

## **TRANSLATION AND TRANSCULTURAL ADAPTATION OF THE PATIENT MEASURE OF SAFETY (PMOS) QUESTIONNAIRE TO BRAZILIAN PORTUGUESE**

Janeide Freitas de Mello<sup>1</sup>   
Sayonara de Fátima Faria Barbosa<sup>2</sup> 

<sup>1</sup>Universidade Federal de Santa Catarina, Hospital Universitário Polydoro Ernani de São Thiago. Florianópolis, Santa Catarina, Brasil.

<sup>2</sup>Universidade Federal de Santa Catarina, Programa de Pós-Graduação em Enfermagem. Florianópolis, Santa Catarina, Brasil.

### **ABSTRACT**

**Objective:** to translate and culturally adapt the Patient Measure of Safety questionnaire to Brazilian Portuguese.

**Method:** a transcultural adaptation study conducted in six stages: translation, synthesis, back-translation, review by experts committee, pre-test, and presentation of the documentation of the entire process to the authors of the instrument.

**Results:** in the initial translation and cultural adaptation stage, two versions of the questionnaire were generated. The divergences between both versions and other suggestions were discussed, and the decisions were made by consensus, thus creating a single version. In the back-translation stage, there were no significant differences between the versions and the original instrument. The assessment of the semantic, idiomatic, cultural and conceptual equivalences of the Patient Measure of Safety items was performed by a committee of experts from different Brazilian regions. The results of the content validity index were above 0.9 for most of the items. The pre-test was conducted with 30 patients. The mean time for the application of the questionnaire was 31.9 minutes. In relation to the understanding of the items by the patients, a regular or poor interpretation was identified only for 6 of the 44 items, which were modified.

**Conclusion:** the “*Questionário de Avaliação da Segurança pelo Paciente*”, name given to the translated and transculturally adapted version, resulted from a thoughtful process, presenting consistency in the equivalence of the translation and constituting an applicable instrument understood by the target population.

**DESCRIPTORS:** Translation. Patient safety. Patient-centered care. Hospital care. Nursing.

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## TRADUÇÃO E ADAPTAÇÃO TRANSCULTURAL DO QUESTIONÁRIO *PATIENT MEASURE OF SAFETY* (PMOS) PARA O PORTUGUÊS BRASILEIRO

### RESUMO

**Objetivo:** realizar a tradução e adaptação transcultural do questionário *Patient Measure of Safety* para o português brasileiro.

**Método:** estudo de adaptação transcultural realizado em seis etapas: tradução, síntese, retrotradução, revisão por um comitê de especialistas, pré-teste e apresentação da documentação de todo o processo para os autores do instrumento.

**Resultados:** na etapa inicial da tradução e adaptação transcultural, foram originadas duas versões do questionário. As divergências entre as duas versões e outras sugestões foram discutidas, e as decisões tomadas por consenso originando-se uma versão única. Na etapa de retrotradução, não houve diferenças significativas entre as versões e o instrumento original. A avaliação das equivalências semântica, idiomática, cultural e conceitual dos itens do *Patient Measure of Safety* foi realizada por um comitê de dez especialistas de diferentes regiões do Brasil. Os resultados do índice de validade de conteúdo foram acima de 0,9 para a maioria dos itens. O pré-teste foi realizado com 30 pacientes. O tempo médio para a aplicação do questionário foi de 31,9 minutos. Em relação à compreensão dos itens do questionário pelos pacientes foi identificada uma interpretação regular ou ruim para somente 6 dos 44 itens, os quais foram alterados.

**Conclusão:** o “Questionário de Avaliação da Segurança pelo Paciente”, denominação atribuída à versão traduzida e adaptada transculturalmente, resultou de um processo criterioso, apresentando consistência na equivalência da tradução e constituindo um instrumento aplicável e compreendido pelo público-alvo.

**DESCRITORES:** Tradução. Segurança do paciente. Assistência centrada no paciente. Assistência hospitalar. Enfermagem.

## TRADUCCIÓN Y ADAPTACIÓN TRANSCULTURAL DEL CUESTIONARIO *PATIENT MEASURE OF SAFETY* (PMOS) AL PORTUGUÊS DE BRASIL

### RESUMEN

**Objetivo:** realizar la traducción y adaptación transcultural del cuestionario *Patient Measure of Safety* al portugués de Brasil.

**Método:** estudio de adaptación transcultural realizado en seis etapas: traducción, síntesis, retrotraducción, revisión a cargo de un comité de especialistas, prueba previa y presentación de la documentación de todo el proceso a los autores del instrumento.

**Resultados:** en la etapa inicial de la traducción y adaptación transcultural se generaron dos versiones del cuestionario. Se debatieron las divergencias entre las dos versiones y otras sugerencias, y las decisiones se tomaron por consenso, dando así origen a una versión única. En la etapa de retrotraducción no hubo diferencias significativas entre las versiones y el instrumento original. La evaluación de las equivalencias semántica, idiomática, cultural y conceptual de los ítems del *Patient Measure of Safety* estuvo a cargo de un comité de diez especialistas de diferentes regiones de Brasil. Los resultados del índice de validez de contenido fueron superiores a 0,9 para la mayoría de los ítems. La prueba previa se realizó con 30 pacientes. El tiempo medio para aplicar el cuestionario fue de 31,9 minutos. En relación con la comprensión de los ítems del cuestionario por parte de los pacientes, se identificó un nivel regular o deficiente de interpretación solamente en 6 de los 44 ítems, los cuales fueron modificados.

**Conclusión:** el “*Questionário de Avaliação da Segurança pelo Paciente*”, denominación asignada a la versión traducida y adaptada transculturalmente, fue el resultado de un proceso criterioso, que presentó consistencia en la equivalencia de la traducción y se constituye como un instrumento aplicable y bien comprendido por el público al que está destinado.

**DESCRITORES:** Traducción. Seguridad del paciente. Asistencia centrada en el paciente. Asistencia hospitalaria. Enfermería.

## INTRODUCTION

In the last decades, it became evident that hospitals are not safe places for the patients. A number of studies point to a high incidence of adverse events related to health care, affecting one out of seven hospitalized patients.<sup>1</sup> In view of this, health organizations have sought to implement safe practices in the sense of avoiding the occurrence of adverse events.<sup>2</sup> Among the various strategies for the promotion of patient safety, patient-centered care has been advocated as an intervention capable of reducing the occurrence of adverse events,<sup>3-5</sup> being included as an essential element in the reforms of the health systems in some countries.<sup>6</sup>

Currently, patient-centered care consists in a philosophy and culture that are expressed by means of partnerships between patients, family members and health care providers.<sup>7-8</sup> This philosophy values the patient's experience by adopting an individualized and integrated care approach, based on the physical and emotional needs of the patient. It includes the patients' participation in their own care so that they are respected and that their autonomy is encouraged, allowing them to express their beliefs and values in open communication with the health professionals.<sup>9-10</sup>

Under this perspective, the patients can contribute to safe care in various ways, such as: acquisition of knowledge in health, by asking questions in relation to the medications, general medical issues and practice of hand hygiene by the professionals; active participation and communicative posture with the health professionals; by developing safety and self-monitoring practices and providing information on their care experience, risks and adverse events.<sup>11-14</sup>

The acquisition of information by the patient to improve the quality of health care has been a practice with an upward trend in some countries. In this sense, various instruments for the evaluation of the patient's experience were developed with the objective of extracting data on specific questions of the health processes and events.<sup>15-16</sup>

However, most of these instruments require that the patients inform on the outcomes of their care (safety incidents, for example), instead of the factors that could represent failures in the care structures and processes or care environment that would result in safety incidents, in the case of this example.<sup>17</sup> Thus, due to the absence of an instrument that can provide patient information on the safety of their care or of the care environment, to be used in improving safety at the very level of the unit, the Patient Measure of Safety (PMOS) questionnaire emerged, developed in England by researchers of the Yorkshire Quality and Safety Research Group (YQSR Group) since 2011.<sup>15,18</sup>

The PMOS was created to be used in the hospitalization unit as a diagnostic tool, aiming to identify strong and weak areas based on the information provided by the patients and allowing intervening and preventing the errors from occurring.<sup>15</sup> This is a measurement instrument devised for the future, providing a proactive assessment of the local and organizational factors that can generate safety incidents in hospitalized patients.<sup>17</sup>

A number of studies using the PMOS obtained high participation of the patients (86%), showing that they are willing to provide information on the safety of their care. They also signaled it as an instrument capable of informing safety improvement actions appropriate to the units where it was applied, being adequate to prevent new harms and to complement results from other methods to evaluate patient safety, such as error and adverse event notifications and the identification of the culture of patient safety, performed with the health professionals.<sup>19-21</sup>

Currently, although we identify various ways of promoting patient participation in the health care processes and tools like the PMOS that can contribute to patient safety, in Brazil it is a topic still little explored.<sup>6</sup>

In this context, the PMOS would be a useful tool to be incorporated into the Brazilian context, in the sense of promoting patient-centered care and to improve quality and safety in health care. It is important to highlight that it is a tool that has been tested, showing to be valid, reliable and well-received by the patients.<sup>15,17-18</sup>

Considering that the development of instruments is a time consuming process and involves certain costs, the transcultural adaptation of an already developed and validated instrument can be a good alternative. In addition to that, using an already validated instrument enables the conduction of studies in different populations and the comparison of characteristics of individuals belonging to different cultural contexts.<sup>22</sup>

Thus, acknowledging the qualities of the PMOS and the need to include patient-centered initiatives and patient safety in health care in Brazil, this study had the objective of translating and transculturally adapting the PMOS to Brazilian Portuguese.

## **METHOD**

This is a translation and transcultural adaptation study with the objective of creating the Brazilian Portuguese version of the PMOS questionnaire. This study was approved by the Research Ethics Committee of the Federal University of Santa Catarina and was conducted in the period from April to November 2017. The authors of the instrument authorized the conduction of the study by email in February 2016.

To conduct the study, the ethical precepts of research with human beings set forth in Resolution No. 466/2012 of the National Health Council were followed. The principles of bioethics, autonomy, non-maleficence, beneficence, justice and equality were observed.

### **Patient Measure of Safety (PMOS) Questionnaire**

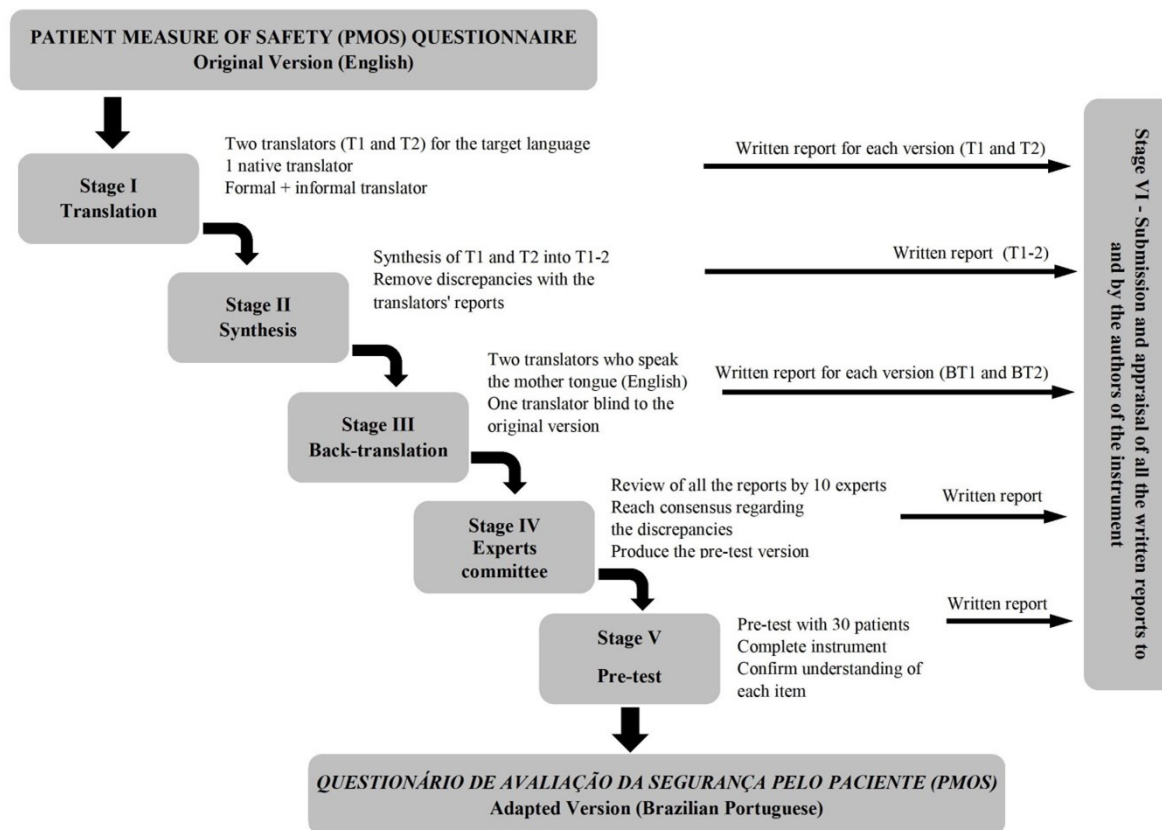
The original version of the PMOS consists in 44 items that assess 9 domains considered as critical for contributing to safety incidents in hospitalized patients, namely: communication and teamwork (9 items); organization and care planning (5 items); access to resources (4 items); ward type and layout (11 items); information flow (3 items); staff roles and responsibilities (4 items); staff training (2 items); equipment (design and functioning) (2 items); and delays (2 items). Item 1 (I was always treated with dignity and respect), not included in none of the domains, and item 25 (Others - Please specify), although included in the "ward type and layout" domain, do not add up to the total of the items in this domain.<sup>15,17,23</sup>

The questionnaire items are presented as statements with which the patients are asked to agree or disagree in a five-point Likert scale: "strongly disagree" (1); "disagree" (2); "neither agree or disagree" (3); "agree" (4); and "strongly agree" (5). The items with negative words are recoded and the respondents can also select the "not applicable" option.<sup>17-18</sup>

Although the original instrument does not contain sociodemographic data, the following information was included in the study: age, gender, schooling, profession, origin (city), hospitalization time, hospital, hospitalization unit, reason for hospitalization and number of previous hospitalizations.

### **Procedures for Translation and Transcultural Adaptation**

The method for the translation and transcultural adaptation of the PMOS questionnaire to Brazilian Portuguese followed these internationally recommended stages for translation and transcultural adaptation of instruments (Figure 1): translation, synthesis, back-translation, review by experts committee, pre-test, and presentation of the documentation of the entire process to the authors of the instrument. Each stage was recorded by means of a written report.<sup>24</sup>



**Figure 1** – Flow diagram of the stages for the translation and transcultural adaptation of the Patient Measure of Safety (PMOS) questionnaire to Brazilian Portuguese. Florianópolis, SC, Brasil, 2017.

### Stage I – Translation

In this stage, two bilingual translators, both with Brazilian Portuguese as their mother tongue (one being a health professional with knowledge on patient safety and the other with lay knowledge on the theme), independently produced two translated versions (T1 and T2).

### Stage II – Synthesis

In stage II, the participants were the researcher, the translator who created version T1 (health professional with knowledge on patient safety) and a professional translator. In this stage, the results of translations T1 and T2 were synthesized, producing a consensual translation: T1-2.

### Stage III – Back-translation

In this stage, the participants were two bilingual women translators, English native speakers and fluent in Brazilian Portuguese. They back-translated the instrument (version T1-2) to its original language, independently and totally blinded to the original version and to the concepts of the construct, generating two back-translated versions (BT1 and BT2).

## **Stage IV – Experts Committee**

The synthesis version of the PMOS translation (T1-2) was submitted to an experts committee to identify its content validity by assessing the semantic, idiomatic, cultural and conceptual equivalences of each item of the questionnaire. This committee was comprised by ten specialists from different Brazilian regions (South, Southwest, and Midwest) with a PhD, mastery of the Portuguese language, development of research studies, and publications in the area.

The specialists evaluated the semantic, idiomatic, cultural and conceptual equivalences for all the items of the original and translated versions of the questionnaire by accessing the *SurveyMonkey*® platform. The agreement or disagreement of the specialists was scored according to a scale with the following options: -1 = not equivalent, 0 = not possible to assess/I do not know, +1 = equivalent, according to other studies.<sup>25–26</sup> For the items that scored -1 or 0, the specialists were asked to describe their suggestions or comments.

Consensus among the specialists was established by calculating the Content Validity Index (CVI), obtained by the calculation of the number of +1 answers divided by the total number of answers, adopting as acceptable a value above 0.9.<sup>27</sup>

## **Stage V – Pre-Test**

With the objective of verifying the understanding of the instrument by the target population and its applicability, a pre-test was conducted with 30 patients, according to the recommendation,<sup>24</sup> hospitalized in surgical, medical and maternity hospitalization units of a university hospital in the South of Brazil.

The participants of the pre-test were patients aged over 18 years old, Brazilian, fluent in Brazilian Portuguese, and with a minimum hospitalization time of 24 hours (inclusion criteria). The patients excluded were those without the ability to accept participating in the research (for example: due to neurological or psychiatric alterations, advanced disease, or in sedation) or those who were too weak or anguished (for example: due to respiratory impairment, pain or immediate postoperative period).

During the pre-test, the time to answer the questions and their comprehension by the patients were observed. This stage did not provide information on the psychometric properties of the questionnaire, which can be modified by the translation and transcultural adaptation process.

After signing the Free and Informed Consent Form, the patients answered the pre-final version of the questionnaire and the question referring to the evaluation of their comprehension, classifying it as good, regular or poor. The items with poor and regular interpretations were reviewed and modified.

## **Stage VI – Submission and appraisal of all the written reports to and by the authors of the instrument**

In this stage, all the reports and forms were sent to the authors of the instrument to verify if the recommended stages were followed and if the reports positively reflected the process.

## **RESULTS**

The original instrument and the translated and transculturally adapted version to Brazilian Portuguese of the PMOS questionnaire are presented in Chart 1.

**Chart 1** – Original instrument and translated and transculturally adapted version to Brazilian Portuguese of the Patient Measure of Safety (PMOS) questionnaire. Florianópolis-SC, Brazil, 2017.

Original - Patient Measure of Safety (PMOS) <sup>15,18</sup>	Translated and transculturally adapted version - Questionário de Avaliação da Segurança pelo Paciente (PMOS)
1. I was always treated with dignity and respect	1. Eu sempre fui tratado (a) com dignidade e respeito
2. I knew who to go to if I needed to ask a question	2. Eu sabia a quem me dirigir se eu precisasse fazer uma pergunta
3. The drugs I have been prescribed were always available in hospital	3. Os medicamentos receitados para mim sempre estiveram disponíveis no hospital
4. I got answers to all the questions I had about my care	4. Eu recebi as respostas para todas as perguntas sobre os meus cuidados
5. Staff were always able to get advice from other teams about my care if needed	5. A equipe sempre foi capaz de receber orientação de outros profissionais sobre o meu cuidado quando necessário
6. A doctor changed my plan of care and other staff didn't know about it	6. O médico alterou meu tratamento e os outros profissionais não sabiam
7. After a shift change staff did not appear to know important information about my care	7. Depois da troca de plantão parecia que a equipe não sabia informações importantes sobre o meu cuidado
8. I knew what the different roles of the people caring for me were	8. Eu sabia quais eram as diferentes funções das pessoas que cuidavam de mim
9. On at least one occasion a member of staff was not able to use the necessary equipment	9. Em pelo menos uma ocasião, um membro da equipe não sabia usar o equipamento necessário
10. My treatment / procedure/ operation did not always happen on time	10. O meu tratamento, procedimento ou cirurgia nem sempre aconteceu na hora marcada
The following aspects of the ward made it difficult for staff to do their jobs: 11. Position of nurses' station 12. Lighting levels 13. Clutter & untidiness 14. Lack of space	Os seguintes aspectos da enfermaria dificultaram a realização de atividades pela equipe: 11. Localização do posto de enfermagem 12. Níveis de iluminação 13 Acúmulo e desordem de materiais e equipamentos 14. Falta de espaço
15. I was on a ward that was not able to deal with my treatment needs	15. Eu estava em uma enfermaria que não atendia as minhas necessidades de tratamento
16. Staff were prompt in answering my buzzer	16. Os funcionários eram disponíveis para atender a minha campainha
17. It was clear who was in charge of the staff	17. Eu sabia quem era responsável pela equipe de enfermagem
18. Sometimes there was no-one available to deal with aspects of my care	18. Às vezes, não havia ninguém disponível para realizar os meus cuidados
19. On at least one occasion a member of staff was not able to carry out a task that they should have been able to do	19. Em pelo menos uma ocasião, um membro da equipe não sabia executar uma tarefa que deveria ser capaz
The following aspects of the ward made it uncomfortable for me: 20. Noise levels 21. Lighting levels 22. Temperature 23. Poor cleanliness 24. Lack of space 25. Other - Please specify	Os seguintes aspectos da enfermaria foram desconfortáveis para mim: 20. Níveis de barulho 21. Níveis de iluminação 22. Temperatura 23. Limpeza inadequada 24. Falta de espaço 25. Outro - Por favor especifique
26. I felt that the attitude of staff towards me was poor	26. Não fiquei satisfeito com a atitude da equipe em relação a mim

**Chart 1 – Cont.**

<b>Original - Patient Measure of Safety (PMOS)<sup>15,18</sup></b>	<b>Translated and transculturally adapted version - Questionário de Avaliação da Segurança pelo Paciente (PMOS)</b>
27. I knew which consultant was in charge of my care	27. Eu sabia qual médico era responsável pelo meu cuidado
28. Staff always seemed to know what they were meant to be doing.	28. A equipe sempre parecia saber o que devia fazer
29. There were enough staff on the ward to get things done on time	29. Havia pessoal suficiente na enfermaria para fazer as coisas na hora certa
30. Staff gave me different information about my care	30. A equipe me forneceu informações diferentes sobre meu cuidado
31. Staff/patients waited a long time for porters to arrive	31. Equipe / pacientes esperavam por muito tempo o profissional responsável pelo transporte
32. Staff did not work together as a team here	32. Aqui os profissionais não trabalharam em conjunto como uma equipe
33. There was equipment that staff found difficult to use (e.g. monitoring equipment, beds, hoists)	33. Havia equipamento que a equipe tinha dificuldade de usar (por exemplo, equipamentos de monitoramento, camas)
34. I have needed treatment and there has been no-one available who was trained to do it	34. Eu precisei de tratamento e não havia ninguém disponível que tivesse sido treinado para fazê-lo
35. Staff were kept waiting for my test results	35. A equipe tinha que esperar os resultados do meu exame
36. Nurses were always able to get help from other staff when they asked for it	36. Os enfermeiros sempre conseguiam a ajuda de outros profissionais quando solicitavam
37. Equipment needed for my care was always working properly	37. O equipamento necessário para meus cuidados sempre estava funcionando adequadamente
38. I always knew which nurse was responsible for my care	38. Eu sempre sabia qual profissional de enfermagem era responsável pelos meus cuidados
39. Equipment and supplies were not always available when needed (e.g. hoists, bedpans, drugs)	39. Nem sempre os equipamentos e materiais necessários estavam disponíveis (por exemplo, comadres, medicamentos)
40. Staff always agreed about my treatment/ care	40. Os profissionais sempre tiveram a mesma opinião sobre meu tratamento / cuidado
41. I always felt staff listened to me about my concerns	41. Eu sempre senti que a equipe ouvia as minhas preocupações
42. Staff seemed to struggle to get help when they needed it	42. A equipe parecia ter dificuldade para conseguir ajuda quando precisava
43. When staff talked about my care with others the information they shared was correct	43. Quando os profissionais falavam sobre o meu cuidado com os outros membros da equipe, a informação que compartilhavam estava correta
44. Information about me that my health care team needed was always available (e.g. drug charts, medical notes, test results)	44. As minhas informações sempre estavam disponíveis quando os profissionais de saúde precisavam (por exemplo, prescrição de medicamentos, anotações médicas, resultados de exames)

In the initial (I) stage of the translation and transcultural adaptation process of the PMOS, two versions of the questionnaire (T1 and T2) were created. The divergences between T1 and T2 and other suggestions were discussed, and the decisions were made by consensus, thus originating the synthesis version: T1-T2 (Stage II).



In this stage (II) the topics discussed and their solutions were the following: for the title, instead of “*Medida de Segurança do Paciente*”, it was decided to use “*Medida da Segurança pelo Paciente*”; for “drugs” (item 3), it was decided to use “*medicamentos*” (T1) and not “*drogas*” (T2), for being the term most frequently used; “shift change” (item 7), was translated as “*mudança de plantão*” (T2) and not as “*passagem de plantão*”, although this is a frequently used expression; “to deal” (item 15), despite the indication for “*lidar*” (T1 and T2), was translated as “*atender*”, considered more appropriate for the item; “poor” (item 23) was translated as “*inadequada*” (T1) instead of “*pobre*” (T2); for “poor” (item 26), the word “*insatisfatória*” (T1) was chosen instead of “*pobre*” (T2); “on time”, instead of “*em tempo*” (T1), was translated as “*na hora certa*”, for considering that it is better understood; “hoists” (item 39) was translated as “*elevadores*” (T1) instead of “*guindastes*” (T2); and the expressions “drug charts” and “medical notes” were translated as “*prescrição de medicamentos*” and “*anotações médicas*” instead of “*gráficos de drogas*” and “*notas médicas*” (T1 and T2).

In relation to the back-translations (BT1 and BT2), produced from version T1-2 (Stage III), there were no significant differences between them and the original instrument. Although some items did not use the same wording of the original instrument, they showed similar content and ideas.

In the Experts Committee stage (IV), the assessments of the semantic, idiomatic, cultural and conceptual equivalences of the instrument’s domains and items were performed.

Most of the CVI results of the PMOS items (mean of the semantic, idiomatic, conceptual and cultural equivalences of each of the items) was above 0.9, according to what is presented in Chart 2. CVI results of 0.9 or below were found for the following items: title of the PMOS (0.78), items 3 (0.90), 5 (0.90), 6 (0.88), 7 (0.83), 9 (0.90), 13 (0.85), 15 (0.90), 18 (0.80), 26 (0.85), 32 (0.85) and the statements in items 20 to 25 (0.88). The CVI means by equivalences resulted in values above 0.9, with the following results: 0.93 for semantic equivalence; 0.96 for idiomatic and conceptual equivalences, and 0.92 for cultural equivalence.

**Chart 2 – Content Validity Indexes (CVIs) of the version translated to Brazilian Portuguese (T1-2) of the Patient Measure of Safety (PMOS). Florianópolis-SC, Brazil, 2017.**

Item	CVI	Item	CVI	Item	CVI	Item	CVI
Title	0.78	Item 11	0.93	Item 22	0.98	Item 34	0.98
Item 1	1.00	Item 12	0.98	Item 23	1.00	Item 35	1.00
Item 2	1.00	Item 13	0.85	Item 24	1.00	Item 36	0.98
Item 3	0.90	Item 14	1.00	Item 25	1.00	Item 37	0.98
Item 4	0.95	Item 15	0.90	Item 26	0.85	Item 38	0.93
Item 5	0.90	Item 16	0.95	Item 27	1.00	Item 39	1.00
Item 6	0.88	Item 17	0.95	Item 28	0.98	Item 40	0.95
Item 7	0.83	Item 18	0.80	Item 29	1.00	Item 41	0.98
Item 8	0.95	Item 19	1.00	Item 30	0.98	Item 42	1.00
Item 9	0.90	Statements of items 20 to 25	0.88	Item 31	1.00	Item 43	0.93
Item 10	0.93	Item 20	0.95	Item 32	0.85	Item 44	0.98
Statements of items 11 to 14	1.00	Item 21	0.98	Item 33	0.95		

Although most of the items evaluated received, in general (by item or equivalence), CVI scores above 0.9, which would indicate an acceptable level of agreement among the specialists, in the second evaluation round the need was identified for grammatical changes, word order inversion

in phrases, and substitution of some terms by synonyms, some suggested by the specialists in the first evaluation round.

Accordingly, the following changes were made in the search for better semantic, idiomatic, conceptual and cultural adequacy: the title was changed to “*Questionário de Avaliação da Segurança pelo Paciente (PMOS)*”, maintaining the acronym in English for ease of identification in the databases; regarding the questionnaire items, the word “*prescritos*” (item 3) was substituted by “*receitados*”, more easily understood by the target population of the questionnaire; “*meu plano de cuidados*” and “*a outra equipe*” (item 6) were respectively changed to “*meu tratamento*” and “*outros profissionais*”, for ease of understanding; “*mudança*” (item 7) was changed to “*troca*”, more adequate from the conceptual point of view; the expression “*não foi capaz*” (item 9) was substituted by “*não sabia*”; “*na hora certa*” (item 10) was changed to “*na hora marcada*”; “*posição*” (item 11) was changed to “*localização*”; the expression “*de materiais e equipamentos*” was added to item 13 for ease of understanding; “*equipe*” (item 16) was substituted by “*funcionários*”, for considering that the people who answer to the bell is not the entire team, but the employees who make up the team; “*era claro*” (item 17) was changed to “*eu sabia*”; “*lidar com aspectos*” (item 18) was changed to “*realizar*”; “*não foi capaz*” (item 19) was changed to “*não sabia*”; the word “*ruído*” (item 20) was changed to “*barulho*”; the word “*maqueiros*” (item 31) was substituted by the expression “*transporte em maca*”, for the existence of professionals (stretcher bearers) exclusively for the transportation of patients not being common to most of the institutions and for this task being performed, most of the times, by Nursing professionals; the word “*elevadores*” (items 33 and 39) was removed, since these pieces of equipment, used for moving or \*removing\* patients, are still little used in most of the Brazilian hospitals; “*ficou aguardando*” (item 35) was changed to “*tinha que esperar*”, for being closer to the purpose of the item, which is assessing the information flow; “*funcionários*” (item 36) was substituted by “*profissionais*”; “*enfermeira*” (item 38) was substituted by “*enfermeiro/enfermeira*”, considering the gender issue; and “*equipe*” (items 40 and 43) was changed to “*profissionais*” to avoid generalizations and to ease understanding.

According to the results of the pre-test (Stage V), the mean time for its application was 31.9 minutes. In relation to the respondents, 53.3% were male and 46.7% female, most with high school (63.3%) and the rest with elementary school (30%) and higher education (6.7%), hospitalized in the surgical (50%), medical (40%) and maternity (10%) units, with a mean hospitalization time of 9.16 days.

Regarding the comprehension of the questionnaire items, a regular or poor interpretation was identified for 6 items, which were modified as follows: in item 17, the word “*enfermagem*” was added, since some respondents were doubtful whether the question referred to Nursing or to Medicine; in item 27, the word “*profissional*” was changed to “*médico*”, because the term “*profissional*” was unclear to the patient, and also considering that the meaning of “consultant” (British English) is physician; in item 31, due to difficulty in understanding, the word “*maca*” was removed because, if maintained, it would not consider other types of transportation such as wheelchair or ambulance, for example; in item 32, the expression “*em conjunto*” was substituted by “*juntos*” for ease of understanding; in item 38, “*enfermeiro/enfermeira*” was changed to “*profissional de enfermagem*”, considering the different Nursing categories existing in Brazil; and, in item 42, the expression “*se esforçar*” was changed to “*dificuldade*” since, in the previous version, the meaning is contrary to what the question intends to evaluate.

Finally, all the reports and versions of the instrument referring to the translation and cultural adaptation process of the PMOS were forwarded to the authors of the original instrument.

## DISCUSSION

The transcultural adaptation of the PMOS questionnaire to Brazilian Portuguese rigorously followed the stages proposed by Beaton et al.,<sup>24</sup> a process that has been followed in Brazil<sup>28</sup> and internationally in most of the transcultural adaptation studies.<sup>29</sup>

In the initial stage of the transcultural adaptation process, there were no discrepancies between the T1 and T2 translations, since many of the differences between both translations were related to the use of synonyms and to the structure of the items (syntax). The words and phrase structuring considered more adequate by the evaluators of the synthesis stage were chosen.

Synthesizing the versions of an instrument consists in comparing them and evaluating their differences with the objective of obtaining a single version. In this process, inappropriate choices are identified and solved by means of a discussion among the evaluators, together with the researchers responsible for the translation.<sup>22</sup>

The back-translations of the PMOS synthesis version showed similitude when compared to each other and to the original instrument, as well as the consistency quality of the PMOS synthesis version. Thus, the first translated version of the PMOS was created to be submitted to the experts committee.

Back-translation is a process to verify the accuracy of a translation. In this stage of the transcultural adaptation process, the translated instrument (synthesis version) is back-translated to its original language and then compared to the original version,<sup>30</sup> seeking to assess if the synthesis version reflects the contents of the original version in order to ensure the consistency of the translation.<sup>31</sup>

For an adequate translation, semantic, idiomatic, conceptual and cultural equivalences are also relevant. Should these equivalences not be found, changes must be implemented with the objective to attain them.<sup>24</sup> In this study, the recommendations to obtain these equivalences were followed, thus ensuring an instrument adapted to the Brazilian culture. The evaluators' suggestions were considered and changes were implemented in most of the PMOS items, as well as in those with CVI values considered inadequate. It is also worth considering that the selection of evaluators from different regions of the country and with the cited qualifications was fundamental for an adequate and appropriate transcultural adaptation to the Brazilian context as a whole.

The Brazilian version of the PMOS was subjected to the pre-test, which aims at maintaining the meaning of the original version, improving comprehension, and finding errors or problems in the application of the instrument in the adaptation process.<sup>24</sup> It represents an important phase, as it allows identifying if it is possible to apply the translated version and if the terms used were adequate for the population.<sup>32</sup>

Performing the pre-test of the PMOS translated version showed good acceptance and ease of understanding, resulting in few changes. Its application to a sample with different profiles verified the results of the assessment of the understanding of the instrument. In this way, the Brazilian version of the PMOS was translated and transculturally adapted, revealing to be a tool that can be used in our environment for the evaluation, by the patients, of aspects that can endanger their safety in the hospital setting.

Seeking to identify other experiences of application of the PMOS similar to this one, no studies dealing with the transcultural adaptation of the PMOS to other languages were found. However, a study was indeed found in which the PMOS was adapted so that it could be used for older adult patients with stroke, acute myocardial infarction, and hip fracture in Australian hospitals. In this study, in addition to the change in health terms less common in the Australian context, the key change to the PMOS consisted in the reduction in the number of items negatively worded from 56% to 28% (from 24 to 12 items), with the intention to reduce the possibility of confusion or inducing unreliable answers.

This choice was justified based on previous studies with adult, older adult and acute hospitalized patients, in which it was found that simple questions would be more effective.<sup>33</sup> In the transcultural adaptation process of the PMOS to Brazilian Portuguese, no difficulties were found related to the negatively worded items; therefore, they were maintained as in the original instrument.

In another study, the PMOS was the base for the elaboration of an instrument that allowed the patients to provide feedback on contributing factors for possible safety incidents in primary care, called Primary Care Patient Measure of Safety (PC PMOS). The final PC PMOS consisted of a tool with 50 items and 15 domains which was well received by patients and professionals during the face validity test. In this study, the contributing factors for safety incidents focused mainly on communication, access to care, factors related to the patient, planning and care organization, execution of the tasks, and information flow.<sup>34</sup>

Consequently, even if small changes were made due to differences between Brazil and England, the translation and cultural adaptation process of the PMOS for its use in Brazil was successful, being conducted in a systematic manner and complying with all the recommended stages. No items were removed from the original questionnaire, and the instrument presented satisfactory values regarding content validity.

As a limitation of the research, the fact that the scale has not undergone the translation and transcultural adaptation process for other countries in its original version is emphasized, which hinders discussion and comparison of the results.

## CONCLUSION

The *Questionário de Avaliação da Segurança pelo Paciente* (PMOS) was the result of a thoughtful transcultural adaptation process. This study showed the importance of following the recommended steps for this process, resulting in an applicable instrument understood by the target population, presenting consistency in the translation and cultural adaptation equivalence for its use in Brazil.

Today, considering the worldwide focus on patient safety, acknowledging the role of the patient in the health care processes and the nonexistence in Brazil of an instrument for evaluation by the patients of aspects that can endanger their safety, it is verified that the instrument, transculturally adapted by means of this study, can be useful in Brazil.

In the fields of teaching and research, the contribution of the transcultural adaptation process of the PMOS lies in the detailed description of each of its stages. Thus, the methodological process of this study can be reproduced in the transcultural adaptation of other instruments, or even the adapted version of the PMOS itself can also motivate other research studies.

The adapted version showed semantic, idiomatic, cultural and conceptual equivalences. However, it is recommended to assess its psychometric properties in future studies so as to identify its reliability and validity, by means of other evaluations. Only by means of this evaluation will it be possible to identify if the adapted instrument possesses the necessary measurement properties.

## REFERENCES

1. D'Amour D, Dubois CA, Tchouaket E, Clarke S, Blais R. The occurrence of adverse events potentially attributable to nursing care in medical units: cross sectional record review. *Int J Nurs Stud* [Internet]. 2014 [cited 2017 Nov 27];51(6):88291. Available from: <https://doi.org/10.1016/j.ijnurstu.2013.10.017>
2. Wise J. Patient Safety lessons from the world's experts. *BMJ* [Internet]. 2018 [cited 2019 May 13];363:k5211. Available from: <https://doi.org/10.1136/bmj.k5211>
3. Berger Z, Flickinger TE, Pfoh E, Martinez KA, Dy SM. Promoting engagement by patients and families to reduce adverse events in acute care settings: a systematic review. *BMJ Quality & Safety* [Internet]. 2014 [cited 2019 May 13];23(7):548-55. Available from: <https://doi.org/10.1136/bmjqs-2012-001769>
4. Shitu Z, Hassan I, Aung MMT, Kamaruzaman T, Musa RM. Avoiding medication errors through effective communication in a healthcare environment. *Movement, Health & Exercise* [Internet]. 2018 [cited 2019 May 13];7(1):115-28. Available from: <http://doi.org/10.2139/ssrn.3573437>
5. Severinsson E, Holm A. Patients' role in their own safety: a systematic review of patient involvement in safety. *Open J Nurs* [Internet]. 2015 [cited 2017 Nov 28];5(7):642-53. Available from: <http://doi.org/10.4236/ojn.2015.57068>
6. Gomes PHG, Mendes Júnior WV. O cuidado centrado no paciente nos serviços de saúde: estratégias de governos e organizações não governamentais. *Revista Acreditação* [Internet]. 2017 [cited 2018 Jan 12];7(13):23-43. Available from: <https://dialnet.unirioja.es/servlet/articulo?codigo=6130783>
7. Gandhi TK, Kaplan GS, Leape L, Berwich DM, Edgman-Levitan S, Edmondson A, Meyer GS. Transforming concepts in patient safety: a progress report. *BMJ Quality & Safety* [Internet]. 2018 [cited 2019 May 13];27:1019-26. Available from: <http://doi.org/10.1136/bmjqs-2017-007756>
8. Santana MJ, Manalili K, Jolley RJ, Zelinsky S, Quan H, Lu M. How to practice person-centred care: a conceptual framework. *Health Expect*. [Internet]. 2018 [cited 2019 May 13];21(2):429-40. Available from: <https://doi.org/10.1111/hex.12640>
9. Clarke S, Ells C, Thombs BD, Clarke D. Defining elements of patient-centered care for therapeutic relationships: a literature review of common themes. *Eur J Person C Healthcare* [Internet]. 2017 [cited 2019 May 13];5(3):362-72. Available from: <http://www.ejpch.org/ejpch/article/view/1337>
10. Kumar R, Chattu VK. What is the name? Understanding terminologies of patient-centered, person-centered, and patient-directed care! *J Family Med Prim Care* [Internet]. 2018 [cited 2019 May 13];7(3):487-8. Available from: [https://doi.org/10.4103/jfmpc.jfmpc\\_61\\_18](https://doi.org/10.4103/jfmpc.jfmpc_61_18)
11. Lastinger A, Gomez K, Manegold E, Khakoo R. Use of a patient empowerment tool for hand hygiene. *Am J Infect Control* [Internet]. 2017 [cited 2019 May 13];45(8):824-9. Available from: <https://doi.org/10.1016/j.ajic.2017.02.010>
12. Davis RE, Sevdalis N, Pinto A, Darzi A, Vincent CA. Patients' attitudes towards patient involvement in safety interventions: results of two exploratory studies. *Health Expect* [Internet]. 2013 [cited 2017 Nov 26];16(4):164-76. Available from: <https://doi.org/10.1111/j.1369-7625.2011.00725.x>
13. Andersson A, Frank C, Willman PO, Hansebo G. Adverse events in nursing: a retrospective study of reports of patient and relative experiences. *Int Nurs Rev* [Internet]. 2015 [cited 2017 Dec 27];62(3):377-85. Available from: <https://doi.org/10.1111/inr.12192>
14. Rainey H, Ehrich K, Mackintosh N, Sandall J. The role of patients and their relatives in "speaking up" about their own safety: a qualitative study of acute illness. *Health Expect* [Internet]. 2015 [cited 2017 Nov 28];18(3):392-405. Available from: <https://doi.org/10.1111/hex.12044>
15. Giles SJ, Lawton RJ, Din I, McEachan RR. Developing a patient measure of safety (PMOS). *BMJ Quality & Safety* [Internet]. 2013 [cited 2017 Nov 24];22(7):554-62. Available from: <https://doi.org/10.1136/bmjqs-2012-000843>

16. Beattie M, Murphy DJ, Atherton L, Lauder W . Instruments to measure patient experience of healthcare quality in hospitals: a systematic review. *Syst Rev* [Internet]. 2015 [cited 2017 Nov 26];4:97. Available from: <https://doi.org/10.1186/s13643-015-0089-0>
17. Lawton R, O'Hara JK, Sheard L, Reynolds C, Cocks K, Armitage G et al. Can staff and patient perspectives on hospital safety predict harm-free care? An analysis of staff and patient survey data and routinely collected outcomes. *BMJ Quality & Safety* [Internet]. 2015 [cited 2017 Nov 25];24:369-376. Available from: <http://doi.org/10.1136/bmjqs-2014-003691>
18. McEachan RR, Lawton RJ, O'Hara JK, Armitage G, Giles S, Parveen S et al. Developing a reliable and valid patient measure of safety in hospitals (PMOS): a validation study. *BMJ Quality & Safety* [Internet]. 2014 [cited 2017 Nov 25];23(7):565-73. Available from: <https://doi.org/10.1136/bmjqs-2013-002312>
19. Lawton R, O'Hara JK, Sheard L, Reynolds C, Cocks K, Armitage G. Can staff and patient perspectives on hospital safety predict harm-free care? An analysis of staff and patient survey data and routinely collected outcomes. *BMJ Quality & Safety* [Internet]. 2015 [cited 2019 May 13];24(6):368-76. Available from: <https://doi.org/10.1136/bmjqs-2014-003691>
20. Lawton R, O'Hara JK, Sheard L, Armitage G, Cocks K, Buckley H. Can patient involvement improve patient safety? A cluster randomized control trial of the patient reporting and action for a safe environment (PRASE) intervention. *BMJ Quality & Safety* [Internet]. 2017 [cited 2019 May 13];26:622-31. Available from: <https://doi.org/10.1136/bmjqs-2016-005570>
21. O'Hara JK, Reynolds C, Moore S, Armitage G, Sheard L, Marsh C. What can patient tell us about the quality and safety of hospital care? Findings from a UK multicentre survey study. *BMJ Quality & Safety* [Internet]. 2018 [cited 2019 May 13];27:673-82. Available from: <http://doi.org/10.1136/bmjqs-2017-006974>
22. Borsa JC, Damásio BF, Bandeira DR. Cross-cultural adaptation and validation of psychological instruments: some considerations. *Paideia* [Internet]. 2012 [cited 2017 Nov 28];22(53):423–32. Available from: <https://doi.org/10.1590/S0103-863X2012000300014>
23. Lawton R, McEachan RRC, Giles SJ, Sirriyeh R, Watt IS, Wright J. Development of an evidence-based framework of factors contributing to patient safety incidents in hospital settings: a systematic review. *BMJ Quality & Safety* [Internet]. 2012 [cited 2017 Nov 25];21(5):369-80. Available from: <https://doi.org/10.1136/bmjqs-2011-000443>
24. Beaton D, Bombardier C, Guillemin F, Ferraz MB. Recommendations for the cross-cultural adaptation of the DASH & QuickDASH outcome measures. Toronto (CA): Institute for Work and Health; 2007. Available from: [http://www.dash.iwh.on.ca/sites/dash/files/downloads/cross\\_cultural\\_adaptation\\_2007.pdf](http://www.dash.iwh.on.ca/sites/dash/files/downloads/cross_cultural_adaptation_2007.pdf)
25. Carvalho REFL. Adaptação transcultural do Safety Attitudes Questionnaire para o Brasil: Questionário de Atitudes de Segurança [Tese]. Ribeirão Preto, SP(BR): Universidade de São Paulo, Escola de Enfermagem de Ribeirão Preto; 2011. Available from: <https://doi.org/10.11606/T.22.2011.TDE-30112011-085601>
26. Weber B. Tradução, adaptação transcultural e validação do método INTERMED para a língua portuguesa: estudo em pacientes hospitalizados [Tese]. Ribeirão Preto SP(BR): Universidade de São Paulo, Escola de Enfermagem de Ribeirão Preto; 2012. Available from <https://10.11606/T.7.2012.tde-08102012-161016>
27. Polit D F, Beck CT. The content validity index: are you sure you know what's being reported? Critique and recommendations. *Res Nurs Health* [Internet]. 2006 [cited 2017 Nov 28];29(5):489–97. Available from: <https://doi.org/10.1002/nur.20147>

28. Lino CRM, Brüggemann OM, Souza ML, Barbosa SFF, Santos EKA. The cross-cultural adaptation of research instruments, conducted by nurses in Brazil: an integrative review. *Texto Contexto Enferm* [Internet]. 2017 [cited 2018 Jan 12]; 26(4):e1730017. Available from: <https://doi.org/10.1590/0104-07072017001730017>
29. Arafat SMY, Chowdhury HR, Qusar S, Hafez MA. Cross cultural adaptation and psychometric validation of research instruments: a methodological review. *J Behav Health* [Internet]. 2016 [cited 2017 Dec 26];5(3):129-36. Available from: <https://doi.org/10.5455/jbh.20160615121755>
30. Coster WJ, Mancini MC. Recommendations for translation and cross-cultural adaptation of instruments for occupational therapy research and practice. *Rev Ter Ocup Univ São Paulo* [Internet]. 2015 [cited 2017 Nov 28];26(1):50-7. Available from: <https://doi.org/10.11606/issn.2238-6149.v26i1p50-57>
31. Ferreira L, Neves AN, Campana MB, Tavares MCGCF. AAOS/IWH guide: Suggestions for cross-cultural scale adaptation. *Aval Psicol* [Internet]. 2014 [cited 2017 Nov 25];13(3):457-61. Available from: <http://pepsic.bvsalud.org/pdf/avp/v13n3/v13n3a18.pdf>
32. Costa Neto F, Lopes MBG, Oliveira FVP, Alves FRV, Melo MRF, Souza CD. Translation and transcultural adaptation of the Hip Fracture Recovery Score assessment tool. *Rev Bras Ortop* [Internet]. 2016 [cited 2017 Nov 23];51(3):353-65. Available from: <https://doi.org/10.1016/j.rboe.2015.08.020>
33. Taylor N, Hogden E, Clay-Williams R, Li Z, Lawton R, Braithwaite J. Older, vulnerable patient view: A pilot and feasibility study of the patient measure of safety (PMOS) with patients in Australia. *BMJ Open* [Internet]. 2016 [cited 2017 Nov 29];6:e011069. Available from: <https://doi.org/10.1136/bmjopen-2016-011069>
34. Hernan AL, Giles SJ, O'Hara JK, Fuller J, Johnson JK, Dunbar JA. Developing a primary care patient measure of safety (PC PMOS): a modified Delphi process and face validity testing. *BMJ Quality & Safety* [Internet]. 2016 [cited 2018 Jan 12];25(4):273-80. Available from: <https://doi.org/10.1136/bmjqs-2015-004268>

## NOTES

### ORIGIN OF THE ARTICLE

Extracted from the thesis entitled “Translation, Transcultural Adaptation and Validation of the Patient Measure of Safety (PMOS) Questionnaire to Brazilian Portuguese”, presented in 2018 at the Graduate Program in Nursing of the Federal University of Santa Catarina.

### CONTRIBUTION OF AUTHORITY

Conception of the study: Mello JF, Barbosa SFF

Data collection: Mello JF

Data analysis and interpretation: Mello JF, Barbosa SFF

Discussion of the results: Mello JF, Barbosa SFF

Writing and/or critical review of content: Mello JF, Barbosa SFF

Review and final approval of the final version: Mello JF, Barbosa SFF

### APPROVAL OF THIS COMMITTEE IN RESEARCH

Approved in the Research Ethics Committee of the Federal University of Santa Catarina, Opinion No.2,391,005; Certificate of Presentation for Ethical Appreciation (*Certificado de Apresentação para Apreciação Ética*, CAAE): 65699817.2.0000.0121.

### CONFLICT OF INTERESTS

There is no conflict of interests.

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### CORRESPONDING AUTHOR

Janeide Freitas de Mello

janeidef@gmail.com