

The Cross-Cultural Analysis (CCA) Project



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**on behalf of the EORTC and the Quality of Life
Cross-Cultural Meta-Analysis Group**

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Datasets received

Type of study	No. of studies	No. of patients
EORTC studies	54	13,144
Other studies	71	26,268
Total	125	39,412



Amount of data available by translation

German	9,434	Italian	876
English	6,242	Korean	501
Norwegian	4,873	Polish	420
Dutch	4,557	Chinese (Taiwan)	345
French	3,210	Turkish	255
Danish	2,543	Farsi	167
Sinhala	1,282	Greek	124
Swedish	1,230	Russian	119
Spanish	982	French (Canada)	110
Chinese(Mandarin)	933	Hungarian	104



Uses of the CCA project data

- 1. Update of Reference Values Manual**
- 2. Assessment of the cross-cultural validity of the EORTC QLQ-C30**
- 3. Investigation of the factor structure of the EORTC QLQ-C30**



Reference Values Manual

- **EORTC QLQ-C30 Reference Values Manual (previously published in 1998) updated using CCA project data**
- **Changes made to format after input from QLG**
- **Reference data for 132 subgroups (old manual had 30)**



Reference Values format (1)

- **If have sufficient data (>100 respondents) data for the following subgroups presented per cancer site:**
 1. **All patients**
 2. **Stage I-II**
 3. **Stage III-IV**
 4. **Recurrent/metastatic**
 5. **Age <50**
 6. **Age 50-59**
 7. **Age 60-69**
 8. **Age \geq 70**
 9. **Males**
 10. **Females**



Reference Values format (2)

- **Three pages for each subgroup:**
 - 1.Characteristics of sample/ scale summary**
 - 2.Tabulation of QLQ-C30 scales**
 - 3.Tabulation of QLQ-C30 items**



Reference Values format (3)

- **Graphs only for overall sample split by gender, age and stage category**
- **Module data are included (breast, head and neck, lung, oesophageal, ovarian), presented separately by age group, stage and gender**



Assessment of cross-cultural validity of the QLQ-C30

- **1) Cross-cultural construct bias**
 - Regression analyses
- **2) Cross-cultural item bias**
 - Differential item functioning (DIF) analyses
 - Interviews with bilingual people
- **3) Response category translation bias**
- **4) Extreme response bias**
 - Item response theory (IRT)



Differential Item Functioning (DIF) Analyses

- **Used to identify whether an item in a scale of the QLQ-C30 functions differently with respect to:**
 - 1. Translation used**
 - 2. Cultural/geographical grouping**
- **relative to other items in the same scale**
- **Parallel interviews with bilingual people used to distinguish linguistic/cultural response patterns**



Results of DIF analyses by translation and cultural group

- **Analyses found some response differences by both translation and cultural group**
- **Pattern of results suggested most response differences were more likely to be caused by translation issues, not culture**



Computer simulations

- **DIF analyses originated in educational settings where there are typically 40 items per test**
 - **QLQ-C30 has just 2-5 items per scale**
 - **Items often have floor/ceiling effects**
 - **Computer simulations conducted to assess performance of DIF analyses applied to QoL instruments**
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Simulation results

- **Use of DIF analyses for short scales results in only slightly lower power than longer scales**
- **Estimated sample size requirements which will inform future DIF studies**



Literature review of DIF analyses applied to QoL scales

- **Choice of statistical method**
- **Criteria for statistical significance**
- **Distinguishing different sources of DIF**
- **Investigation of translation DIF**



Publications

- **Translation DIF analyses**
 - Quality of Life Research 2006;15:1103-1115
- **Cultural DIF analyses**
 - Quality of Life Research 2007;16:115-129
- **Scale-level cultural analyses**
 - Journal of Clinical Epidemiology 2007 (in press)
- **Performance of DIF analyses in short scales (simulations)**
 - About to submit to Quality of Life Research
- **Review of DIF applied to QoL settings**
 - Drafted



Future work of CCA project

1. DIF analyses of change in QoL
2. Practical impact of DIF analyses
3. Translation of response categories



DIF analyses of change in QoL

- **Previous analyses have examined baseline QoL only**
- **Additional DIF analyses will examine change in QoL from baseline to on treatment and off treatment**
- **This reflects common analysis approach of QoL data in clinical trials**



What is the practical impact of the DIF analyses?

- **Examine scenarios to assess the practical impact of DIF analyses on clinical trials**
- **Work so far suggests this corresponds to a small but clinically important difference**



Assessment of response category translations in QLQ-C30

- The following response categories occur in 28 of 30 items of the EORTC QLQ-C30 (and also in modules):
 - Not at all
 - A little
 - Quite a bit
 - Very much
- Lack of translation equivalence has the potential to bias results of all items



Mean scores (0-100 Visual Analogue Scale)

English (n=58)

German (n=4)

Not at all	1.7	Überhaupt nicht	0.3
A little	24.0	Wenig	16.5
Quite a bit	62.0	Mässig	49.3
Very much	91.1	Sehr	93.5



Assessment of response category translation

- **New analyses to determine evidence of differences in translation of response categories**
- **Item response theory approach**
- **Possible student(?) to collect more data from bilingual people in parallel with statistical analyses**



Assessment of extreme response bias

- **Substantial evidence in literature that those from certain cultures (e.g. East Asia) may be less likely to choose extreme categories on rating scales**
- **Aim to assess this effect using CCA data**



Contributors (1)

- We acknowledge the support of EORTC groups (contributed 54 studies)
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