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Translation and cross-cultural adaptation of the instrument Patient Safety in Pediatric Drug Administration: Spanish version

Traducción y adaptación transcultural instrumento Seguridad de Paciente en Administración de Medicamentos Pediatria: Versión español

Tradução e adaptação transcultural do instrumento Segurança do Paciente na Administração de Medicamentos na Pediatria: versão espanhola

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Abstract

Objetive: Translate, adapt and validate the content of the instrument Patient Safety in the Administration of Medicines in Pediatrics Portuguese version for Spanish in the reality of Peru. **Method:** Methodological study, based on the steps: initial translation into Spanish by freelance translators; synthesis of translations; Back translation of the synthesis of the instrument to the original language; test of the prefinal version with three nurses and evaluation of the psychometric properties of the PSAMP-Ev instrument, for precise content validation and reliability (homogeneity: Cronbach's Alpha) was started after approval by the Ethics Committee. **Results:** in the translation and back-translation steps by the expert committee, all versions and components of the instrument and all translated versions, and the pre-final version of the instrument has been developed for practice testing. After changes were made in the wording of some items of the translated version to simplify it grammatically and, in some cases, to adapt it to a more widely used language, aiming at better understanding by the target population. In the analysis of psychometric properties, The content validity coefficient obtained by the specialist committee is adequate (>0.80), with the final Cronbach's Alpha of the instrument of 0.91. **Conclusion:** the instrument Patient Safety in the Administration of Medicines in Pediatrics - english version is translated, adapted, validated and adequate reliability.

Keywords: Patient Safety; Pediatrics; Translating; Adaptation, Nursing Care.

Resumen

Objetivo: Traducir, adaptar e validar el contenido del instrumento Seguridad del paciente en la Administración de Medicamentos en Pediatría versión portugués para el español en la realidad de Perú. **Método:** Estudio metodológico, a partir de las etapas: traducción inicial para idioma español por dos traductores independientes; síntesis de las traducciones; Retrotraducción de la síntesis del instrumento para el idioma de origen; test de la versión prefinal con tres enfermeras y evaluación de las propiedades psicométricas del instrumento en la versión español, de acuerdo validación de contenido y de confiabilidad. Fue aprobado por el comité de ética. **Resultados:** las etapas de traducción y retrotraducción por el comité de especialistas consolido las versiones y componentes del instrumento y las traducidas quedando la versión prefinal del instrumento para testar en la práctica asistencial después de realizadas modificaciones en la redacción de algunos ítems de la versión traducida. En el análisis de las propiedades psicométricas, el Coeficiente de validez de contenido obtenida por el comité de especialistas es adecuado (>0,80), con Alfa de Cronbach final del instrumento de 0,91. **Conclusión:** el instrumento Seguridad del Paciente en la Administración de Medicamentos en Pediatría – versión español se encuentra traducido, adaptado, validado y adecuada confiabilidad.

Palabras clave: Seguridad del Paciente; Pediatría; Traducción; Adaptación, Atención de Enfermería.

Resumo

Objetivo: Traduzir, adaptar e validar o conteúdo do instrumento Segurança do Paciente na Administração de Medicamentos em Pediatria versão em português para o espanhol na realidade do Peru. **Método:** Estudo metodológico, baseado nas etapas: tradução inicial para o espanhol por tradutores autônomos; síntese de traduções; Retrotradução da síntese do instrumento para o idioma original; teste da versão pré-final com três enfermeiras e avaliação das propriedades psicométricas do instrumento SPAMP-vE, para validação precisa do conteúdo e confiabilidade (homogeneidade: Alfa de Cronbach), foi iniciado após aprovação pelo Comitê de Ética. **Resultados:** nas etapas de tradução e retrotradução pelo comitê de especialistas consolidou-se todas as versões e componentes do instrumento, incluindo o instrumento original, instruções e todas as versões traduzidas, e se desenvolveu a versão prefinal do instrumento para testes na prática assistencial. No processo de equivalência semântica, idiomática y conceptual foi enfatizada a influência do nível sociocultural e profissional na compreensão das questões do instrumento pelo público-alvo. Assim, foram realizadas modificações na redação de alguns itens da versão traduzida para simplificá-la gramaticalmente e, em alguns casos, para adequá-la a uma linguagem mais utilizada, visando melhor compreensão pela população-alvo. Na análise das propriedades psicométricas, o Coeficiente de Validade de conteúdo obtida pelo comitê de especialistas foi adequada (>0,80), com Alfa de Cronbach final do instrumento de 0,91. **Conclusão:** o instrumento Segurança do Paciente na Administração de Medicamentos na Pediatria – versão espanhol encontra-se traduzido e adaptado, apresentando validade e confiabilidade adequadas.

Palavras-chave: Segurança do paciente; Pediatria; Tradução; Adaptação, Cuidados de Enfermería.

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INTRODUCTION

The medication system is composed of a set of processes that are interconnected, interdependent, and interdisciplinary, which aim to provide quality, effective, and safe medical care to the patient. It consists of six stages, namely: medical prescription, dispensing, drug preparation, drug administration and patient monitoring.[1]

The preparation and administration of the medication, the monitoring, recording of the procedure performed and of possible complaints / adverse reactions presented by the patient comprise the final opportunity to intercept errors derived from the other processes of the system, causing damage to approximately 1.3 million of individuals annually.[2,3] Once the nursing team is responsible for the final part of this system, its action becomes crucial to avoid errors that may cause some kind of harm to the patient being assisted.[4]

The administration of medicines in pediatrics is one of the most complex activities, due to errors or near errors that are more frequent in hospitalized children than in adults. Therefore, professionals who prepare and administer medication must have safety actions in the procedure, from the manipulation of the medication to the moment of executing the technique in the patient.[5,6]

In this regard, in the study of 500 prescriptions in pediatric services, 37.4% had an incorrect action (illegible indication, did not indicate the dose, route or frequency of administration), 16.2% two incorrect actions, 11, 0% three incorrect actions and in 4.4% of the prescriptions all actions were incorrect.[7]

Spanish multicenter study for the Prevention of Medication Errors, estimates that there are an average of 17 daily, errors per 100 hospitalized patients related to the medication system (16% in prescription, 27% in transcription / validation, 48% in dispensing and 9% in administration), of which 85% affected the patient and 0.35% caused damage.[8]

Taking into consideration that patient safety is defined as the reduction, to an acceptable minimum, by the risk of unnecessary damage associated with health care7, which, when under nursing care, can encompass a wide variety of possible failures involved in each of the stages of the medication administration process.[9]

Thus, the interest of using validated and reliable technologies that evaluate the process of drug administration in those responsible, to be used in realities that have not yet been explored, as in the case of Peru, came from findings that indicate that among the existing medication errors in pediatrics, the majority of administration, being the wrong dose the most frequent type of error, followed by the omission of medication and by the medication administered at the wrong time.[10]

The study is justified because the use of tools represents an appropriate approach to improve patient safety and will promote: child safety in the use of drugs in health facilities; review of a high-risk process for pediatric patients; the identification of the fragile points to propose improvements and corrections, using the PSAMP instrument; good practices in all stages of the drug administration process; standardization of actions, capable of enabling safe patient care in health institutions in Peru.

It is also highlighted that in Peru, there is a notable lack of instrument validation studies, for this reason, cross-cultural adaptation is the best option for evaluation instruments, allowing its applicability in any country, culture and language. Highlighting that translation and adaptation studies facilitate the comparison of the results of the same instrument in different countries and cultures, especially in the field of promoting patient safety in the administration of medications.[11]

Therefore, in the absence of an instrument in Spanish, for use in Peru, that evaluates the actions of patient safety in the administration of medicines in pediatrics in the hospital environment, the instrument Patient Safety in the Administration was selected of Medications in Pediatrics (PSAMP), reliable in the Portuguese language, because in the content validation stage I achieved adequate results in the content validity index (CVI) in practical relevance (0.775), clarity (0.760) and relevance (0.938), obtaining the final version of the instrument in Portuguese consisting of 28 items. Cronbach's alpha was 0.851 indicating high internal consistency. The clinical validation stage identifies that the professionals reported satisfactorily developing 19 actions,[12]

In addition, it is chosen to use the Patient Safety Instrument in the Administration of Pediatric Medicines (PSAMP) because it follows the recommendations of the Security Protocol for the Prescription, Use and Administration of Medicines that the Ministry of Health[13] of Brazil has implemented within the framework of the actions developed for patient safety in health institutions, said instrument was built and validated in pediatrics in the Brazilian Portuguese language,[12] but it needs to be translated into Spanish and adapted to be inserted in the Peruvian context.

Based on the above, the objective was to translate, adapt and validate the content of the instrument Patient Safety in the Administration of Medicines in Pediatrics Portuguese version for Spanish in the cultural reality of Peru.

METHOD

Study Design

Methodological study that proposed to translate and adapt the instrument for Patient Safety in the Administration of Medications in Pediatrics (PSAMP) for the Spanish language of Peru. For the development of the study, five stages were followed, referring to the translation, adaptation of the instruments, and the guidelines suggested by Beaton et al.,[14] which consist of: 1) initial translation; 2) synthesis of translations; 3) Back translation to the source language; 4) review by a committee of specialists; and 5) pre-final version test (Figure 1).

Process

The first stage consisted in the preparation of two independent translations (T1 and T2) for the Spanish language. The T1 translation was prepared by a native Peruvian nurse bilingual in Portuguese and Spanish, having more than 20 years of experience

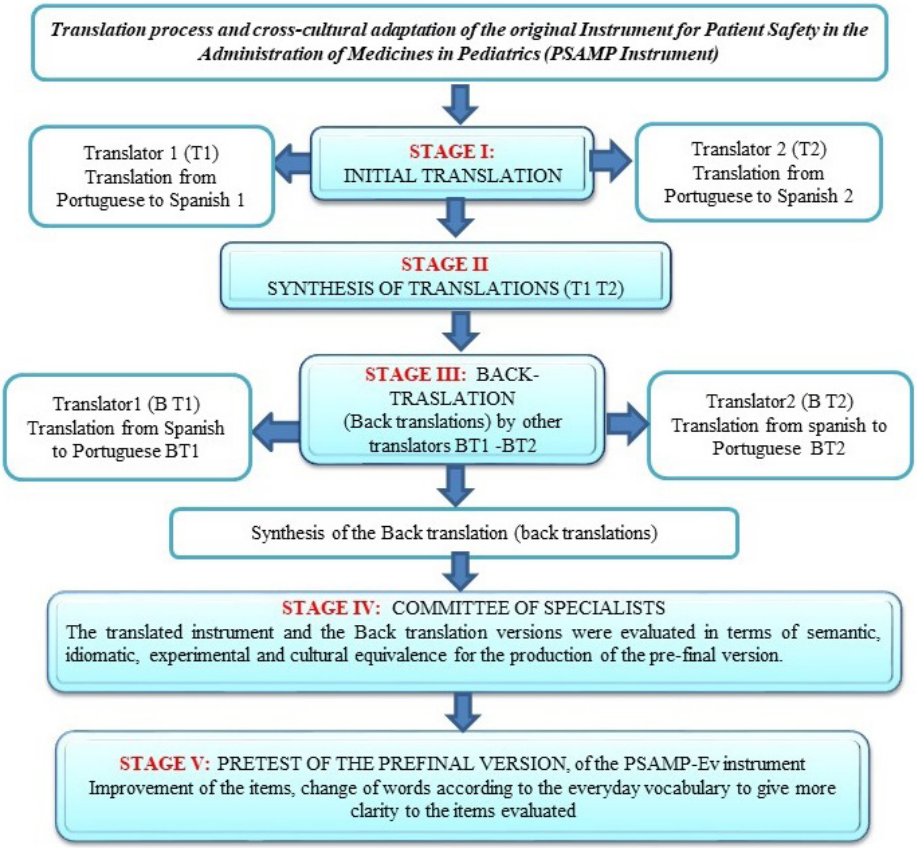

Figure 1. Graphic representation of the translation and cross-cultural adaptation process of the PSAMP instrument.
Source: Own author based on Beaton et al.[14]

in university teaching. The professional was informed about the concepts and objectives of the study and the purpose of translating it was to acquire equivalence in the Peruvian clinical perspective. The translator responsible for preparing the T2 translation was a Peruvian professor, linked to the language center of the National University of Tumbes, Peru, with a command of Portuguese and Spanish. This translator did not have clarification of the objectives of the research, thus being more sensitive to the detection of subtle differences between the meanings of terms or phrases in the translation process for the Spanish language.

The second stage, synthesis of the translations, started from the initial translations T1 and T2, which were synthesized by a third person and gathered in a single instrument (T12). The items in this synthesis version were evaluated based on the analysis of the closest terms of the original instrument, identifying convergences and divergences of the translations and managing to unify a preliminary version of the instrument.[14] The T12 version was prepared by a nurse trained in Brazil with dual nationality (Chilean and Brazilian) and bilingual (Portuguese and Spanish), with experience in pediatrics and patient safety.

The third stage, Back-translation to the original language, started from version T12, having been developed by two back-translators clarified about the objectives of the instrument. The first back-translator was Brazilian, a university professor of the Spanish language and with more than five years of teaching in the language. The second back-translation was prepared by a bilingual Brazilian nurse in the Spanish language, a university professor in Brazil with more than 30 years and vast experience in translation and validation studies. At this stage, the independent back-translated versions BT1 and BT2 were produced, completely blind from the original version.

In the fourth stage, for the review by a committee of nine specialists, I examine the versions produced until then (T1, T2, T12, BT1 and BT2), in addition to the original version of the PSAMP-Portuguese version. Thus, it was composed of the four translators (two of the translation and two of the back translation); translation synthesizer; back translation synthesizer; a doctor of applied linguistics and a methodologist; a teacher with a command of the Spanish language and five years of experience in the area of linguistics and a nurse with experience in the area of pediatrics and five years of experience in the area of linguistics.[11] They all have a command of Portuguese and Spanish.

The committee formed was responsible for the evaluation of the semantic equivalences (grammatical and vocabulary evaluation), idiomatic (equivalent expressions for Spanish), experimental (terms consistent with the experience lived by the target population) and conceptual (translated concepts must be explored and events experienced by the Peruvian population).[15]

From the specialists' analyzes, the suggested alterations were made and the pre-final version of the PSAMP instrument, Spanish version (PSAMP-Ev), was prepared.

With the pre-final version of the instrument, the test was developed, comprising the fifth stage of the translation process. This stage was carried out with nurses from the pediatric emergency service of the Lambayeque Regional Hospital.

Thus, the pre-final version of the instrument was obtained, which was submitted content validation by another committee of specialists, which will be called in this study by content judges. The members of this committee were selected through a search in the Investigators and Innovators Registry Directory.

The author's recommendations[16] are followed, who suggests that the number of judges should be from six to twenty subjects. For this, an odd number of specialists weres chosen, since this condition avoids the equality of opinions and, with this, allows the majority decision. Then, a number of at least seven specialists will be used, which corresponds to 100% + 1 in addition to the recommendation according to the author.[16]

The selection of the judges was carried out in February 2018, through intentional sampling, in which the researcher intentionally selects subjects who know the attributes of the research instrument.

To compose the sample, the judges would need to have a doctorate in Nursing and obtain a score equal to or greater than five, according to the classification system described by the author of the instrument in Portuguese.

The content validation was carried out with the seven judges, having been adopted as criteria for selection: having clinical experience in the administration of medications in the children's hospital care and / or having knowledge or having carried out research on the validation of measurement instruments. All were doctors and teachers of higher education, with an average of eight years in assisting children with a chronic condition, with seven being nurses.

Participants

The nurses of the pediatric emergency service of the Lambayeque Regional hospital who participated in the test were individually guided to respond to the instrument according to their daily experience in nursing care for hospitalized children. The instruments were handed over to the nurses and their return requested on their next shift. After autocomplete each nurse reported her impressions of him and her responses to each item.

For the content validation, the PSAMP-vE instrument and an instrument for validation were given to the judges, addressing the items of clarity, practical relevance and theoretical relevance.[16]

Analysis

The content validation of the Spanish version was carried out by means of the validation of the psychometric properties, considering or Coefficient of content validity (CVC), which corresponds to the degree to which the instrument is valid in relation to its content,[14] being used, for Therefore, the scores of the judges from 1 (bad) to 5 (excellent) on the Likert scale for each aspect evaluated, for the calculation was carried out as follows:

1. Based on the judges' marks, the average of the marks for each item was calculated. (Mx):

$$Mx = \frac{\sum_{I=}^{j} x}{j} I$$

Σxi represents the sum of the judges' marks and J represents the number of judges who will evaluate each item

2. Based on the average, the content validity coefficient of each item was calculated (CVC_i);

$$CVC_i = \frac{Mx}{Vmáx}$$

$V_{máx}$ represents the maximum value that the item could receive.

3. The error calculation (Pei) was performed, to discount possible biases of the evaluating judges, for each item:

$$Pei. = \left(\frac{x}{j}\right) j$$

4. With this, the final content validity coefficient of each item (CVC_c) was thus calculated:

$$CVC_c = CVC_{i--}P_{ei}$$

5. For the calculation of the instrument's total CVC (CVC_t), for each of the characteristics (Practical Relevance; Clarity of Language and Theoretical Relevance) the following was used:

$$CVC_t = Mcvc_i - Mpe_i$$

$Mcvc_i$, represents the average of the content validity coefficients of the instrument items and Mpei, the average of the errors of the instrument items. The CVCt refers to the value calculated for the instrument in general. This is the average calculated for all the items regarding Practical Relevance; Clarity of Language and Theoretical Relevance.

It is highlighted that, despite the recommendation that only the questions that obtained a CVC greater than 0.8 were considered acceptable, it was decided not to withdraw the items from the instrument so that the reliability assessment could proceed, in the case Homogeneity was verified through internal consistency measured by Cronbach's Alpha. The coefficient measures the degree of covariance of the items with each other, serving as an indicator of the internal consistency of the pre-test itself and varies from 0 to 1, in which zero indicates the total absence of internal consistency of the items; and 1 the consistency of 100%. Acceptable alpha values are between 0.70 and 0.90, showing that the measurements were reliable.[15]

Ethical considerations

The study was initiated after approval by the Ethics Commission of the Regional Hospital of Lambayeque, Peru. The author of the aforementioned instrument authorized the carrying out of this process of translation, cross-cultural adaptation and validation

for Spanish in the cultural reality of Peru. Informed consent was requested from the participants, ensuring their anonymity.

RESULTS

Chart 1 identifies the items of the PSAMP instrument in the Portuguese version and its final version in Spanish (PSAMP-Ev), after the translation and validation of the instrument by the specialists, as well as after the analysis of the psychometric properties by the judges of content.

According to the evaluation shown in Chart 1, nine items were kept unaltered and seventeen in their content had modifications. It is highlighted that they were grouped; item 6 with 5 and item 20 with 19, since the judges considered that the complementary actions corresponded to a single item. Thus, the final version was made up of 26 items.

In the test, the pre-final version of the PSAMP-vE instrument was applied to three female nurses, two being 30 years old and one 41 year old, with more than five years in nursing care in the

Chart 1. Evaluation of the equivalence between the original instrument in the Portuguese language and the translated version for Spanish. Lambayeque, Peru, 2018.

Response items of the PSAMP instrument in Portuguese.		**Response items of the PSAMP instrument in Spanish, final version**	
1- Nunca		1- Never	
2- Quase nunca		2- Almost never	
3- A veces		3- Sometimes	
4- Quase sempre		4- Almost always	
5- Sempre		5- Always	
	SPAMP instrument items in Portuguese.	**Items of the prefinal version of the SPAMP instrument in Spanish, after the equivalence assessment.**	**Action and Items of the final version of the SPAMP instrument in Spanish, after content and reliability validation.**
1.	Utiliza no mínimo dois identificadores (nome completo, data de nascimento ou número do prontuário) para confirmar o paciente antes de administrar medicamentos.	Use at least two identifiers (patient's full name, date of birth, or file number) to identify the patient before administering medications.	CHANGED: Use at least two identifiers (child's full name, date of birth, or medical record number) to identify the child before administering the medication.
2	Confere o nome do medicamento com a prescrição antes de administrá-lo ao paciente.	Confers the name of the medication with the prescription before administering it to the patient.	CHANGED: Confirm the name of the medicine with the prescription before giving it to the child.
3	Leva ao leito apenas os medicamentos prescritos a um único paciente.	Bring only the prescribed medications to bed for a single patient.	CHANGED: Bring to bed only the medications prescribed for a single child.
4	Administra o medicamento por ordem verbal somente em caso de emergência.	Administer the medication by verbal order only in an emergency.	SUSTAINED
5	Confere se o paciente não é alérgico ao medicamento prescrito.	Check if the patient is not allergic to the prescribed medication.	CHANGED: Confirm if the child is not allergic to the prescribed medication, identifying it differently with a bracelet and notice in the medical record, alerting the entire team.
6	Identifica o paciente alérgico de forma diferenciada com pulseira e aviso em prontuário, alertando toda a equipe.	Identify the allergic patient in a differentiated way with a bracelet and notice in the medical file, alerting the entire team.	CLUSTERED with the item 5
7	Identifica a via de administração prescrita para o medicamento.	Identify the prescribed route of administration for the drug.	SUSTAINED

Chart 1. Continued...

	SPAMP instrument items in Portuguese.	Items of the prefinal version of the SPAMP instrument in Spanish, after the equivalence assessment.	Action and Items of the final version of the SPAMP instrument in Spanish, after content and reliability validation.
8	Verifica se a via prescrita é a tecnicamente recomendada para administrar o medicamento.	Check if the prescribed route is the recommended technique for administering the medication.	SUSTAINED
9	Lava as mãos antes do preparo e administração de medicamentos.	Wash your hands before preparing and administering medications.	SUSTAINED
10	Utiliza materiais e técnicas asséptica para administrar medicamentos por via intravenosa e para outras vias que exijam esse tipo de técnica.	Uses aseptic materials and techniques to administer medications intravenously and for other routes that require this type of technique.	CHANGED: It uses aseptic materials and techniques to administer medications according to the different routes of administration.
11	Prepara o medicamento imediatamente antes da sua administração.	Prepare the medicine immediately before administration.	SUSTAINED
12	Administra o medicamento na hora certa.	Administer the medication at the correct time.	SUSTAINED
13	Adéqua os horários de administração dos medicamentos à rotina de uso já estabelecida antes da internação.	Adapt the medication administration schedules to the routine already established before hospitalization.	SUSTAINED
14	Confere atentamente a dose prescrita para o medicamento.	Carefully check the prescribed dosage for the medication.	CHANGED: Confirm carefully the dosage according to the doctor's prescription for the drug.
15	Confere a velocidade de gotejamento, a programação e o funcionamento de bombas de infusão contínua com a prescrição.	Confers drip speed, programming and operation of infusion pumps continues with prescription.	CHANGED: Confirm the drip rate, the programming and operation of infusion pumps continues with the medical prescription.
16	Realiza dupla checagem dos cálculos para preparo e para administração de medicamentos potencialmente perigosos ou de alta vigilância.	Double check calculations for preparation and administration of potentially dangerous drugs or high surveillance drugs.	CHANGED: Double-check, by two professionals, the dilution and administration calculations of potentially dangerous drugs or high surveillance drugs.
17	Utiliza instrumentos de medida padrão no preparo de medicamentos para medir doses com exatidão (ex: seringas milimetradas).	Use standard measuring instruments in the preparation of medications to measure the exact dose (eg, millimeter syringes).	CHANGED: Use standard measuring instruments in the preparation of medications to measure the exact dose (eg: millimeter syringes, dosed cups).
18	Devolve à farmácia as sobras de medicamentos não administrados.	Return unadministered medicine leftovers to the pharmacy.	SUSTAINED
19	Registra na prescrição o horário da administração do medicamento imediatamente após cada dose.	Record in the prescription the time of administration of the medication immediately after each dose.	CHANGED: Record in the transcript the schedule of administration and in the Clinical History occurrences of the medication immediately after administering each dose.
20	Registra em prontuário todas as ocorrências relacionadas aos medicamentos (ex: adiamentos, cancelamentos, desabastecimento, recusa do paciente e eventos adversos).	Register in the registration form all occurrences related to medications (eg: postponements, cancellations, shortages, rejection or refusal of the patient and adverse events).	CLUSTERED: with item 19.

Chart 1. Continued...

	SPAMP instrument items in Portuguese.	Items of the prefinal version of the SPAMP instrument in Spanish, after the equivalence assessment.	Action and Items of the final version of the SPAMP instrument in Spanish, after content and reliability validation.
21	Registra em prontuário e notifica à Gerência de Riscos e/ou Núcleo de Segurança do Paciente os eventuais incidentes relacionados à terapia medicamentosa.	Record in the medical file and notifies the risk management and / or the Patient Safety Center of any incidents related to drug therapy.	CHANGED: Notify the Quality Management office in the Registration and Reporting Form of incidents, adverse reactions and adverse events.
22	Mantém registro adequado de medicamentos preparados que serão armazenados (com data e horário da manipulação, concentração do medicamento, nome do responsável pelo preparo e validade)	Maintain an adequate record of prepared drugs that will be stored (with date and time of handling, drug concentration, name of the person responsible for preparation and validity).	SUSTAINED
23	Monitora a temperatura da geladeira de acondicionamento de medicamentos, registrando os valores máximo e mínimo diariamente.	Monitors the temperature of the drug conditioning refrigerator by recording the maximum and minimum values daily.	CHANGED: Monitor the temperature of the medicine conditioning refrigerator by recording the values daily.
24	Esclarece dúvidas sobre a prescrição junto ao prescritor antes de administrar o medicamento (ex: inelegibilidade da prescrição, indicação do medicamento, posologia, "fazer se necessário", "a critério médico", unidade de medidas utilizadas, forma farmacêutica, via de administração e dose).	Clarify doubts about the prescription with the prescriber before administering the drug (eg: ineligibility of the prescription, indication of the drug, dosage, "if necessary", "at medical discretion, unit of measures used, pharmaceutical form, route of administration and dose)	CHANGED: Clarifie doubts about ineligibility of the prescription, indication of the drug and dosage before administering the drug.
25	Orienta o paciente e o acompanhante sobre o medicamento administrado (nome), aspecto (cor e formato) justificativa da indicação, frequência com que será administrado e efeitos esperados.	Guide the patient and the companion on the drug administered (name), appearance (color and shape), justification of the indication, the frequency which it will be administered and the expected effects.	CHANGED: Guide the child and the companion on the medication administered and the justification for the indication, the frequency which it will be administered and the expected effects.
26	Checa se o medicamento a ser administrado possui forma farmacêutica (ex: ampola, frasco, comprimido) compatível com a via de administração prescrita.	Verifie if the medicine to be administered has the pharmaceutical form (eg: ampoule, bottle, tablet) compatible with the prescribed route of administration.	CHANGED: It verifies if the medicine to be administered has a pharmaceutical presentation compatible with the route of administration of the medical prescription.
27	Avalia o paciente para identificar, quando possível, se o medicamento teve o efeito desejado.	Evaluate the patient to identify, when possible, if the drug had the desired effect.	CHANGED: Evaluate the child to identify, when possible, if the medication had the desired effect.
28	Informa ao prescritor todos os efeitos diferentes do esperado (em intensidade e forma) para o medicamento.	Inform the prescriber of all effects different from what is expected (in intensity and form) for the drug.	CHANGED: It inform the doctor who prescribed all the different effects than expected (in intensity and form) for the drug.

unit hospital, each being in a different unit: Pediatric Intensive Care Unit (PICU), emergency and hospitalization. The mean time used to autocomplete the PSAMP-Ev instrument was 10 minutes. The nurses' evaluation of the elements of the pre-final version of the PSAMP instrument in Spanish language shows that the items were understandable, with clear and easily eligible answer options, without the need for modifications.

Once all the stages of the process of translation and cross-cultural adaptation of the instrument were concluded, the pre-final version of the PSAMP-Ev instrument was obtained, with the analysis of the psychometric properties of validity (content-CVC) being performed; and reliability (homogeneity: Cronbach's alpha).

Table 1 shows that most of the 26 items evaluated obtained CVCc> 0.80 (cut-off point), except: four items of practical relevance, seven items on clarity of language and one item on theoretical relevance.

The criteria of practical relevance, clarity of language and theoretical relevance presented, respectively, a CVCt of 0.97; 0.97 and 0.96. As the CVCt of the three criteria of the scale (PP, CL, RT) were acceptable, it was decided to keep the statements and as close as possible to the original scale.

The committee of judges allowed an analysis of the structures of each item, whose contributions and suggested alterations in the validation process made it possible to refine the items. Thus, the justifications for maintaining, altering, grouping and / or excluding the items, according to the judges' suggestions, can be observed in Chart 1.

The reliability of the instrument with its 26 items was evaluated by means of the internal consistency, measured by the calculation of the Cronbach's alpha coefficient, which was 0.921.

From the evaluation of the judges, the Cronbach's Alpha related to practical relevance (0.91), clarity of language (0.91) and relevance (0.91) was calculated, which denotes internal consistency adequate.[14] If any item were excluded, the alpha would remain 0.91, which suggests high reliability and reliability of the instrument to observe patient safety in the administration of medications in pediatrics (Table 1).

This stage enabled the development of the second version of the instrument for patient safety in the administration of medications in pediatrics (PSAMP-Ev), (Chart 1). Afterwards, the final version of the PSAMP-Ev instrument was obtained, the same one that was sent to the author16 who issued a favorable opinion, agreeing with the translation and the alterations made in the PSAMP instrument, since the Spanish version presents the same content and sense of the original version, ratifying the cross-cultural adaptation of the PSAMP instrument in the Spanish version for use in Peru.

Chart 2 of the instrument is presented below in its final version in Spanish.

DISCUSSION

The translation and adaptation of instruments previously validated in other countries are a legitimate procedure that, in addition to reducing costs and facilitating exchanges between researchers at the international level, enables dialogues about patient safety in various aspects, including those regarding safety in patients the administration of medications.

Pediatric patient safety is complex and involves actions promoted by health institutions to reduce to an acceptable minimum the risk of unnecessary harm associated with health care.[15]

Given this fact, the procedure of translation and cultural adaptation of the instrument for patient safety in the administration of medicines in pediatrics (PSAMP) was carried out systematically, so that the 28 items were adapted in terms of semantic and idiomatic equivalences, experimental and conceptual by the committee of judges. In this way, it was possible to arrive at an instrument with 26 items with more clarity and suitability to be used in the test stage, with modifications that involve exemplifications and substitutions of terms and expressions, whose main objective was to facilitate the understanding of the items of the test instrument by the study subjects and thus ensure cross-cultural equivalence.[16]

It is emphasized that cultural adaptation studies should not only consider the differences between countries or their languages, it is important that aspects related to local or regional realities are also weighed, analyzing how much is gained with the cultural approach and how much is lost with generalizability and comparability.[17] Thus, despite the instrument having had its original version validated, we opted for the revalidation of the Spanish version, since the characteristics of the target population, their interests, and the nature of health service provision can be different between countries.

During the pre-test, it was observed that the three nurses had doubts regarding the patient safety items in the administration of medications, such as: Use at least two identifiers (full name of the child, date of birth or medical history number) to identify the child before preparing and administering medications, in view of not identifying patients by name or date of birth and prioritizing institutional aspects, such as bed number or biomedical content as a cause of hospitalization and / or pathology, These are aspects that depersonalize care and perhaps favor the appearance of possible incidents and adverse events, therefore it is important to use two identifiers suggests the improvement in the knowledge and monitoring of the health team combined with the direct action of Patient Safety in the service pediatrics.

In this regard, it is admitted that it is not yet a routine care for children hospitalized in the hospital, since it is only identified in the clinical history[18] or the Kardex registry (daily nurse record sheet where the medications, dose, frequency and the route of administration and other treatments),[19] which the nurse uses each time he administers medicine when taking the child to bed or identifies it by the bed number. The World Health Organization (WHO)[20] recommends as goal number one, the correct identification of the patient. Patient identification serves two purposes: first, to determine with certainty that children are legitimate recipients of treatment; second, to guarantee that the medication, when it is carried out, is effectively what the child needs.

However, in daily practice it is observed that the identification of the patient is still a stage of nursing care that has not yet been

Table 1. Distribution of the content validity coefficient for each item (CVCc) and the Cronbach's alpha indices for the total item according to the analysis of the judges. Lambayeque, Peru, 2018.

CVCc*			Ítem	Item-total statistics Cronbach's alpha if item was excluded		
PP†	CL‡	R?				
1	1	1	1. Use at least two identifiers (child's full name, date of birth, or medical record number) to identify the child before administering the medication.	0,921	0,921	0,920
0,71	0,71	0,80	2. Confirm the name of the medicine with the prescription before giving it to the child	0,919	0,919	0,919
0,94	0,91	0,97	3. Bring to bed only the medications prescribed for a single child.	0,920	0,919	0,920
0,63	0,74	0,91	4. Administer the medication by verbal order only in an emergency.	0,919	0,918	0,918
0,83	0,66	0,92	5. It confirms if the child is not allergic to the prescribed medication, identifying it differently with a bracelet and notice in the medical record, alerting the entire team.	0,919	0,919	0,920
0,97	0,89	0,97	6. Identify the prescribed route of administration of the drug.	0,920	0,920	0,920
0,97	0,97	0,94	7. Check to see if the prescribed route is the recommended technique for administering the medication.	0,920	0,920	0,920
0,83	0,83	0,83	8. Wash your hands before preparing and administering medications.	0,920	0,920	0,919
1	1	1	9. It uses aseptic materials and techniques to administer medications according to the different routes of administration.	0,919	0,919	0,919
1	1	1	10. Prepare the medicine immediately before administration.	0,921	0,921	0,921
0,89	0,89	0,89	11. Give the medicine at the correct time.	0,921	0,921	0,921
0,80	0,77	0,83	12. Adjust the medication administration schedules to the routine already established before your hospitalization.	0,920	0,920	0,920
0,71	0,71	0,69	13. Please carefully confirm the dosage according to the medical prescription for the drug.	0,919	0,919	0,919
0,77	0,74	0,89	14. Confirm the drip rate, programming and operation of continuous infusion pumps with medical prescription.	0,919	0,919	0,920
0,97	0,94	0,94	15. It performs a double check, by two professionals, of the dilution and administration calculations of potentially dangerous drugs or high surveillance drugs.	0,918	0,918	0,919
0,94	0,91	0,94	16. It uses standard measuring instruments in the preparation of medicines to measure the exact dosages (e.g: millimeter-sized syringes, dosed vessels)	0,920	0,920	0,920

Nota: *CVCc: Content Validity Coefficient for each item; † PP: Practical Relevance; ‡ CL: Clarity of Language; ? R; Relevance;?? CVCt: Total Content Validity Coefficient of the characteristic. Source: Research data.

Table 1. Continued...

CVCc*			Ítem	Item-total statistics Cronbach's alpha if item was excluded		
PP†	CL‡	R?				
0,89	0,84	0,91	17. Returns the leftover unused medications to the pharmacy.	0,920	0,919	0,920
0,89	0,84	0,9	18. Record in the Kardex the schedule of administration and in the Clinical History occurrences of the medication immediately after administering each dose.	0,920	0,920	0,919
0,89	0,86	0,91	19. Report incidents, adverse reactions and adverse events to the Quality Management office in the Registration and Report Card.	0,919	0,920	0,921
0,91	0,97	1	20. Maintains an adequate record of prepared drugs that will be stored (with date and time of handling, drug concentration, name of the person responsible for preparation and validity).	0,920	0,919	0,921
0,94	0,91	1	21. Monitors the temperature of the medicine conditioning refrigerator by recording the values daily.	0,920	0,919	0,920
0,83	0,69	0,83	22. Clarifies doubts about ineligibility of the prescription, indication of the drug and dosage before administering the drug.	0,920	0,920	0,920
0,97	0,89	0,97	23. Guides the child and the companion on the medication administered and the justification for the indication, the frequency with which it will be administered and the expected effects.	0,919	0,920	0,920
0,91	0,89	0,89	24. It verifies if the medicine to be administered has a pharmaceutical presentation compatible with the route of administration of the medical prescription.	0,921	0,921	0,921
1	1	1	25. Evaluate the child to identify, when possible, if the medication had the desired effect.	0,919	0,919	0,919
0,89	0,89	0,89	26. Inform the doctor who prescribed all the different effects than expected (in intensity and form) for the drug.	0,921	0,921	0,921
0,97??	0,97??	0,96??				

Nota: *CVCc: Content Validity Coefficient for each item; † PP: Practical Relevance; ‡ CL: Clarity of Language; ? R; Relevance;?? CVCt: Total Content Validity Coefficient of the characteristic. Source: Research data.

implemented, despite the WHO recommendations, which may not guarantee the quality and safety of drug administration. It is highlighted that the strategy of implanting identification bracelets, as one of the tools to promote care that prioritizes the patient safety, is understood as a low-cost practice for institutions and easy to install in the routine of care for professionals health.[21] Therefore, the role of the nurse is highlighted as fundamental due to the importance of the correct identification of the patient and its relationship with the occurrence of errors in child health care.

It was also observed during the test that the item: Double-check calculations for the preparation and administration of potentially dangerous drugs or high surveillance drugs is not an action that the nursing professional performs routinely. The double check is a procedure by which a second health professional verifies the dose calculation process, in the presence or absence of the professional who performed the first checkup. It is highlighted that it is one of the systems that allows errors to be intercepted, since it is very unlikely that two different people are wrong in controlling

Chart 2. Final version translated into Spanish of the Patient Safety in Medication Administration instrument (SPAM-vE). Lambayeque, Peru, 2018.

Domains	MEDICINE ADMINISTRATION	Never	Almost never	Sometimes	Almostost always	Always
		1	2	3	4	5
Correct Patient	1. Use at least two identifiers (child's full name, date of birth, or medical record number) to identify the child before administering medication.					
Correct medicine	2. Confirm the name of the medicine with the prescription before giving it to the child.					
	3. Bring to bed only the medications prescribed for a single child.					
	4. Administer the medication by verbal order only in an emergency.					
	5. Confirm if the child is not allergic to the prescribed medication, identifying it differently with a bracelet and notice in the medical record, alerting the entire team.					
Correct via	6. Identify the prescribed route of administration for the drug.					
	7. Check if the prescribed route is the recommended technique for administering the medication.					
	8. Wash your hands before preparing and administering medications.					
	9. Use aseptic materials and techniques to administer medications according to the different routes of administration.					
Correct time	10. Prepare the medicine immediately before administration.					
	11. Administer the medication at the correct time.					
	12. Adapt the medication administration schedules to the routine already established before hospitalization.					
Correct dose	13. Confirm carefully the dosage according to the doctor's prescription for the drug.					
	14. Confirm drip rate, programming and operation of continuous infusion pumps with medical prescription.					
	15. Double check by two professionals of dilution calculations and administration of potentially dangerous drugs or high surveillance drugs.					
	16. Use standard measuring instruments in the preparation of medications to measure the exact dose (ex: millimeter syringes, dosing cups).					
	17. Return any unadministered leftovers to the pharmacy.					
Correct registration of the administration	18. Record in the transcript the schedule of administration and in the clinical history occurrences of the medication immediately after administering each dose.					
	19. Notify the Quality Management office in the Registration and Reporting Form of incidents, adverse reactions and adverse events.					
	20. Maintain an adequate record of prepared drugs that will be stored (with date and time of handling, drug concentration, name of the person responsible for preparation and validity).					
	21. Monitors the temperature of the medicine conditioning refrigerator by recording the values daily.					

Chart 2. Continued...

Domains	MEDICINE ADMINISTRATION	Never	Almost never	Sometimes	Almostost always	Always
		1	2	3	4	5
Orientation correct	22. Clarifie doubts about ineligibility of the prescription, indication of the drug and dosage before administering the drug.					
	23. Guide the child and the companion on the drug administered and the justification, indication, frequency which it will be administered and the expected effects.					
Correct way	24. Verifie if the medicine to be administered has a pharmaceutical presentation compatible with the route of administration of the medical prescription.					
Correct answer	25. Evaluate the child to identify, when possible, if the medication had the desired effect.					
	26. It informs the doctor who prescribed all the different effects than expected (in intensity and form) for the drug.					

the same dose of medication. This system is advisable, in the use of infusion pumps, when high-risk drugs are used to detect errors in the infusion rate.[22] Therefore, the nursing professional must encourage the performance of double checks to avoid errors that may result in serious harm to patients.

It is noted that the clinical and academic experience of the judges allowed a critical analysis of the structures that make up each item, this evaluation being conducted and based on guidelines already tested in other studies,[14,16] so that the contributions and changes suggested in the process adaptation made it possible to improve the items, taking into consideration the safety of the patient in the administration of medications in pediatrics.

In the theoretical dimension, all the items of the scale obtained more than 50% association of the items evaluated in the final version with the original instrument, demonstrating the congruence of the committee of specialists in the validation of content and opinions regarding the factors measured on the instrument. The criteria used in this stage of the study showed that the Content Validity Coefficient of each item (CVCc) is greater than 0.80 in the three characteristics evaluated (practical relevance, clarity and theoretical relevance). Regarding the items considered adequate, it was decided to keep the statements and as close to the original instrument as possible, proving that these criteria refined the instrument, allowing a greater understanding and clarity of the terms used in the instrument, identifying strengths and weaknesses, and favored alterations based on the theoretical dimensions of the construct.

The scale test even allowed the participation of nurses with different types of specialization and levels of experience in pediatrics, a fact that demonstrated that the instrument can be understood by all nurses. It is highlighted that the title of the scale adopted in the Spanish version remained: "Patient safety in the administration of medications in Pediatrics Spanish version (PSAMP-Ev)".

There are limitations that must be taken into account. First, as mentioned above, the sample was small in relation to the study in which the original version was validated. Second, carry out the application of the instrument in clinical practice and its incorporation into routine activities for the administration of medications in pediatrics.

CONCLUSION

Based on the proposed objective and the results obtained, it can be concluded that the instrument Patient Safety in the Administration of Medicines in Pediatrics Spanish version (PSAMP-Ev) is translated and cross-culturally adapted for Spanish in the cultural reality of Peru.

Semantic, idiomatic, experimental and conceptual equivalences were identified between the items of the original instrument in Portuguese and the final version in Spanish. Regarding content validation, or the total CVCc of the scale was 0.97, opting to keep the statements and the maximum proximity with the original instrument.

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Data analysis. Francisca Elisângela Teixeira Lima. Lorena Pinheiro Barbosa. Paulo César de Almeida.

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