

**PŘEKLAD A LINGVISTICKÁ VALIDACE SEBEHODNOTÍCÍCH NÁSTROJŮ BOLESTI
U DĚTÍ S-FPS, S-COS DO ČESKÉHO JAZYKA**
*TRANSLATION AND LINGUISTIC VALIDATION OF SELF-REPORTING PAIN
TOOLS S-FPS, S-COS FOR CHILDREN INTO CZECH*

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ABSTRACT

Background: The development of pain assessment techniques in children is complicated due to their age. Most evaluation tools are developed abroad, in a foreign language.

Aim: The aim of the translation was to create a tool that is conceptually equivalent to the original version.

Methods: The language translation and validation was a 10-phase process supported by quantitative and qualitative methods.

Results: Czech versions (CZ-v) of pain assessment tools S-FPC, S-COS were created based on positive results of the content validity index (0.75 – 1), modified kappa statistics (0.667 – 1), professional nursing feedback and cognitive debriefing with children and their parents.

Conclusions: Translation and language validation were demanding and time-consuming, due to numerous challenges, such as involving translators and expert who met the inclusion criteria. In the next phases of the study, the psychometric properties of the tools will be evaluated.

Key words: Pain. Child. Assessment. Preschool. linguistic validation.

ABSTRAKT

Východiska: Vývoj hodnotících metod bolesti u dětí vzhledem k jejich věku velmi komplikovaný. Většina evaluačních nástrojů je vyvinuta v zahraničí.

Cíl: Cílem překladu bylo vytvořit nástroj, který je koncepčně rovnocenný původní verzi.

Metodika: Jazyková validace byla provedena metodou 10-fázového procesu doplněného kvantitativními a kvalitativními metodami.

Výsledky: České verze nástrojů pro hodnocení bolesti S-FPC, S-COS byly vytvořeny na základě pozitivních výsledků indexu obsahové validity (0,75 – 1), modifikovaného kappa (0,667 – 1), profesionální sesterské zpětné vazby a kognitivního rozhovoru s dětmi a jejich rodiči.

Závěr: Překlad a jazyková validace byly obtížné a časově náročné z důvodu komplikovaného zapojení překladatelů a odborníků, kteří splňovali kritéria zařazení. V dalších fázích studie budou vyhodnoceny psychometrické vlastnosti nástrojů.

Klíčová slova: Bolest. Dítě. Hodnocení. Předškolák. Jazyková validace

INTRODUCTION

To assess pain in patients aged 6+, numerous assessment tools have been developed. However,

much less is known about self-reporting pain in children aged 3 to 5 years (Von Baeyer et al., 2017). It is a subjective experience that is influenced by several factors, such as person's own experience, the function of the nervous system, or the influence of the environment (Koyama et al., 2005). Information about pain can be obtained from self-report, physical reaction of the organism or behavioural manifestations. Although self-report is considered the gold standard, there are not enough suitable tools of this type for all age groups of children. At present, pain assessment by parents or healthcare professionals still predominates, but this assessment may not be accurate as it is influenced by the assessor's personality (Stanley et al., 2013; Emmott et al., 2017). Each child feels and expresses pain individually and for this reason, self-report is considered the most accurate assessment method. Some experts state that assessment tools are also suitable for children from the age of 3, but in their research studies, these children are usually part of a group that includes older children, which leads to an incorrect overestimation of their abilities (Chan et al., 2016; Von Baeyer et al., 2017).

The newly developed S-FPS (Simplified Faces Pain Scale) and S-COS (Simplified Concrete Ordinal Scale) methods may be useful for assessment of pain in preschool children. These new assessment methods are characterized by their simplicity, where S-FPS contains only 3 categories of black and white faces representing pain and S-COS includes 3 single-coloured cubes of different sizes. Spearman r coefficient (r_s) for correlation with FLACC were 0.72 for S-FPS, and 0.62 for S-COS (Emmott et al., 2017; Bayram et al., 2020), which suggests that they are valid in this patient population. Furthermore, researchers in Turkey attempted to validate these new tools, conducting research on children undergoing adenotonsillectomy at the age of 3 – 6 years (Bayram et al., 2020). However, the researchers did not

describe the tool's language translation process. Comparisons between the widely used FLACC (Face, Legs, Activity, Cry, Consolability), the FPS-R (Faces, Pain, Scale – Revised) and the new tools S-FPS, S-COS were conducted using r_s . The study suggested that the translated versions of the new tools for assessing pain in preschool children was valid (p -value less than 0.05 was considered significant for all comparisons) (Bayram et al., 2020). Translating each assessment tool into the target language and adapting it to a different culture is a complex process and to obtain a high-quality translation, universally accepted guidelines should be followed, such as the International Society for Pharmacoeconomics and Results Research (ISPOR) (Tab. 1) and the recommendations of the World Health Organization (WHO) (Wild et al., 2005; WHO, 2020). For the translation and language validation of instruments, it can be useful to follow an algorithm proposed by Mandysová (2019), which is based on ISPOR principles. It provides a detailed description of the procedure and contains a decision tree regarding each step, thus providing an in-depth guidance

for researchers engaged in the process. The algorithm was developed by Mandysová during her research project that aimed to translate a pain scale for stroke patients from English into Czech and it was already used in a research to guide the translation of a foreign instrument from English to Finnish (Dumo et al., 2021).

The above-mentioned algorithm by Mandysová (2019) encompasses the idea that the translation should be transculturally valid; word-by-word translation is discouraged. In particular, transcultural validation includes feedback, a preliminary test on the target group of users or cognitive conversation (Mandysová, 2019). Transcultural validation may use a combination of quantitative and qualitative methods (Wild et al., 2009). Quantitative methods may include numerical Likert scale evaluation, and the use of Item Content Validity Index (I-CVI) and modified kappa (k^*) statistics. Qualitative methods focus on resolving ambiguities through discussions with experts, cognitive interviews and user observations (Mandysová, 2019). The assessment tools S-FPS, S-COS have not been translated

Table 1 Phase of translation (Mandysová, 2019; Wild et al., 2005)

Phase	Description	Implementation
1	Preparation	Consent was obtained from the original developers for the translation. Criteria were established for: translators, expert panels and methods for testing the translated tool.
2	Forward translation	First translation (into Czech) Two translators (A+B) translated independently the original from English (Translator A created preliminary CZ-v1, and Translator B created preliminary CZ-v2)
3	Reconciliation	Evaluation report Expert panel 1 (10 NE) evaluated both preliminary CZ-v using a three-point accuracy scale. The results from the experts were analysed using I-CVI and k^* statistics. The results were consolidated by the first author into one document. An expert panel 2 (4 NE) produced a preliminary CZ-v3.
4	Back translation	Translator (C) translated unified preliminary CZ-v3 back into English.
5	Back translation review	Translator (B) compared the back translation with the original version while considering the comments of Translator C and discussed the translated English text with the original author.
6	Harmonization	Expert panel 3 (2 NE) and translator B discussed translation discrepancies and finally agreed on the creation of a preliminary CZ-v4.
7	Cognitive debriefing	A representative sample of users (7 paediatric patients) were involved. This step consisted of analytical interviews and a feasibility assessment of the final preliminary CZ-v4.
8	Review of cognitive debriefing results and finalization	Expert panel 3 and Translator B reviewed the results and consulted with the author. Everyone agreed on the changes resulting from this review, the creation of the final CZ-v.
9	Proofreading	Panel of experts 3 and the first author developed the final CZ-v.
10	Final report	The final CZ-v will be included in the final report in Czech, which will be part of the doctoral study thesis.

Legend: NE = nursing experts

into Czech yet, and a self-report instrument for pre-schoolers in the Czech Republic is still missing.

STUDY AIMS

The aim of the study is to translate the self-report pain tools S-FPS, S-COS for children into Czech and to conduct linguistic validation based on the ISPOR guidelines and Mandysová's (2019) algorithm.

METHODS

The study had the character of a linguistic validation and it was performed at the University Hospital Olomouc in the Czech Republic. It took place from 09/2020 – 10/2021. The study was approved by the Ethics Committee of Palacký University Olomouc and the management of the Faculty Hospital Olomouc.

Furthermore, original developers of the S-FPS and S-COS gave consent to translate and to use the tools. Children were enrolled only if written consent by the parents was obtained, pre-schoolers unwilling to cooperate were not included in the study. The ISPOR guidelines (Wild et al., 2005) and Mandysová's algorithm (Mandysová, 2019; Mandysová, Herr, 2019) were used to guide the process of instrument translation and validation.

Participants - Translators

The criteria for the selection of translators specified in the ISPOR guidelines were fulfilled (Wild et al., 2005). Specifically, three translators took part in the process (Tab.1, phase 2, 4, 5, 6, 8). Translators A and B were doctoral students and also nurses

with 10+ years of work experience.

Participants - Nursing experts

Experts for the panels were selected and approached through the doctoral study programme at Palacký University Olomouc. A total of 10 experts on panel 1 commented on the quality of the translated preliminary CZ-v1 and 2. Panel 2, consisting of 4 experts, focused on language and cultural regulation. Panel 3 consisted of 2 experts; it worked out the discrepancies existing across the different versions of the instruments translated and created a single synthesized version suitable for the clinical environment. The recommended numbers and qualifications of experts were based on literature (Pudas-Täkhä et al., 2014; Mandysová, 2019; Mandysová, Herr, 2019).

Participants – Patients (children)

Children reported their pain level immediately before, during, and 5 – 10 minutes after a painful procedure (blood collection through a venepuncture) (Tab. 1, phase 7).

TRANSLATION PROCEDURE

Forward translation and Reconciliation

Translators A and B were given the original version of the S-COS and S-FPC and were asked to translate both instruments into Czech. Each of the translators worked independently. Preliminary CZ-v1 (developed by Translator A) and 2 (by Translator B) were statistically evaluated using I-CVI, k^* and P_c (the probability of chance agreement) (Tab. 2).

Table 2 Quantitative results of Preliminary CZ-v

Preliminary S-COS-CZ-v1						Preliminary S-FPS-CZ-v1					
Items	N	A	I-CVI	P_c	k^*	Items	N	A	I-CVI	P_c	k^*
Item 1	10	9	0.9	0.01	0.899	Item 1	10	9	0.9	0.01	0.899
Item 2	10	8	0.8	0.044	0.791	Item 2	10	7	0.7	0.117	0.66
Item 3	10	9	0.9	0.01	0.899	Item 3	10	8	0.8	0.044	0.791
Item 4	10	8	0.8	0.044	0.791	Item 4	10	8	0.8	0.044	0.791
Item 5	10	9	0.9	0.01	0.899	Item 5	10	8	0.8	0.044	0.791
Preliminary S-COS-CZ-v2						Preliminary S-FPS-CZ-v2					
Items	N	A	I-CVI	P_c	k^*	Items	N	A	I-CVI	P_c	k^*
Item 1	10	4	0.4	0.205	0.245	Item 1	10	4	0.4	0.205	0.245
Item 2	10	7	0.7	0.117	0.66	Item 2	10	5	0.5	0.246	0.337
Item 3	10	6	0.6	0.205	0.497	Item 3	10	4	0.4	0.205	0.245
Item 4	10	6	0.6	0.205	0.497	Item 4	10	5	0.5	0.246	0.337
Item 5	10	4	0.4	0.205	0.245	Item 5	10	6	0.6	0.205	0.497

Legend: N = total number of nursing experts

Table 3. Preliminary and final CZ-v of the S-COS, S-FPS

Tranl. item	Item type	Original S-COS	Final S-COS-CZ-v	Original S-FPS	Final S-FPS-CZ-v
1	title	S-COS	S-COS	S-FPS	S-FPS
2	instruction for use	These blocks show how much something can hurt	Tyto kostičky ukazují, jak moc může něco bolet	These faces show how much something can hurt	Tyto tváře ukazují, jak moc může něco bolet
3	instruction for use	One block [researcher points to leftmost block] shows a small amount of hurt	Jedna kostička (tazatel ukáže na kostku úplně vlevo) ukazuje malou bolest	This face [point to left-most face] shows a little bit of hurt	Tato tvář (ukážete na tvář úplně vlevo) ukazuje malou bolest
4	instruction for use	Two blocks [researcher points to middle blocks] shows a medium amount of hurt	Dvě kostičky (tazatel ukáže na prostřední kostky) ukazují střední bolest	This face [point to middle face] shows a medium amount of hurt	Tato tvář (ukážete na prostřední tvář) ukazuje střední bolest
5	instruction for use	And 3 blocks [researcher points to rightmost blocks] shows very much hurt	A tři kostičky (tazatel ukáže na kostky úplně vpravo) ukazují největší bolest	And this face [point to right-most face] shows very much hurt.	Tato tvář (ukážete na tvář úplně vpravo) ukazuje největší bolest
6	instruction for use	Touch the blocks that show how much you hurt right now.	Dotkni se kostiček, které ukazují, jak moc tě to teď bolí	Touch the face that shows how much you hurt right now.	Dotkni se tváře, která ukazuje, jak moc tě to bolí právě teď

Table 4 Pre-test - observed problems / reactions

Items	Observed reactions	7 Patients / children
Understanding the instructions	The patient understood the instructions.	P3, P5, P6, P7
	The patient needed to repeat the instructions.	P1, P2, P4,
Remember the meaning of the pictures	The patient remembered the meaning of the pictures.	P3, P5, P6, P7
	The patient was unsure.	P1, P2, P4,
Confidence in choosing the answer	The patient was sure of the chosen option.	P3, P5, P6, P7
	The patient was unsure.	P1, P2, P4,
Respondent's burden	The patient did not have a problem choosing a variant.	P3, P5, P6, P7
	The patient needed to repeat the meaning of the pictures and more time.	P2
	The patient needed more time.	P1, P4

The obtained results of the I-CVI and the k^* statistic were evaluated based on the formulas described by Polit et al. (2007) and Mandysová (2019). Specifically, I-CVI equalled the number of health experts who agreed on the accuracy of the translation (on a 3-point scale); $k^* = (I-CVI - Pc) / 1 - Pc$; $Pc = [10! / A! \times (10 - A)!] \times 0.5^{10}$ where A = number of experts who agreed that the item is accurate. (Polit et al., 2007; Mandysová, 2019).

The panel of experts 2 (4 NE) and the first author created a preliminary CZ-v3 by unifying the first two CZ-v, taking into account the results of the statistical evaluation I-CVI and k^* .

Back translation and Harmonization

Translation and harmonization (Tab. 3) were developed in accordance with the ISPOR guidelines (Wild et al., 2005).

Pre-test and Finalization

The final preliminary CZ-v4 was tested on 7 patients from the target group for whom the instrument is intended, and they were selected based on precise criteria. A representative sample of users applied the tool according to the instructions and the respondents were observed during the testing. A subsequent analytical interview was conducted where children were asked to paraphrase the instructions (Tab. 4).

The aim of the interview was to evaluate the comprehensibility of the instructions accompanying the tools. The nurse and the parent also expressed their opinion concerning the new assessment tools. The results of the test were discussed by panel 3 and Translator B. No further translation changes were required. The copyright owner was informed. All parties agreed and the final CZ-v was created. This step successfully concluded the translation process.

RESULTS

The new S-COS and S-FPS assessment tools for pre-school children show a set of pictures and the instructions for use have been translated. Each assessment tool contains 5 items (5 instructions for each tool). The title was not translated; it is not part of the items. There was a partial agreement among the translators, where the differences mainly lay in the specifics of children's speech. Experts discussed the use of diminutives and words easily understood by young children. The results show satisfactory values and no further corrections were necessary. A pre-test suggested that the tools are transculturally equivalent.

DISCUSSION

The translation was performed using Mandysová's decision tree algorithm for the translation and linguistic validation and based on ISPOR guidelines. This translation method has recently come into use by Dumo et al. (2021), because the aim is to create a tool that is conceptually equivalent to the original version and is used correctly at the same time (Wild et al., 2005; Mandysová, 2019; Bobkowska et al., 2021; Tobberup et al., 2022). Namely for children, it is very difficult to develop a new assessment technique or to translate an existing method so that it is understandable and appropriate to their age and cognitive abilities. One of the most complicated age periods is the pre-school age. Children are beginning to assert themselves as personalities, and at the same time there are great differences in knowledge amongst them (Chan et al., 2016). Based on this fact, Canadian researchers have developed the S-FPS and S-COS (Emmott et al., 2017) translation tools, and Turkish researchers have already translated and validated the tools into Turkish (Bayram et al., 2020). The translation process was demanding because it was necessary to meet the selection criteria, identify and involve participants: translators, health professionals, children with parents.

Other experts who participated in validation studies are of similar opinion (Mandysová, 2019; Bobkowska et al., 2021; Tobberup et al., 2022). The children had to understand what we wanted from them and since the evaluation involved 3 stages, it was necessary to always maintain children's interest and willingness to cooperate. When a child and parent consented to participate in the study, they often revoked the decision during the evaluation and withdrew. Another significant factor that made the translation difficult and slower was the involvement of a combination of professionals with appropriate education, language skills (translators) and NE. Health experts were also selected for the position of Translator A + B, as it was important that they know clinical terminology in the target language (Wild et al., 2005; Mandysova et al., 2019). Translators A and B were also mothers who were aware of the need to choose the vocabulary used by pre-school children, which was a great advantage. Panel 2 agreed on a single version taking into account children's language and intellectual abilities. When the back translation was obtained, minor differences were consulted with the copyright owner. Throughout the pre-test, the children were observed and asked about the comprehensibility of the instructions, the meaning of the pictures or remembering the instructions. An integral member of the overall evaluation was the parent and NE. Statistical methods I-CVI and k* suggested the content validity.

Limitations

This translation algorithm requires the involvement of a large number of participants who had to meet the criteria. The translators had to demonstrate the required command of English and at the same time be NE, which was essential for the final clinical use. Research with young children is always challenging, even more so if they have to cooperate when they are in pain.

CONCLUSION

The translation according to the decision tree algorithm provided a detailed procedure for translating the assessment tool from English into Czech while respecting the author's rights. A Mandysova's decision tree algorithm is science-based and follows the international translation guidelines of ISPOR and WHO. In addition to content validity, it is desirable to determine the psychometric characteris-

tics of these tools before they can be recommended for clinical practice.

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