Supplemental Methodology for Translating Instruments Developed in a Language other than English

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OBJECTIVE

Procedures used to linguistically validate PROs are well documented for instruments originally developed in English. However, methodology concerning measures with non-English source languages is largely uncharted. This paper outlines the challenges associated with translating PROs developed in a language other than English and recommends supplemental methodology for improving this process.

METHODS

To establish guidelines for translating non-English PROs, several case studies of previous validations were performed. Four case studies, which explored any issues that arose during the translation or cognitive debriefing processes, were examined. Special attention was paid to maintaining conceptual equivalence, addressing colloquialisms native to the development setting and compensating for differing grammatical rules.

VOCABULARY

- ***Linguistic Validation:*** A process conducted to confirm the conceptual equivalence between an original Patient-Reported Outcomes (PRO) instrument and a foreign language version of the same instrument. The process also ensures the acceptability of the instrument in different languages and in different cultural contexts. Linguistic Validation may involve up to four distinct phases: creation of a harmonized translation, back translation, cognitive debriefing, and international harmonization.
- ***Harmonized Translation:*** A comprehensive translation created through the collaboration of two independent translators to determine the best wording for each phrase.
- ***Back Translation:*** A translation of a translation, from the new language into the source language. After completion the back translation is compared against the initial questionnaire to verify that all concepts were translated as they were intended in the original. All discrepancies between the original and the back translation are resolved through discussions among the forward and back translators.
- ***Cognitive Debriefing:*** A process by which trained bilingual interviewers ask patients or healthy volunteers to paraphrase each question or response contained in an instrument. The paraphrase is used to assess the ability of the subject to understand the instructions, questions, and response options, and to identify any difficult or confusing terms.
- ***International Harmonization:*** A review process involving the project manager, survey research expert and all forward and back-translators for all languages being validated during which survey items and response sets are reviewed one-by-one to confirm their equivalence across languages. Translators are encouraged to point out any issues they faced during the translation or debriefing processes.

CASE STUDIES

All four case studies involve questionnaires that were developed in a non-English setting and translated for the US into English. Two of the cases involve translation into additional languages. Each questionnaire underwent linguistic validation (see Figure 1) which includes the creation of a harmonized translation and subsequent cognitive debriefing interviews [1,2,3]. For the purpose of this study, we have identified all significant issues arising from the questionnaire's non-English source language as well as those involving standard difficulties that arise in the linguistic validation process. All significant issues related have been noted in the case studies that follow.

Cancer Dyspnoea Scale (CDS) *developed in Japanese, translated into English and then seven additional languages*

Corporate Translations was provided with the original Japanese questionnaire as well as an English translation. No information regarding the methodology used to create this translation was available. Since the US English version would be the basis for all subsequent translations, the critical first step in our process was to review the English to ensure that the concepts captured were identical to those found in the Japanese original.

Before beginning the usual linguistic validation process, the Japanese original was initially translated into English by two in-house linguists. A third in-house linguist reviewed the client-provided English version against the Japanese original. Subsequently, two project managers who were native English speakers reviewed the two translations against the provided English translation in order to identify any conceptual differences between the three English versions. Finally, a meeting including the three linguists and the two project managers was convened to verify that all items had been properly translated into English and across languages and that each concept was equivalent to the corresponding Japanese. This specialized protocol was augmented by consultation with the developer of the original questionnaire.

Once the validity of the US English base instrument was established, translations were created for Bulgarian (Bulgaria), English (UK), French (Canada), Hungarian (Hungary), Italian (Italy) and Spanish (Spain, US) settings. Cognitive debriefing interviews were conducted with a sample of patients with extensive Small Cell Lung Cancer to verify the comprehension of each new translation as well as the previously-created English (US) translation.

CDS issues that arose during the review of the existing English translation and creation of new translations:

Translation	Item*	Original Wording	Initial Translation	Description
English (US) review	We would like to ask you about your _____	Breathlessness or difficulty breathing		Further review of the Japanese original was required to ensure that these two conceptually similar terms were adequately distinguished from one another in the English translation
English (UK)	We would like to ask you about your breathlessness or _____	Difficulty in breathing	Difficulty breathing	A change was made for better grammatical flow
English (US) review	Please answer each question by circling only the _____ that best describes the breathing difficulty that you _____ during the past few days.	numbers		Instructions were believed to be ambiguous. A patient could interpret this to mean that multiple answers could be circled for each question. The singular version of number was used to clarify the directions.
English (UK)	Please answer each question by circling only the number that best describes the breathing difficulty that you _____ during the past few days.	Felt	experienced	A change was made for better grammatical flow
Bulgarian/ French/ Hungarian	Did you feel as if you are _____?	Panting	Breathing heavily/ trying to catch your breath/ gasping	Multiple translations had difficulty capturing the source concept
English (US) review	Do you feel such breathing difficulty that _____?	You don't know what to do about it		The Japanese questionnaire uses a colloquialism to express a strong sense of both physical and emotional discomfort, which did not translate well into English; the intended meaning was explained to all translators by a bilingual project manager. After discussion with the developer, the provided English translation was maintained
Hungarian/ Italian	Do you feel _____?	Short of breath	As if you've run out of air/ out of breath	Two languages had difficulty with this concept; detailed explanations of its intended meaning from the project manager assisted in making sure the concept was accurately rendered
Italian	Do you feel as if you are _____?	Drowning	About to drown	The initial translation indicated being on the cusp or drowning, not actually drowning; a change was made to better reflect the source concept
* Blank spaces (_____) within the item column identify the location of problematic text which is further outlined in the columns that follow				

Other than poor subject comprehension of the technical terminology present in the questionnaire's title, the main issue that came up during translation, debriefing and international harmonization was the seeming grammatical inconsistency of the alternate response option set (one of two sets that were translated and tested among subjects). Answering "do you feel short of breath?" with the options of very difficult, difficult, some difficulty, rather easy and very easy seemed awkward to many subjects and translators across languages. The grammatical coupling of the items with their response choices and the mixing of both adjectives and adverbs worked well in the Japanese development setting, but was problematic in other linguistic contexts. Though subjects noted the inconsistency between the question and answers, they were able to easily utilize the provided scale to voice their responses.

DN4 Questionnaire *developed in French, translation into English and Dutch*

In Case 2 Corporate Translations was provided with the original French questionnaire as well as an English and a Dutch translation. It is unknown whether the Dutch was derived from the English or the French version of the questionnaire. For added quality assurance, a new English translation was created from the original French questionnaire under the guidance of a bilingual project manager. A Dutch backtranslation was created and compared against the new English translation. Cognitive debriefing interviews were conducted with a demographically stratified sample of Dutch (Belgium) subjects representing the general population.

Issues that arose during the translation phase:

Item	Initial Translation	Adjustment	Description
_____ of the patient	Interrogation/ history-taking	Interview	A direct translation of the French word was not appropriate for other clinical settings
Does the pain exhibit one or more of the following characteristics? Burning, sensation of painful cold, _____	Electric discharges	Electrical shocks	The literal translation of the phrase did not work well, so the translation team researched other pain questionnaires to better define the concept
Is the pain associated with one or more of the following symptoms in the same area? _____, _____, numbness, itching	Tickle, tingling	Tingling, pins and needles	The Dutch had difficulty distinguishing between these two types of itch.

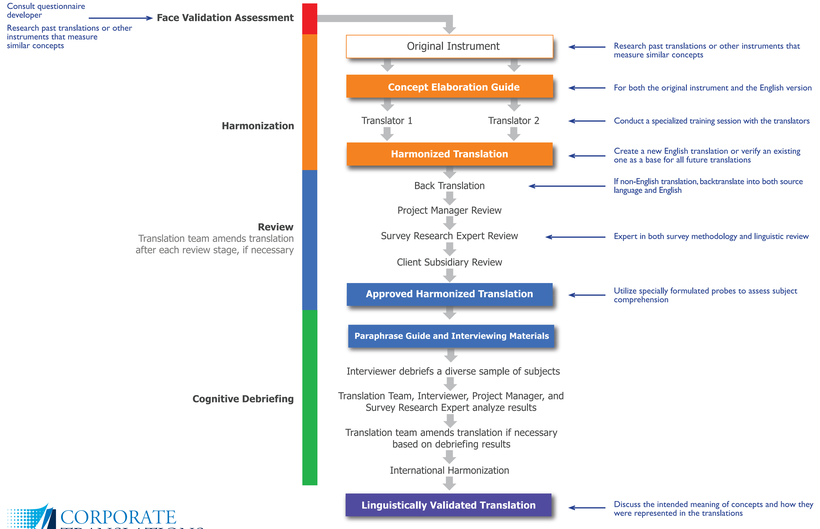
Issues that arose during the cognitive debriefing interviews:

Item	Initial Translation	Proposed Adjustment	Change made?
Electrical charges		Conceptually difficult for subjects, but alternate wording was not possible	No
Tingling/ Pins and Needles/ Itching		Subject had difficulty distinguishing between these items, but alternate wording was not possible	No
Is the pain located in an area where the examination shows_____	?	;	Yes

Several stylistic issues arose, in which one or more subjects thought that a synonymous word would sound better in place of an existing one within the translation. Since these issues had no effect on comprehension, the original translation was preserved in these cases.

Figure 1: Standard Linguistic Validation Process Chart + Proposed Modifications

**Please refer to Table 1 for further explanation of these proposed modifications.*



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Hôtel Dieu 16 (HD-16) *developed in French, translated into English*

This questionnaire presented in Case 3 was translated from its original French into English and then back-translated from English to French for comparison. Cognitive debriefing interviews were conducted with a demographically stratified sample of English (US) subjects representing the general population. An internal bilingual project manager was assigned.

Few issues arose during the translation phase, since French and English are linguistically and culturally similar. During debriefing, a few issues surfaced due to stylistic preferences for sentence construction and word choice. While the translated concepts were clear to subjects, they, in some cases, seemed unnatural.

Issues that arose during the cognitive debriefing interviews:

Item	Initial Translation	Proposed Adjustment	Change made?
I lose my _____ from time to time during the day	stamina	energy	No
I don't often _____ getting any exercise	feel up to	feel like	Yes
I regularly break things _____ clumsiness	out of	due to	Yes
I often need to retreat to a _____	calm space	quiet place	Yes

In cases where both the original translation and proposed adjustment were equally suitable for use, no change was made. Changes were made to correct awkward sentence constructions or to replace uncommonly used terminology.

Pain Detect Scale *developed in German, translated into English*

Case 4 involved the Pain Detect Scale. This questionnaire was translated from German to English and then back-translated from English to German for comparison. Cognitive debriefing interviews were conducted with a demographically stratified sample of English (US) subjects representing the general population. An internal bilingual project manager was assigned.

Issues that arose during the translation phase:

Item	Initial Translation	Adjustment	Description
Mark the picture that best describes the _____	change of pain over time	course of your pain	An adjustment was needed to reflect pain patterns, rather than a before and after assessment
Questionnaire's response scale	Never, very mild, mild, middle, severe, very severe	Never, hardly noticed, slightly, moderately, strongly, very strongly	English (US) had difficulty mixing frequency and intensity in a single response scale; the use of "middle" also presented conflicts
Do you have _____ in the area of your pain, like electric shocks?	Pain attacks like lightning/ quick as a flash	Sudden pain attacks	The literal translation did not accurately capture the intended concept in the original
Do you have sudden pain attacks in the area of your _____?	Electrifying pain	Pain, like an electric shock	In English (US), the term "electrifying" represents a much stronger intensity than it does in German

The only comprehension issues that arose during the cognitive debriefing phase had to do with medical terminology (nociceptive, neuropathic) which was to be used only by the clinician and did not require understanding from a general subject population.

RECOMMENDATIONS

Creating linguistically validated translations of non-English PRO source instruments poses numerous problems. Since most translators and project managers are English-based, an English adaptation of the instrument may need to be created prior to moving forward with other translations. Extreme care must be taken to accurately interpret all of the source instrument's concepts. Recommended enhancements to the standard validation process are detailed below:

Table 1: Proposed process modifications for the linguistic validation of non-English source instruments

Recommendation	Rationale
Conduct a specialized training session with the translators in order to review the development of the original document and the English translation	It is important to communicate to the translators the intention of the original questionnaire and its development. Also, in knowing that the English version with which they are working is a translation and not the original questionnaire, they can take added care in capturing the concepts or ask the project manager clarifying questions as necessary.
Confirm concepts and any existing translations with the questionnaire developer before moving forward	If the questionnaire utilizes colloquialisms or presents other potential translation difficulties, the translation team will need to confirm their intent or, if possible, adjust the original questionnaire for a higher degree of translatability. Although considered part of the standard linguistic validation process, this step becomes especially crucial when working with non-English source questionnaires.
If an English translation does not exist, create and validate one before moving forward; if an English translation does exist confirm that it closely matches the original	Since a majority of the translation team will be English based and because finding translators who can work with language pairs that do not include English is difficult, an English translation is vital for quality assurance, cost management and a quick turn-around
Create a concept elaboration guide for both the original instrument and the English translation	Concept elaboration guides provide additional information about word choices, phrases or technical terminology which helps the translators to accurately capture the original concept. Since English is often the source language of questionnaires undergoing translation, standard process usually only requires a single concept elaboration guide. As an enhancement, the guide created from the source instrument can be compared to the one created for the English version as further evidence that the English closely matches the source.
Research past translations or any other instruments that measure similar concepts to identify how a particular symptom or item is most commonly represented in the target language	This can help add further understanding to the items within the questionnaire and may clear up confusion around less common wording used to express symptomology
If translating into a language other than English, create backtranslations in both the source language and in English for review	This is an added quality assurance step. It ensures that the translation accurately reflects the original concepts.
Assign a Survey Research Expert, who is skilled in both survey methodology and linguistic review, to work with the translations	It is important that a Survey Research Expert reviewer understands the process of linguistic validation and is aware of any difficulties that may arise. He or she should also be able to verify that questionnaire items between versions are comparable linguistically and would elicit the same responses.
During cognitive debriefing, utilize specially formulated probes to assess subject comprehension of response sets, recall periods or idiomatic expressions	Probes can assess the subject understanding of potentially problematic portions of the questionnaire beyond what paraphrasing can. The interpretation of recall periods and response sets, in particular, can vary across linguistic and cultural settings.
During an international harmonization meeting, discuss the intended meaning of concepts and how they were represented in the translations, placing extra emphasis on colloquialisms and the formulation of response sets	Although focus has been placed on these issues throughout the entire linguistic validation process, an international harmonization meeting can neatly summarize any difficulties that were faced and provide a good forum for interaction between linguists representing all translations of the questionnaire. Although this step is generally recommended as part of the standard linguistic validation process, we feel that it should be a compulsory measure when working with multiple translations of a non-English source text.

CONCLUSIONS

Linguistically validating translations of PRO questionnaires developed in non-English settings presents special challenges. Evidence suggests that, in these situations, standard procedures may be insufficient to produce conceptually equivalent translations acceptable for use in multinational clinical trials. In such cases, expanded procedures are recommended.

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