges because Chinese is not a language commonly spoken in Brazil. Another important limitation is the abstention of potential respondents, a fact that hindered the generalization of results to the population under study.

Therefore, after establishing the psychometric properties (reliability, sensitivity, and validity) of the version adapted to the Brazilian context, the questionnaire on high-alert medications can be recommended as an instrument to be used by other studies in the field of patient safety and high-alert drugs, especially in the teaching of nursing, considering that the role of nurses is to have knowledge concerning drug administration in hospital facilities, including the medications addressed here. Hence, in regard to the teaching of nursing, this questionnaire can enable an overview of the knowledge of nurses concerning the theme addressed, supporting the development of strategies for future interventions.

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