

Full Length Research Paper

Semantic validation of subtitles and analysis of understanding of pictograms taken from the United States Pharmacopeia Dispensing Information (USP-DI)

Izadora M. da C. Barros¹, Thaciana dos S. Alcântara¹, Anne Caroline O. dos Santos¹, Felipe P. Paixão¹, Germana G. de Araújo² and Divaldo P. de Lyra Junior^{1*}

¹Laboratory of Teaching and Research in Social Pharmacy, Department of Physiology, Federal University of Sergipe, Brazil.

²Arts and Design Center, Federal University of Sergipe, Brazil.

Received 12 June, 2014; Accepted 1 December, 2014

The aim of this study was to validate pictogram subtitles and analyze the understanding of pictograms taken from the United States Pharmacopeia Dispensing Information (USP-DI). The subtitles of 25 pictograms from the USP-DI were translated and retro-translated, and the generated subtitles were compared by two committees of judges to evaluate semantic and cultural equivalence. Semantic validity was analyzed by submitting the translated subtitles to a convenience sample of 23 elderly people in Aracaju-SE (Brazil). Additionally, 15 of the 81 USP-DI pictograms were presented to participants individually, without subtitles and in random order, to analyze participants' understanding of them. The process of cross-cultural translation and validation resulted in a Portuguese version of each pictogram's subtitle. Changes in grammatical structure were applied to some items. Twelve subtitles showed less than 80% concordance of interpretation between judges, and were modified. The semantic validation phase indicated that four participants had difficulty understanding one particular subtitle. The analysis of understanding phase indicated that only one pictogram met the criterion for acceptable understanding established by ISO 3864. The Brazilian Portuguese version of pictogram subtitles from the USP-DI presents cross-cultural equivalency with the original English version. Most of the USP-DI pictograms assessed in the present study were not well understood by participants. The pictograms that did not meet the comprehension criteria are being redrawn in ways specific to the local culture.

Key words: Cross-cultural adaptation, pictograms, validation, comprehension, elderly.

INTRODUCTION

Cognitive ability and memory function characteristically decline with age. This hampers comprehension of basic

health-related information, increasing the risk of treatment regimen non-adherence (Liu et al., 2009).

*Corresponding author. E-mail: danielankrah@kbth.gov.gh, d.ankrah@uu.nl. Tel: +233272579447.

Author(s) agree that this article remain permanently open access under the terms of the [Creative Commons Attribution License 4.0 International License](https://creativecommons.org/licenses/by/4.0/)

Hence, poorer comprehension and retention of health-related information expose elderly patients to an increased risk of therapeutic failure (Cornélio et al., 2009). Low patient literacy is one of the factors that most influences non-adherence to treatments (Braich et al., 2011). A low-literacy or illiterate patient is more likely to have difficulty with reading related to health services (e.g., prescriptions, package inserts, educational materials), and thus can be considered to have low “health literacy” (Maragno, 2009). Health literacy is the capacity of individuals to obtain, process, and understand the basic health-related information needed to make appropriate decisions about their health. It involves the ability to understand and interpret text, documents, and numbers effectively, skills that may seem distinct but are highly correlated with one another (Weiss et al., 2005).

The incorporation of visual guides is an alternative means of transmitting information to patients that facilitates the understanding of prescribed pharmacotherapy (Vaillancourt and Grenier, 2011). Among the different types of these guides are pictograms, which are graphic symbols displaying and signaling information relevant to the treatment. Pictograms associate images with concepts, and can be used to convey information in a clear, fast, and simple manner (Mansoor and Dowse, 2006).

In clinical practice, studies have shown that complementing pictograms with written information may increase the degree to which patients comprehend, recall and adhere to their treatment regimen (Mansoor and Dowse, 2003; Dowse and Ehlers, 2005; Mwingira and Dowse, 2007). Corroborating these data, Korenevsky et al. (2013) showed that participants preferred pictograms which were presented along with simple text. Thus, it is important that pictograms be accompanied by simple text in order to maximize treatment regimen comprehension and minimize medication errors.

As shown earlier, the use of simple language along with pictographic resources, which communicate a culturally appropriate message, can minimize the impact of communication barriers (Moreira et al., 2003). Furthermore, according to Dowse and Ehlers (2011), text not written in the reader’s first language represents a significant barrier to information access and diminishes the use and accessibility of leaflets containing pictograms. Therefore, there is a need to validate native-language subtitles that are intended to be used as a supplementary system of verbal communication.

Accordingly, the translation and validation of guides for use in a different culture requires the careful preservation of semantic equivalence between the original and translated versions. With regard to the translation of the subtitles in question, this equivalence may be said to be achieved fully when all items have the same significance to individuals belonging to the culture for which the translation is intended as they did to members of the culture for which the original items were intended. The

present study aimed to validate translated pictogram subtitles and analyze people’s understanding of the pictograms taken from the United States Pharmacopeia-Dispensing Information (USP-DI).

MATERIALS AND METHODS

Translation and cross-cultural adaptation

Translation and cross-cultural adaptation was carried out from March to May 2012, in accordance with international recommendations (Guillemin et al., 1993). Twenty-five pictogram subtitles out of the 81 total pictograms from the USP-DI were studied (Table 1). Subtitles were selected by the researchers involved in the present study, with consideration for the greater need for pharmaceutical services among the elderly.

Subtitles were first translated separately by two researchers whose first language is Portuguese, and who are graduate students in pharmacy, natives of Aracaju, capital of Sergipe, and fluent in English. These researchers were aware of the objectives and concepts of the present study. The two translations were compared, and ambiguities or discrepancies resolved by generating a consensus translation. Then, back-translation was performed by a Brazilian professor from the University of Sydney, Australia, who has resided in that country for 31 years, and a Brazilian professor from the University of Minnesota, USA, who has resided in that country for four and a half years. These two professors did not participate in the previous translation steps and were unaware of the objectives of the present study.

The material translated into Portuguese back-translated subtitles were as submitted for the purposes of evaluation and adaptation to a expert committee consisting of four pharmacists and three graphic artists (designers), who have basic training in communication, all of whom were natives of Brazil, bilingual, and informed of the purpose of the present study. The purpose of this committee was to compare, evaluate semantic and idiomatic equivalencies between the original version and the Portuguese version. The subtitles were assessed by the expert committee by Likert scale with semantic and idiomatic equivalence (-1: not equivalent, 0: undecided, +1: equivalent). For both a comparative and descriptive analysis, between scales of judges was held.

After the evaluation of semantic and idiomatic equivalence, the subtitles were presented to another committee of judges, composed of five pharmacists, each one being a native resident of one of the five regions of Brazil (North, Northeast, Southeast, Midwest, and South), in order to evaluate the cultural equivalence of the subtitles. The purpose of this committee was to verify that the back-translation used expressions that could be understood in all regions of Brazil.

Semantic validation

Semantic validation (Fegadolli et al., 2010) was subsequently conducted between June and July, 2012 to identify problems related to the understanding, acceptance, and relevance of subtitles, and to evaluate the need for any adaptation of the subtitles. Participants were 23 elderly patients living in an aged care facility in Aracaju-SE, Brazil. Subtitles were evaluated for attributes such as pictogram–subtitle equivalence, understandability, and appropriateness. The following questions were asked concerning all subtitle–pictogram pairs: Do you think the sentence accords with the image? Do you have difficulty understanding the sentence? How would you say or express it? Could you tell me, in your words, what this phrase

Table 1. Pictogram subtitles from the USP-DI.

S/N	Original USP-DI subtitles
1	Take 1 h before meals
2	Take 1 h after meals
3	Take 2 times a Day
4	Take 4 times a Day
5	Take 3 times a Day
6	Take by mouth
7	Do not store near heat or in sunlight
8	Take with meals
9	Do not take with meals
10	Wash hands/place drops in ear/wash hands again
11	Wash hands/place drops in nose/wash hands again
12	Wash hands/insert into vagina/wash hands again
13	Wash hands/place drops in lower eyelid/wash hands again
14	Do not store medicine where children can get in
15	Do not drink alcohol while taking this medicine
16	This medicine may take you drowsy
17	Store in refrigerator
18	Use this medicine as a gargle
19	Chew
20	Dissolve under the tongue
21	For headaches
22	Do not take if pregnant
23	Do not take if breast-feeding
24	Inhaler
25	Shake well

means to you?

Analysis of understanding of USP-DI pictograms

The participants were shown 15 of the 81 USP-DI pictograms. Pictograms were selected based on their expected relevance to the participants, and their expected usefulness in participants' everyday lives.

Pictograms were printed in monochrome, each with a size of 28 mm ($\pm 5\%$) \times 28 mm ($\pm 5\%$), as recommended by the International Organization for Standardization [ISO] 9186. Pictograms were presented without subtitles and in random order. The ISO specifies methods for testing the comprehensibility of graphical symbols, including methods to be used in testing the extent to which a variant of a graphical symbol communicates its intended message, and the methods to be used in testing which is a variant of a graphical symbol, is the most comprehensible (ISO, 2007).

Two researchers, one undergraduate research student and one master's student in pharmacy, presented pictograms to participants individually. Both followed the same presentation protocol. Before administering the pictograms, the researchers came to a consensus about what kinds of responses would be regarded as correct or incorrect.

Responses were coded as "correct" when they matched the specific subtitles given for each pictogram by the USP-DI, as shown in Table 1. Responses that did not match these legends were coded as "incorrect." Participants who said they did not understand the images and reported no meaning for them had their responses

coded as "do not know."

Participants were informed that the pictograms related to the use of prescription drugs, but did not receive any explanation of the significance of individual pictograms. Pictograms were presented without their accompanying subtitles. The respondents were asked to verbally report how they interpreted each image by answering the question, "If you had to take a prescription drug and the usage information was represented by this figure, what would you understand?" Responses were transcribed for further evaluation.

After this process, the two researchers independently assessed the participants' interpretations as either correct or incorrect. Discrepancies in coding were resolved by consensus after discussion. The ISO 3864 provides guidelines regarding the minimum acceptable rate of understanding of a pictogram (ISO, 1984). According to ISO 3864, pictograms are considered understandable when at least 67% of the sample's answers concerning these images are correct.

This study was submitted to the Research Ethics Committee from the University Hospital at the Federal University of Sergipe. All study participants were informed of the objectives and nature of the study and signed a volunteer informed consent form, as per the National Health Council Resolution n° 196/96.

RESULTS

During the steps of translation, changes were made to the grammatical structure of a few subtitles to obtain

Table 2. Description of the modifications carried out in the subtitles of pictograms, in Aracaju (SE), 2010.

Before	After
Do not store near heat or in sunlight	Do not save near heat or in sunlight
Store in refrigerator	Save in refrigerator
Do not store medicine where children can get in	Do not save medicine where children can get in
Take with meals	Take with food
Do not take with meals	Do not take with food
Dissolve under the tongue	Let dissolve under the tongue

(breakfast, lunch, and dinner). Subtitle 20 “dissolve under your tongue” was changed by the judges to “let dissolve under the tongue” to convey more clearly the intention that the pill be allowed to dissolve under the tongue by itself.

Of the 23 participants assessing subtitles’ semantic validity, three (13%) had completed a college education, five (21.7%) had completed high school, twelve (52.1%) had not completed high school, one had completed middle school (4.3%), and two (8.6%) were illiterate. Four participants had difficulty understanding the subtitle of pictogram 6; of these, one had completed a college education, two had not completed high school, and one was illiterate. Additionally, participants suggested modifications to two subtitles. For subtitle 3, 17 (74%) participants suggested changing “take twice a day” to “take in the morning and in the evening”; for subtitle 4, 19 (82%) participants suggested it be changed to “take in the morning, at noon, in the afternoon, and in the evening”. However, the researchers chose not to apply these changes to the final versions of these subtitles, because the times suggested by the participants cannot be considered standard for all treatments.

In the image/subtitle equivalency evaluation, 23 (100%) participants did not understand the images associated with subtitles 7 and 16, and could not see the relationship between those pictograms and their subtitles. Eighteen (78.2%) participants incorrectly understood pictograms 8 and 9, reporting that the meaning was “take the pill before eating food”.

Pictogram understanding

One hundred and sixteen individuals were interviewed regarding their understanding of the pictograms. Most (88.7%) of the participants were female. Their ages ranged from 60 to 90 years, with 68% of respondents between 60 and 75 years old. The education levels were as follows: 24% of participants had completed secondary education (that is, they had up to 12 years of education); 3.4% had not completed high school; 12% had completed higher education; 12.9% had completed primary education; 21.5% had not completed primary education;

7.7% had had only early childhood education; and 13.7% had not had any schooling. Regarding income, 60.3% of participants reported earning from zero to three times the minimum wage.

Most participants did not understand most of the USP-DI pictograms selected for the present study (Table 3). Only pictogram 10 gave a comprehension level greater than 67% (68% understanding), indicating that that pictogram is comprehensible for the target population of the municipality, according to the ISO 3864 standards.

DISCUSSION

The result of this study showed that the USP-DI pictograms selected for the present study tend to be poorly understood by elderly people in Brazil, as only one pictogram reached the understanding criterion of ISO 3864. Complexity in a prescription reduces elderly people’s ability to correctly interpret the instructions of a pharmacotherapeutic regimen. Consequently, adherence to the treatment regimen is likely to be reduced, the disease diagnosed is likely to worsen, and patient morbidity and mortality is likely to increase, leading to increased rates of hospitalization and increased health care costs (Korenevsky et al., 2013). This problem is exacerbated by the characteristic lower literacy and diminished memory function and cognitive ability of elderly patients, since these factors increase the difficulty of understanding essential information.

With respect to the translation of subtitles, due to the absence of previous studies of pictogram subtitles, the results of the present study cannot be compared to those of other studies. The lack of extant similar studies emphasizes the importance of the adaptation and validation of subtitles intended for use as a supplementary verbal means of information transmission in the Brazilian pharmaceutical practice.

The translated versions generated by the two translators matched in all subtitles. Silva and Thuler (2008) stress that it is important for translation to be performed by professionals whose mother tongue and culture are the same as those of the target audience. In addition, literal equivalence in translation may be insufficient to

Table 3. Understanding USP-DI pictograms. Aracaju, 2012 (n = 116).

S/N	Subtitle (USP-DI)	Correct [n (%)]	Wrong [n (%)]	Do not know [n (%)]
1	Take 1 h before meals	29 (25)	79 (68.2)	8 (6.8)
2	Take 1 h after meals	32 (27.5)	74 (63.9)	10 (8.6)
3	Take 2 times a Day	41 (35.3)	66 (56.8)	9 (7.7)
4	Take 4 times a Day	7 (6)	93 (80.3)	16 (13.7)
5	Take 3 times a Day	12 (10.3)	86 (74.2)	18 (15.5)
6	Take by mouth	49 (42.2)	53 (45.8)	14 (12)
7	Do not store near heat or in sunlight	3 (2.5)	82 (70.8)	31 (26.7)
8	Take with meals	16 (13.7)	87 (75.1)	13 (11.2)
9	Wash hands/place drops in ear/wash hands again	34 (29.3)	70 (60.4)	12 (10.3)
10	Wash hands/place drops in nose/wash hands again	79 (68)	33 (28.6)	4 (3.4)
11	Wash hands/insert into vagina/wash hands again	34 (29.3)	58 (50.1)	24 (20.6)
12	Do not store medicine where children can get in	52 (44.8)	53 (45.8)	11 (9.4)
13	Do not drink alcohol while taking this medicine	38 (32.7)	63 (54.4)	15 (12.9)
14	This medicine may take you drowsy	0 (0)	73 (63)	43 (37)
15	Store in refrigerator	25 (21.5)	62 (53.5)	29 (25)

maintain the intention of an item between different cultures (Malloy-Diniz et al., 2010). Therefore, the present study not only performed a literal translation, but also considered relevant features of the culture of the target population, as advocated by the literature (Louis and Parker, 2000).

Some changes were made to certain subtitles by the committee evaluating semantic, idiomatic, and cultural equivalence, in order to enhance understanding. Amaral et al. (2011) pointed out that the committee of judges should critically evaluate an instrument and verify that it has not been translated literally. The committee should instead capture the intent of the original instrument, even if a number of words need to be changed. In short, after evaluation by the committee of judges, the translated versions must show semantic, idiomatic, conceptual, and cultural equivalence along with retention of the original meaning.

Some participants had difficulties understanding subtitles in the semantic validation phase. Conti et al. (2012) reported that the translation of an instrument can only be finalized after its evaluation by the target population. Moreover, the instrument should be translated and validated by members of the target population to ensure that distortions have not occurred during the translation process (Cha et al., 2007). Thus, the submission of translated versions to target populations allows the detection and correction of discrepancies that might have occurred during the translation, and evaluation of its clarity and appropriateness.

Conclusion

Most of the USP-DI pictograms assessed were not well

understood by elderly people. Of the pictograms selected for the comprehension test, only one met the comprehension criterion established by ISO 3864. Thus there is a need to design and validate new, culturally adapted pictograms for use in Brazil. Therefore, subtitles of pictograms validated in this study, along with the pictograms which are being redesigned, will be used to increase elderly people's understanding and recall of information relevant to the use of prescription medicine.

REFERENCES

- Amaral ACS, Cordás TA, Conti MA, Ferreira MEC (2011). Equivalência semântica e avaliação da consistência interna da versão em português do Sociocultural Attitudes Towards Appearance Questionnaire-3 (SATAQ-3). *Cad. Saúde Pública* 27:1487-97.
- Braich PS, Almeida DR, Hollands S, Coleman MT (2011). Effects of pictograms in educating 3 distinct low-literacy populations on the use of postoperative cataract medication. *Can. J. Ophthalmol.* 46:276-81.
- Cha ES, Kim KH, Erlen JA (2007). Translation of scales in cross-cultural research: issues and techniques. *J. Adv. Nurs.* 58(4):386-95.
- Conti MA, Ferreira MEC, Amaral ACS, Hearst N, Cordás TA, Scagliusi FB (2012). Equivalência Semântica da versão em português do "Body Change Inventory". *Cien. Saude Colet.* 17(9):2457-2469.
- Cornélio RCAC, Pinto ALT, Pace FHL, Moraes JP, Chebli JMF (2009). Non-adherence to therapy in Crohn's disease patients: prevalence and risk factors. *Arq. Gastroenterol.* 46(3):183-189.
- Dowse R, Ehlers MS (2005). Medicine labels incorporating pictograms: do they influence understanding and adherence? *Patient Educ. Couns.* 58(1):63-70.
- Dowse R, Ramela T, Browne SH (2011). An illustrated leaflet containing antiretroviral information targeted for low-literate readers: Development and evaluation. *Patient Educ. Couns.* 85:508-15.
- Fegadolli C, Reis RA, Martins STA, Bullinger M, Santos CB (2010). Adaptação do módulo genérico DISABKIDS® para crianças e adolescentes brasileiros com condições crônicas. *Revista Bras. Saúde Matern. Infant.* 10.
- Guillemin F, Bombardier C, Beaton D (1993). Cross-cultural adaptation of health-related quality of life measures: literature review and

- proposed guidelines. *J. Clin. Epidemiol.* 46:1417-32.
- International Organization for Standardization (1984). *International Standards for Safety Colours and Safety Signs. ISO 3864.* Geneva, Switzerland: International Organization for Standardization.
- International Organization for Standardization (2007). *Graphical Symbols – Test Methods – Part 1: Methods for Testing Comprehensibility. ISO 9186-1.* Geneva, Switzerland: International Organization for Standardization.
- Korenevsky A, Vaillancourt R, Pouliot A, Revol M, Steed E, Besançon L, Wahrendorf MS, Patel JR (2013). How Many Words Does a Picture Really Tell? Cross-sectional Descriptive Study of Pictogram Evaluation by Youth. *Can. J. Hosp.Pharm.* 66(4):219-26.
- Louis, RM, Parker RA (2000). *Metodologia de pesquisa: do planejamento à execução.* Ed São Paulo: Pioneira.
- Liu CJ, Kemper S & McDowd J (2009). The use of illustration to improve older adults' comprehension of health-related information: Is it helpful?. *Patient Educ. Couns.* 76(2):283-288.
- Malloy-Diniz LF, Mattos P, Leite WB, Abreu N, Coutinho G, De Paula JJ, Tavares H, Vasconcelos AG, Fuentes D (2010). Tradução e adaptação cultural da Barratt Impulsiveness Scale (BIS-11) para aplicação em adultos brasileiros. *J Bras. Psiquiatr.* 59:99-105.
- Mansoor L, Dowse R (2003). Effect of pictograms on readability of patient information materials. *Ann. Pharmacother.* 37(7-8):1003-1009.
- Mansoor L, Dowse R (2006). Written medicines information for South African HIV/AIDS patients: does it enhance understanding of cotrimoxazole therapy? *Health Educ. Res.* 22(1):37-48.
- Maragno CAD (2009). *Associação entre letramento em saúde e adesão ao tratamento medicamentoso [dissertation].* Porto Alegre: Faculdade de Farmácia da Universidade Federal do Rio Grande do Sul.
- Moreira MF, Nóbrega MML, Silva MIT (2003). Comunicação escrita: contribuição para a elaboração de material educativo em saúde. *Rev. Bras. Enferm.* 56:184-88.
- Mwingira B, Dowse R (2007). Development of written information for antiretroviral therapy: comprehension in a Tanzanian population. *Pharm. World Sci.* 29(3):173-182.
- Silva FC, Thuler LCS (2008). Tradução e adaptação transcultural de duas escalas para avaliação da dor em crianças e adolescentes. *J. Pediatr.* 84:344-49.
- United States Pharmacopeia (USP) (2014) – Pictograms. Accessed: 28 out 2014. Available: <http://www.usp.org/usp-healthcareprofessionals/related-topics/resources/usp-pictograms/download-pictograms>.
- Vaillancourt R, Grenier S (2011). International pictogram project for the labelling of medication. *Can. J. Hosp. Pharm.* 64(1):82–6.
- Weiss BD, Mays MZ, Martz W, Castro KM, DeWalt DA, Pignone MP, Mockbee J, Hale FA (2005). Quick assessment of literacy in primary care: the newest vital sign. *Ann. Fam. Med.* 3(6):514-22.