# RECOMMENDATIONS TO THE EUROPEAN REGULATORS FOR THE CULTURAL ADAPTATION OF HEALTH-RELATED QUALITY OF LIFE MEASURES

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## INTRODUCTION AND OBJECTIVES

- With the growing use of Patient-Reported Outcomes (PROs) and Health-Related Quality of Life (HRQL) questionnaires for the evaluation of medicines in Europe, the need for international measures has increased.
- In response to European regulators' concerns about the methodology used to achieve "international validation" (i.e. cultural adaptation) of HRQL measures in the context of Phases II to IV clinical trials, Mapi Research Institute have investigated current guidelines, focusing on HRQL questionnaires.

## METHODS

- We identified papers relevant to translating HRQL questionnaires into other languages and adapting them to other cultures published between January 1966 and February 2003 by searching Medline, Embase, and Mapi Research Institute's databases. The first two databases were explored for the words: "quality of life," "questionnaires" and "health status indicators" matched with "translating" and "cross-cultural comparison."
- We considered papers without language restrictions and excluded duplicates. In this way we identified 208 references. We also explored the MAPI Research Institute's database for the words: "translation issues," "cross-cultural comparison," and "cross-cultural research." This provided us with another 236 references.
- The titles and abstracts of the 444 references were reviewed for relevance to the study. Again, duplicates were excluded and papers were included if: 1. they proposed a set of guidelines or recommendations or 2. they reviewed, compared or criticized methods to adapt HRQL questionnaires from a source culture to a target culture.

## RESULTS

- Thirty papers met our inclusion criteria:
  - 19 papers representing 14 guidelines:
    **1.** AAOS (American Association of Orthopaedic Surgeons), **2.** the EORTC Group, **3.** the EUROQOL Group, **4.** the European Group for Health Measurement and Quality of Life Assessment (Nottingham Health Profile - NHP), **5.** the FACIT Group, **6.** Herdman et al, **7.** the International Quality of Life Assessment (IQOLA) Group, **8.** the Johns Hopkins University (Sickness Impact Profile - SIP), **9.** Mapi Research Institute, **10.** Mathias et al,,**11.** the Medical Outcomes Trust (MOT),. **12.** Spielberger and Sharma, **13.** Steward and Napoles-Springer; and **14.** the World Health Organisation (WHO).

  - and 11 papers reviewing methods.

  The review highlighted a lack of consensus regarding the terminology to qualify the process of adapting a PRO measure from a source to a target language, and the scope covered by this terminology. Common points included multiple forward translations, reconciliation sessions, some form of back-translations and psychometric validation. Differences were seen in the importance given to back-translation, focus groups, cognitive debriefing, and recruitment criteria for translators. With only two articles comparing methodologies, the review could not determine the best method to apply among the 14 identified. Finally only two papers explored in detail the key issue of equivalence of HRQL measures across countries and cultures.

## CONCLUSION

- This review demonstrates disparity in definitions and methods. There is also no evidence proving that one method leads to better results than another. Moreover only few researchers highlight the crucial importance of equivalence of instruments across countries and cultures
- Since 1995, Mapi Research Institute has referred to the process aiming at the production of appropriate translated language versions as a Linguistic Validation. This process deals with the linguistic and cultural aspects of the target language versions. The linguistic validation is complemented by the evaluation of the measurement properties of the target language versions, i.e. the psychometric validation.
- The two-phase process is termed by the Institute as Cultural Adaptation.
- Our experience has shown that rigour in the Linguistic Validation process produces translated versions:
  - Providing greater fidelity to the intent of the author of the original questionnaire;
  - Using a language acceptable and familiar to respondents;
  - Enabling the tracing of the decision-making process.
- To address the problematic of equivalence, we have adopted Stewart and Napoles-Springer's framework[1] for assessing equivalence. Their proposal includes 6 dimensions of equivalence of translated questionnaires: conceptual, semantic, operational, psychometric, item and criterion. Three types of equivalence are particularly relevant to the Linguistic Validation: conceptual, semantic and operational.
- We propose providing regulators with an overview of what most researchers in our review recommend **as minimum requirements for the Linguistic Validation step of HRQL measures.**
- This proposal is presented in the form of a checklist (Table 1):
  - Including a maximum of 11 steps from Conceptual Definition to International Harmonization, depending on the target culture and/or language studied.
  - Linking each step to its dimension of equivalence.
    Items 1 and 10 cover conceptual equivalence (CE).
    Items 2, 3, 4, 5, 6, 7, 8, 9, 10 and 11 apply for semantic equivalence (SE).
    Item 10 is relevant to operational equivalence (OE).
- Concerning the second phase of cultural adaptation and the three other types of equivalence proposed by Stewart and Napoles-Springer, we suggest that:
  - Psychometric properties of the translated questionnaires be evaluated during the clinical trials to provide evidence of psychometric equivalence, as they are not always available prior to the clinical trials;
  - Item equivalence should be checked if items are weighted. In other cases, constraints of time and resources might not enable manufacturers to evaluate this equivalence through response theory, or ranking of items or Thurstone's method of equal-appearing intervals.
  - Concerning criterion equivalence, we find it difficult to ask for evidence in approval files, and we recommend that collaboration between researchers and manufacturers be established to obtain norms in each culture.

**REFERENCE:**

1. Stewart AL, Napoles-Springer A. Health-Related Quality of Life Assessments in Diverse Population Groups in the United States. Medical Care 2000; 38(9) Supl II:102-124

**TABLE 1: Checklist for the linguistic validation of an existing HRQL questionnaire to a target culture**

The following checklist is primarily intended to help regulators decide with confidence whether a HRQL questionnaire has been translated for use in a target culture in such a way that it will accurately measure the same concepts as the original. The emphasis of this checklist is on establishing justification for the numerous subjective decisions leading to the translated version.

| Items and Equivalence | Description | Yes / No | Minimal requirements |
|---|---|---|---|
| 1 CE | Is there detailed information describing consultation with the developer including:<br>- The underlying HRQL concepts to be measured and their respective response scale for each item of the questionnaire<br>- Existence and performance of other translations of the questionnaire | | Agreement from developers |
| 2 SE | Is there detailed information about the forward translators including:<br>- How the translators were selected<br>- Their native language and culture,<br>- Time and experience in the target language<br>- Level of education<br>- Familiarity with HRQL concepts translated | | Translators should be native of the target country and live in the target country |
| 3 SE | Is there detailed information about the initial forward translation process including:<br>- How many forward translations were performed?<br>- Did the translators work independently or as a team? Why or Why not?<br>- How were the translators instructed? | | At least independent two forward translations |
| 4 SE | Is there detailed information describing the analysis and reconciliation process leading to a single forward translation (Version 1) including?<br>- Who was involved in this process? And Why?<br>- What were the differences between the forward translations?<br>- How were the differences resolved? | | Both forward translators and a third party |
| 5 SE | If no back translation was made, was Version 1 approved as the Target Version for pilot testing? Is this decision well justified? | | |
| 6 SE | If one or more back translations were made, is there detailed information about the back translator(s) including:<br>- How the translators were selected; their native language and culture<br>- Time and experience in the target language<br>- Level of education<br>- Familiarity with HRQL concepts translated | | At least one back translation |
| 7 SE | Is there detailed information about the back translation process including:<br>- How many backward translations were performed?<br>- Did the translators work independently or as a team? Why or Why not?<br>- How were the translators instructed? | | Committee review<br>Coordinating center if any |
| 8 SE | Is there detailed information about how the back translation(s) was/were analyzed and how Version 1 was revised to produce Version 2 including:<br>- Who was involved in this process? And Why? | | Committee review<br>Coordinating center if any |
| 9 SE | Was Version 2 approved as the Target Version for pilot testing and is this decision well justified? | | |
| 10 CE OE | Pilot testing of the target version on a sample group of subjects from the target population aims to verify that respondents from the target population clearly understand, accept and can easily respond to the target language version.<br>Is this testing process well described including:<br>- Number of subjects<br>- Information about the subjects that demonstrate that they belong to the target population<br>- Instructions to the subjects,<br>- Type of testing: in-depth face-to-face structured interviews, panel discussion, or other; and who was involved?<br>- Problems and other points of discussion encountered by the subjects<br>- Statistical analysis (if any)<br>- Developers recommendations<br>- Resulting modifications of the target version (Version 3) | | Test on sample of subjects living in the target country |
| 11 SE | International Harmonization (IH)<br>Was this process undertaken? If Yes, was this process well described including:<br>- Number of countries involved,<br>- Who was involved in this process?<br>- What were the differences between the countries and how they were resolved?<br>- Resulting modifications of the target version (Version 4) | | IH has proven to be a useful Quality control step |