

**INTRODUCTION and BACKGROUND**

With increased international collaboration and the growing use of Health-related Quality of Life (HRQL) and Patient Reported Outcomes (PRO) evaluation in clinical research, the need for international measures has grown. As most are developed in English, they need to be culturally adapted to obtain equivalence between the source and target measures.

In response to European regulators' concern about the methodology employed to achieve this, the European Regulatory Issues on Quality of Life Assessment (ERIQA) group and Mapi Research Institute are investigating current guidelines for cross-cultural adaptation of Health-related Quality of Life measures.

**OBJECTIVES**

- To identify methods used for cultural adaptation of HRQL measures
- To study the methods used and make a synthesis

**METHODOLOGY**

Relevant papers were identified from Medline, Embase, and Mapi Research Institute's database.

- The first two databases were explored with: "quality of life", "questionnaires", "health status indicators" matched with "translating" and "cross-cultural comparison". Papers published between January 1966 and April 2001 were considered without language restrictions. Duplicates were excluded. 173 references were identified.
- The search on the Institute's database used "translation issues", "cross-cultural comparison", and "cross-cultural research" as keywords and identified 236 references.

On author reviewed the titles and abstracts of the 409 references for relevance to the study.

Papers were included if: 1) they proposed a set of guidelines or recommendations or 2) they reviewed and criticised methods to cross-culturally adapt HRQL measures from a source language to a target language.

**FINDINGS**

**32 papers** met the inclusion criteria, 18 proposing guidelines, and 14 reviewing methods. (See Tables 1 and 2 for References).

**14 sets of guidelines were identified** (produced by Groups, Institutions or individuals):

Chwalow, the EORTC Group, the EUROQOL Group, the FACIT Group, Guillemin, Beaton et al (AAOS --American Association of Orthopaedic Surgeons), Herdman et al, the Johns Hopkins University (Sickness Impact Profile -- SIP), the International Quality of Life Assessment (IQOLA) Group, Mapi Research Institute, the Medical Outcomes Trust (MOT), the European Group for Health Measurement and Quality of Life Assessment (Nottingham Health Profile -- NHP), Patrick et al, Spielberger and Sharma, and the World Health Organisation (WHO).

**Table 1: Guidelines**

1.	Bonomi AE, Cella DF, Hahn EA et al. Multilingual translations of the Functional Assessment of Cancer Therapy (FACT) quality of life measurement system. <i>Quality of Life Research</i> 1996;5: 309-320
2.	Bullinger M, Alonso A, Apolone G et al. Translating health status questionnaires and evaluating their quality: the IQOLA approach. <i>J Clin Epidemiol</i> 1998;51 (11): 913-923
3.	Chwalow JA. Cross-cultural validation of existing quality of life scales. <i>Patient Education and Counseling</i> 1995; 26: 313-318
4.	Conway K, Mear I, Giroulet C, Acquadro C. Mapi Research Institute's Manual for the Linguistic Validation of HRQL Questionnaires. Unpublished document. January 2001
5.	Cull A, Sprangers M, Aaronson N on behalf of the EORTC Quality of Life Study Group. Translation Procedure. Unpublished document. July 1998
6.	European Group for Health Measurement and Quality of Life Assessment: Hunt SM, Alonso J, Bucquet D, Niero M, Wiklund I, McKenna S. Cross-cultural adaptation of health measures. <i>Health Policy</i> , 1991;19: 33-44
7.	EUROQOL Group. Translation Guidelines for the EUROQOL EQ-5D. Unpublished document. April 2000
8.	Guillemin F, Beaton. Guidelines for the process of cross-cultural adaptation of self-report measures. 2000
9.	Herdman M, Fox-Rushby J, Badia X. Equivalence and the translation and adaptation of health-related quality of life questionnaires. <i>Quality of Life Research</i> 1997; 6: 237-247
10.	Herdman M, Fox-Rushby J, Badia X. A model of equivalence in the cultural adaptation of HRQL instruments: the universalist approach. <i>Quality of Life Research</i> 1998;7: 323-335
11.	Hunt SM; Cross-Cultural Issues in the use of socio-medical indicators. <i>Health Policy</i> 1986; 6: 149-158
12.	The Johns Hopkins University. Guidelines for Translation of the Sickness Impact Profile. Unpublished Document. January 1996.
13.	Lohr KN, Aaronson NK, Alonso J et al. Evaluating quality of life and health status instruments: development of scientific review criteria. <i>Clinical Therapeutics</i> 1996;18 ( 5):979-992
14.	Mathias SD, Fifer, Patrick DL. Rapid translation of quality of life measures for international clinical trials: avoiding errors in the minimalist approach. <i>Quality of Life Research</i> 1994;3: 403-412
15.	Patrick DL, Wild DJ, Johnson TH, Wagner TH, Martin MA. Cross-Cultural Validation of Quality of Life Measures. In Orley J, Kuyken W (eds) <i>Quality of Life Assessment: International Perspectives</i> . Berlin Heidelberg: Springer Verlag 1994: 19-32
16.	Sartorius N, Kuyken W. Translation of Health Status Instruments. In Orley J, Kuyken W (eds) <i>Quality of Life Assessment: International Perspectives</i> . Berlin Heidelberg: Springer Verlag 1994: 3-18
17.	Spielberger CD, Sharma S. Cross-Cultural Measurement of Anxiety. In Spielberger CD, Diaz-Guerrero R (eds): <i>Cross-Cultural Anxiety</i> . Hemisphere Pub, Washington, 1976:13-28
18.	Ware JE, Keller SD, Gandek B et al. Evaluating Translations of Health Status Questionnaires. Methods from the IQOLA Project. <i>International Journal of Technology Assessment in Health Care</i> 1995; 11 (3):525-551

**Table 2: Reviews**

1.	Acquadro C, Jambon B, Ellis D, Marquis P. Language and Translation Issues. In Spilker B (eds) <i>Quality of Life and Pharmacoeconomics in Clinical Trials</i> , second edition. Philadelphia: Lippincott-Raven Publishers, 1996: 575-585
2.	Anderson RT, Aaronson NK, Wilkin D. Critical Review of the international assessments of health-related quality of life. <i>Quality of Life Research</i> , 1993;2: 369-395
3.	Anderson RT, Aaronson NK, Bullinger M, McBee WL. A review of the progress towards developing health related quality of life instruments for international clinical studies and outcomes research. <i>Pharmacoeconomics</i> 1996 Oct; 10(4): 336-355
4.	Berzon R, Shumaker S. Evaluating health-related quality of life measures for cross-national research. <i>DIA Journal</i> 1994;28: 63-67
5.	Brislin RW. Backtranslation for cross-cultural research. <i>Journal of Cross-cultural psychology</i> 1970; 1(3):185-216
6.	Bullinger M, Anderson, Cella D, Aaronson N. Developing and Evaluating cross-cultural instruments from minimum requirements to optimal models. <i>Quality of Life Research</i> 1993; 2: 451-459
7.	Bullinger M, Power MJ, Aaronson NK, Cella DF, Anderson RT. Creating and Evaluating Cross-Cultural Instruments. In Spilker B (eds) <i>Quality of Life and Pharmacoeconomics in Clinical Trials</i> , second edition. Philadelphia: Lippincott-Raven Publishers, 1996: 659-668.
8.	Elder JW. Comparative Cross-National Methodology. <i>Annual Review of Sociology</i> 1976; 2:209-230
9.	Guillemin F, Bombardier C, Beaton D. Cross-cultural adaptation of Health-related quality of life measures: literature review and proposed guidelines. <i>J Clin Epidemiol</i> 1993; 46 (12):1417-1432
10.	Guyatt GH. The philosophy of health-related quality of life translation. <i>Quality of Life Research</i> , 1993; 2:461-465
11.	Hui CH, Triandis HC. Measurement in Cross-Cultural Psychology. A Review and Comparison of Strategies. <i>Journal of Cross-Cultural Psychology</i> 1985; 16 (2): 131-152
12.	Leplège A, Verdier A. The adaptation of health status measures: methodological aspects of the translation procedure. In Shumaker SA, Berzon R (eds). <i>The International Assessment of Health-Related Quality of Life: Theory, Translation, Measurement &amp; Analysis</i> . Rapid Communications Oxford, New York 1995 93-101
13.	Perneger TV, Leplège A, Etter JF. Cross-Cultural Adaptation of a Psychometric Instrument: Two Methods Compared. <i>J Clin Epidemiol</i> 1999; 5 (11):1037-1046
14.	Stewart AL, Napoles-Springer A. Health-Related Quality of Life Assessments in Diverse Population Groups in the United States. <i>Medical Care</i> 2000; 38 (9) suppl II: 102-124

**DISCUSSION****1. Terminology and Definitions**

There is a lack of consensus regarding:

1. Terminology to qualify the process of adapting a health-related quality of life measure from a source language to a target language,
2. The scope covered by this terminology.

For some authors (Table 1, 8), cross-cultural adaptation "*is used to encompass a process that looks at both language (translation) and cultural adaptation issues in the process of preparing a questionnaire for use in another setting*". Others define it in two steps "*translation (linguistic validation) and evaluation of the psychometric properties of the HRQL measure* (Table 1, 4; Table 2, 1). Others only state that "*translation methods included the production of forward and backward translations, use of difficulty and quality ratings, pilot testing, and cross-cultural comparison of the translation work*" (Table 1,2). For the Johns Hopkins University, translating the SIP into other languages involves the translation itself, the evaluation of the psychometric properties and weighting of the translation, and field testing (responsiveness, norms, etc) (Table 1, 12).

Only two articles explore in details languages issues (Table 1, 16; Table 2, 1), and two the key issue of "equivalence" in the cross-cultural use of HRQL questionnaires (Table 1, 9-10).

**2. Methods**

Guidelines can be split into two categories: "Instrument-specific": SF-36 (2, 18), EQ-5D (7) SIP (12), FACT (1), EORTC (5), NHP (6), STAI (17)] or "Generic": for instance Herdman (9,10), Patrick et al (14, 15), MOT (13), Mapi Research Institute (4).

The several adaptation methods have several points in common, including: multiple forward translations, reconciliation sessions, and some forms of backtranslation.

There are methodological differences such as the importance given to the backtranslation procedure, the focus groups (use of monolingual or bilingual panels), the cognitive debriefing, the recruitment criteria for translators, the work of the translators (independent or not).

Few articles compare methodologies. Only one article discusses this issue by providing empirical evidence (Table 2, 13).

**CONCLUSIONS AND NEXT STEPS**

This brief review of methodologies demonstrates a great disparity in definitions and methods. Clear, concise and accessible definitions of the discipline-specific words and phrases authors use in their professional communication would greatly increase efficiency and effectiveness in research, and policy making. Further investigations are needed in order to:

- Create a standard glossary, regularly updated, which could greatly contribute to the advancement of the field
- Suggest further research in order to compare methods and explore empirical evidence of the effectiveness of methods.
- Propose recommendations for regulators on how to evaluate the quality of the translations used in multinational randomized controlled trials (i.e. minimum requirements).