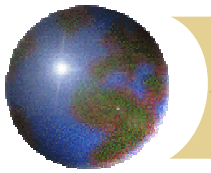


*LITERATURE REVIEW OF
GUIDELINES FOR CROSS-CULTURAL
ADAPTATION OF HRQL MEASURES*

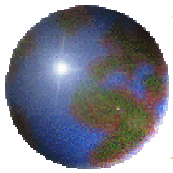
Catherine Acquadro, MD; Katrin Conway, Isabelle Méar,
Mapi Research Institute, Lyon, France



Why?

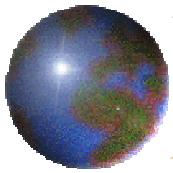
European regulators concerned by the methodologies used to translate HRQL measures

- ➡ Nov. 1999 meeting with EMEA CPMP Chairman: How do you know that a HRQL questionnaire is internationally validated?
- ➡ 2004: enlargement of the EU (15 + 10)



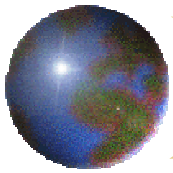
Objectives

- ❖ To identify methods used for translating HRQL measures
- ❖ To identify any critical review of methods used, and finally
- ❖ To attempt to answer regulators' concerns



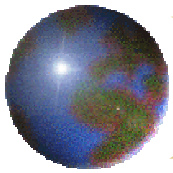
Methods

- Medline, Embase, and Mapi Research Institute's database.
- first two databases explored with «quality of life», «questionnaires», «health status indicators» matched with "translating" and "cross-cultural comparison". Papers published between January 1966 and April 2002 were considered. 179 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.



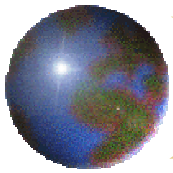
Results

- ➊ 415 abstracts were reviewed.
- ➋ Papers were included if:
 - ▣ 1) they proposed guidelines or recommendations, or
 - ▣ 2) they reviewed and criticised methods.
- ➔ 32 papers met the inclusion criteria
- ➔ 14 sets of guidelines were identified



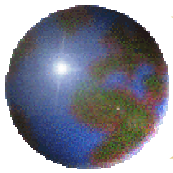
Results

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. Chwalow et al, 10. Mapi Research Institute, 11. the Medical Outcomes Trust (MOT), 12. Patrick et al, 13. Spielberger and Sharma, and 14. the World Health Organisation (WHO).



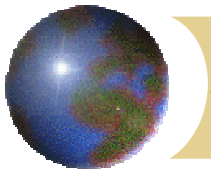
Results

- ❖ Inconsistency between definitions
- ❖ Different ways/methods of achieving the same goal



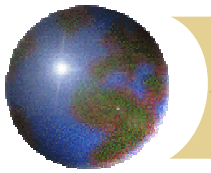
Definitions

- The review highlighted a lack of consensus regarding:
 - 1. the terminology to qualify the process of translating a HRQL measure from a source to a target language, and
 - 2. the scope covered by this terminology



Definitions

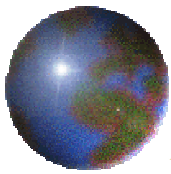
- cross-cultural adaptation *"is used to encompass a process that looks at both language (translation) and cultural adaptation issues in the process of preparing a questionnaire for use in another setting"*.
- Cultural adaptation is performed in two steps « *translation (linguistic validation) and evaluation of the psychometric properties of the HRQL measure* »
- « *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* »
- Translating the [...] into other languages implies the translation itself, the evaluation of the psychometric properties and weighting of the translation, and field testing (responsiveness, norms, etc)



Methods

- ❖ **Common point:** a multi-step process
- ❖ **Differences** in the translators' recruitment criteria, the work of the translators (independent or not), the number of forward translations, the importance given to backtranslation (1, 2 or 3), the patients' involvement (focus group, use of monolingual or bilingual panels, cognitive debriefing, other tests, etc), the use of international harmonisation.
- ❖ **Only one article compared methodologies**

Perneger TV, Leplège A, Etter JF. Cross-Cultural Adaptation of a Psychometric Instrument: Two Methods Compared. J Clin Epidemiol 1999; 5 (11):1037-1046



Methods

MAPI Research Institute

CONCEPTUAL DEFINITION	<ul style="list-style-type: none"> Definition of the concepts underlying each item of the questionnaire
Source questionnaire	
FORWARD TRANSLATION	<ul style="list-style-type: none"> Production of two independent translations by two professional translators in the target language in the target country Reconciliation meeting between the two "forward" translators and the local project manager to obtain a consensus version. Quality control by the MAPI Research Institute
Forward version A1 And Forward version A2	
Forward version B	
BACKWARD TRANSLATION	<ul style="list-style-type: none"> Translation of forward version B into the source language by one independent translator Comparison of the source questionnaire with the "backward" translation by the local team to check the conceptual content of forward version B Quality control by the MAPI Research Institute
Forward version C	
COGNITIVE DEBRIEFING	<ul style="list-style-type: none"> Interviews with patients/healthy subjects to test the interpretation of the translation Quality control by the MAPI Research Institute
Forward version D	
INTERNATIONAL HARMONISATION	<ul style="list-style-type: none"> Comparison of the target language versions with each other and with the original to ensure conceptual equivalence during a meeting with professional translators representing all the countries involved Quality control by the MAPI Research Institute
Final version	<ul style="list-style-type: none"> Final proof-reading
PSYCHOMETRIC EVALUATION	

WHO (Sartorius, Kayken 1994)

PHASES OF TRANSLATION PROCESS

I. PREPARATION FOR TRANSLATION

- Identification of candidate instrument
- Approval/Copyright for translation
- Examination of candidate instrument's appropriateness (etic aspects of candidate instrument)
- Creation of bilingual panel
- Identification and operationalization of emic constructs

II. TRANSLATION PROCESS

- Translation by 2 translators working together
- Writing of emic items
- Monolingual review
- Bilingual review
- Linguistic Analyses
- Back-translation by independent translator
- Iteration if needed

III. QUALITY CONTROL MEASURES

- Review by bilingual panel
- Iteration if needed

IV. RELIABILITY AND VALIDITY STUDIES

- Review by bilingual panel

FACT SCALES (Bonomi et al 1996)

Start : Source Document (English version)

Step 1

Forward Translation (native language-speaker residing in USA): English → Target Language
 Forward Translation (native language-speaker residing in Europe): English → Target Language

Result : Two independent forward translations

Step 2

Reconciliation of forward translations (native language-speaker not involved in forward translation process)

Result : Reconciled version that includes input from both forward translations

Step 3

Back translation of reconciled version (native English speaker): Target Language → English

Result : Back translation into English to compare source document

Step 4

Review by 3-4 bilingual health professionals residing in native countries

Result : Revised language versions based on reconciliation of discrepancies among source document, Step 2 forward translation, and Step 3 back translation

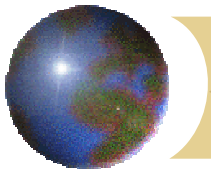
Step 5

Spelling and grammatical verification

Result : Revised language documents ready for pre-testing in native countries

Pretesting with patients (n=15-20) in native countries

Psychometric Evaluation

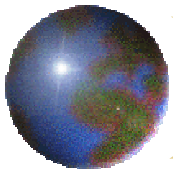


Only one article compared methodologies ...

- ➔ Problem: What is the best method?
- ➔ What does Popper say?
- ⊕ Science advances by deductive *falsification* through a process of "conjectures and refutations."
- ⊕ Experiment and observation test theories, not produce them.
- ⊕ It is imagination and creativity, not induction, that generates real scientific theories, which is "*how Einstein could study the universe with no more than a piece of chalk*".

Popper. The Logic of Scientific Discovery. 1934

- ➔ In other words, we don't know what is the best method (could be all, some or none!)



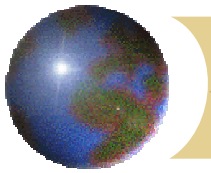
Suggestions



Produce a glossary



Develop a checklist

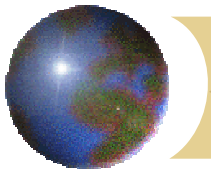


Produce a glossary

On-going (Mapi Research Institute, Cochrane QOL MG and ERIQA Group)

- Adaptation
- Bilingual
-
- Cultural Adaptation
- Cross-cultural Adaptation
-
- Equivalence
- Language
-

- Linguistic validation
-
- Source
 - Source instrument
 - Source language
- Target
 - Target country
 - Target language
-
- Translation



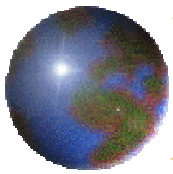
Why a Checklist?

➔ *A checklist as a first step for a Guideline*

« ...When developing guidelines, it is important to be clear on the purpose.

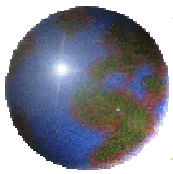
It is also important to strike a balance between what is ideal in theory and what is reasonable in practice. »

Michael F. Drummond. Introduction: The Rationale for Guidelines. *DIA Journal* 1996; 30:491-493



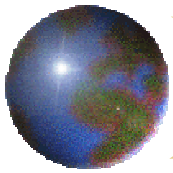
Checklist: Proposal

Item	Description	Yes/No	Comments
1	<p>Is there detailed information describing consultation with the developer including:</p> <ul style="list-style-type: none"> • The underlying HRQOL concepts to be measured and their respective response scales for each item of the instrument • Existence and performance of other translations of the instrument 		
2	<p>Is there detailed information about the forward translators including</p> <ul style="list-style-type: none"> • How the translators were selected • their native language and culture • time and experience in the source and target cultures • affiliation with the target population • level of education • familiarity with the HRQOL concepts to be translated 		<p>Proposal: Forward translations should be performed by native translators living in target country(ies)</p>
3	<p>Is there detailed information about the initial forward translation process including:</p> <ul style="list-style-type: none"> • How many forward translations were made? • Did the translators work independently or as a team? Why or why not? • How were the translators instructed? 		
4	<p>Is there detailed information describing the analysis and reconciliation process leading to a single forward translation (Version 1) including:</p> <ul style="list-style-type: none"> • Who was involved in this process and why were they involved? • What were the differences between the forward translations? • How were differences resolved? • Did the developer agree with the conceptual equivalence of Version 1? 		
5	<p>If no back translation was made was Version 1 approved as the Target Version for pilot testing and is this decision well justified?</p>		
6	<p>If one or more back translations were made is there detailed information about the back translators including:</p> <ul style="list-style-type: none"> • how the translators were selected • their native language and culture • time and experience in both cultures • level of education • Familiarity with the HRQOL concepts to be translated? 		



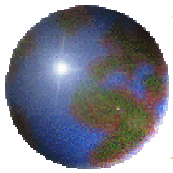
Checklist: Proposal

Item	Description	Yes/No	Comments
7	<p>Is there detailed information about the back translation process including:</p> <ul style="list-style-type: none"> • How many back translations were made? • Did the translators work independently or as a team? Why or why not? • How were the translators instructed? 		
8	<p>Is there detailed information about how the back translations were analyzed and how Version 1 of the forward translation was revised to produce Version 2? The information must include:</p> <ul style="list-style-type: none"> • Who was involved in this process and why? • What were the differences between the translations and how were they resolved? • Can all of the items be adequately translated? 		
9	<p>Was Version 2 approved as the Target Version for pilot testing and is this decision well justified? Did the developer agree with the conceptual equivalence of Version 2?</p>		
10	<p>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.</p> <p>Is this testing process well described including:</p> <ul style="list-style-type: none"> • number of subjects, • information about the subjects that demonstrates that they belong to the target population • instructions to the subjects • debriefing: in-depth face-to-face structured interviews, panel discussion or other, and who was involved • how the subjects understood each of the items in the instrument. • problems and other points of discussion encountered by the subjects • developers recommendations • resulting modifications of the target version of the instrument 		<p>Proposal: Test on sample of subjects living in the target country</p> <p>To be mandatory</p>
11	<p>International Harmonisation (IH)</p> <p>Was this process necessary? If Yes, is this process well described including:</p> <ul style="list-style-type: none"> • number of countries involved • who was involved in the process? • What were the differences between countries and how were they resolved? • Resulting modifications of the target versions of the instrument 		<p>If several countries involved, IH has proven to be a useful Quality Control Step</p>



Conclusion

The idea is to promote a collaboration effort between all parties involved:
ERIQA, Regulators, Pharmaceutical Companies, Researchers, ISPOR QOL Special Interest Group



Thank You!

