LINGUISTIC VALIDATION OF THE SYMPTOMS DISTRESS MODULE (SDM) IN 25 LANGUAGES

by Mear I[1], D'Uva F[1], Wu AW[2], Mollon P[3]

[1] Mapi Research Institute, Lyon, France, [2] Johns Hopkins Bloomberg School of Public Health, Baltimore, USA, [3] Pfizer, Sandwich, UK

The Symptoms Distress Module (SDM)

- A 20-item questionnaire designed to assess the impact (distress) of common HIV-related symptoms (either due to HIV disease or its treatments).
- Response categories: 5 response choices ranging from "I do not have this symptom" to "I have this symptom and it bothers me a lot".
- Developed in US English by Dr Albert W. Wu[2], PhD, and the Adult AIDS Clinical Trials Group[2].
- Self-administered.
- The linguistic validation in 25 languages was sponsored by Pfizer.

Reference: Justice AC, Holmes W, Gifford AL, Rabeneck L, Zackin R, Sinclair G, Weissman S, Neidig J, Marcus C, Chesney M, Cohn SE, Wu AW; Adult AIDS Clinical Trials Unit Outcomes Committee. Development and validation of a self-completed HIV symptom index. J Clin Epidemiol. 2001 Dec;54 Suppl 1:S77-90.

Context

Assessment of HIV symptoms and their impact in an international clinical trial

Need for a reliable, valid and responsive instrument in 25 languages that:

- Measures the distress resulting from the symptoms which are commonly found in HIV patients, either due to their disease, or due to the medications used to treat it.
- Allows for data pooling across countries.

Countries and Languages

Europe
. Belgium (Dutch, French)
. France (French)
. Germany (German)
. Italy (Italian)
. The Netherlands (Dutch)
. Poland (Polish)
. Spain (Spanish)
. Sweden (Swedish)
. Switzerland (French, German, Italian)
. United Kingdom (English)

North America
. Canada (English, French)
. USA (Spanish)

South America
. Argentina (Spanish)
. Brazil (Portuguese)
. Mexico (Spanish)

Others
. Australia (English)
. South Africa (English, Afrikaans, Sesotho, Xhosa, Zulu)

Methodology

Objective: to produce culturally relevant target language versions which are conceptually equivalent to the original instrument.

In each country, a consultant was recruited as co-ordinator and supervisor of the process.

Original US English SDM

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Forward step*
- Production of 2 translations from source language to target language (professional translators),
- Production of a reconciled target version (V1) by the consultant.

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Backward step*
- Backward translation of V1 into English,
- Comparison of the backward translation with the original and discussion of discrepancies led to the modification of V1, and establishment of a new version (V2).

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Review by clinicians
- Review of V2 by a clinician (external investigator) recommended by PFIZER,
- Discussion of the suggestions made by the clinician with the consultant and establishment of a new version (V3).

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Cognitive debriefing
- Comprehension test on a sample of 5 patients with AIDS, with asymptomatic HIV, or under HAART therapy for HIV, during in-depth face-to-face interviews, to see whether the wording was understandable and acceptable. Alternative wordings were explored in the target languages during a "thinking aloud" exercise,
- Production of a new version (V4) following respondents' feedback.

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Finalisation process
- Production of final target version (V5), following final proofreading step.

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Report
- Report outlining the methodology followed for the production of the language versions and the list of concepts and alternative wordings on which the translations were based.

** For Belgian Dutch, Belgian French, Swiss French, Swiss German, Swiss Italian, Australian English, and Canadian English the forward and backward steps were not performed. Instead, an **adaptation** of an existing related language version was performed.*

*Note: For Brazilian Portuguese, Canadian French, Argentinean Spanish, Mexican Spanish, South African English, UK English, German and Italian, **existing items were available.** One forward & backward translation was therefore performed to create the **instructions**, followed by Pilot Testing (Review by clinicians & Cognitive Debriefing) on the whole instrument. For French, work was carried out on the instructions only, as the existing items had already undergone Pilot Testing.*

Issues Encountered

- During the linguistic validation process, the main issues encountered were of a cultural and linguistic nature, as follows:

Example 1: the translation of the instruction "The questionnaire is very brief and should take no more than 5 minutes to complete".
Example 2: the translation of items referring to symptoms which are described using more than one term or expression

Example 1: the translation of the instruction "The questionnaire is very brief and should take no more than 5 minutes to complete".

Concept: In this instruction, patients are informed that the questionnaire they are about to complete is not long, and they should consequently not expect to spend longer than 5 minutes to complete.

Issue: Although a literal translation was possible in all languages, the cognitive debriefing interviews revealed that patients did not react well to this instruction. The inclusion of the reference to an upper time-limit for completion of the questionnaire was perceived as being a constraint to the respondents who felt under pressure or rushed, as if they were in an examination.

Solution: In order to avoid this unnecessary stress being felt by the respondents, it was decided to use an alternative translation in certain languages where this problem was encountered. The translation retained in these cases was: "The questionnaire is very brief and should not take long to complete".

Example 2: the translation of items referring to symptoms which are described using more than one term or expression.

Concept: Each item refers to one or several related symptoms.

Issue:
a) Some items contain one symptom which is described using more than one term or expression. It became apparent that certain languages only have one term which suitably conveys the concept.
b) Other items contain several related symptoms. It was therefore important to ensure that, when the item contained more than one similar symptom, a single term was **not** used.

Solution:
a) The following items refer to one symptom. Single terms were therefore acceptable translations in languages which did not have several equivalent terms:
⇨ Item 3 ("Feeling dizzy or lightheaded"): "**dizzy**" and "**lightheaded**" are synonymous
⇨ Item 8 ("Felt sad, down or depressed"): "**sad**", "**depressed**" and "**down**" are synonymous
⇨ Item 9 ("Felt nervous or anxious"): "**nervous**" and "**anxious**" are synonymous

b) The following items refer to more than one symptom. Appropriate terms or expressions therefore needed to be found to translate each concept:
⇨ Item 15 ("Bloating, pain or gas in your stomach"): "**bloating**" (abdominal distension, sometimes visible) is not the same as "**gas**" (excess gas which can be felt, but which does not necessarily induce bloating)
⇨ Item 17 ("Problems with having sex, such as loss of interest or lack of satisfaction"): "**loss**" (a decrease, i.e. less interest in sex *than before*) is not the same as "**lack**" (an absence, i.e. the respondent experiences no satisfaction)
⇨ Item 19 ("Problems with weight loss or wasting"): "**weight loss**" (a decrease in one's body weight) is not the same as "**wasting**" (= lipoatrophy; fat or muscle loss which does not necessarily involve weight loss)

Conclusion

- The aim of this project was to produce 25 culturally relevant language versions of the 20-item SDM which were conceptually equivalent to the validated original to allow international pooling of data. Centralising the project co-ordination, along with the active participation of the developer, allowed for the application of appropriate equivalents in the target language versions. The issues encountered during linguistic validation highlight the value of international input in instrument design.

- Further psychometric analysis will be important in order to validate the cultural equivalence of the 25 translated versions to the original English questionnaire.

General Recommendations

- After selecting an instrument, ensure rigorous translation methodology

- When refining or developing an instrument for international use, integration of international feedback early in the process may facilitate linguistic validation.