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Full Length Research Paper

Cross-cultural adaptation and validation to Brazil of the "Medication Counseling Behavior Guidelines"

Anne Caroline Oliveira dos Santos[1], Felipe Pimentel Paixão[2], Alessandra Rezende Mesquita[3], Izadora Menezes da Cunha Barros[4], Kérilin Stancine Santos Rocha[1], Sabrina Cerqueira Santos[1], Chiara Ermínia da Rocha[4], and Divaldo Pereira de Lyra Júnior[1*]

[1]Laboratory of Teaching and Research in Social Pharmacy (LEPFS), Department of Pharmacy, Federal University of Sergipe, São Cristóvão, SE, Brazil.
[2]University Hospital, Federal University of Sergipe, Aracaju, SE, Brazil.
[3]Federal University of Minas Gerais, Belo Horizonte, Brazil.
[4]Department of Pharmacy, Federal University of Sergipe, Lagarto, SE, Brazil.

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This work aimed to translate cross-culturally adapts, and validate the "Medication Counseling Behavior Guidelines" instrument into Brazilian Portuguese. The process of cross-cultural adaptation was carried out using international recommendations. The generated versions were evaluated for the semantic, idiomatic, cultural, and conceptual equivalences and the pre-test was carried out with undergraduate pharmacy students. The reliability of the instrument was evaluated through inter-observer reliability, test-retest, and internal consistency tests. The final version was submitted for content validation. The process of cross-cultural translation and validation result in the Brazilian-Portuguese version of the tool was done. During the translation and back-translation stages, only grammatical changes were made to establish cross-cultural equivalence between the versions under analysis. Regarding the semantic evaluation, six items (15.4%) revealed less than 80% agreement between the judges and were adjusted. Agreement greater than 80% was verified for all items assessed as cultural and conceptual equivalences. In the pre-test, four items (10.2%) were modified. Inter-observers and test-retest reliability demonstrated good to excellent reproducibility for most items (ICC = 0.60-0.98) and internal consistency was considered high (Cronbach's alpha = 0.99). Psychometric evaluation demonstrated and confirmed the validity of the Brazilian-Portuguese version of the tool to assess patient counseling practices. The tool can be used by pharmacists and undergraduate pharmacy students to improve the quality of patient counseling.

Key words: Validation studies, health communication, counseling, simulation training.

INTRODUCTION

Pharmacists have been identified as important professionals in counseling patients regarding the rational use of medicines (Melo et al., 2017; Alaqeel and Abanmy, 2015). They are also considered strategic healthcare professionals to identify, solve, and prevent drug therapy problems (Castronovo et al., 2018; Huysmans et al., 2014). For this reason, pharmacists must establish an effective therapeutic relationship with patients. The quality

*Corresponding author. E-mail: kesaratmu@yahoo.com. Tel: +662-564-4440-79/1803. Fax: +662-564-4398.

of the pharmacist-patient relationship depends, above all, on the quality of the communication established between them over time. This relationship does not necessarily improve with professional experience but will be more effective as the professional receives more education and training on communication (Cantwell et al., 2011; Moore et al., 2013).

A key component in health education training has been the development and validation of communication skills assessment tools for use in encounters with simulated or real patients. In a systematic review, it was showed that communication assessment tools vary considerably in content, psychometric properties, and usability. Moreover, no revised instrument was well evaluated in all these categories (Schirmer et al. 2005). Although the fields of medicine and nursing have excelled in the development and use of validated instruments and standard assessment methods, there is growing concern about the authenticity and validity of clinical skills assessments of healthcare professionals and students (Barros et al., 2015; Cunha et al., 2017; Jesus et al., 2015).

In pharmacy field, some organizations have published specific guidelines about patient counseling since the 1960s (American Society of Health-System Pharmacists, 1997; De Young, 1996). However, the literature lacks studies on the validation of instruments and procedures used to evaluate the communication skills of pharmacists and undergraduate pharmacy students (Jesus et al., 2016; Wallman et al., 2013). An instrument applicable to this purpose is the “Medication Counseling Behavior Guidelines,” which is considered the first attempt to approach patient counseling skills within the context of pharmacist-patient communication (Federation International Pharmaceutical, 2005). It is a validated instrument for the English language, developed by the United States Pharmacopeia (USP) and is currently considered the most understandable model of approaching patient counseling for its completeness in evaluating pharmaceutical competencies in patient care (Federation International Pharmaceutical, 2005; Puumalainen et al., 2005). Thus, the aim of this study was to translate and cross-culturally adapt the instrument "Medication Counseling Behavior Guidelines" into Brazilian Portuguese.

MATERIALS AND METHODS

Study design

An adaptation and validation study was performed from March to December 2012 in the Northeast region of Brazil for the cross-cultural adaptation of the "Medication Counseling Behavior Guidelines" into Brazilian Portuguese. This instrument was designed by United States Pharmacopeia (USP) (Puumalainen et al., 2005) and contains 35 questions divided into four categories:

1) Counseling introduction: included items related to initial counseling, such as providing basic and pertinent information related to drugs, and understanding the clinical conditions of the patient;
2) Counseling content: covered items related to drug selection, instructions for use, storage, and general impression about the pharmacist's knowledge;
3) Counseling process: contained elements of non-verbal communication, counseling understanding, and overall impression of the counseling service;
4) Counseling conclusion: covered if the pharmacist addressed a consoling conclusion, verified patients' understanding, and prepared follow-up plan.

Participants

Pharmacy undergraduate students of three educational institutions of Sergipe state, Federal University of Sergipe (two campuses in different cities: São Cristovão and Lagarto) and Tiradentes University were selected to compose the sample. Students of both genders, volunteers, and that were enrolled in the second or third year of undergraduate Pharmacy course were randomly selected. Students who had not attended the “Pharmaceutical Services” subject were excluded because they had not learned yet the theoretical-practical references necessary for "Good Pharmaceutical Dispensing" (Marques and Lyra Junior, 2012). All students that agreed to participate were informed of the study’s purpose and invited to sign the Consent Form.

Cross-cultural adaptation

The protocol of cross-cultural adaptation was conducted using recommendations from international literature (Beaton et al., 2000; Gasparino and Guirardello, 2009; Guillemin et al., 1993; Guillemin, 1995; Pasquali, 2010):

Translation

The instrument was translated from English into Portuguese by two Pharmacy researchers, experts in communication with patients, fluent in English, and having Portuguese as their native language. These experts knew the objectives and conceptual framework of the study. The two translations were compared, and ambiguities or discrepancies in the translated words were addressed, generating a consensually translated version (Version 1) (Beaton et al., 2000).

Back translation

During the back-translation process, Version 1 of the instrument in Portuguese was translated again into the original language (English) by two different translators who did not participate in the previous stage, as well as by researchers and specialists in the field of Pharmacy. Translators had Portuguese as their native language, had lived in the USA and Australia for more than 25 years, and were fluent in both languages. These experts did not receive information about the objectives and concepts underlying the study (Guillemin et al., 1993). The two translations were compared, and the ambiguities or discrepancies were solved by a consensual translation (Version 2).

Expert panel

Two expert panels compared all versions (original, translated, and back-translated), evaluating the items according to semantic, idiomatic, cultural, and conceptual equivalences (Beaton et al., 2000). Two specific assessment forms were adapted and used for

analysis of equivalence: "Evaluation of semantic and idiomatic equivalents" and "Evaluation of cultural and conceptual equivalents" (Lino, 1998).

Expert panel 'A' was composed by five researchers specialized in the field of knowledge, selected by convenience. They evaluated the semantic and idiomatic equivalence comparing the original instrument with the translated and back-translated versions, and the evaluation form. This expert panel was asked to document the reason for each proposed change in the "Evaluation of semantic and idiomatic equivalents" form. At the end of this step, Version 3 of the instrument was generated.

Subsequently, expert panel 'B' evaluated cultural and conceptual equivalence by comparing the original scale with the translated version. It was considered as appropriate translation, the questions accepted by at least 80% of experts (Beaton et al., 2000; Fumimoto et al., 2001). The expert panel was formed by Pharmacy teachers and/or researchers in the field of knowledge and selected by convenience. In addition, each expert was native and resident of each of the five Brazilian regions. During this step, Version 4 of the instrument was generated.

Pre-test

This step consisted of administering the translated version of the instrument (Version 4) to a suitable sample of 40 Pharmacy undergraduate students attending a Brazilian public university, in Aracaju city, Sergipe state. The sample size of the pre-test was based on the literature, which suggests 30 to 50 individuals from the target population (Beaton et al., 2000; Gasparino and Guirardello, 2009).

Pharmacy students received guidance on using the scale and completing the instrument. Students completed the instrument by evaluating the pharmacist, based on an audiovisual recording from a simulated patient case. Each question of the instrument had a "not clear" answer option that could be checked by participants if the item was not easily understood. In this case, students could point out their critiques and suggestions regarding the content of unsuitable items. Students were also asked to evaluate the response scale, selecting the "not clear" option for the score that was considered ineffective to assess a certain item.

This step aimed to ensure the correction of possible inconsistencies in meanings, allowed the detection of errors, and confirmed whether the questions were comprehensible (Beaton et al., 2000; Gasparino and Guirardello, 2009). At the end of this step, Version 5 of the instrument was generated.

Reliability

Inter-observer reliability was evaluated comparing the results of two different independent researchers, as well as test-retest reliability, in which the same researcher applied the instrument twice to all subjects within a one-month interval (Melchiors et al., 2007).

In addition, the internal consistency of the instrument was evaluated, which refers to the degree of correlation between items and with the overall research result (Freitas and Rodrigues, 2005). One hundred and eighty-two undergraduate Pharmacy students of three higher education institutions in Sergipe state participated in this stage.

Content validation

After reliability tests, the instrument was submitted for content validation. This protocol was evaluated by expert panel 'C,' formed by five Pharmacy expert researchers selected by convenience. In the protocol, the items of the instrument were divided into two components: "Pharmacotherapeutic knowledge," that included the introduction and content of counseling, and "Communication skills," that contained the process and conclusion of counseling.

This expert panel was informed about the purpose of the instrument. They received instructions to evaluate the instrument regarding form, representativeness, and relevance of each item, considering the criteria established by Vituri and Matsuda (2009). During the evaluation, a dichotomous scale ("Yes" and "No") was used. In case of "No" response, the evaluator should point out their critiques and make suggestions about the changes that they considered most relevant. The items of the instrument were considered validated when the concordance between the expert panel was greater than or equal to 80% (Polit and Beck, 2003).

Statistical analysis

Data analysis was performed using BioEstat 5.0 software. Student's t-test was used to evaluate the differences between students' responses in the tests carried out by research 1 and 2 and in the test-retest. The inter-observer and test-retest reliability analyses used the intraclass correlation coefficient (ICC), adopting the criteria of Cicchetti and Sparrow (1981), which classifies the ICC into poor (<0.40), satisfactory (0.40-0.59), good (0.60-0.74), and excellent (0.75-1.00). The internal consistency was evaluated using Cronbach's alpha coefficient, whose values vary between 0 and 1; the closer the values are to 0, the less the items are related to each other (Rodriguez-Añez et al., 2008). Values between 0.75 and 0.90 indicate high internal consistency (Freitas and Rodrigues, 2005). A 95% confidence interval was adopted, and the differences were considered statistically significant when $p<0.05$.

Ethical aspects

This study was approved by the Research Ethics Committee of the University Hospital, Federal University of Sergipe (Brazil) under the registration code 'CAAE 08721412.8.0000.0058.

RESULTS

Participants

In this study, 235 students answered the instruments and their total completion took approximately 20 min. Of these students, 13 were eliminated because they did not answer the instrument in its entirety, presenting blank answers for one or more items. Thus, 222 students composed the final sample (40 students participated of the pre-test and 188 participated of the reliability tests). Most of the students were female (71.6%), with a mean age of 19.74 ± 1.93 years, and were in the second (79.7%) and third year (20.3%) of Pharmacy undergraduate course.

Cross-cultural adaptation

The translation and validation resulted in the Portuguese version of the instrument entitled "Guia Comportamental de Orientação sobre Medicamentos" (Appendix 1). This translated and validated instrument was composed of 35 questions that measure pharmaceutical competences in patient counseling.

Table 1. Comparison of the answers to the test applied by the researcher 1 and 2 and the test-retest applied by the researcher 1 regarding the questions concerning the Counseling introduction (mean ± standard deviation).

Variable	Test		p-value	R1		p-value
	R1	R2		Test	Retest	
Question 4	6.88 ± 2.04	7.09 ± 1.92	0.08	6.88 ± 2.04	7.12 ± 1.69	**0.02***
Question 5	5.01 ± 3.01	5.37 ± 2.82	0.04*	5.01 ± 3.01	5.06 ± 2.86	0.74
Question 6	5.87 ± 2.89	6.20 ± 2.53	0.03*	5.87 ± 2.89	5.87 ± 2.74	0.97

R1 = researcher 1; R2 = researcher 2. * = statistically significant difference for p <0.05.

The translation and back-translation steps were carried out without major difficulties, and all items of the instrument were translated. In this stage, only grammatical changes were made in some items to assure equivalence between words, languages and the cultural context, thus establishing cross-cultural equivalence between the versions under analysis. Regarding the evaluation of semantic and idiomatic equivalence, the most items obtained agreement ≥ 80%.

After the changes proposed by expert panel 'A,' the items of the instrument were submitted for cultural and conceptual equivalence evaluation to expert panel 'B,' who were natives and residents of the five Brazilian regions. There was an agreement among evaluators of 80% or more for all items. It is important to point out that all the modifications proposed by the expert panel were accepted.

The items of the original version of the instrument are measured by an 11-point Likert scale that are classified as follows: 0 and 1 = not done; 2 = poor; 3, 4 and 5 = unsatisfactory; 6 and 7 = satisfactory; and 8, 9, and 10 = excellent. Regarding the category "not done," it should be indicated when the item was applicable, but the patient counseling was not provided. However, this category (0 or 1) caused doubts regarding the duality of options to judge the counseling. As a result, the scale was reduced to 10 points with scores from 1 to 10, with score 1 classified as "not done". In addition to the Likert scale, a "not applicable" (N/A) item was part of instrument's structure and should be selected when counseling on a given issue was not done because it did not apply to the situation.

Pre-test

The instrument was considered adequate, with clear and easy-to-understand terms and expressions by the 40 undergraduate Pharmacy students who evaluated the content of the instrument. It was necessary to change items 3, 5, 29, and 32, because they were evaluated as "not clear". Items 3 and 29 had some of their wording replaced in order to guarantee the adequacy of the semantic equivalence. In items 5 and 32, explanatory expressions were included, to facilitate their clarity and comprehension. Regarding the assessment scale, no undergraduate Pharmacy student evaluated it as not suitable.

Reliability

Regarding the domain 'Counseling introduction,' there was a statistically significant difference in the tests applied by researchers 1 and 2 in two items (p <0.05) and in the test-retest there was a difference in only one item (p <0.05). Table 1 shows the items that presented a statistically significant difference in inter-observer reliability and the test-retest. In relation to inter-observer reliability, two items were considered excellent (ICC = 0.84-0.76, p <0.0001) and the others obtained a satisfactory to good ICC reproducibility (CI = 0.53 - 0.73, p <0.0001). Test-retest reliability showed good to excellent reproducibility for all items (ICC = 0.62-0.86, p <0.0001).

In relation to the domain 'Counseling content,' the answers provided to researcher 1 were different from those provided to researcher 2 in nine items (p <0.05) and also different from those provided in the retest for seven items (p <0.05). Table 2 shows the items that presented a statistically significant difference in inter-observer reliability and the test-retest. However, in this domain, inter-observer reliability presented responses with good to excellent reproducibility in 10 items (ICC = 0.61-0.83, p <0.0001). Only one item presented poor reproducibility (ICC = 0.35, p =0.0006) and tree were considered satisfactory (ICC = 0.42 - 0.56, p <.0.0001). On the other hand, the reliability of the test-retest obtained excellent reproducibility in eight items (ICC = 0.75-0.88, p <0.0001) and good reproducibility for the others (ICC = 0.49-0, 69, p <0.0001).

In the domains 'Counseling process' and 'Counseling conclusion,' there was a statistically significant difference in the items given to researchers 1 and 2 only for three items (p <0.05). When compared to the retest, only three items had a statistically significant difference (p <0.05). Table 3 shows the items that presented a statistically significant difference in inter-observer reliability and the

Table 2. Comparison of the answers to the test applied by the researcher 1 and 2 and the test-retest applied by the researcher 1 regarding the questions concerning the Counseling Content (mean ± standard deviation).

Variable	Test		p- value	R1		p-value
	R1	R2		Test	Retest	
Question 9	5.26 ± 2.86	5.84 ± 2.77	< 0.0001*	5.26 ± 2.86	5.63 ± 2.77	0.01*
Question 12	3.42 ± 3.08	4.37 ± 3.14	< 0.0001*	3.42 ± 3.08	3.87 ± 3.02	0.005*
Question 14	3.60 ± 3.16	3.80 ± 3.12	0.25	3.60 ± 3.16	3.89 ± 3.11	0.04*
Question 15	4.28 ± 3.01	4.70 ± 2.98	0.02*	4.28 ± 3.01	4.67 ± 2.86	0.02*
Question 16	2.50 ± 2.38	3.02 ± 2.72	0.001*	2.50 ± 2.38	2.80 ± 2.56	0.03*
Question 17	2.50 ± 2.41	3.02 ± 2.81	0.001*	2.50 ± 2.41	2.73 ± 2.54	0.09
Question 20	1.80 ± 1.99	2.28 ± 2.50	0.001*	1.80 ± 1.99	2.15 ± 2.44	0.004*
Question 21	2.10 ± 2.04	2.53 ± 2.48	0.005*	2.10 ± 2.04	2.47 ± 2.36	0.005*
Question 22	4.59 ± 3.06	4.90 ± 3.06	0.04*	4.59 ± 3.06	4.89 ± 2.93	0.05
Question 23	6.90 ± 2.21	7.14 ± 2.06	0.01*	6.90 ± 2.21	6.97 ± 2.17	0.53

R1 = researcher 1; R2 = researcher 2. * = statistically significant difference for p <0.05.

Table 3. Comparison of the answers to the test applied by the researcher 1 and 2 and the test-retest applied by the researcher 1 regarding the questions concerning the Counseling process and conclusion.

Variable	Test		p- value	R1		p-value
	R1	R2		Test	Retest	
Question 27	6.90 ± 2.14	6.43 ± 2.40	0.0006*	6.90 ± 2.14	6.82 ± 2.21	0.001*
Question 29	6.84 ± 2,46	6.48 ± 2.62	0.006*	6.84 ± 2.46	6.74 ± 2,55	0.03*
Question 30	7.65 ± 1.47	7.37 ± 1.80	0.01*	7.65 ± 1.47	7.54 ± 1.55	0.02*
Question 32	6.53 ± 2.91	6.33 ± 2.96	0.16	6.53 ± 2.91	6.79 ± 2.73	0.001*

R1 = researcher 1; R2 = researcher 2. * = statistically significant difference for p <0.05.

test-retest. In this domain, the inter-observer reliability presented excellent reproducibility (ICC = 0.76 - 0.98; p <0.00001) for all items, except for one item that represented good reproducibility (ICC = 0.73; p <0.0001). Test-retest reliability obtained excellent reproducibility for all items with ICC ranging from 0.85 to 0.98 (p <0.0001).

The evaluation of internal consistency resulted in high Cronbach's alpha coefficient values for all the items and domains evaluated (Introduction, Content, Process, and Conclusion of counseling) and also considering the general score, demonstrating the homogeneity of the test. Values of the internal consistency analysis by domain and considering the general score can be found in Table 4.

Table 4. Analysis of internal consistency by domain (Introduction, Content, Process and Conclusion of Counseling) and considering the general score of the instrument “Guia Comportamental de Orientação sobre Medicamentos”.

Domain	Cronbach alpha coefficient
Introduction	0.91
Content	0.92
Process	0.95
Conclusion	0.95
General	0.99

Content validation

All items in the instrument were relevant in representing the domain they intended to measure. However, expert panel 'C' suggested changes in six items (15.4%) that were accepted to improve the clarity and completeness of the instrument. Items 16, 23, and 25 were modified to assure semantic equivalence, and item 5 was modified to attain conceptual equivalence. In addition, explanatory expressions were added to items 14 and 18 to facilitate their clarity and understanding.

DISCUSSION

The need for tools to assess pharmacist's counseling and

communication skills during care justifies the interest in a Brazilian version of the tool. The instruments must meet two essential requirements: reliability and validity. Such reliable measures are replicable and consistent, that is, they generate the same results (Toffoli et al., 2016). Epstein et al., (2015) point out that the use of a foreign instrument without its adaptation may threaten the validity and accuracy of the evaluations carried out. In this sense, the process of cross-cultural adaptation was of primary importance in the validation process.

As proposed by Borsa et al. (2012), the cross-cultural adaptation of the instrument was carried out not only through a literal translation but also through the careful evaluation of its measures, considering the context and specific cultural aspects. For Brazil, in particular, this task is critical due to regional, social, and cultural differences which makes this task relevant (Pilz et al., 2014). In addition, grammar and vocabulary aspects were evaluated, and pronouns and verbal tenses were standardized to solve discrepancies in meaning and content between versions. Adaptations were also made, through the inclusion of terms and expressions appropriate to the reality of the five Brazilian regions. Thus, evaluations by the expert panels ensured semantic, idiomatic, cultural, and conceptual equivalence between the translated and original versions of the instrument.

Regarding the pretest, the purpose of this step was to ensure that the adapted version preserved equivalence with the original version, in addition to detecting errors and evaluating the suitability and comprehensibility of the items (Mesquista et al., 2012). In addition, Gasparino and Guirardello (2009) showed that the changes made at this stage contributed to improving the clarity and understanding of the instrument's items. Thus, the suggestions were important to guarantee the grammatical and semantic equivalence of the translated instrument.

By analyzing the mean of the undergraduate Pharmacy students' responses in the three moments that the instrument was evaluated (test research 1, test research 2, and retest), it was observed that some questions presented differences in students' answers. However, these differences were not sufficient to render the instrument unfeasible concerning its reliability. The inter-observer and test-retest reliability tests showed that the reproducibility of the instrument was considered good to excellent for most items evaluated according to Cicchetti and Sparrow criteria (1981).

In this study, high values of internal consistency for test-retest were obtained. The high values obtained in the reliability tests can be explained by the substantial number of items that composed the instrument, sufficient enough to reduce the sampling error, but not excessive to the point of causing impulsive and relapsing responses or increasing the incidence of unanswered items due to student fatigue or disinterest (Cronbach et al., 2004). In addition, the period between measurements was a factor to consider. Long periods favor the acquisition of new learning and in short periods, the results can be contaminated by the memory effect (Martins, 2006). Therefore, a one-month interval between test-retest applications was adopted, following recommendations described in the literature, to avoid interferences in the results (Melchiors et al., 2007).

In reference to content validation, the instrument has proved to be relevant to its purpose through evaluation by the expert panel. The content validation is determined by judging the proportion in which the items selected to measure a theoretical construct represent all the important facets of the concept measured. This measure also includes the apparent validity of the instrument, that is, the apparent consistency between what is to be measured and the chosen measuring instrument (Pilatti et al., 2010). Thus, it is possible to affirm that all items were considered validated as to their content, once they exceeded the standard of at least 80% of agreement as adopted.

The translation and validation of the instrument "Guia Comportamental de Orientação sobre Medicamentos" into Brazilian Portuguese met the requirements of adequacy, pertinence, and acceptability concerning each item of the instrument. Similarly, the requirements of reproducibility and linearity essential for the reliability of the instrument were satisfied. By analyzing the clarity and comprehensibility of the items it is possible to provide a validated instrument capable of evaluating the quality of pharmaceutical care to improve the activities of these professionals.

Conclusion

This study showed that the Brazilian Portuguese version of the instrument entitled "Guia Comportamental de Orientação sobre Medicamentos" had good validity and reliability performance. The stages of translation and back-translation were satisfactory in complying with conceptual requirements, considering the linguistic aspects and the meaning of the content in the Brazilian reality. Measurement reliability tests affirmed the instrument's ability to produce similar results in successive applications. Finally, the evaluation of content validation made it possible to state that the instrument's components were relevant in representing the domain that it intends to measure. Moreover, the tool can be used by pharmacists and undergraduate Pharmacy students to improve the quality of patient counseling.

CONFLICT OF INTERESTS

The authors have not declared any conflict of interests.

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APPENDIX 1. INSTRUMENT *"Medication Counseling Behavior Guidelines"* (USP, 1997-1999). Cross-cultural adapted and validate to Brazilian Portuguese *GUIA COMPORTAMENTAL DE ORIENTAÇÃO SOBRE MEDICAMENTOS*

CATEGORIA 1: ÍTENS REFERENTES À INTRODUÇÃO DA ORIENTAÇÃO.

	N/A	Não feita	Péssimo	Insatisfatório			Satisfatório		Excelente		
1. No início, conduz a orientação, apresentando-se e identificando quem é o paciente ou o seu responsável	-	1	2	3	4	5	6	7	8	9	10
2. Explica a finalidade da orientação	-	1	2	3	4	5	6	7	8	9	10
3. Revisa a prescrição do paciente antes da orientação	-	1	2	3	4	5	6	7	8	9	10
4. Obtém informações prévias e pertinentes relacionadas ao medicamento (por exemplo, idade, alergias, outros medicamentos, gravidez, amamentação)	-	1	2	3	4	5	6	7	8	9	10
5. Adverte o paciente sobre o uso de outros medicamentos ou substâncias, incluindo medicamentos isentos de prescrição (MIPs), fitoterápicos e bebidas alcoolicas, os quais poderiam interagir com o medicamento prescrito (aumentando, diminuido ou anulando sua ação)	-	1	2	3	4	5	6	7	8	9	10
6. Avalia se o paciente tem outras condições clínicas as quais poderiam influenciar os efeitos desse medicamento ou a probabilidade de uma reação adversa	-	1	2	3	4	5	6	7	8	9	10
7.Avalia a compreensão do paciente (ou do responsável) sobre o(s) motivo(s) da farmacoterapia prescrita	-	1	2	3	4	5	6	7	8	9	10
8. Avalia quaisquer preocupações reais e/ou problemas potenciais do paciente	-	1	2	3	4	5	6	7	8	9	10

CATEGORIA 2. ÍTENS REFERENTES AO CONTEÚDO DA ORIENTAÇÃO.

	N/A	Não feita	Péssimo	Insatisfatório			Satisfatório		Excelente		
9. Discute o nome e a indicação do medicamento	-	1	2	3	4	5	6	7	8	9	10
10. Explica a posologia, incluindo o horário de utilização e a duração da terapia, quando apropriado	-	1	2	3	4	5	6	7	8	9	10
11. Auxilia o paciente (ou o responsável) no desenvolvimento de um plano de cuidados para incorporar a farmacoterapia à sua rotina	-	1	2	3	4	5	6	7	8	9	10
12. Explica quanto tempo levará para o medicamento fazer efeito	-	1	2	3	4	5	6	7	8	9	10
13.Discute as recomendações de armazenamento e instruções complementares (por exemplo, agitar bem, manter refrigerado)	-	1	2	3	4	5	6	7	8	9	10
14.Diz ao paciente (ou ao responsável) quando ele/ela deve voltar para adquirir novamente o medicamento	-	1	2	3	4	5	6	7	8	9	10
15.Enfatiza os benefícios da utilização do medicamento conforme prescrito	-	1	2	3	4	5	6	7	8	9	10
16.Alerta sobre os efeitos adversos potenciais (significativos) dos medicamentos	-	1	2	3	4	5	6	7	8	9	10

CATEGORIA 2.Cont'd.

17.Discute como prevenir ou controlar os efeitos adversos do medicamento, caso ocorram	-	1	2	3	4	5	6	7	8	9	10
18. Discute as precauções associadas ao uso do medicamento (por exemplo, evitar operar máquinas ou dirigir)	-	1	2	3	4	5	6	7	8	9	10
19.Discute as interações significativas entre medicamento-medicamento, medicamento-alimento e medicamento-doença	-	1	2	3	4	5	6	7	8	9	10
20. Explica detalhadamente o que fazer se o paciente esquecer de utilizar uma dose	-	1	2	3	4	5	6	7	8	9	10
21. Discute com o paciente (ou o responsável) os potenciais problemas em tomar o medicamento conforme prescrito (por exemplo, custo, acesso)	-	1	2	3	4	5	6	7	8	9	10
22. Ajuda o paciente (ou o responsável) a gerar soluções para os problemas potenciais	-	1	2	3	4	5	6	7	8	9	10
23. Fornece informações detalhadas sobre a farmacoterapia	-	1	2	3	4	5	6	7	8	9	10

CATEGORIA 3. ÍTENS REFERENTES AO PROCESSO DA ORIENTAÇÃO.

	N/A	**Não feita**	**Péssimo**	**Insatisfatório**			**Satisfatório**			**Excelente**	
24. Usa linguagem acessível ao paciente (ou ao responsável)	-	1	2	3	4	5	6	7	8	9	10
25. Usa conhecimentos embasados na literatura para dar suporte durante a orientação ao paciente (ou ao responsável)	-	1	2	3	4	5	6	7	8	9	10
26. Responde com compreensão e empatia	-	1	2	3	4	5	6	7	8	9	10
27. Apresenta fatos e conceitos em uma ordem lógica	-	1	2	3	4	5	6	7	8	9	10
28. Mantém o controle e o direcionamento da orientação	-	1	2	3	4	5	6	7	8	9	10
29. Investiga informações adicionais (por exemplo, hábitos de vida, crenças)	-	1	2	3	4	5	6	7	8	9	10
30. Utiliza perguntas abertas	-	1	2	3	4	5	6	7	8	9	10
31. De maneira geral, apresenta comportamentos não-verbais efetivos:	-	1	2	3	4	5	6	7	8	9	10
31 a. Contato visual apropriado	-	1	2	3	4	5	6	7	8	9	10
31 b. Voz é audível; tom e velocidade da fala são bons	-	1	2	3	4	5	6	7	8	9	10
31 c. Linguagem corporal, posturas e gestos confirmam a mensagem falada	-	1	2	3	4	5	6	7	8	9	10
31 d. Distância entre o profissional de saúde e o paciente (ou o responsável) é apropriada	-	1	2	3	4	5	6	7	8	9	10
32. Verifica a compreensão do paciente (ou do responsável), por meio de feedback (retorno da informação)	-	1	2	3	4	5	6	7	8	9	10
33. Resume, reconhecendo e/ou enfatizando os pontos-chave da informação	-	1	2	3	4	5	6	7	8	9	10
34. Fornece uma oportunidade para preocupações ou perguntas finais	-	1	2	3	4	5	6	7	8	9	10
35. Ajuda o paciente (ou o responsável) a planejar o acompanhamento e os próximos passos da farmacoterapia	-	1	2	3	4	5	6	7	8	9	10

CATEGORIA 4. ÍTENS REFERENTES À CONCLUSÃO DA ORIENTAÇÃO.

	N/A	Não feita	Péssimo	Insatisfatório			Satisfatório		Excelente		
32. Verifica a compreensão do paciente, através de feedback (retorno da informação)	-	1	2	3	4	5	6	7	8	9	10
33. Resume, reconhecendo e/ou enfatizando os pontos-chave da informação	-	1	2	3	4	5	6	7	8	9	10
34. Fornece uma oportunidade para preocupações ou perguntas finais	-	1	2	3	4	5	6	7	8	9	10
35. Ajuda o paciente a planejar o acompanhamento e os próximos passos	-	1	2	3	4	5	6	7	8	9	10