

# INTEGRATION OF INTERNATIONAL INPUT INTO INSTRUMENT DESIGN: TRANSLATABILITY ASSESSMENT

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## Background

The last 20 years have seen the development of numerous Patient Reported Outcomes (PRO) measures which are increasingly used in multinational research and clinical practice. However, most of these PRO instruments are developed within and for one culture. Based on the assumption that the original concepts are universally appropriate to all languages and cultures, instruments destined for international use are translated following a standard procedure - Linguistic Validation<sup>i</sup>. Experience in Linguistic Validation projects has however revealed the interdependence of translation and original instrument and the importance of integrating an international component in the design of instruments, which can be done through a new approach - a Translatability Assessment.

<sup>i</sup> C. Acquadro, B. Jambon, D. Ellis, P. Marquis. *Language and translation issues. In: Quality of Life and Pharmacoeconomics in Clinical Trials, Second Edition, edited by B. Spilker. Lippincott-Raven Publishers, Philadelphia 1996: 575-585*

## Objectives

- Integration of an international component in the development phase.
- Identification of possible linguistic and conceptual difficulties.
- Assessment and anticipation of potential translation issues.
- Optimisation of an original instrument for easier translation into various languages.
- Easy comprehension for patients.
- Increased cross-cultural equivalence between original and translations.
- Enhanced comparability of data.

## Development

- Experience in linguistic validation has shown that the translation process usually reveals difficulties when adapting the format, instructions, concepts, idiomatic expressions, response scales or demographic items to different languages. The Translatability Assessment proposes a review of these aspects and suggests re-formulations in the original, taking into account the context and constraints of other languages and cultures.
- Through experience in previous Translatability Assessments of a variety of instruments and of various language groups, Mapi Research Institute has established a working methodology for this new approach.
- In the absence of international development, this may be a cost-and time-effective compromise between the simultaneous and sequential approaches to instrument development<sup>ii</sup>.

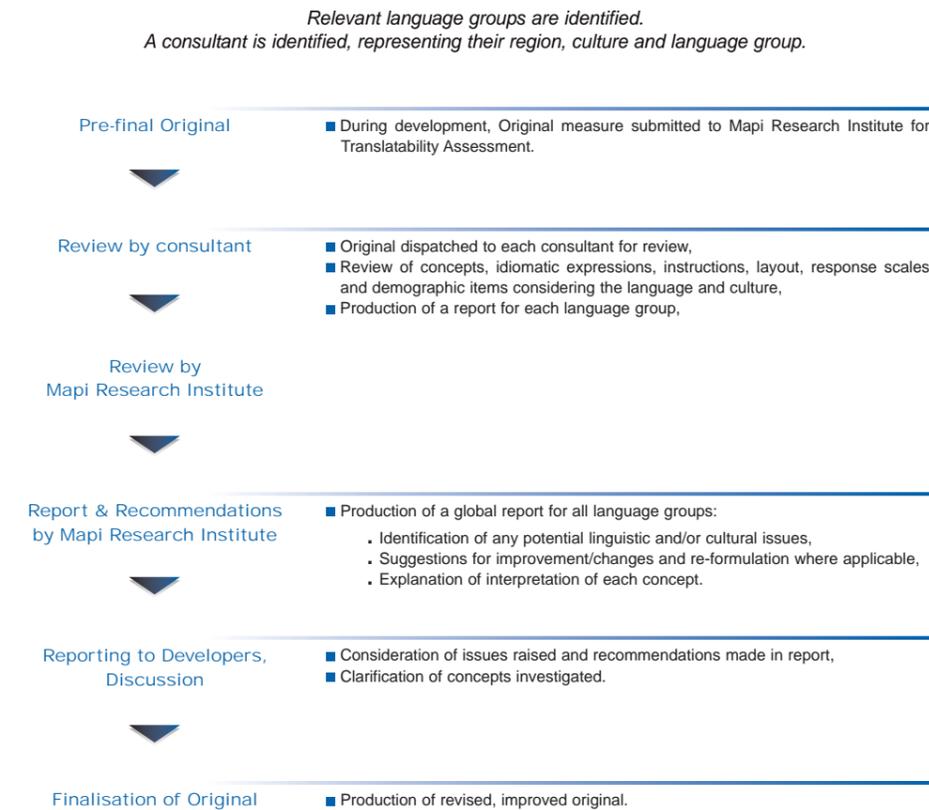
<sup>ii</sup> M. Bullinger, M.J. Power, N.K. Aaronson, D.F. Cella, R.T. Anderson. *Creating and Evaluating Cross-Cultural Instruments. In: Quality of life and pharmacoeconomics in clinical trials, second edition, edited by B. Spilker. Lippincott. Raven Publishers, Philadelphia 1996: 659-668*

## Conclusion

- The Translatability Assessment may be a practical and easy way to integrate an international component in the design of new measures, thereby facilitating the subsequent translation by anticipating and solving its difficulties.

## Methodology

**Objective:** To perform an international critical review of a pre-final original in collaboration with the developer and consultants representing different language groups.



## Results

- From experience in previous Translatability Assessments, some illustrative examples of cultural and linguistic issues can be given:

### Conceptual issues

Original Item: "... on how many days were you unable to do your work?"

Concept: The question enquires about both paid and unpaid/volunteer work.

Issue: In English, the word "work" can be used to refer to all notions, while in other languages, each notion needs to be defined separately.

Solution: Refer more generally to "daily activities".

### Idiomatic Expressions

Original Item: "... was the right asthma inhaler at hand?"

Concept: "Asthma inhaler" should refer to the medication and not the device.

Issue: In languages other than English the word "inhaler" refers solely to the device and not to the product or medication.

Solution: Use the word "medication" instead of "inhaler".

### Layout issues

Original Item: Response choice scale indicated once only at beginning of measure.

Concept: Patients are to remember response choices when answering questions.

Issue: It is difficult for patients to keep in mind the scale and nuances, they have to refer to the beginning of the questionnaire each time they answer a question.

Solution: Repeat the response choices after each question - modify layout.

### Instructions

Original Item: "... answer all questions by circling the appropriate number ..."

Concept: Indicate answer by putting a circle around the appropriate response.

Issue: In some European countries it is quite unusual to circle responses and there is no convenient word to describe "circling". Some countries use a cross or tick.

Solution: Using boxes to check/mark with a cross/tick.

### Response scales

Original Item: "All the time; Most times; Half the time; A few times; Never"

Concept: Measurement of frequency.

Issue: Mixing of both notions of "times" (individual occasions) and "time" (global notion) is confusing for respondents and cannot be rendered as such in other languages - the 2 notions are rendered using 2 completely different words.

Solution: Refer consistently to expressions using either "times" or "time".

### Demographic issues

Original Item: "Indicate your level of schooling" - option: "no schooling at all"

Concept: The respondents are asked to indicate their level of education and have options to choose from. The option shown implies that he/she did not go to school.

Issue: In Italy, this is seen as an illegal question as it elicits an illegal answer. It is illegal in Italy to not go to school. This option cannot be given to respondents.

Solution: Modify options - e.g. use "lowest level of education" instead.

## General Recommendations

- While developing an original instrument for international use, watch out for use of idiomatic expressions and language/culture-specific terms, which may lead to difficulties in translation and in ensuring cross-cultural equivalence.
- During instrument design, integrate international input early in the process.