

Linguistic validation of the Chronic Respiratory Questionnaire - Self-Administered Standardized format (CRQ-SAS) for use in international studies

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Background

The Chronic Respiratory Questionnaire - Self-Administered Standardized format (CRQ-SAS)

- A 20-item questionnaire designed to assess health related quality of life in patients with chronic respiratory disease.
- Developed in Canadian English by Gordon Gyuatt and Holger Schünemann, and comprising both First Administration and Follow-up versions.
- Self-administered.
- The linguistic validation in 11 languages was sponsored by F.Hoffmann-La Roche Ltd.

Context

Chronic Respiratory Problems Assessment in International Clinical Trials

Need for a reliable, valid and responsive instrument in 11 languages that:

- Measures the feelings, limitation of activities and overall health of patients suffering from chronic respiratory problems.
- Allows for data pooling across countries.

Countries and languages

Europe

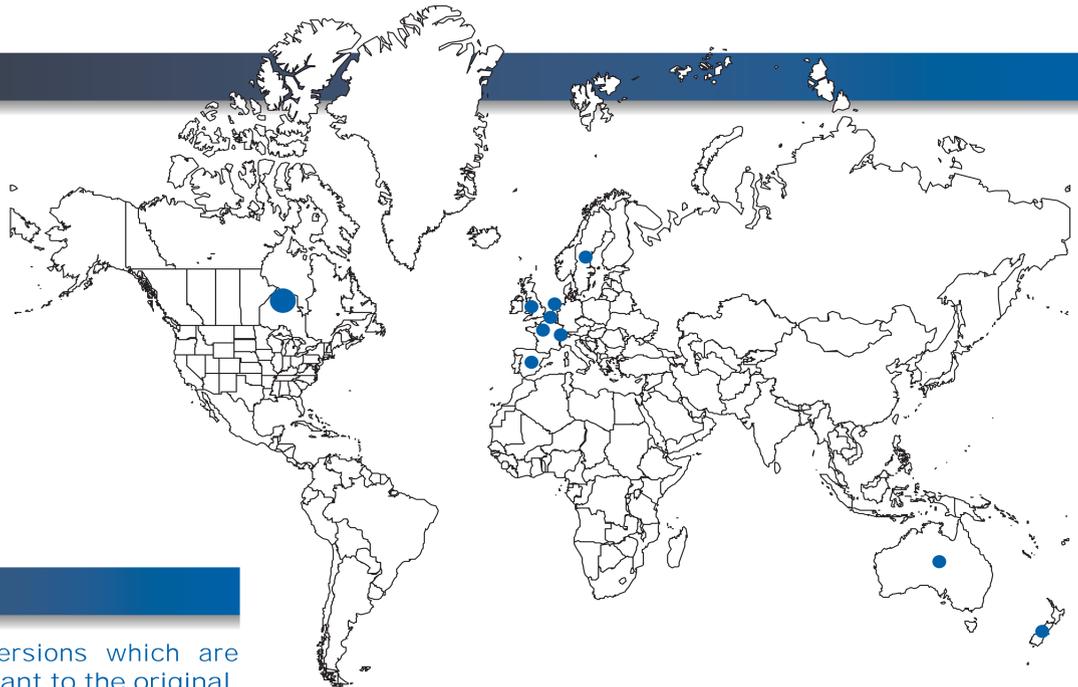
- . Switzerland (German)
- . France (French)
- . Belgium (Belgian French, Belgian Dutch)
- . Spain (Spanish)
- . The Netherlands (Dutch)
- . United Kingdom (UK English)
- . Sweden (Swedish)

North America

- . Canada (Canadian French)

Others

- . New Zealand (New Zealand English)
- . Australia (Australian English)



Methodology **

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

Linguistic Validation Methodology

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

Original Canadian English Clinical CRQ-SAS

Forward step*

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

Backward step

- Backward translation of V1 into English,
- Comparison of the backward translation with the original; discussion of discrepancies between the consultant and MAPI RESEARCH INSTITUTE, and review by the developer, leading to the modification of V1 and establishment of a new version (V2).

Review by clinicians

- Review whenever possible of V2 by a clinician in each country, recommended by F.HOFFMANN-LA ROCHE LTD.
- Discussion of the suggestions made by the clinician with the consultant, and establishment of a new version (V3).

Cognitive debriefing

- Comprehension test on 5 subjects (both male and female) suffering from COPD, 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.

Finalisation process

- Establishment of final target version (V4) following the discussion of cultural and linguistic issues raised by respondents.

Report

- Summary of the problems encountered and solutions retained in the course of the translation process.

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

** Acquadro C., Jambon B., Ellis D. and Marquis P. Language and translation issues. In Spilker B, ed. Quality of Life and Pharmacoeconomics in Clinical Trials. Philadelphia: Lippincott-Raven Publishers, 1996: 575-585.

** Acquadro C., Conway K., Giroulet C., Mear I.: Linguistic Validation Manual for Patient-Reported Outcomes (PRO) Instruments, Mapi Research Institute, Lyon, 2004.

Issues encountered

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

- Example 1: translation of "upset"

- Example 2: translation of idiomatic expressions

- Example 3: translation of "social activities"

Example 1: Translation of "upset"

Concept

When asking about the patient's psychological well-being, mood and energy, the original questionnaire uses the term "upset", associating it with different adjectives: "angry or upset" (question 1), "upset, worried, or depressed" (question 12), "upset or scared" (question 19).

Issue

Translating "upset" was challenging in all languages, as the term has a very wide semantic field.

Solution

Close analysis of each separate occurrence of "upset" led to the conclusion that the meaning relates to the context of the sentence in which it was used. The developers of the questionnaire suggested that in the context of questions 1 and 12, "upset" was to be understood as "annoyed", but that in the context of question 19, the intended meaning relates to a state of discomposure, such as being "agitated". The ensuing translation choices faithfully reflected this conceptual clarification.

Example 2: Translation of idiomatic expressions

Concept

In the course of the questionnaire, several markedly idiomatic expressions are used, such as "sluggish" or "down in the dumps", to convey a specific state of mind.

Issue

These expressions, though common and widely understood in the source language, did not always have a colloquial equivalent in some of the target languages.

Solution

Together with patients and developers of the instrument, conceptual equivalence for these expressions was attained in the form of a more neutral wording (e.g. "slow" for "sluggish" or "depressed" for "down in the dumps") in the target languages.

Example 3: Translation of "social activities"

Concept

Question 5 investigates the extent to which the patient suffers from shortness of breath during his "social activities" which should refer to get-togethers or outings with family / friends.

Issue

In some of the target languages, a literal translation of "social activities" conveyed the meaning of "volunteer social/community-oriented action".

Solution

In order to guarantee semantic consistency, it was decided to have the translation of "social activities" followed by a few specific examples within brackets in order to leave no doubt on the intended meaning (e.g.: "social activities (such as meetings with family, friends, neighbours or groups)").

Conclusion

- The aim of this project was to produce 11 language versions of the Chronic Respiratory Questionnaire - Self-Administered Standardized format (CRQ-SAS), which are culturally relevant and conceptually equivalent to the validated original to allow international pooling of data. Finding equivalents of typical English phrases is a common difficulty in instruments developed in one particular cultural setting. The issues encountered during linguistic validation highlight the value of international input in instrument design.

General recommendations

- When refining or developing a new instrument for international use:
 - idiomatic expressions should have equivalents in other languages to avoid difficulties in finding suitable equivalents with cross-cultural appropriateness;
 - integrate international feedback early in the process.
- Ensure rigorous translation methodology.