Patient safety in the surgical environment: translation and cross-cultural adaptation of validated instrument

Segurança do paciente no ambiente cirúrgico: tradução e adaptação cultural de instrumento validado

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Keywords

Patient safety; Translating; Questionnaires; Operating room nursing; Perioperative nursing; Nursing service, hospital

Descritores

Segurança do paciente; Tradução; Questionários; Enfermagem de centro cirúrgico; Enfermagem perioperatória; Serviço hospitalar de enfermagem

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Abstract

Objective: To translate and adapt the Safety Attitudes Questionnaire/Operating Room Version into Portuguese. **Methods**: Methodological research of cross-cultural adaptation which applied the stages: translation, synthesis, back-translation, expert panel evaluation, pretest, submission and evaluation of the reports by the authors of the original instrument. The content validation was performed using the semantic, idiomatic, conceptual, experiential and content equivalence. A total of 12 experts participated and the agreement index corresponded to $\geq 80\%$.

Results: The stages of translation and back-translation were considered adequate and in the synthesis evaluation by the experts, changes were indicated in 41 items from the total of 137. Regarding the equivalence of the validation process carried out by the experts, the general consensus of the instrument obtained 84.1% equivalence, 9.3% of non-equivalence and 6.6% undecided. In the pretest, the mean time to fill in the questionnaire corresponded to 16.5 minutes.

Conclusion: The process of translation and adaptation presented adequacy as to the validity of content through the indices obtained in equivalences and understanding for the subjects, and it was approved by the authors.

Resumo

Objetivo: Traduzir e adaptar o Safety Attitudes Questionnaire/Operating Room Version para a língua portuguesa. **Métodos**: Pesquisa metodológica de adaptação transcultural que empregou as etapas: tradução, síntese, retrotradução, avaliação por comitê de juízes, pré-teste, submissão e avaliação dos relatórios pelos autores do instrumento original. A validação de conteúdo foi realizada mediante as equivalências semântica, idiomática, conceitual, experiencial e de conteúdo. Participaram 12 juízes e o índice de concordância correspondeu a \geq 80%.

Resultados: As etapas de tradução e retrotradução foram consideradas adequadas e na avaliação da síntese pelos juízes foi indicada alteração em 41 itens, do total de 137. Em relação ao processo de validação das equivalencias realizado pelos juízes, o consenso geral do instrumento obteve 84,1% de equivalência, 9,3% de não equivalência e 6,6% de indecisos. No pré-teste, o tempo médio de preenchimento correspondeu a 16,5 minutos.

Conclusão: O processo de tradução e adaptação apresentou adequação quanto à validade de conteúdo mediante os índices obtidos nas equivalências e compreensão pelos sujeitos, e foi aprovado pelos autores.

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Introduction

During the last decade, patient safety became a constant concern for the health sector in all its dimensions. This topic is currently intensely debated due to the evidence of the impact of errors and adverse events in health systems.

Among the challenges imposed by the health sector in order to provide quality and safe care, surgical environments are highlighted. In this scenario, the activities are complex, interdisciplinary and with heavy reliance on individual performance in a high risk environment for the occurrence of adverse events. (1,2)

Thus, monitoring and assessing the safety culture in healthcare organizations allows the identification and management of patient safety in the surgical environment; this assessment can be used for the purpose of benchmarking and trend analysis. It should be added that it may provide a basis for the situational diagnosis, continuing education programs, implementation of care protocols and monitoring of adverse events.

The literature emphasizes the distinction between culture and safety climate and emphasizes that safety culture has been assessed using psychometric questionnaires that measure the climate of safety attitudes and perception of health professionals on patient safety in hospital organizations. (3) In this perspective, safety culture represents the organization's values and actions related to safety and safety climate focusing on perceptions of professionals on safety management in the institution. (4)

In this sense, research instruments require translation and adaptation between cultures and countries, in order to keep the content, the psychometric characteristics and their validity to be used in different populations. ⁽⁵⁾ It is noteworthy that the advantage of the process of adaptation of an existing instrument is to allow comparison of data from different populations and contexts with greater equity, and also enable us to understand their similarities, differences and common characteristics. Other advantages include the anonymity, the lowest cost and time savings in the construction of instruments that assess the same construct. ⁽⁵⁾

The literature regarding the translation and adaptation of psychometric instruments recommends the use of six stages, defined as follows: Translation, synthesis of translation, back translation, expert panel evaluation, pretest, submission and evaluation of the reports by the instrument's authors. (6)

Among the questionnaires available to measure safety climate, we may city the Safety Attitudes Questionnaire (SAQ).⁽⁴⁾ The questionnaire was translated and validated for various countries such as Germany, Denmark, Greece, China, Sweden, Turkey, New Zealand.⁽⁷⁻¹³⁾ Different versions of SAQ were designed to be applied in various scenarios such as intensive care units, medical and surgical clinics, operating rooms, emergency services, outpatient and primary care, among others.^(14,15)

Considering the surgical environment and the lack of instruments capable of measuring the safety climate in operating rooms, in the perception of health professionals, in the Brazilian context, we decided to translate and adapt the version of the Safety Attitudes Questionnaire/Operating Room Version.

The Safety Attitudes Questionnaire/Operating Room (SAQ/OR) is a modified version of the Safety Attitudes Questionnaire (SAQ) developed by researchers at the University of Texas in the United States of America (USA), and has the same properties of SAQ generic version, in relation to patient safety construct adapted to the surgical environments and the scale of answers. (15) It should be noted that the SAQ/OR was translated and adapted for Sweden and Japan, maintaining its psychometric properties. (2,16,17)

Other versions of the instrument have been developed through research to relate the results of the SAQ/OR with patient safety in the surgical environment. In this sense, a study evaluated the impact of the implementation of the checklist in health professionals attitudes towards safety in a surgical center in Japan. (17) Another study, conducted in the USA used the SAQ/OR to identify differences in communication and collaboration between nurses and surgeons. (18)

From a structural point of view, the questionnaire is divided into three parts: the first is related to the quality of communication and collaboration among professionals working in the operating room, where the subject must answer about the relationship they have with each of the professional categories. The second part consists of 58 items with assertions designed to measure the perception of the professional towards safety and to verify that the subject completed the first part of the instrument. And finally, the third part, composed of socio-demographic information (gender, ethnic group, professional category, length of experience, shift operations, etc.), at the end there is a space for three possible recommendations for improving patient safety in the operating room. The assertions are answered by a five points Likert scale with valuation and an item "it does not apply". (15)

We believe that the translation and cultural validation of SAQ/OR will allow the measurement, through the perception of the professionals, of the safety climate in the operating room in the Brazilian reality, contributing to safe and quality of care in hospitals. Thus, this aims to describe the process of translation and cross-cultural adaptation of the SAQ/OR for the Brazilian context.

Methods

This is a methodological study of translation and cross-cultural adaptation of the SAQ/OR, used to measure the health professional safety climate in the operating room to the Brazilian reality.

Considering the various methods described in the literature for translation and cross-cultural adaptation of measuring instruments, in this study we opted for the model proposed by Beaton.⁽⁵⁾

The recommendations of this model include six stages, namely: translation, synthesis of translations, back translation, experts panel evaluation, pretest, submission and evaluation of the reports by the authors of the instrument. (5)

Translation

This first stage of the cross-cultural adaptation process occurred through the translation of the instrument by two independent translators, fluent in English and who had as their native language, Portuguese. It should be noted that only one of the

translators knew the objectives of the study as well as the concepts of the questionnaire.

The following versions were analyzed and compared by the researchers and the inconsistencies or doubts were clarified with the translators. At that time, a synthesis of the translation was carried out.

Back translation

At this stage, two back-translation were performed, the synthesis version in Portuguese returned to the English language, with the participation of two independent translators, whose native language was English and who did not know the original instrument. Again, there was the synthesis of these back-translations by the authors, resulting in the two versions. At the end of this research stage, we produced the final version and all reports were inserted into a spreadsheet for evaluation of equivalence by the experts.

Experts Panel Evaluation

The final Portuguese version was submitted to the expert panel in order to make the equivalences: semantic, idiomatic, conceptual, experiential and content.

Thus, according to the model adopted⁽⁵⁾ the semantic equivalence considers the adaptation of words according to the grammar and vocabulary of the language into which the adjustment occurs; idiomatic equivalence refers to colloquialisms, informal or slang used in the country of origin, which present translation difficulties. At this point, the expert panel may suggest similar expressions to the final version. The conceptual equivalence is whether the words are conceptual connotations are appropriate to the context of the Brazilian health services; experiential equivalence refers to identify the adapted version expresses the experience of the daily services in the Brazilian cultural context; and finally, the content equivalence to evaluate the items of the instrument in relation to the understanding, clarity and redundancies.

The experts received an invitation letter and guidance for completing the equivalence using an electronic spreadsheet. The total assessed items corresponded to 137. It was established validity index \geq 80% of consensus among the experts for each item

evaluated. The spreadsheet, nominated form (Figure 1) contained: the items of the original instrument (English), the two translations (T1 and T2) to the Portuguese spoken in Brazil, the synthesis of the translations made, the two back-translations (BT1 and BT2) and synthesis of the two back-translations performed by the researcher and the supervisor.

In figure 1, we can observe the spreadsheet with the items and equivalents, so by clicking on the corresponding cell of equivalence spaces emerged for experts score. This spreadsheet provided the visualization of all translations, back translations, synthesis and evaluation of the five equivalence of the 137 items of the instrument.

Finally, each expert found that the translated version was entirely understandable, considering their concepts and their meanings for the Brazilian culture, comparing the original instrument and the translated one.

The experts panel was composed by 12 professionals presenting at least one of three criteria, namely: being fluent in English language; having

experience in the area of patient safety; having experience in the translation and validation of research instruments.

The items that did not get this consensus were discussed in a face-to-face/virtual meeting with the experts, with the personal attendance of five Experts and participation by videoconference of three experts from various regions of Brazil, the researcher, the supervisor, two people to support registration and one for technical support for online meetings, lasting five hours.

Pretest

After that, we carried out the pretest with 30 health professionals, who work in operating rooms in a private hospital in southern Brazil, applying a Portuguese version of the SAQ/OR. The report covered all steps and it was approved by the American authors.

The study was registered in Brazil under the Platform Presentation of Certificate number to Ethics Assessment (CAEE) 19332613.4.0000.5392.

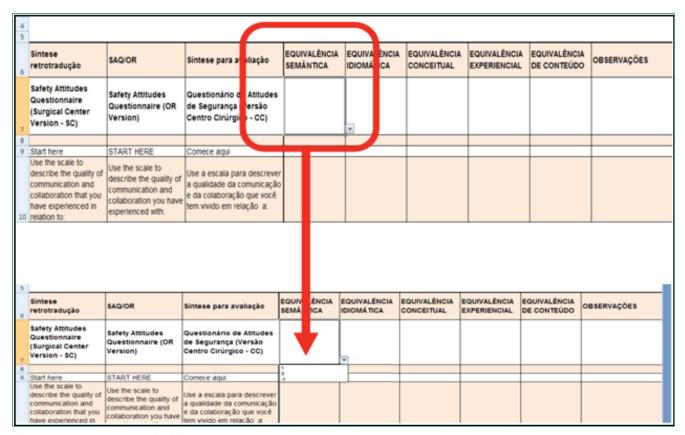


Figure 1. Validation form of SAQ/OR and equivalence for the Portuguese version

Results

The cross-cultural adaptation process of SAC/OR was carried out at all stages satisfactorily.

From the 12 experts who joined the panel of this study, 9 (75%) were nurses, 2(16.7%) were physicians and 1(8.3%) was a translator. Their ages ranged between 33 and 72 years, with a mean of 51.5 years (SD±10.85). As to the mean time of graduation, it corresponded to 28.1 (SD±10.91). Regarding the legal nature of the participants' institution, 9 (75%) worked in the public sector and 3 (25%) in the private sector. Regarding the last titration, 50% of specialists had a PhD, 25% were full professors, 8% had a Master's degree in Political Science and another 8% had a Master's degree in Nursing and 9% were specialists in Operating rooms, Sterilized Material Center and Post-Anesthesia Recovery in Nursing, showing the participants' experience with teaching and research.

In relation to the equivalence of the validation process carried out by the experts, the general consensus instrument was 84.1% of equity, 9.3% of non-equivalence and 6.6% undecided.

Regarding the semantic equivalence, this corresponded to 85.2% of equity, 8.4% of non-equivalence and 6.4% undecided. The idiomatic equivalence was 85.5% of equity, 7.6% of non-equivalence and 6.9% undecided. Concerning the validation of conceptual equivalence, data showed that there were 85% equivalence, 8.5% of non-equivalence and 6.5% undecided. The experiential equivalence was 82.3% of equity, 11.8% of non-equivalence and 5.9% undecided. Finally, the content

equivalence presented 82.8% of equivalence, 10% of non-equivalence and 7.2% undecided. It is noteworthy that the experiential validity was 12% of non-equivalence and content validity was 10% of non-equivalence and the instrument was a total 84% of consensus among the experts.

However, 41 items did not reach consensus ≥ 80% in at least one of the equivalencies. Of these 12 (8.7%) items referred to the statements about patient safety, 10 (7.2%) to the health professions, in the first part of the questionnaire, 8 (5.8%) to the third part of the health professions questionnaire, as these items referred to the same professions, they were grouped. Finally, 11 (8.0%) items related to sociodemographic data.

Chart 1 describes the items related to professions that did not reach consensus and which were discussed at the meeting with the experts, which made up the final version of the instrument. Since the item with the highest discrepancy between the experts concerned the Nurse Anesthetist.

Other issues that have raised questions related to items such as: resident, intern of surgery and anesthesia resident or intern, which resulted in the option surgical resident and intern and resident of anesthesia. Along the same lines, another word which caused debates referred to the preceptor of surgery and anesthesia, which were defined as surgeon/surgeon assistant and anesthetist/anesthesiologist assistant.

The questions related to patient safety item "26. I am provided with adequate, timely information about events in the hospital that might affect my work." had the highest percentage of disagreement,

Chart 1. Final consensus on the health professions

SAQ/OR*	Synthesis for evaluation	Final version
Staff Surgeons/Surgical Attendings	Cirurgião da Equipe do Hospital/Outro Cirurgião	Cirurgião/Cirurgião Assistente
Surgical Residents & Fellows	Residente ou Estagiário de Cirurgia	Residente de Cirurgia e Interno
Surgical Technicians (scrub techs) & PAs	Cirurgião Auxiliar	Instrumentador e Circulante de Sala
Anesthesiologists/Anes- thesia Attendings	Médico Anestesiologista/Preceptor de anestesia	Anestesiologista/Aneste- siologista Assistente
Anesthesia Residents & Fellows	Residente ou Estagiário de Anestesia	Residente de Anestesia e Interno
CRNAs**	Enfermeira anestesista	Enfermeiros Anestesistas
Anesthesia Technicians (techs)	Técnicos de Anestesia	Auxiliar do Anestesiologista
OR Nurses (scrub and circulating)	Enfermagem de Centro Cirúrgico (Instrumentadores e circulantes)	Enfermeiro de Centro Cirúrgico
Hospital Assistants (HA's)/Nursing Assistants	Enfermeira Assistencial do Centro Cirúrgico	Enfermeiro Assistencial
Floor/ward nurses	Enfermeiro - chefe/Gerente do bloco operatório/Centro Cirúrgico	Enfermeiro - Chefe de Centro Cirúrgico

^{*}SAQ/OR - Safety Attitudes Questionnaire/Operating Room; **CRNAs - Certified Registered Nurse Anesthetists

Chart 2. Final consensus on the items that evaluate patient safety

Item	SAQ/OR	Synthesis for evaluation	Final Version
07	All the necessary information is available before the start of a procedure.	Toda informação necessária está disponível para mim, antes do início de um procedimento.	Toda informação necessária está disponível, antes do início de um procedimento.
12	In the OR, it is difficult to discuss errors.	Neste Centro Cirúrgico é difícil discutir sobre erros.	Na Sala de Cirurgia é difícil discutir os erros.
17	Hospital management does not knowingly compromise the safety of patients.	A administração do hospital não se compromete conscientemente com a segurança dos pacientes.	A administração do hospital não compromete, conscientemente, a segurança dos pacientes
19	Decision making in the ORs utilizes input from relevant personnel.	A tomada de decisão no Centro Cirúrgico utiliza informações relevantes dos profissionais.	A tomada de decisão no Centro Cirúrgico utiliza informações dos profissionais envolvidos.
22	This hospital deals constructively with problem physicians and employees.	O hospital trabalha de maneira construtiva os profissionais considerados problemáticos.	O hospital lida de maneira construtiva com os profissionais problemáticos.
26	I am provided with adequate, timely information about events in the hospital that might affect my work.	Recebo informações adequadas e oportunas sobre os eventos do hospital que podem afetar o meu trabalho.	Recebo informações adequadas e oportunas sobre ocorrências no hospital, que podem afetar o meu trabalho.
39	I am frequently unable to express disagreement with staff/ attending physicians.	Eu, frequentemente, não consigo expressar desacordo com a equipe dos profissionais que trabalham aqui.	Frequentemente, não consigo expressar desacordo com a equipe médica.
40	Truly Professional personnel can leave personal problems behind when working.	Pessoas, realmente, profissionais conseguem deixar os problemas pessoais para trás quando estão trabalhando.	Profissionais conseguem deixar os problemas pessoais para trás, quando estão trabalhando.
42	Trainees in my discipline are adequately supervised.	Estagiários da minha profissão são, adequadamente, supervisionados.	Estagiários da minha área são supervisionados adequadamente.
44	I have made errors that had the potential to harm patients.	Cometi erros os quais tiveram potencial para prejudicar os pacientes.	Cometi erros que poderiam prejudicar os pacientes.
45	Staff/Attending physicians in the ORs here are doing a good job.	A equipe de profissionais ou trabalhadores deste Centro Cirúrgico estão fazendo um bom trabalho.	A equipe médica deste Centro Cirúrgico faz um bom trabalho.
57	The staff surgeon/attending surgeon should be formally in charge of the OR staff during the surgical procedure.	O cirurgião da equipe ou o cirurgião assistente deveria estar na coordenação da equipe médica durante o procedimento cirúrgico.	O cirurgião ou o cirurgião assistente deveria estar formalmente na coordenação da equipe da Sala Cirúrgica, durante o procedimento cirúrgico.

*SAQ/OR - Safety Attitudes Questionnaire/Operating Room

and discussed, especially as the word event, which was replaced by occurrences.

The other changes were related to the order of composition of the statements, punctuation and grammar (Chart 2).

The other 11 items that did not reach consensus refer to sociodemographic data, the third part of the questionnaire. It is noteworthy that in the face-to-face/virtual meeting they were defined using the table of the Brazilian Institute of Geography and Statistics (IBGE) for the classification of Brazilian ethnic groups that composed the instrument.

In the face-to-face/virtual meeting 41 items reached 100% consensus and the suggestions were accepted and incorporated into the final version of the instrument, resulting in the Portuguese version of the questionnaire, which was subjected to pretest with 30 operating room professionals in a Brazilian private hospital.

Professionals who answered the questionnaire were 10 surgeons, 10 anesthesiologists, five nurses and five surgical technician/attending.

Pretest

The objective of the pretest is to assess the understanding of the items and the time taken to fill the

questionnaire, so each participant was interviewed by the researcher on the understanding of each item and the time taken to fill the instrument was recorded. In this study, the mean filling time was 16.5 minutes.

Participants reported no difficulty in understanding the questionnaire items. However, four respondents indicated that the font size made it difficult for them to read the items, and they also identified difficulties with the instrument layout regarding the assertion of the response on the same line, this was solved accentuating the colors between the lines.

Both the original instrument as the Brazilian version contains two pages, only one subject in the pretest showed that the questionnaire was extensive and another participant pointed out that there were similar questions. However, as the average completion time is in accordance with the guidelines of the authors of the original questionnaire, we chose to keep the formatting and all instrument items.

Submission to the authors of the questionnaire

All reports produced, the final version of the questionnaire and the pretest results were sent to the

authors of the questionnaire at the University of Texas, USA, who approved the Portuguese version of the SAQ/OR and authorized the questionnaire validation.

This version of the instrument was referred to as: *Questionário de Atitudes de Segurança (Versão Centro Cirúrgico)* However, the international literature and the original questionnaires adopt the SAQ nomenclature for translated and adapted instruments, so we adopted the abbreviation of SAQ/VCC for the Brazilian instrument.

Discussion

Considering that the performance of a translation cannot be effective due to cultural differences and language, and therefore, when adapting a research instrument we should consider the technical, linguistic and semantic aspects. This investigation was conducted in a rigorous process of cross-cultural adaptation and the stages have been fulfilled according to the proposed model.

The cross-cultural adaptation process SAQ/OR for the Portuguese language and the context of the Brazilian surgical centers has been completed properly, meeting all purposes in all steps described in the method adopted.

Studies that performed the transcultural adaptation of the SAQ in generic version and in versions of SAQ/OR adapted to Switzerland and Japan^(2.17) also followed the international recommendations of adaptation processes.⁽⁷⁻¹⁶⁾

Due to the complexity of the instrument and of equivalence evaluated the use of spreadsheet provided a visualization of all stages of the translation process, offered participants flexibility in the assessment of items and their observations and also favored the quantitative analysis of the responses.

The content validation performed by a multidisciplinary expert panel and the participation of a translator involved in the process, as recommended in the literature,⁽⁶⁾ enriched the discussion of the terms and their translation into Portuguese.

In this context, the analysis by the expert panel regarding the evaluation of equivalence involved qualitative and quantitative procedures. Among the items that did not reach consensus and involved complex questions, we highlighted the items related to the health professions who work in the operating room. We emphasize that the original instrument context of the professions and the legislation governing the health professions are different in Brazil, especially in the surgical environments, an example is the function of nurse anesthetist, that in Brazil is exercised by the anesthesiologist, a medical professional.

Understanding the items was identified in the pretest, with no exclusion, only layout changes were necessary in the original instrument. Thus the three dimensions were kept as the original instrument, the first part concerning communication and collaboration among health professionals, 58 questions that assess the safety climate and the personal information, also the question about the previous instrument filling and the open question referring to the three recommendations for improving patient safety in the operating room.

Researches that deal with cross-cultural adaptation of the SAQ/OR in the Japanese and Swedish languages indicated minor changes due to cultural differences. (16,18) However, adaptation to the Swedish context indicated deleting an item on patient safety.

Another matter pointed out in the pretest was the font size. However, since the questionnaire has two pages, increasing the size of the letters would result in the addition of a page, so we chose to preserve the format.

Regarding questions about the safety of the patient, out of the 58 questions that compose the questionnaire, only 12 did not reach consensus and were discussed at the meeting, it corroborates the methodological rigor of the translation and back-translation processes. When considering the complexity of the questionnaire, it is worth noting that small adjustments were necessary on questions related to patient safety and that they concerned the experiential and content equivalence.

Thus, considering the gap of instruments available to measure the perception of health professionals across the patient safety in the surgical environment, the SAQ/VCC can contribute as a

management tool and support strategies for both the assessment of the safety climate as the quality of communication and collaboration among the team of professionals working in the operating room and corroborate for the assessment of safety culture in health care.

Conclusion

This study performed the translation and cross-cultural adaptation of the questionnaire SAQ/OR, an instrument which assesses the safety climate in the surgical environment. The process was carried out rigorously as recommended in the literature reaching the objectives, besides that, the original version was approved by the authors of the original instrument.

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Collaborations

Lourenção DCA and Tronchin DMR collaborated with the study design, data collection, analysis and interpretation of data, writing, critical review of the intellectual content and approved the final version to be published.

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