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 language groups 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 may need to be improved and refined for use.

Methods
The first wave of cognitive interviews on the newly developed measure was conducted and resulted in a number of revisions. The revised 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 test being proposed for the preliminary measure.
• Ranking the level of difficulty they would have in finding an equivalent rendering for the test 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 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 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 three 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 Review

<table>
<thead>
<tr>
<th>Existing Item</th>
<th>Translation Issue</th>
<th>Final Item</th>
</tr>
</thead>
<tbody>
<tr>
<td>overly, slightly difficult</td>
<td></td>
<td></td>
</tr>
<tr>
<td>very difficult</td>
<td></td>
<td></td>
</tr>
<tr>
<td>extremely difficult</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Conclusions
• During the cognitive interview process for the development of any outcomes measurement instrument, the translatability issues may arise that will either offer a new 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 development 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 language, other issues that also arise during present day or cross cultural rendering of concepts can become apparent.

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

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- 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
  - Easy translation with the same meaning is possible.

  2. Slightly difficult
  - Some departure from a direct translation would be necessary to maintain construct 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 idiom is more than one term might be needed, or 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 test with clarity. Even with an alternate that is conceptually equivalent, there may be some doubt in the reader about the intended meaning being presented clearly enough to direct quality.

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

- Table 1: Changes to Draft Instrument Resulting from Translatability Assessment Combined with Cognitive Interview Review