**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 Phase II to III clinical trials, Mapi Research Institute has conceived 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 1994 and February 2003 by reviewing Medline, Embase, and Mapi Research Institute’s database. The first four databases were explored for the words “quality of life,” “questionnaire,” and “health state indicators” methodologically related to “cultural adaptation” and “cross-cultural research” of measures. This provided us with another 386 references.
- The titles and abstracts of the 444 references were reviewed for relevance to the study. Papers were excluded if they presented a set of guidelines or recommendations. Of the 290 papers reviewed, 130 duplicates were excluded, and 9 papers that were not written in English were removed. The remaining 161 papers were reviewed by 6 assessors, who used a form to evaluate them. Each reviewer evaluated the proper validation of the questionnaire in the target population.

**RESULTS**

- Thirty papers met our inclusion criteria:
  - 19 papers representing 14 guidelines:
- The remaining 52 papers were reviewed by the assessors.

**CONCLUSION**

- This review demonstrates disparity in definitions and methods. There is a lack of evidence proving that one method leads to better results than another. Moreover only few researchers highlight the overall importance of experiences from assessments across countries and cultures.
- Since 1995, Mapi Research Institute has referred to the two-phase process of obtaining appropriate translated versions as a Linguistic Validation. This process deals with the linguistic and cultural aspects of the target language versions. This linguistic validation is complemented by the evaluation of the measurement properties of the target language versions, i.e. psychometric validation.
- The two-phase process is termed by the Institute as Cultural Adaptation.
- This experience has shown that the focus in the Linguistic Validation process produces translated HRQL questionnaires from a source culture to a target culture.

**REFERENCES**

- Steward and Napoles-Springer; and
- Mathias et al.

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

<table>
<thead>
<tr>
<th>Items and Equivalence</th>
<th>Description</th>
<th>Yes / No</th>
<th>Minimal requirements</th>
</tr>
</thead>
</table>
| 1 CE                  | Is there detailed information describing the study protocol, including:  

The underlying HRQL concept to be measured and the respective response scales for each item of the questionnaire.  

- Literature and performance of other translations of the questionnaire.  

Agreement from developers. |
| 2 SE                  | Is there detailed information about the forward translators including:  

- How the translators were selected.  

- Their native language and culture.  

- Time and experiences in the target language.  

- Level of education.  

- 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:  

- How many forward translators were involved?  

- Did the translators work independently or as a team?  

- Why or why not?  

- How was the translation assessed?  

- At least independant two forward translations. |
| 4 SE                  | Is there detailed information describing the analysis and reconciliation process leading to a single forward translation (Version 1) including:  

- Who was involved in this process?  

- Was the translation reviewed and/or was a consensus reached?  

- At least independent two forward translations. |
| 5 SE                  | Is there detailed information about the back translation(s) including:  

- How the translators were selected.  

- Their native language and culture.  

- Time and experiences in the target language.  

- Level of education.  

- Familiarity with HRQL concepts translated.  

- At least one back translation. |
| 6 SE                  | Is there detailed information about the back translation process including:  

- How many back translations were performed?  

- Did the translators work independently or as a team?  

- Why or why not?  

- How was the translation assessed?  

- Committee review.  

- Coordinating center if any. |
| 7 SE                  | Is there detailed information about the back translation process including:  

- How many back translations were performed?  

- Did the translators work independently or as a team?  

- Why or why not?  

- How was the translation assessed?  

- Committee review.  

- Coordinating center if any. |
| 8 SE                  | Is there detailed information about how the back translated(s) were reviewed and analyzed and how Version 1 was revised to produce Version 2 including:  

- Who was involved in this process?  

- Was the translation reviewed and/or was a consensus reached?  

- Committee review.  

- Coordinating center if any. |
| 9 SE                  | Pilot testing of the target version on a sample group of subjects from the target population to verify that respondents from the target population clearly understand, except when easily understood by the target language version.  

- Pilot testing process will include:  

- Number of subjects.  

- Information about the subjects that demonstrate that they belong to the target population.  

- Instructions to the subjects.  

- Baseline assessment by expert panel discussion, or other; and who was involved?  

- Evaluation of the pilot testing process.  

- Statistical analysis (if any).  

- Developers recommendations.  

- National Harmonization (NH).  

- Is this process understood?  

- Was this process well documented?  

- Number of countries involved.  

- Was the translation reviewed and/or was a consensus reached?  

- Resulting modifications of the target version (Version 4).  

- On a sample of subjects living in the target country. |
| 10 CE OE              | Is there detailed information about how the back translated(s) were reviewed and analyzed and how Version 1 was revised to produce Version 2 including:  

- Who was involved in this process?  

- Was the translation reviewed and/or was a consensus reached?  

- Resulting modifications of the target version (Version 4).  

- National Harmonization (NH).  

- Is this process understood?  

- Was this process well documented?  

- Number of countries involved.  

- Was the translation reviewed and/or was a consensus reached?  

- Resulting modifications of the target version (Version 4).  

- On a sample of subjects living in the target country. |