Translatability of Response Sets Used In Patient-Reported Outcomes and Best Practices for Development

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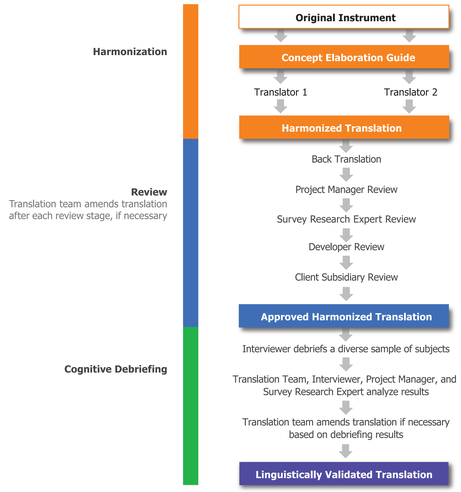
OBJECTIVE

The objective of this study was to determine the best response sets for use in Patient-Reported Outcomes (PRO) instruments intended for translation and subsequent data collection in multinational clinical trials and to make recommendations for response option sets to avoid. As sound response sets are essential for data collection, a high degree of translatability is vital.

This is a follow-up study with additional guidelines for the creation of response options that are both translatable and collect good data.

LINGUISTIC VALIDATION

Linguistic Validation is a process that is conducted to confirm that a Patient-Reported Outcomes 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 also 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 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 debriefed among in-country native speakers of the language, with varying demographic and educational backgrounds, to check for conceptual equivalence and clarity.



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METHODS

Twelve response sets from previously translated PRO instruments were analyzed from linguistic validation projects completed by Corporate Translations. All observed response sets underwent two analyses: analysis of translated response sets and a translatability assessment of the response sets by a sample of seven linguists. Observed response sets included measures of patient's symptom severity, frequency of symptoms as reported by the patient, and patient agreement level.

In this follow-up study, subject feedback on response sets was gathered from cognitive debriefing data and analyzed. Based on the findings of this study, response sets were developed and translated. Translatability of each response set was assessed.

RESULTS

The following set of response options is regularly observed in PROs. This response set, which can be used to measure level of symptom severity or frequency, was shown to cause considerable translation difficulty.

Response Set 1 – Commonly used to measure satisfaction or severity				
❑ Not at all	❑ A little bit	❑ Somewhat	❑ Quite a bit	❑ A great deal

Twenty-three (23) different translations of this response set were available for analysis. It was observed that the idiomatic concept of "bit" is not ideal for inclusion in response sets as it is often omitted in translation because "bit" is a non-existent concept in many languages.

- For "a little bit."
  - Eleven (11) omitted the concept of "bit."
  - For nine (9) of those instances, the only possible equivalent was "a little."
  - The remaining two (2) translations rendered a back-translation of "slightly" and "to a small extent."
- For "quite a bit".
  - For four (4) of the languages, the only possible equivalent was "quite a lot."
  - The colloquial nature of the source, "quite a bit," caused translation difficulty and confusion for the linguists.
- Without probing, subjects of cognitive debriefing made the following comments regarding this response set:
  - 3 of 5 German/Germany subjects stated that they could not distinguish between "a little bit" and "somewhat."
  - 3 of 5 French/Canada subjects claimed that "somewhat" was too close to "quite a bit" in French. Furthermore, 4 out of 5 subjects claimed that "a great deal" is not entirely clear in French.
- Linguist input revealed that "somewhat," when translated, will overlap conceptually with "a little bit" or "quite a bit" in some languages. Additionally, overlap persists between "quite a bit" and "a great deal."

When patient satisfaction is being measured by this response set, response set A is a recommended alternative over response set 1:

Recommended Alternative to Response Set 1 to measure satisfaction				
❑ Very Dissatisfied	❑ Dissatisfied	❑ Neither Satisfied nor Dissatisfied	❑ Satisfied	❑ Very Satisfied

RESULTS (Continued)

The observed back-translations for each response option were found to have no overlap and demonstrate clear conceptual equivalency when translated. "Satisfied" and "dissatisfied" are easily translated, and can be supplemented with the concept "very" for the response option anchors.

When symptom severity is being measured by this response set, response set B is a recommended alternative over response set 1:

Recommended Alternative to Response Set 1 to measure symptom severity				
❑ Very mild	❑ Mild	❑ Moderate	❑ Severe	❑ Very Severe

For response set 2, as seen below, twenty-three translations were available for analysis. Although some minimal difficulties exist with "mild" for three (3) of the observed languages and "severe" for seven (7) of the observed languages, these response options for symptom severity are highly recommended as an alternative to the response set using "a little bit" and "quite a bit." Both "mild" and "severe" were translated with conceptual equivalency, only requiring minor revision during the back-translation review process.

Response Set 2 – Commonly used to measure of frequency					
❑ None of the time	❑ A little of the time	❑ Some of the time	❑ A good bit of the time	❑ Most of the time	❑ All of the time

Response sets with more than five (5) options and those with ambiguous and verbose response options were observed to cause translation difficulty, as was found to be the case with response set 2.

Out of the twelve (12) observed languages, seven (7) were not able to achieve conceptual equivalency in translating this response set without difficulty.

- Five (5) of the languages were observed to have had great difficulty in achieving distinction between each response option during translation due to the size of the response option set.
- Seven (7) of the languages had difficulty in attaining conceptual clarity as a result of the ambiguity of the response options.
- In four (4) instances of the observed languages, the only possible translation that best reflects the source was to reduce the response options to a single word.
- Presented in this poster as an alternative to measure frequency is response set C.

The following frequency response option set is the best alternative to Response Set 2.

Recommended alternative to Response Set 2 to measure frequency				
❑ Not at all	❑ Rarely	❑ Sometimes	❑ Often	❑ Always

Of the twenty-three (23) observed languages, all were observed to maintain clear conceptual equivalency. The distinctive concepts found in the source allow linguists to translate this response set without difficulty. Out of all the observed languages, only three (3) languages required minor translation revisions to this response set during back-translation review. Furthermore, this response set contains fewer options, and will prevent conceptual overlap when translated. For response sets requiring more than 5 options, use of a Numeric Rating Scale (NRS) is recommended as its anchors (for example: "no pain at all" or "extreme pain" to " never" or "always") are highly translatable. Visual Analogue Scales are also highly translatable, and preferred. According to the linguists who participated in the translatability assessment, a maximum of five (5) response options would be ideal in order to prevent concept overlap.

Conducting a translatability assessment on response sets prior to use is recommended whenever possible. A Translatability Assessment is a review of a questionnaire carried out by linguists of various languages to identify concepts that may cause translation difficulty. The translatability assessment review will ensure that all questions are translatable and written clearly for improved respondent comprehension. A face validation assessment should also be performed by survey research analysts so that the response options are presented in a logical order and are designed to actually obtain the data the sponsor intends to collect.

Translatability and face validation assessments were conducted on the following response set:

Response Set 3						
❑ Very Satisfied	❑ Somewhat Satisfied	❑ Slightly Satisfied	❑ Neither Satisfied nor Dissatisfied	❑ Slightly Dissatisfied	❑ Somewhat Dissatisfied	❑ Very Dissatisfied

RESULTS (Continued)

This response set contains 7 options in ascending order. The concepts of "somewhat" and "slightly" are very likely to cause concept overlap in many languages. Furthermore, this contains more than 5 progressive options, which was concluded to cause concept overlap in many languages. As a result, this response set was revised to a Numerical Rating Scale:

Improved Response Set 3 following a Translatability Assessment						
❑ Very Satisfied			❑ Neither Satisfied nor Dissatisfied			❑ Very Dissatisfied
1	2	3	4	5	6	7

Translatability and face validation assessments were also conducted on a questionnaire which contained the following response set:

Response Set 4				
❑ Not at all worried	❑ Not really worried	❑ Undecided	❑ Somewhat Worried	❑ Very Much Worried

This response set was revised as a result of two issues; the mid-point is illogical, as scale goes from having minor concern, then being unsure of concern, which then proceeds to having somewhat more concern again. Secondly, the concept of "somewhat" was also observed to cause concept overlap when translated within response sets.

The response set was revised to:

Improved Response Set 4 following a Translatability Assessment					
❑ Not at all worried	❑ A little worried	❑ Moderately worried	❑ Very worried	❑ Extremely worried	❑ Not sure

This response set was created to prevent concept overlap, as recommended by the linguist, and also contains a logical mid-point. Furthermore, the respondent still has an option to indicate if they are "unsure" or "do not know." Although this set contains six options, the final option of "not sure" is separate from the logical progression of the other 5 options in ascending order and will therefore not result in concept overlap. This response set was translated into 8 languages and was translated with conceptual equivalency 100% of the time. The linguists encountered no difficulties when translating this response set.

A key component of this response set is the addition of an auxiliary option, which is supplementary to the rest of the set. This may give the respondent the choice to say that they are not sure or in the case of physical assessment questions, indicate if the activity is impossible. The importance of an auxiliary option in response sets was observed in the debriefing of the following response set:

Response Set 5				
❑ Not at all difficult	❑ A little difficult	❑ Moderately difficult	❑ Very difficult	❑ Extremely difficult

During cognitive debriefing of the questionnaire using this response set, 13% of subjects indicated that they could not choose one of these options because it was impossible for the subject to perform the physical activity that they were being asked about. It is recommended that when response sets appear in questionnaires where a patient is assessing their physical abilities, an auxiliary option of "impossible" should be included. Without auxiliary options, the subject may be forced to provide an answer that is not accurate, and hinder data validity. This response set should be presented in the following way:

Improved Response Set 5 following a Translatability Assessment					
❑ Not at all difficult	❑ A little difficult	❑ Moderately difficult	❑ Very difficult	❑ Extremely difficult	❑ Impossible

CONCLUSIONS

Response sets in PROs should achieve conceptual equivalence across languages, with no overlap between options. The latter three observed response sets are recommended for patient agreement level and patient-reported symptom severity and frequency, respectively. Ambiguous terminology and idiomatic phrasing, as found in response set 1, and response sets containing more than 5 options should be avoided. Both face validation and translatability assessments of response sets are recommended during instrument development to identify concept overlap in translation. Where appropriate, the use of Numerical Rating Scales is recommended, especially in cases where more than five (5) response options are desired. Such measures avoid concept overlap and translatability issues.

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