



ORIGINALES

Reliability of the patient safety instrument in drug administration in pediatrics - Spanish versión

Confiabilidade do instrumento Segurança do Paciente na Administração de Medicamentos na Pediatria- Versão espanhola
Confiabilidad del instrumento Seguridad del Paciente en Administración de Medicamentos en Pediatría- Versión española

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ABSTRACT:

Objective: To evaluate the psychometric properties in terms of reliability of the instrument Patient Safety in the Administration of Medicines in Pediatrics, Spanish version.

Method: Methodological study of evaluation of the psychometric properties carried out with 25 nurses from the pediatric units of a Peruvian hospital. For the evaluation of homogeneity (Cronbach's alpha), the nurses completed the instrument for Patient Safety in the Administration of Medications in Pediatrics Spanish version, composed of nine domains and 26 items; and for stability (Wilcoxon test-retest), they autocompleted the instrument again 30 days after the first collection, for comparison of both measurements.

Results: In reliability, Cronbach's alpha varied from 0.792 to 0.821, considered an acceptable parameter, presenting high internal consistency, maintaining the 26 items, in the final version. In the stability of the instrument, the domains presented, in the test, a mean of 68.0 + 25.5 to 99.5 + 2.5; and in the retest 86.0 + 14.8 I tied 96 + 11.8. Six domains were found without significant difference ($p > 0.05$) between test and retest.

Conclusion: The instrument presented psychometric properties that prove its reliability, providing subsidies for safer nursing practice and allowing standardization of care in the administration of medications.

Descriptors: Patient Safety; Drug Utilization; Pediatric Nursing; Psychometrics; Reproducibility of Results; Pediatrics.

RESUMO:

Objetivo: Avaliar as propriedades psicométricas em termos de confiabilidade do instrumento Segurança do Paciente na Administração de Medicamentos na Pediatria, versão espanhol.

Método: Estudo metodológico realizado com 25 enfermeiras das unidades pediátricas de um hospital peruano. Para avaliação da homogeneidade (alfa de Cronbach) as enfermeiras autoperceberam o SPAMP-vE, composto por nove domínios e 26 itens; e para estabilidade (Teste-reteste de Wilcoxon) autoperceberam novamente o instrumento após 30 dias da primeira coleta, para comparação de ambas medidas.

Resultados: Na confiabilidade, o alfa de Cronbach, variou de 0,792 a 0,821, considerado um parâmetro aceitável, apresentando alta consistência interna, mantendo-se os 26 itens, na versão final. Na estabilidade do instrumento, os domínios apresentaram, no teste, média de $68,0 \pm 25,5$ até $99,5 \pm 2,5$; e no reteste $86,0 \pm 14,8$ até $96 \pm 11,8$. Evidenciaram-se seis domínios sem diferença significativa ($p > 0,05$) entre teste e reteste.

Conclusão: Instrumento apresentou propriedades psicométricas que comprovam sua confiabilidade, fornecendo subsídios para prática de enfermagem mais segura e permitindo padronização do cuidado na administração de medicamentos.

Palavras-chave: Segurança do Paciente; Uso de Medicamentos; Enfermagem Pediátrica; Psicometria; Reprodutibilidade dos Testes; Pediatria.

RESUMEN:

Objetivo: Evaluar las propiedades psicométricas en términos de confiabilidad del instrumento Seguridad del Paciente en la Administración de Medicamentos en Pediatria, versión española.

Método: Estudio metodológico de evaluación de las propiedades psicométricas realizado con 25 enfermeras de las unidades pediátricas de un hospital peruano. Para evaluación de la homogeneidad (alfa de Cronbach) las enfermeras autocompletaron el instrumento de Seguridad del Paciente en la Administración de Medicamentos en Pediatria versión española, compuesto por 9 dominios y 26 ítems; y para estabilidad (Test-retest de Wilcoxon) autocompletaron nuevamente el instrumento después de 30 días de la primera recolección, para comparación de ambas medidas.

Resultados: En la confiabilidad, el alfa de Cronbach, vario de 0,792 a 0,821, considerado un parámetro aceptable, presentando alta consistencia interna, manteniéndose los 26 ítems, en la versión final. En la estabilidad del instrumento, los dominios presentaron, en el test, media de $68,0 \pm 25,5$ hasta $99,5 \pm 2,5$; y en el retest $86,0 \pm 14,8$ até $96 \pm 11,8$. Se evidenciaron seis dominios sin diferencia significativa ($p > 0,05$) entre test y retest.

Conclusión: El instrumento presentó propiedades psicométricas que comprueban su confiabilidad, proporcionando subsídios para la práctica de enfermería más segura y permitiendo estandarización del cuidado en la administración de medicamentos.

Palabras clave: Seguridad del Paciente; Utilización de Medicamentos; Enfermería Pediátrica; Psicometría; Reproducibilidad de los Resultados; Pediatría.

INTRODUCTION

The medication system it is formed by several processes, such as prescription, dispensing, preparation, administration and monitoring of the patient to monitor the action or reaction to the medication ⁽¹⁾. It is the competence of all members involved in the provision of health care, being the nursing professional responsible for the preparation and administration of medications, which is one of the most complex activities due to errors or almost errors that are more frequent in hospitalized children than in adults ⁽²⁾, which could cause very serious damage and even death, in addition to generating high costs annually throughout the world ⁽³⁾

Among the existing medication errors in pediatrics, the majority are 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 ⁽⁴⁾. Thus, a wide

variety of possible errors involved in each of the stages of drug administration is observed, directly linked to nursing care, which goes against the concept of patient safety, which deals with reducing, to an acceptable minimum, the risk of unnecessary harm associated with health care ⁽⁵⁾.

Therefore, it is necessary to promote patient safety in drug administration. Thus, in Brazil, the instrument Patient Safety in the Administration of Medicines in Pediatrics (PSAMP) was developed and validated, with a Content Validity Index (CVI) of 0.938 and Cronbach's alpha of 0.851 ⁽⁶⁾. Thus, it is a tool for the diagnosis of patient safety in the drug administration process capable of evaluating the actions of patient safety during the administration of drugs in children hospitalized in pediatrics, as it contemplates the safety protocol in the prescription, use and administration of medications ⁽⁷⁾.

The PSAMP instrument is the only one built in a Portuguese version which has been translated, adapted, according to Beaton ⁽⁸⁾, and validated for the Spanish language the instrument Patient Safety in the Administration of Medications in Pediatrics (PSAMP-Sv) in the context of Peru ⁽⁹⁾, which reached a Content Validity Coefficient (CVC) of 0.97 for practical relevance, 0.97 for clarity of language and 0.96 for theoretical relevance. It is composed of 26 items distributed in nine domains related to safety in the administration of medications in children ⁽⁷⁾. To be used in Peru with professionals who prepare and administer medications, the instrument must demonstrate concordance and internal consistency. The study is justified because the PSAMP-Sv instrument is an appropriate tool to evaluate actions to promote patient safety in the administration of medications carried out by the nursing professionals in the inpatient units. Thus, for the application of the translated and adapted instrument together with the nurses caring for the children,

It is necessary that its psychometric properties be evaluated, as in the case of reliability, considering the stability and homogeneity of the instrument.

The reliability of an instrument allows to know the degree to which it consistently reproduces the results applied on different occasions in addition to representing one of the main measurement properties, which needs to be evaluated when a new measure is developed, and offers information on the need to improve an existing instrument ⁽¹⁰⁾.

In this way, the objective was to evaluate the psychometric properties in the reliability aspect of the Patient Safety instrument in the Administration of Medicines in Pediatrics, Spanish version.

METHOD

Methodological study of evaluation of the psychometric properties of the PSAMP-vE instrument carried out with the nurses responsible for the preparation, administration of medicines and monitoring of children in a hospital in Peru during the period from April to May 2018. Following the ethical precepts in force in each country, the study was approved in Brazil by the Research Ethics Committee of the Federal University of Ceará (favorable opinion no. 2,583,089) and in Peru by the Ethics Committee of the referred hospital (code 0211-052-17) and the informed consent of the study participants.

The universe of the study consisted of 220 nurses who work in the hospital, of which only the nurses who work in pediatrics were chosen given that the actions of the administration of medications to children hospitalized in pediatrics and that is evaluated with the instrument PSAMP-Sv. The sample was made up of all 25 pediatric nurses who met the following inclusion criteria: act in the process of administering medications to hospitalized children and adolescents and have a professional relationship in the hospital for at least six months. The exclusion criteria were: being on vacation, leave or away from their activities in the data collection period; be a nurse whose sector of origin was not the one chosen to be the object of research.

The PSAMP-Sv instrument, translated and culturally adapted, has 26 items, distributed in nine domains, which are: 1- Right patient; 2- Right medication. 3- Right way; 4- Right time; 5- Right dose; 6- Right registration; 7- Right orientation; 8- Right form; and 9- Right answer. It is considered as a Likert scale, in which each element consists of five points, which vary, from 1 to 5, being 1-never, 2-almost never, 3-sometimes, 4-almost always and 5-always, with score between 26 to 130 points.

For data collection, the nurses completed the PSAMP-Sv instrument on the day of their shift, marking in the items the score corresponding to their practice in the medication administration process, as recommended by the author of the PSAMP version in Portuguese ⁽⁶⁾. After 30 days, the same instrument was applied to the nurses who again self-completed the PSAMP-Sv instrument for comparison of both measurements. The mean time for the nurse to self-complete the instrument was 10 minutes, varying between 5 and 15 minutes.

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For homogeneity, Cronbach's alpha was used to evaluate practical relevance, clarity of language and theoretical relevance. It is a coefficient that produces values between 0 and 1, that is, between 0 and 100%, values greater than 70% being considered satisfactory for the present study ⁽¹¹⁾. And for stability, the test-retest was used in order to analyze the correlation between the results of the two applications, by means of the Wilcoxon test (12), considering statistical significance $p < 0.05$.

RESULTS

The 25 nurses who participated in the study are all female, the age range varied from 27 to 41 years with an average of 33.3 (+ 3.8) years and a predominance of the age group of 27-31 years (44.0%), regarding their professional training, 84.0% had another specialty and is not pediatrics, 48.0% of the professionals had more than three to five years of training and 48.0% reported the same from six to ten years of professional experience, noting that 72.0% of them have between two and four years of experience in pediatrics, 40.0% of the nurses mentioned an average weekly workload of 37 hours and 100.0%, 52.0% have a work contract.

In the case of the homogeneity and reliability of the PSAMP-Sv instrument in the 26 items, the Cronbach's alpha varied from 0.792 to 0.821, which demonstrated a high internal consistency of the instrument, with a mean of 0.812, confirming the maintenance of the 26 items in the final version (Table 1).

Table 1 - Cronbach's alpha values in the absence of any of the instrument items. Lambayeque, Peru, 2019 (N = 26 items).

Ítem	Cronbach's alpha if the item was excluded
Ítem 1	0,817
Ítem 2	0,823
Ítem 3	0,820
Ítem 4	0,798
Ítem 5	0,792
Ítem 6	0,818
Ítem 7	0,822
Ítem 8	0,814
Ítem 9	0,819
Ítem 10	0,820
Ítem 11	0,808
Ítem 12	0,816
Ítem 13	0,824
Ítem 14	0,817
Ítem 15	0,820
Ítem 16	0,809
Ítem 17	0,798
Ítem 18	0,808
Ítem 19	0,800
Ítem 20	0,804
Ítem 21	0,821
Ítem 22	0,814
Ítem 23	0,806
Ítem 24	0,813
Ítem 25	0,805
Ítem 26	0,821

Source; research data

In the test, the domains of the PSAMP-Sv instrument presented mean and standard deviation of 68.0 + 25.5 to 99.5 + 2.5; and in the retest from 86.0 + 14.8 to 96 + 11.8, respectively. In the stability evaluation, of the nine domains of the PSAMP-Sv instrument, six did not show significant difference ($p > 0.05$) between the test and the retest, according to the Wilcoxon test. These results demonstrate that the association between the two applications was satisfactory, despite the fact that three domains (Correct Patient, Correct Dose, and Correct Response) presented statistically significant differences (Table 2).

Table 2 - Comparison of the means and standard deviation of the domains of the PSAMP-Sv instrument in the test-retest. Lambayeque, Peru, 2019 (N = 25).

Domains	Test		Retest		p†
	Mean±SD*	Median	Mean±SD*	Median standard deviation	
Right patient	68,0 ± 25,5	50,0	96,0 ± 11,8	100,0	<0,0001
Right medicine	91,0 ± 9,9	93,7	86,0 ± 14,8	93,7	0,172
Right way	93,2 ± 10,0	100,0	92,7 ± 7,6	93,7	0,550
Right time	91,3± 10,3	91,6	93,0 ± 9,2	100,0	0,524
Right dose	87,6 ± 10,5	85,0	93,8 ± 7,1	95,0	<0,039
Right record	81,2 ± 17,1	81,2	88,5 ± 15,1	100,0	0,055
Right orientation	84,5 ± 18,8	100,0	91,0 ± 12,2	100,0	0,149
Right shape	96,0 ± 9,3	100,0	93,0 ± 11,4	100,0	0,317
Correct answer	99,5 ± 2,5	100,0	95,5 ± 7,1	100,0	<0,011
Total instrument	88,7 ± 5,8	90,4	91,5 ± 7,0	93,3	0,063

SD: standard deviation; † p: Wilcoxon test

This stage made it possible to prepare the final version of the instrument for patient safety in the administration of medications in pediatrics (PSAMP-Sv), with 26 items distributed in nine domains (Table 1).

Table 1 - Final version translated into Spanish of the Patient Safety in Medication Administration instrument (PSAM-Sv). Lambayeque, Peru, 2019.

Domains	MEDICINE ADMINISTRATION	Never	Hardly ever	Sometimes	Usually	Always
		1	2	3	4	5
Patient Right	1. Use at least two identifiers (child's full name, date of birth, or medical record number) to identify the child before administering medication.					
Medicine Right	2. Confirm the name of the medicine with the prescription before giving it to the child.					
	3. Bring to bed only medications prescribed for a single child.					
	4. Administer 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.					
Right way	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. Uses aseptic materials and techniques to administer medications according to the different routes of administration.					
Right time	10. Prepare the medicine immediately before administration.					
	11. Administer the medication at the correct time.					
	12. Adjust the medication administration schedules to the routine already established before your hospitalization.					
Right dose	13. Please carefully confirm the dosage according to the medical 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 the dilution calculations and administration of potentially dangerous drugs or high surveillance drugs.					
	16. Uses 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.					
Right administration record	18. Record in the Kardex the schedule of administration and in the medical history occurrences of the drug immediately after administering each dose.					
	19. Report incidents, adverse reactions and adverse events to the Quality Management office in the Registration and Report Card.					
	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).					
	21. Monitors the temperature of the medicine-conditioning refrigerator by recording the values daily.					
Right orientation	22. Clarifies doubts about ineligibility of the prescription, indication of the drug and dosage before administering the drug.					
	23. Guides the child and the companion on the medication administered and the justification, the indication, the frequency with which it will be administered and the expected effects.					

Right form	24. Verifies 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. Inform the doctor who prescribed all the different effects than expected (in intensity and form) for the drug.					

DISCUSSION

The PSAMP-Sv instrument provided psychometric properties similar to the PSAMP instrument in the Portuguese version. Cronbach's alpha in the SPZ AMP Instrument, version in Portuguese, ranged from 0.841 to 0.855 ⁽⁶⁾, also staying within the acceptable parameter⁽¹¹⁾. Similar results were presented in another instrument of safe practices for drug administration, consisting of 54 items divided into 10 areas, whose level of concordance varied from 90 to 100% and Cronbach's alpha of 0.94 ⁽¹³⁾. Another study that used the Portuguese version of the Medical Office Survey on Patient Safety Culture to assess the culture of patient safety in Primary Health Care in Brazil presented Cronbach's alpha of 0.95 ⁽¹⁴⁾.

When comparing the nine domains of the section, three (Correct Patient, Correct Dose and Correct Answer) presented a significant difference ($p > 0.05$) between the test and the retest. These domains also presented a significant difference in the original version in Portuguese ⁽⁶⁾. Thus, the test-retest allowed to foresee that the behavior of the nurses may be altered over different periods of time ⁽¹⁵⁾, once it is possible that there may have been an awareness regarding the safe administration of medications after autocompletion of the instrument, which carried the intention of improving behavior ⁽¹⁶⁾. However, despite the variation of responses between three domains in the test-retest, the association between the two applications was satisfactory, demonstrating stability for use in comparison of individual measures ⁽¹⁷⁾. Finally, the reliability of both homogeneity in terms of stability, considered the main measurement properties of the PSAMP-Sv instrument, evidence that it has the ability to reproduce consistently, in time and space, so as to ensure the quality of the results to be applied in other studies. This version in Spanish can be considered as the first reliable version of Spanish of the original version, since, by means of Cronbach's alpha, it presented high reliability, remaining within the acceptable parameter ⁽¹¹⁾.

In addition, the clinical application of this instrument included safety actions in the administration of medications in pediatrics through a new validity tool and reliable in the Spanish populations of nurses in relation to the execution of the correct nine of the preparation and administration of the medication.

Thus, through the growing number of studies carried out by nurses with the intention of translating, adapting and validating instruments the adoption of techniques and methods with satisfactory psychometric properties is necessary, in addition to evaluating reliability and validity to ensure the quality and methodological rigor of the research ⁽¹⁸⁾. Although, other validation models need to be investigated in the application of the instrument in clinical practice in Nursing to support the development

of the scale in addition to evaluating reliability and validity to ensure the quality and methodological rigor of the research⁽¹⁸⁾. Although, other validation models need to be investigated in the application of the instrument in clinical practice in Nursing to subsidize the development of the scale and its incorporation into routine activities for the administration of medicines in pediatrics, and obtain a safer practice.

As a limitation, the fact that the instrument has been validated in a single hospital stands out and with pediatric nurses. According to the literature, the reliability of an instrument is not a fixed measurement property, therefore, the reliability of the same instrument may vary depending on the context of the population that has been evaluated⁽¹⁹⁾.

It is considered that the evaluation of the psychometric properties of the PSAMP-Sv instrument can contribute to the advancement of scientific knowledge, to the extent that a valid and reliable instrument is available, which can be applied in the clinical practice of the nursing team, in order to qualify the assistance provided and to promote safety in the administration of medications to hospitalized pediatric patients.

CONCLUSION

The instrument of Patient Safety in the administration of medicines in Pediatrics Spanish version (PSAMP-Sv) is considered reliable once the reliability presented high internal consistency, with the final version consisting of 26 items, distributed in nine domains.

The study makes the SPAMP-vE instrument available to evaluate patient safety in the administration of medications in pediatrics, once valid and reliable instruments can standardize the care and adequate performance of specific Nursing procedures to promote patient safety.

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