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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 (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 renditions of the intended PRO text across differences in language. 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 construct 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?

**Results**

During the second wave of the cognitive interview process, three of the 35 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 PREP development, these items were revised before the test of the new measure was finalized. (Table 1)

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

<table>
<thead>
<tr>
<th>Existing Item</th>
<th>Translation Issue Final Item</th>
</tr>
</thead>
<tbody>
<tr>
<td>French, German and Spanish would need to no “worrying,” since “worrying thoughts” has no direct translation in these languages.</td>
<td>“Keep your mind free” is somewhat</td>
</tr>
<tr>
<td>New item requires German to translate it directly. Solutions like “head free of...” and how difficult it is for you to worry might be considered in these languages.</td>
<td></td>
</tr>
</tbody>
</table>

**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
- 2. Slightly difficult
- 3. Moderately difficult
- 4. Very difficult
- 5. Extremely difficult

**Conclusions**

- During the cognitive interview process for the development of any PRO measure, issues 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 the PRO data alone, issues of a translatability assessment can be useful in adding awareness and greater weight to other aspects of item development, such as the need that might be needed to alter the integration and quality of the PRO 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 late stages of its use.

**Limitations**

- Although there are often translation issues common to many language families, 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.

**Disclosures**

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