USING TRANSLATABILITY ASSESSMENT TO REFINE A PATIENT- REPORTED OUTCOME (PRO) MEASURE DURING THE DEVELOPMENT PROCESS

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Introduction

The Critical Path Institute (C-Path) PRO Consortium's Depression working group is developing a patient reported symptom assessment for patients with Major Depressive Disorder (MDD). This new 35-item measure is called the "*Symptoms in Major Depressive Disorder Scale*" (SMDDS). During the last two waves of the cognitive interview process which supported the development of the SMDDS, a translatability assessment was conducted using five languages selected as good representatives of major linguistic groups. The five representative languages were French, German, Russian, Spanish and Chinese.

The purpose of assessing translatability for this newly developed Patient Reported Outcome (PRO) measure was to determine whether there would be problems achieving cognitively equivalent renderings of the intended PRO text across different languages once the measure became finalized and prepared for use in global clinical trials.

Objective

To show how translatability assessment (TA) during the PRO instrument development process can be used to identify areas where wording change is needed to improve and refine the measure.

Methods

The first wave of cognitive interviews on the newly developed measure was conducted and resulted in a number of revisions. The revised draft measure prepared for wave two cognitive interviews was also prepared for TA. To conduct the TA, a translation consultant who was experienced in the translation of patient reported measures was selected for each of the five representative languages, and given the text of the revised draft symptom measure to review and evaluate.

The review process consisted of:

- Reading each item in the current text being proposed for the preliminary measure
- Ranking the level of difficulty they would have in finding an equivalent rendering for the text in each item/response option/instruction
- Answering additional questions about each item and response scale

The additional questions included:

- Can common, non-ambiguous language be found to render this item into the target language and maintain concept equivalence?
- Is it possible to find a translation for this item that does not use words that have more than one meaning?
- If an idiom has been used in the presentation of this item, can localized idioms be found to provide an equivalent representation of concept?

Difficulty Ratings:

The difficulty ratings ranged from 1 (no difficulty) to 5 (extreme difficulty). If difficulty ratings were higher than 1, explanatory comments were required, which included the identification of the approaches that could be taken to achieve concept equivalence.

1. No difficulty
A more or less direct translation with the same meaning is possible.

2. Slightly difficult
Some departure from a direct translation would be necessary to maintain concept equivalence. This might include: changes in word order, substitute phrasing, use of the closest available verbal tense, etc.

3. Moderately difficult
A significant departure from a direct translation would be necessary to render the item into the target language. For example, to convey the equivalent concept, an available idiom or more than one term might be necessary to match the scope of meaning of an English item.

4. Very difficult
There is some difficulty in finding an appropriate way to convey the concept presented in the source text with clarity. Even with an alternate that is conceptually equivalent, there may still be some doubt in the reader about the intended meaning being presented clearly enough to protect data quality.

5. Extreme difficulty
Translators would face extreme difficulty to appropriately convey the concept presented in the source text with clarity. There may be cultural taboos, political or other sensitivity issues, or specific terminology may not exist for that concept. The rendering may not be possible.

Results

During the second wave of the cognitive interview process, three items in the draft version of the SMDDS showed difficulty in patient comprehension.

The same three items demonstrated difficulty in the translatability assessment process conducted concurrently with the cognitive interviews. TA findings revealed that the structure and language used in the items was the main barrier to accurate translation of the concept.

Due to the convergence of these two problematic findings during the PRO development, these items were revised before the text of the new measure was finalized. (Table 1)

Overall review of translatability assessment results showed that most of the items in the SMDDS can be rendered easily to maintain concept equivalence.

However, issues were substantial for three items and they supported changes in those items that were made as a combined result of the translatability review and the final cognitive interview process.

Table 1. Changes to Draft Instrument Resulting from Translatability Assessment Combined with Cognitive Interview Results:

Existing Item	Translation Issue	Final Item
Overall, in the past 7 days, how difficult was it for you to **keep your mind free of worrying thoughts**?	-French, German and Spanish would need to say "worries", since "worrying thoughts" has no direct translation into those languages. This ends up conveying a focus remarkably close to the "worry" item (Item 11). -"Keep your mind free" is somewhat idiomatic to English, and problems would be found in Russian and German to translate it directly. Solutions like "head free of…" and "how difficult was it for you to not worry" might be considered in those languages.	Overall, in the past 7 days, how difficult was it for you to **stop thinking about your problems**?
Over the past 7 days, how much have you **looked forward to things with enjoyment**?	-This item received the highest average difficulty rating of all items (2. 4). -"How much" is avoided in French and German to translate this item because it measures a non-countable construct (feeling like crying). "How often" would be a more typical way of measuring this construct. -Idiomatic phrases reflecting the same concept as "to look forward to" are found in all languages except Spanish (which would use a phrase like "awaited events with enthusiasm"). The suggested saying in French already refers to enjoyment, so "with enjoyment" would be redundant and therefore left out in French in order to match the English concept.	Over the past 7 days, how much **of the time** have you **felt enjoyment**?
Over the past 7 days, how much have you felt **useful**?	-This item received one of the highest difficulty ratings of all items (1.8). -"How much" is avoided in French and German to translate this item because it measures a non-countable construct (feeling like crying). "How often" would be a more typical way of measuring this construct.	Over the past 7 days, how much **of the time** have you felt **useful**?

Conclusions

- During the cognitive interview process for the development of any outcomes assessment measure, difficulties may arise that will either result in a necessary change to the draft measure on their own, or they may arise but not clearly justify a change.
- When it is unclear whether a change to a measure is necessary based on cognitive interviews alone, results of a translatability assessment can be useful in adding awareness and greater weight to other aspects of item structure that might need to be altered to improve the integrity and quality of the measure.
- Conducting a translatability assessment during the developmental process for a new outcomes assessment measure can provide important information to the developer, and result in improvements that will make the new measure easier to effectively translate into multiple languages during later stages of its use.

Limitations

Although there are often translation issues common to many language families, not all difficulties in rendering concepts accurately can be determined via the use of representative languages. Once the actual translation process is begun with the specific target languages, other issues may arise that also present difficulty in cross cultural rendering of concepts.

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