OBJECTIVE

The objective of this study was to determine the applicability of the *bother* concept as used in Patient Reported Outcomes (PRO) instruments across languages and cultures. In American English, the concept of *bother* is versatile in that it may connote negative mental states and physical sensations as well as social disturbances. Because of this versatility, the concept may have different meanings across languages and cultures. In observing the term *bother* in Patient Reported Outcomes instruments, it will be determined whether the concept remains equivalent across cultures.

BACKGROUND

An observational study on the versatility of the word *bother* was conducted by Dylan Glynn, in which 2,000 statements were selected at random (serendipity and bias were also observed). *Bother* appeared in the context of physical pain only seven times out of the 2,000. It was additionally discovered that *bother* is most commonly found in the context of “imposition, condemnation and tease” (Glynn, 2010).

The degree of *bother* resulting from a condition or treatment is frequently measured in clinical trials through the use of PRO instruments. Upon developing an instrument on urinary tract problems, the concept of *bother* became difficult to measure, as the term is ambiguous in nature. In order to prevent confusion, *bother* needed to appear in conjunction with definitions of symptoms (Coyne, 2008).

LINGUISTIC VALIDATION

Linguistic Validation is a process that is conducted to confirm that a PRO questionnaire is acceptable for use in different languages and in different cultural contexts. Without this careful development of a translation and subsequent cognitive debriefing, one could not be reasonably certain that the adapted instrument is both conceptually equivalent to the original and can also be clearly understood by the average individual. The linguistic validation process begins with two translators independently translating the instrument into the target language. The translators then exchange drafts and work together to develop one reconciled or “harmonized” version. At that point, the harmonized translation is provided to a third translator who translates the text back into English without access to the original English. Both the harmonized translation and the English back translation are and work together to develop one reconciled or “harmonized” version. At that point, the harmonized translation is provided to a third translator who translates the text back into English without access to the original English. Both the harmonized translation and the English back translation are.

METHODS

To determine the meaning of *bother* and its derivatives, bothered and bothersome across many languages and cultures, translators, interviewers, and general population subjects from multiple culuturallinguistic disciplines were asked to fill out a questionnaire following the translation and cognitive debriefing of a poriarsis PRO instrument which contained *bother* as the key concept. Translators were asked to provide the equivalent of *bother* for their target language, evaluate the difficulty of appropriate terminology selected, and provide an explanation of any conceptual distinctions between the target language and English terms. Interviewers explained how they defined the concept for subjects who were not able to paraphrase the term during the cognitive debriefing interviews. General population subjects provided elaboration of the concept within their native languages.

Of the 153 respondents, twenty-one were interviewers, thirty-six were translators and ninety-six were interview subjects. To further investigate the concept of *bother*, all back-translations and cognitive debriefing data resulting from linguistic validation of the translated instrument were analyzed. In an analysis of back-translations, there was focus on the how the term *bother* was translated, and compared with a control term skin. Additionally, all instances where *bother* was mentioned and/or paraphrased incorrectly in cognitive debriefing were observed.

RESULTS

Breakdown of Sample

<table>
<thead>
<tr>
<th>Subjects, N=96</th>
<th>Average Age: 48.4</th>
<th>Average Education: 13.1 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Standard Deviation Age: 14.6</td>
<td>Standard Deviation Education: 3</td>
<td></td>
</tr>
<tr>
<td>Min-Max Age:</td>
<td>Min-Max Education: 22-84</td>
<td>6-24 years</td>
</tr>
<tr>
<td>Males: Females:</td>
<td>39-57</td>
<td></td>
</tr>
</tbody>
</table>

Interviewers, N=21

<table>
<thead>
<tr>
<th>Average Age: 44.5</th>
<th>Average Education: 17.7 years</th>
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</thead>
<tbody>
<tr>
<td>Standard Deviation Age: 12.1</td>
<td>Standard Deviation Education: 2.4</td>
</tr>
<tr>
<td>Min-Max Age:</td>
<td>Min-Max Education: 28-72</td>
</tr>
<tr>
<td>Males: Females:</td>
<td>5-16</td>
</tr>
</tbody>
</table>

Linguists, N = 36

<table>
<thead>
<tr>
<th>Average Age: 49.4</th>
<th>Average Education: 17.9</th>
</tr>
</thead>
<tbody>
<tr>
<td>Standard Deviation Age: 10.7</td>
<td>Standard Deviation Education: 2.3</td>
</tr>
<tr>
<td>Min-Max Age:</td>
<td>Min-Max Education: 29-72</td>
</tr>
<tr>
<td>Males: Females:</td>
<td>11-25</td>
</tr>
</tbody>
</table>

Total, N = 153

<table>
<thead>
<tr>
<th>Average Age: 48.2</th>
<th>Average Education: 14.8</th>
</tr>
</thead>
<tbody>
<tr>
<td>Standard Deviation Age: 13.5</td>
<td>Standard Deviation Education: 3.6</td>
</tr>
<tr>
<td>Min-Max Age:</td>
<td>Min-Max Education: 22-84</td>
</tr>
<tr>
<td>Males: Females:</td>
<td>55-98</td>
</tr>
</tbody>
</table>

Languages – Countries Represented

- Arabic – Israel
- Bulgarian – Bulgaria
- Czech – Czech Republic
- Danish – Denmark
- Dutch – Belgium
- Dutch – Netherlands
- English – Canada
- English – Israel
- English – UK
- French – Belgium
- French – Canada
- German – Austria
- German – Germany
- Hebrew – Israel
- Hungarian – Hungary
- Italian – Italy
- Japanese – Japan
- Norwegian – Norway
- Polish – Poland
- Romanian – Romania
- Russian – Israel
- Russian – Russia
- Spanish – Columbia
- Spanish – Mexico
- Spanish – Spain
- Spanish – US

FINDINGS

The results of an instrument including the *bother* concept could be diverse, depending on its interpretation. To demonstrate how results may be skewed, observe the following item, as it may be interpreted across respondents:

> How much is your psoriasis *bothering* you in terms of scaling and flakiness?

How much is your psoriasis *troubling* you in terms of scaling and flakiness?

How much is your psoriasis *disordering* you in terms of scaling and flakiness?

How much is your psoriasis *discomforting* you in terms of scaling and flakiness?

This demonstrates, for example, that while something such as psoriasis may be “annoying” to someone, it may not be showing “discomfort.” Furthermore, as discovered in debriefing, the various interpretations of *bother* may cause confusion as to whether it is in the concept of mental *bother* or physical *bother*.

CONCLUSIONS

When developing the wording of PRO instruments, the concepts and terminology chosen should be applicable across different languages to allow for the pooling and comparison of data. While all respondents understood *bother* to have a negative connotation, a large variety of definitions and synonyms provided across languages shows a lack of conceptual equivalency. Given the fragmented results from the questionnaires we distributed to linguists, interviewers and subjects, the variable *bother* may not be the most ideal measurement of degree of symptom severity in a PRO instrument.

REFERENCES