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

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 “cultural comparison”.

Papers published between January 1966 and April 2001 were considered without language restrictions. Duplicates were excluded. 137 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 FACT Group, Gulenmin, 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 (IQLQA) 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 Shamma, and the World Health Organisation (WHO).

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 “translating” (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 language 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-SD (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).

LITERATURE REVIEW OF GUIDELINES FOR CROSS-CULTURAL ADAPTATION OF HRQL MEASURES

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