


Translation of the Pediatric Nausea Assessment Tool (PeNAT) Into Spanish and Evaluating Understandability Among Spanish-Speaking Hispanic American Children and Adolescents Receiving Chemotherapy

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Abstract

Introduction: We aimed to create a Spanish-language version of the Pediatric Nausea Assessment Tool (PeNAT) and examine its understandability among Spanish-speaking, Hispanic American children. **Methods:** *Translation:* Forward and backward translations of the PeNAT documents were performed and verified by a bilingual panel. Four monolingual, Spanish-speaking dyads (child/parent) and four bilingual dyads piloted the Spanish-language PeNAT documents. Four additional bilingual dyads read both versions and completed the PeNAT using their preferred version. These were reviewed for errors due to misunderstanding. **Understandability:** Children aged 4–18 years about to receive chemotherapy who spoke Spanish at home and were without impairments precluding PeNAT use were eligible. Participants used the Spanish-language PeNAT during a chemotherapy block. Parents gave feedback on the PeNAT documents. Recruitment continued until 10 consecutive participants offered no substantive suggestions for revision. **Results:** *Translation:* All child/parent dyads completed the PeNAT without errors attributable to misunderstanding. The Spanish-language PeNAT was preferred by three of four bilingual dyads. *Understandability:* Ten cancer patients (mean age: 10.6 years) used the Spanish-language PeNAT. All parents felt their child understood the PeNAT; none felt the documents were hard or very hard to use. **Conclusion:** The Spanish-language PeNAT was understood by Spanish-speaking Hispanic American children. Further psychometric testing is warranted.

Keywords

oncology, pediatrics, Spanish, nausea, patient-reported outcome

Adult cancer patients, pediatric cancer patients, and parents of pediatric cancer patients consistently rank chemotherapy-induced nausea and vomiting (CINV) among the most bothersome adverse effects that they or their children experience (Carelle et al., 2002; Coates et al., 1983; Dupuis, Johnston, et al., 2018; Dupuis et al., 2010). Although not yet optimized, vomiting control has improved considerably due to new antiemetic agents and the availability of clinical practice guidelines (Patel et al., 2017). Chemotherapy-induced nausea, however, remains prevalent and bothersome (Dupuis, Kelly, et al., 2018; Kovacevic et al., 2019).

Adult cancer patients can usually describe the severity of nausea they feel using self-report visual analog or adjectival rating scales such as the Multinational Association of Supportive Care in Cancer Antiemesis Tool (Hesketh et al., 1998).

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Thus, nausea severity assessment by adult cancer patients using validated measures has become expected in adult antiemetic trials. Validated instruments to assess nausea severity by children are perhaps even more important than adult instruments since children may have difficulty communicating how severe their nausea is or may be reluctant to do so spontaneously. While validated tools are available (Baxter et al., 2011; Dupuis et al., 2006), they are not used widely in pediatric antiemetic trials or in clinical care. As a result, the supportive care of children with cancer has been compromised.

In 2006, we developed and validated the Pediatric Nausea Assessment Tool (PeNAT) for assessment of nausea severity by English-speaking children aged 4–18 years receiving chemotherapy (Dupuis et al., 2006). The PeNAT is derived from the Wong-Baker pain scale and consists of a script that focuses the child on nausea and a series of four faces. It is often used in conjunction with a diary (Lavoratore et al., 2011) where patients and parents record the time of emetic episodes and the patient's nausea severity scores. Spanish is spoken in approximately 13% of American households by over 41 million people (U.S. Census Bureau, 2018). There is no validated, Spanish-language tool that Hispanic American pediatric patients can use to measure and communicate their nausea severity. In order to address this gap, we aimed to translate the PeNAT into Spanish and evaluate its understandability among Hispanic American pediatric cancer patients.

Method

This study was conducted in two phases. First, the English-language PeNAT and supporting documents were translated into Spanish. This phase was conducted by the UT Health San Antonio Team (P.I. E. Garcia Frausto) and was awarded a waiver of consent. In the second phase, the understandability of the Spanish documents was tested in pediatric cancer patients and their parents in a qualitative, prospective study. This phase was conducted at the UT Health San Antonio, San Antonio, USA, Children's Hospital and Research Center at Oakland, Oakland, USA, and SickKids, Toronto, Canada. The institutional research board or research ethics board at each participating site approved the study, and participants provided informed consent or assent as appropriate.

Phase 1—Translation

The previously validated English-language PeNAT and supporting documents (script, diary, and patient/family instructions) were translated into Spanish by a masters-prepared Hispanic translator for pediatric oncology services at a pediatric hospital. Following Brislin's (1970) model of back-translation, a second translator (a Mexican-trained physician) translated the Spanish documents back into English without having seen the English versions.

Using a process known as “decentering” (Jones & Kay, 1992), an expert panel of five educated, culturally diverse, bilingual (Spanish and English) individuals examined the

original English-language PeNAT documents, the translated Spanish version, and the back-translated version for errors that might lead to differences in meaning. If errors were found, the translation—back-translation process was to be repeated. The expert panel members discussed each individual Spanish-translated and back-translated line at a face-to-face meeting.

All participating dyads were cancer patients and their parents. They were identified by a member of the study team (E. Garcia Frausto) during a usual cancer care visit. The Spanish documents were first piloted by four monolingual, Spanish-speaking child/parent dyads. Two children were 4–8 years old, and two were between 9 and 18 years old. Each dyad received the Spanish PeNAT administration script, CINV diary page, and diary instruction sheet. A Spanish-speaking investigator read the PeNAT administration instructions verbatim to the child/parent dyad and then read the Spanish CINV diary page instruction sheet verbatim while showing them the sample Spanish CINV diary page. They were then asked to complete a Spanish CINV diary page.

Next, four bilingual (Spanish and English) child/parent dyads were given the English version of the PeNAT. The English-language PeNAT was administered to two children aged 4–8 years and two children 9–18 years old as described above. Another four (two children aged 4–8 years and two children 9–18 years) bilingual (Spanish and English) child/parent dyads were given the Spanish version. Each participant was then asked to complete a CINV diary page in the language they had been given. Finally, four bilingual (Spanish and English) child/parent dyads were given both the English and Spanish versions of the PeNAT documents for review. They were asked whether they preferred the English version or the Spanish version. Each participant was then asked to complete a CINV diary page in the language of their preference. All completed diary pages were reviewed in detail to identify errors due to misunderstanding.

Phase 2—Understandability Testing

All patients scheduled to receive chemotherapy at participating sites were screened for eligibility. Patients aged 4–17.99 years whose primary language in the home was Spanish and who were to receive a chemotherapy block (consecutive days that chemotherapy is given) that contained moderately to highly emetogenic, IV chemotherapy (Paw Cho Sing et al., 2019) were eligible to participate. Patients or patients with parents with a physical or cognitive impairment that precluded the use of the PeNAT were excluded. Patients participated in the study once.

Using the Spanish PeNAT documents developed in the first phase, a study team member administered the Spanish PeNAT to each child participant and instructed their parent on its administration. Participants were then asked to complete a CINV diary page on each day of the acute phase of the upcoming chemotherapy block. The acute phase was defined as beginning with the administration of the first dose of chemotherapy of the chemotherapy block and ending 24 hr after

administration of the last chemotherapy dose of the chemotherapy block. Patients used the Spanish PeNAT to assess the severity of their present nausea at minimum twice (on waking each morning and at bedtime) on each day of the acute phase plus whenever they felt nauseated or whenever their parent felt that they may be nauseated. Nausea severity was assessed by the child themselves, not by their parent. Nausea severity assessments, time of day that the patient vomited or retched, and the name and administration time of each medicine given to prevent or treat CINV were recorded on the CINV diary provided. A study team member provided verbal and written instructions on how to complete the CINV diary pages.

Participants returned the completed CINV diary pages on their next hospital visit or a study team member collected them at the end of the acute phase. Within 3 days of completion of the study chemotherapy block, a study team member solicited information from participants by telephone about the readability, clarity, and ease of use of the Spanish-language PeNAT and supporting documents using a standard questionnaire (Online Appendix I). Patient demographic data and information regarding the chemotherapy, antiemetic doses, and, for inpatients, time of their administration were collected from the health record.

Sample Size and Data Analysis

Patients were recruited in consecutive sets of five until no substantive suggestions for revision to the Spanish documents were received in two consecutive groups. In each set of five patients, no more than three patients were older than 8 years.

Investigators reviewed responses from the CINV diaries and questionnaires after each set of five patients completed the study. Based on these responses, possible revisions to the original translated documents were considered. Any revisions were incorporated into the documents that were tested in the next set of five patients. If significant revisions were made, the revised documents were planned to be subjected to back-translation and review by an expert panel as described in Phase I.

Descriptive statistics were used to describe patient demographic characteristics and the extent of CINV control they reported. CINV control was defined as complete (no vomiting, no retching, and maximum PeNAT score of 1), partial (no more than two emetic episodes in any 24-hr period or a maximum PeNAT score of 2), or failed (more than two emetic episodes in any 24-hr period or a maximum PeNAT score of 3 or 4).

Results

Translation

Review of the back-translation of the PeNAT documents identified two differences: translation of the words “tummy” and “feeling.” The expert panel discussed the use of these two words at length since the term used for “tummy” varies widely within cultures. Common slang terms such as *panza* and other translations such as, *estomago*, *estomagito*, *barriga*, *barrigita* or *vientre* were considered. The expert panel decided to use both *estomago* and *barriga* to remain culturally sensitive. They also agreed that

there is no exact Spanish translation for “dry heave or retch” and decided to use the word *asco* for this term.

The CINV diaries completed by the first four monolingual, Spanish-speaking child/parent dyads contained no errors attributable to misunderstanding. Similarly, the CINV diaries completed by the 12 bilingual child/parent dyads contained no errors attributable to misunderstanding. Three of four bilingual dyads who were given both English and Spanish versions of the PeNAT documents stated a preference for the Spanish version of the documents. No changes were made based on child or parent feedback, and the Spanish PeNAT and supporting documents were finalized (Online Appendix II).

Understandability Testing

The characteristics of the patient participants, their treatments, and the extent of CINV control they experienced are presented in Table 1. In all, 10 patients participated: five at Children’s Hospital and Research Center at Oakland, four at UT Health San Antonio, and one at SickKids. Most patients had acute lymphoblastic leukemia and received moderately emetic chemotherapy during the study chemotherapy block. The median duration of the acute phase was 2 days (range: 1–6 days), and the median number of nausea severity assessments reported by patients was 4.5 (range: 2–12). The median maximum reported PeNAT score was 1 (range: 1–4).

Parents’ feedback regarding their experience administering the Spanish-language PeNAT to their children is summarized in Table 2. All parents stated that the Spanish-language script for PeNAT administration was complete. Almost all (9/10) parents believed that their child was able to communicate the severity of their nausea using the PeNAT and that this was done easily. No parent thought that their child was reporting the severity of a symptom other than nausea when using the PeNAT. No parent stated that the diary was hard or very hard to use.

Two parents made suggestions on how to improve the PeNAT. One suggested that it be transformed to an electronic platform (e.g., computer app). This was not within the scope of the present study. Another offered that the word “asco” be changed to “quiero vomir.” The translation of “retching” was discussed extensively early in this study, and *asco* was chosen. The investigators revisited this issue and decided not to make a change since this comment was raised by a single participant. Further, since nausea is not always accompanied by vomiting, the investigators did not want to conflate the two symptoms by translating nausea as a linked item. One parent stated that the PeNAT was “a perfect way for children who cannot express themselves well.”

Almost all parents (9/10) stated that nothing about the CINV diary was confusing or hard to understand. One parent had a little difficulty understanding where to note the assessment times (night vs. day). This parent suggested that pictures could be added to make this clearer. This was considered by the investigators but not implemented since it was raised by only a single participant. Four parents stated that they especially

Table 1. Patient Demographic and Treatment Characteristics.

Characteristic	First Set (N = 5)	Second Set (N = 5)	All Patients (N = 10)
Patients			
Age (years)			
4–8 (number; %)	2 (40)	2 (40)	4 (40)
8–18 (number; %)	3 (60)	3 (60)	6 (60)
Median (range)	13 (5–17)	12 (4–17)	(4–17)
Cancer diagnosis (number; %)			
Acute lymphoblastic leukemia	4 (80)	3 (60)	7 (70)
Other ^a	1 (20)	2 (40)	3 (30)
Treatments			
Moderately emetic chemotherapy (number; %)			
Cyclophosphamide 1 g/m ² + cytarabine 90 mg/m ²	1 (20)	0	1 (10)
Cyclophosphamide 1 g/m ² + cytarabine 75 mg/m ² + IT methotrexate	2 (40)	0	2 (20)
Methotrexate 5 g/m ²	1 (20)	0	1 (10)
Methotrexate 250 mg/m ² + vincristine	0	1 (20)	1 (10)
Methotrexate 5 g/m ² + vincristine	0	1 (20)	1 (10)
Highly emetic chemotherapy (number; %)			
Cisplatin + doxorubicin	0	1 (20)	1 (10)
Cyclophosphamide + dactinomycin	1 (20)	0	1 (10)
Cyclophosphamide 430 mg/m ² + Erwinia asparaginase + etoposide	0	1 (20)	1 (10)
Etoposide + ifosfamide 1.8 g/m ²	0	1 (20)	1 (10)
Antiemetic prophylaxis (number; %)			
Diphenhydramine	0	1 (20)	1 (10)
Ondansetron	4 (80)	2 (40)	6 (60)
Ondansetron + aprepitant	1 (20)	2 (40)	3 (30)
CINV control reported (number; %)			
Complete	3 (60)	3 (60)	6 (60)
Partial	0	2 (40)	2 (20)
Failed	2 (40)	0	2 (20)

Note. N = number; IT = intrathecal; CINV = chemotherapy-induced nausea and vomiting.

^a Includes solid tumor, brain tumor.

liked the PeNAT faces. Two said that they liked that the diary was short and easy to complete. No parent found the CINV diary hard or very hard to complete. Since no changes were made to the Spanish-language PeNAT and supporting documents based on the experience of two consecutive sets of five participants, study enrolment ceased once 10 participants completed the study.

Discussion

We have translated the previously validated English-language PeNAT into Spanish and shown it to be well understood by Spanish-speaking Hispanic American pediatric cancer patients and their parents. The scarcity of non-English, validated patient-reported outcome measures has been identified as a potential source of research bias (Grant et al., 2020). Nausea is a prevalent treatment-related symptom that reduces quality of life (Dupuis et al., 2016; Hinds et al., 2009). As a subjective symptom, it is especially important for patients, rather than proxies, to assess its severity. The availability of a validated patient report symptom severity tool in a patient's preferred language is fundamental to this process both in clinical practice and in research.

McKinnon and Jupp (2019) report mixed success when the PeNAT was used as a clinical tool. Barriers included the low rate of families being offered the PeNAT by clinical pharmacists, the onerous nature of a paper-based tool, and perceptions by clinicians, patients, and parents that nausea, even when identified, cannot be prevented or improved.

The PeNAT has been used to measure nausea severity in several pediatric studies (Carroll et al., 2018; Flank, Nadeem, Khanna et al., 2017; Flank et al., 2018; Flank, Sparavalo, Vol et al., 2017; Kovacevic et al., 2019). All were restricted to English-speaking patients and families. In a post hoc analysis of one of these studies, non-White race was identified as a risk factor for acute-phase chemotherapy-induced nausea (Dupuis et al., 2019). The availability of the PeNAT in many languages would have permitted a more culturally and ethnically diverse population to participate in the primary study. This, in turn, may have permitted a more detailed description of the association between race and chemotherapy-induced nausea.

Nausea severity self-report using a validated tool should now be an expected measure in every pediatric antiemetic and antinauseant trial and prospective study. With the availability of a Spanish-language PeNAT, we expect that Spanish-speaking Hispanic American pediatric patients will be eligible to participate in such studies. As a result, more information

Table 2. Parent Responses to Questions Regarding Their Experience Administering the Spanish-Language PeNAT to Their Children.

Question	Response	Number of Responses		
		First Set (N = 5)	Second Set (N = 5)	All (N = 10)
PeNAT				
Do you think that I said enough at the beginning about how to use the tool so that your child was really able to tell us about how much nausea he/she was feeling?	Yes	5	5	10
	No	0	0	0
Do you think that your child was able to tell me how much nausea he/she was feeling using this tool?	Yes	4	5	9
	No	1	0	1
Was it easy for your child to pick a face that matched how he/she was feeling?	Yes	4	5	9
	No	1	0	1
Do you think that your child was influenced by a feeling other than nausea when using this tool?	Yes	0	0	0
	No	5	5	10
Overall, please rate how easy or difficult the diary was to use?	Very easy	1	3	4
	Easy	2	2	4
	Neutral	2	0	2
	Hard	0	0	0
	Very hard	0	0	0
CINV diary				
Was there anything about the diary that you found confusing or hard to understand?	Yes	1	0	1
	No	4	5	9
Was there anything about the diary that you particularly liked?	Yes	2	4	6
	No	3	1	4
Can you think of a way to make the wording used in the diary better?	Yes	1	0	1
	No	4	5	9
Overall, please rank how easy or difficult the diary was to use.	Very easy	1	3	4
	Easy	2	2	4
	Neutral	2	0	2
	Hard	0	0	0
	Very hard	0	0	0

Note. PeNAT = Pediatric Nausea Assessment Tool; CINV = chemotherapy-induced nausea and vomiting.

regarding the prevalence and severity of chemotherapy-induced nausea in Spanish-speaking Hispanic American pediatric patients will be obtained. With this new information, CINV control in this group of patients will be more readily optimized.

Strengths of this study include the use of rigorous and recognized medical translation methods and the inclusion of patients and parents in the translation process and understandability testing. Our work has several limitations. Our results are limited to the Hispanic American Spanish speakers since this translation may not be appropriate in other Spanish-speaking countries or cultures. The English-language PeNAT has been shown to have reliability and validity, and the Spanish-language PeNAT can be assumed to also display these psychometric properties. However, future formal validation studies to determine the reliability and responsiveness of the Spanish-language PeNAT specifically would be ideal. Although seven to 10 participants are thought to be sufficient to determine understandability (Willis, 2004), demonstration of the performance of the Spanish-language PeNAT in a larger number of Spanish-speaking Hispanic American pediatric patients would be worthwhile.

Conclusion

The Spanish-language PeNAT that we have created is well understood by Spanish-speaking Hispanic American children.

The PeNAT is intended as a clinical and research tool. Efforts are underway to integrate PeNAT scores into the electronic health record and to develop an electronic version. With the availability of the Spanish-language PeNAT, Spanish-speaking Hispanic American children and adolescents may use it to articulate their need for individualized intervention to improve CINV control. In addition, the Spanish-language PeNAT will facilitate equitable access of Hispanic American pediatric oncology patients to antiemetic clinical trials.

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Supplemental Material

The supplemental material for this article is available online.

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