The objective of this study was to determine the best response sets for use in Patient-Reported Outcomes (PRO) translation and subsequent validation. The research team conducted a questionnaire translation and translation validation project with the goal of ensuring that the adapted instrument is both conceptually equivalent to the original and also clearly understandable to 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 resolve any misunderstood or “unnatural” issues. At that point, the harmonized translation is provided to a third translator who translates the text back into English without access to the original translation. Both the harmonized translations and the English back translations are reviewed by a project manager and a survey research expert; adaptations to the translation are made as needed. Once the final translation has been approved, it is distributed to all interested parties, native speakers of the language, with varying demographic and educational backgrounds, to check for conceptual equivalence and clarity.

METHODS

Two response sets from previously translated PRO instruments were analyzed from linguistic validation studies. These response sets were used for an initial translation and translation validation assessment of the response sets by a small group of bilingual translators. They were then translated into 34 different languages, and expert linguists assessed the frequency of questions as translated by the patient and patient agreement level. In this study, each subject’s word choice was referenced from cognitive debriefing data. Analyses were performed to determine the effectiveness of translation and translation validation. The following results are based on the translated questionnaire.

RESULTS (Continued)

The observed best translation for each response option was found to be based on the observed “clinical” clear conceptual equivalence when translated. “Satisfi ed” and “dissatisfi ed” are easily translated, and can be supplemented with the concept “very” for the response option anchors. When symptom severity is measured by this response set, response set B is a recommended alternative to measure severity.

CONCLUSIONS

Response sets in PROs should achieve conceptual equivalence across languages, with no overlap between responses in response sets. Response sets with more than fi ve (5) options and those with ambiguous and verbose response options were observed to cause translation difﬁ culty as was found in the case with response set 2.

Th e following set of response options is regularly observed in PROs. This response set, which used to mean levels of symptom severity or frequency, was shown to cause translation difﬁ culty. It was observed that the linguistic concept of “fair” could best be translated in response sets in situations where “fair” is a non-essential concept in many languages.

Twelve response sets from previously translated PRO instruments were analyzed from linguistic validation studies. These response sets were used for an initial translation and translation validation assessment of the response sets by a small group of bilingual translators. They were then translated into 34 different languages, and expert linguists assessed the frequency of questions as translated by the patient and patient agreement level. In this study, each subject’s word choice was referenced from cognitive debriefing data. Analyses were performed to determine the effectiveness of translation and translation validation. The following results are based on the translated questionnaire.

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