Face Validation and Translatability Assessment of Clinical Outcomes Assessments

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OBJECTIVE

The objective of this study was to combine Face Validation and Translatability Assessment procedures and apply them to the same instrument. Completing both processes will improve both the survey methodology and translatability of newly created clinical outcomes assessment questionnaires. These very same processes can be used to supplement psychometric validation prior to the creation of new or revised questionnaires. The instrument used for this study concerned work or productivity loss due to a health condition.

METHODS

A number of steps can be carried out by a language service provider (LSP) to improve the survey methodology and translatability of a questionnaire. At each stage of the Face Validation and Translatability Assessment process, all proposed changes to the original source text must be approved by the developer.

The following methodology was used to assess and ultimately improve the Work and Productivity Loss Questionnaire (WPLQ), a questionnaire used to measure the impact of a health condition on one's employment, working hours, and ability to function at work. The questionnaire is versatile by design so it can be adapted for use in patients with a variety of diseases or illnesses.

Face Validation, conducted by survey research analysts, encompasses the following:

- Ensure questions are unambiguous
- Remove double negatives to ensure clarity of questions
- Eliminate double-barreled questions which can collect bad data
- Ensure that skip patterns are easy to follow
- Make revision recommendations for developer approval
- Implement developer approved revisions
- Ensuring reading level is acceptable to subjects with a wide range of educational levels
- Eliminating any technical terminology

Translatability Assessment, conducted by linguists, encompasses the following:

- LSP and client collaborate to determine into which languages the questionnaire will ultimately be translated
- Questionnaire is sent to linguists within each desired language group
- Linguists review and determine which concepts may cause translation difficulties and make revision recommendations for developer approval
- Approved revisions are implemented

An optional third component of the Face Validation and Translatability assessment is pilot testing:

- Revised questionnaire is tested on English-speaking subjects
- Subjects paraphrase the text to ensure understanding and to confirm conceptual clarity of items
- Subjects may suggest revisions to improve clarity for developer approval
- Approved revisions are implemented

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METHODS (Continued)

For the Face Validation and Translatability Assessment of the WPLQ, the language groups were Western European, Eastern European, Indian, Scandinavian, Asian and Middle Eastern. The developers of the WPLQ opted to pilot test different specifications of the questionnaire after Face Validation and Translatability Assessment on 30 English-speaking volunteers who suffer from either insomnia or migraines. Debriefing occurred in three separate sessions on three versions of the questionnaire, differing in length. The results represented are from the session in which the full questionnaire was debriefed on 10 of the 30 subjects. All changes manifested from the debriefing session of the full questionnaire.

RESULTS

Tables 1, 2 and 3 display examples of revisions made during the Face Validation and Translatability Assessment. All revisions made are not reflected here, as the assessments resulted in many revisions to the text.

CONCLUSION

Conducting both the Face Validation and Translatability Assessment can ensure sound survey methodology and improve the translatability of questionnaires, allowing for correction of any issues prior to launching the source instruments in a clinical trial and prior to the linguistic validation process. Additionally, the two assessments should be considered as a supplement to psychometric validation. To conclude, applying these processes can facilitate faster and more efficient translation and subsequent linguistic validation.

REFERENCES

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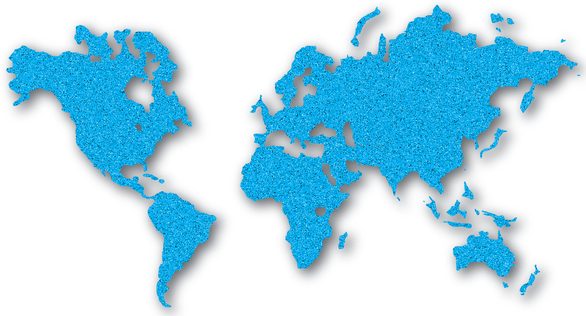

Table 1: Selected revisions made to the WPLQ as a result of the Face Validation Assessment

Assessment conducted by: Survey Research Analysts

Original Text	Revised Text	Justification
Is the primary reason that you are currently not employed because the above listed health condition interferes with your ability to work?	If you are not currently employed, is the MAIN reason because your <Health condition> interferes with your ability to work?	Based upon the survey research analysts' knowledge of respondent behavior, the sentence was revised.
Were you employed during the previous two weeks?	Were you employed or self-employed during the previous two weeks?	It is not entirely clear whether those who are "self-employed" are to be included in the sample. The text was revised to include data collection from the self-employed.
You may skip the completion of the rest of this questionnaire	After answering question 2, you have completed this questionnaire	Following a screener question, it was not clear whether respondent was to proceed with the remaining items. The instruction was reworded and "after answering question 2" was added to ensure absolute clarity.
How would you rate your effectiveness while you were working during this time period?	How would you rate your productivity while you were working during this time period?	This question was found under a heading entitled "productivity." Therefore, the question was revised to measure "productivity" rather than "effectiveness" for consistency.
Did you work additional hours to make up work from days or hours which you missed because of your health condition?	(Two questions created) - Did you work additional hours to make up lost hours because of your health condition? - Did you work additional days to make up for days lost because of your health condition?	The original item was a double-barreled question asking for two pieces of data at once. It also lacked additional space for the respondent to fill in lost hours or days. As a result, the original question was divided into two different items, and space added for the respondent to fill in lost hours or days.

Table 2: Selected revisions made to the WPLQ as a result of the Translatability Assessment

Assessment conducted by: Linguists

Original Text	Proposed by Language Group...	Revised Text	Justification
Work and productivity loss attributable to your health condition	Middle Eastern	Work and productivity loss due to your health condition	"Attributable" is a difficult concept to translate. "Due to..." will increase translatability.
Were you employed or self-employed during the previous two weeks?	Eastern European	Were you employed or self-employed (working for pay) during the previous two weeks?	In some languages, the translated concept for "employment" may not imply paid work. As a result, the text "(working for pay)" was added.
Too uncomfortable to work	Eastern European Scandinavian	Too physically uncomfortable to work	For some languages, the concept of "comfort" needs to be more clear and supplemented with the word "physically." The concept of "physically" was added to the source to correct this.
Make up hours/work [that were lost from your health condition]	Indian	Compensate for hours/work [that were lost from your health condition]	"make up [lost work]" is text that will make the translation process more difficult for Indian languages in the sample, as well as others.

Table 3: Selected revisions made as a result of Pilot Testing

Assessment conducted by: Interviewer and Survey Research Analysts

Original Text	Revised Text	Justification
Please respond to the question only if you are not currently employed.	Please respond to the question only if you are currently unemployed.	8 out of 10 subjects felt that clarification about employment status was needed, and they opted for "unemployed."
[fill in the] days [you work] per week. [fill in the] hours [you work] per day.	[fill in the] DAYS [you work] per week. [fill in the] HOURS [you work] per day.	2 of 10 subjects suggested that emphasis be placed on the words "days" and "hours" so it is clear as to what should be provided. As a result, the developer chose to capitalize all instances of "days" and "hours".
Have you ever left a job because of your health condition?	Have you ever had to quit a job because of your health condition?	3 out of 10 subjects stated that someone may have to leave a job either voluntarily or involuntary, and this question was therefore not clear. Since the question was intended to collect data on those who left their job voluntarily, the question was revised to reflect this.
Please skip to the next question if not missing work due to your health condition during the previous two weeks.	Please skip to the next question if you did not miss work due to your health condition during the previous two weeks.	3 out of 10 subjects felt the wording of the question would be less confusing if revised.
Please skip to the next question if you did not work while affected by your health condition.	Please skip to the next question if you did not work while affected by your health condition.	1 subject had difficulty with the skip pattern. This subject felt the easy solution would be to underline the word "not" for emphasis. Although only 1 subject commented, the developer approved this change for clarity.