EORTC QUALITY OF LIFE GROUP

TRANSLATION PROCEDURE

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Second Edition

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INTRODUCTION

A. AIM

The aim of this procedure is to produce translations of questionnaires which are:

1. Clear i.e. able to be read and understood;
2. Expressed in language in common use;
3. Conceptually equivalent to the original.

N.B. It is not the purpose of the translation procedure to modify the original questionnaire.

B. SUMMARY OF PROCEDURE

Introduction

The translation procedures described apply to the translation of any document for the EORTC Quality of Life (QL) Group. In practice this will most often involve the translation of the EORTC QLQ-C30 and modules. Accordingly, for simplicity, these guidelines refer specifically to the example of translating questionnaires.

The aim of the EORTC QL Group is always to secure good quality translations of its instruments to meet the above criteria. The QLQ-C30 is now available in 43 languages and several disease-specific modules already exist in multiple translations. Where an approved translation already exists this should normally be adopted. However, existing translations may on occasion require revision or refinement for subsequent use e.g. to produce gender-specific translations. Translations may be needed for use in countries where a variant of the parent language is spoken e.g. Spanish as spoken in Argentina or Mexico Vs Castilian Spanish. The original translation guidelines (Cull et al, 1994) have therefore been updated in the light of experience to introduce greater flexibility for dealing with such varying requirements efficiently while maintaining the quality controls required for EORTC approved translations.

Translation of EORTC instruments should not be initiated without first checking with the EORTC QL Unit and/or the principal author of the questionnaire, whether the required translation is already available or in preparation. This is to avoid redundancy of effort. The need for revision of an existing translation should first be discussed with the QL Unit (for QLQ-C30, phase III & IV modules) or the principal author (for phase I & II modules). Contact information is provided in Appendix I. The questions to be asked are listed in the preparatory checklist in Appendix II.

Instructions and/or Response categories of questionnaires

Where an approved translation of the instructions and/or response categories for a questionnaire already exists in the language required these do not need to be translated again
except in exceptional circumstances i.e. unless the need for a substantial improvement in the translation has been agreed with the principal author of the instrument. The existing translation of instructions and response categories should normally be adopted.

**Uniformity of wording across modules**

The EORTC Guidelines for Module Development (Blazebly et al, September, 3rd edition, p6) require that those who are developing new modules should consult existing EORTC modules before devising new items. If items are adopted from pre-existing EORTC modules the original wording of those items should normally be adhered to. It follows from this that the existing translations of those items should also be adopted. The aim is to ensure uniformity of wording for the same item across different modules in all translations. This can be easily achieved by consulting the EORTC Item Bank. The Item Bank is a database of more than 6,000 translations of items from the EORTC measurement system. Detailed instructions for its use can be found in the EORTC Item Bank Guidelines (Vachelec, et al 2001) available from the QL Unit.

If however, the module developer feels that the existing translation can be substantially improved and/or requires revision for the context of the new module then the standard translation procedure should be adopted. The resulting translation should be discussed with the coordinator of the translation of the original module. Coordinators of other modules, which incorporate the same item(s), should be included in the discussion. Where possible consensus should be achieved about the ‘best’ translation which should then be incorporated in all the relevant modules. Relevant contact information is provided in Appendix I.

**NOTE: - IT IS THEREFORE IMPORTANT TO CHECK WHETHER, AND IF SO, HOW MUCH OF A QUESTIONNAIRE IS TO BE TRANSLATED BEFORE EMBARKING ON THE TRANSLATION PROCESS.**

**Translation procedures**

For all translations the translator(s) should be a native speaker of the language into which the questionnaire is being translated, with a high level of fluency in the other relevant language. The translation back to the original language (usually English) should be undertaken independent of the forward translation i.e. by a different translator, independent of the first, who should be a native speaker of that language and fluent in the language from which the questionnaire is being backtranslated.

a. **For questionnaires originating in English e.g. EORTC QLQ-C30**

Generally EORTC questionnaires are held in English and it is from the approved English version that all other translations are derived. The translation process begins with forward translation into the required language, followed by translation back into English. This process is repeated until a satisfactory translation is obtained (See Section I & Appendix III.1).

b. **For questionnaires originating in any other language**

The process begins with translation into English. The English version is then translated back into the language of origin and the process repeated until a good English translation is obtained. Particular care should be taken in developing the English translation since this is
the version of the questionnaire from which all other translations are derived. A report on the
English translation and the procedure by which it was derived should have been approved
before the English version is used as the basis for subsequent translations (See Section II and
Appendix III.2).

c. Translation/cultural adaptation for a language spoken in several countries

Ideally, separate translations from the English original, following the full forward-backward
procedure, should be prepared for each country in which the language is spoken. If this is
impractical, a translation prepared for use in one country may be culturally adapted and pilot-
tested in another country in which (a variant of) that language is spoken. In that case it is
particularly important that the pilot-testing should be rigorous and fully documented (See
Section III and IV).

Pilot-testing

All translations must be pilot-tested. Unsatisfactory translations should be revised and re-
tested (See Section IV and Appendix IV).

Preparation and submission of translation reports

Each stage of the translation process should be documented and a report submitted to the
principal author of the questionnaire (See Section V). Reports on the translation of the
EORTC QLQ-C30 and on Phase III & IV modules should be sent to the Translation
Coordinator, QL Unit. Reports on the translation of all other modules should be sent to the
principal author of the module. The process may be completed more efficiently if the report is
submitted in 2 parts: (i) The report of the translation procedure can be reviewed before pilot-
testing to allow any translation difficulties to be resolved as far as possible before pilot work is
undertaken. (ii) The full report of the pilot-testing procedure and results must be passed by
peer review before the translation can be finally approved.

Peer review and formal approval of translations

The QL Unit’s Translation Coordinator or the principal author of the questionnaire
independently reviews translation reports. In the event of doubt or difficulty about the
procedures employed they may appoint up to 2 members of the EORTC QL Group to provide
additional independent reviews. Formal acceptance of translations i.e. as approved by the
EORTC QL Group, will depend on the recommended translation procedures having been
employed and/or any deviations from the protocol (and the reasons for the deviations) being
approved by these reviewers. Approved translations of EORTC questionnaires are the
property of the EORTC Quality of Life Group and are protected by its copyright.

Reference:

Blazeby J, Sprangers M, Cull A, Groenvold M, Bottomley A. EORTC Quality of Life
Group: Guidelines for Developing Questionnaire Modules. 3rd Edition September
C. ORGANISATION

EORTC QLQ-C30:

Approved translations are distributed only through the EORTC QL Unit at the EORTC Data Center in Brussels subject to the standard conditions governing dissemination of the QLQ-C30. Users must check with the EORTC QL Unit before embarking on any translation of the EORTC QLQ-C30. Overall responsibility for overseeing translations of the EORTC QLQ-C30 rests with the Translation Coordinator, QL Unit on behalf of the Group.

If, after checking with the QL Unit, it has been established that no translation exists (nor is in preparation) in the required language, the EORTC QLQ-C30 should be translated in its entirety, i.e. instructions, questionnaire items and response categories. This can be organised by the QL Unit. Use of this translation (EORTC QLQ-C30) is subject to the same conditions with respect to copyright and licensing as all other translations of EORTC QLQ-C30.

Modules:

Overall responsibility for overseeing translations rests with the principal author of the module on behalf of the Group. Individuals wishing to translate an EORTC module from English into language X will need to ascertain whether the module or any of its constituent parts i.e. instructions, questionnaire items, response categories already exist in translation in language X (NB response categories/instructions are likely to overlap with EORTC QLQ-C30 as well as pre-existing modules)

- Where available, pre-existing translations of the instructions and response categories in language X should be used unless there are good reasons for believing these need to be revised. This should be discussed with the principal author of the module and/or Translation Coordinator, QL Unit (where the translations of the instructions/response categories of the QLQ-C30 are in question).

- Where the module includes items from other modules, which have already been translated into language X the pre-existing translations of those items, should be used unless there are good reasons for seeking a new translation of them. The case for a new translation should be discussed with the Module Development Committee.

These steps are important to determining how much of the module will require to be translated.

Approved translations are the property of the EORTC Quality of Life Group and protected by its copyright. Rules for the dissemination and use of translations of modules are laid out in the Guidelines for Module Development (Blazeby et al, 2001). These rules vary with the stage of development of the module. Phase III modules are distributed on behalf of the module developer by the QL Unit. Phase IV modules, which have demonstrated satisfactory psychometric properties on international field testing are subject to the same user’s agreement as the EORTC QLQ-C30, are also distributed through the EORTC QL Unit of the EORTC Data Center in Brussels. The conditions for using Phase I & II modules, which are distributed by the principal authors of the module, are reproduced in Appendix V.
Individuals involved in the translation process must respect the EORTC copyright.
SECTION I: TRANSLATION PROCEDURE FROM ENGLISH

A. FORWARD TRANSLATION (ENGLISH -> LANGUAGE X)

1. When it has been established whether all of the questionnaire or only some items require to be translated, two translators, native speakers of the language of translation (X) who have a high level of fluency in English, will be required. It should be considered from the outset whether language X will require separate forms to be used for male and female respondents and this should be specified in the report.

2. The two translators should independently translate the questionnaire into the required language (X).

3. The person responsible for coordinating the translation process should then compare the translations.
   a) Where there is agreement, the translation can be accepted for the provisional forward translation
   b) Where there are differences, the coordinator of the translation process should aim to resolve these by discussion with the translators to yield a provisional forward translation.
   c) Where disagreement is difficult to resolve on a few items, alternative wording may be offered in the provisional forward translation (for resolution through the back translation process).
   d) In the case of multiple or fundamental disagreements, a third independent translator may be invited to arbitrate. This third translator should independently translate the problem sections of the questionnaire before being included in the discussion. The disagreement may be resolved by discussion with the translators or by proposing alternative wording for the back translation (as in c. above).

4. The process should be documented. The coordinator should record the stance of each translator in sufficient detail to explain any difficulties encountered and the rationale for the solutions reached. Copies of all interim forward and back translations should be kept for inclusion in the translation report.

5. This process results in a single provisional forward translation (which may offer alternative wording for some items).

The provisional forward translation is then ready for back translation.
B. BACK TRANSLATION (LANGUAGE X -> ENGLISH)

1. Two translators, native English speakers with a high level of fluency in language X, will be required.

2. The translators should independently translate the relevant sections (of the questionnaire) from the provisional forward translation back into English i.e. without reference to the English original.

3. The person coordinating the translation process should compare the English translations with the original questionnaire.

   a) Where there is agreement between a translation and the original those sections of the provisional forward translation may be considered semi-final, i.e. ready for pilot-testing.

   b) Where there are differences the coordinator should attempt to resolve these by discussion with the translators. Where agreement can be reached the relevant sections of the provisional translation may then be regarded as semi-final i.e. ready for pilot-testing.

   c) Where agreement still cannot be reached the provisional forward translation may require revision. Revisions may be arrived at by repeating the forward-backward translation process (if necessary incorporating an additional independent translator) until the back translation is sufficiently similar to the original questionnaire.

   d) In the case of persistent difficulty alternative wording of the item(s) in question may be incorporated in the provisional translation used in pilot-testing. The interview used in the pilot-test would then incorporate questions designed to identify the wording which best meets the aims of the translation process (i.e. clear; language of common use; conceptual equivalence to original).

4. The process should be documented. The coordinator should record the stance of each translator in sufficient detail to explain any difficulties encountered and the rationale for the solutions reached. Copies of all interim forward and backward translations as well as the provisional forward translation (which will be used in pilot-testing) and its back translation, should be clearly marked for identification purposes and kept for inclusion in the translation report.

The provisional forward translation can then proceed to pilot-testing.
A. FORWARD TRANSLATION (LANGUAGE X -> ENGLISH)

1. When it has been established whether the entire questionnaire or only some items require to be translated, two translators, native English speakers with a high level of fluency in the relevant language (X), will be required. It should be considered from the outset whether language X will require separate forms for male and female respondents and this should be specified in the report.

2. The two translators should independently translate the relevant sections of the original questionnaire into English.

3. The person responsible for coordinating the process should compare the two translations.
   a) Where there is agreement the translation can be accepted as the provisional English translation.
   b) Where there are differences the coordinator should aim to resolve these by discussion with the translators to yield to a single provisional English translation.
   c) Where disagreement is difficult to resolve on a few items, alternative forms may be offered in the English version (for resolution in the back translation process).
   d) In the case of multiple or fundamental disagreement, a third independent translator may be invited to arbitrate. The third translator should independently translate the problem sections of the document before being included in the discussion.

4. The process should be documented. The coordinators should record the stance of each translator in sufficient detail to explain any difficulties encountered and the rationale for the solutions reached. Copies of all interim forward and back translations should be kept for inclusion in the translation report.

5. This process results in a single provisional forward translation (which may offer alternative wording for some items).

This process results in a provisional English translation ready to be translated back to the original language.
B: BACK TRANSLATION (ENGLISH -> LANGUAGE X)

1. Two translators, native speakers of the language of translation (X) with a high level of fluency in English, will be required.

2. The translators should independently translate the relevant sections (of the questionnaire) from the provisional English translation back into language X, i.e. without reference to the original questionnaire.

3. The person coordinating the translation process should now compare the translations with the original questionnaire.
   a) Where there is agreement between the back translation and the original questionnaire, that section of the English translation may be considered semi-final, i.e. ready for pilot-testing.
   b) Where there are differences the coordinator should attempt to resolve them by discussion. Where agreement can be reached the relevant agreed sections of the provisional English translation can be regarded a semi-final, i.e. ready for pilot-testing.
   c) Where agreement still cannot be reached, the provisional English translation may need to be revised. Revisions are arrived at by repeating the backward-forward translation (original in X -> English -> X) if necessary incorporating an additional independent translator, until the back translation is sufficiently similar to the original document.
   d) In the case of persistent difficulty alternative wording of the item(s) in question may be incorporated in the provisional English translation used in pilot-testing. The interview used in the pilot-test would then incorporate questions designed to identify the wording which best meets the aims of the translation process (i.e. clear; language in common use; conceptually equivalent to original).
   e) This process should be documented. The coordinator should record the stance of each translator in sufficient detail to explain any difficulties encountered and the rationale for the solutions reached. Copies of all interim forward and backward translations as well as the provisional English translation and its back translation, should be clearly labelled for inclusion in the translation report.

The provisional English translation can then proceed to pilot-testing.
SECTION III: CULTURAL ADAPTATION

These procedures apply when the questionnaire is already available in translation in the mother language (e.g. German for Germany; Spanish for Spain) and is required for use in another country where this language (or a variant of it) is spoken (e.g. German for Austria; Spanish for Mexico).

NB Cultural adaptation procedures should also be followed when English language versions of instruments are intended for use in countries other than the UK.

1. Two translators, native speakers of the required language, (e.g. Austrian German; Mexican Spanish) will be required.

2. The two translators should independently review the questionnaire in the mother language (e.g. German; Spanish) to identify any item not expressed in the language in common use in their country (e.g. Austria; Mexico). The translators should suggest modifications. Their proposals and their justifications should be documented.

3. The person responsible for coordinating the process should compare the two “translations”.
   a) Where there is agreement that the mother language is acceptable those items may be accepted for the provisional translation.
   b) Where there are differences the coordinator should aim to resolve these by discussion with the translators to yield a single provisional translation.
   c) Where disagreement is difficult to resolve on one or two items alternative wording may be offered in the provisional translation.

4. Where modifications to the mother language have been proposed these items should be back-translated by an independent translator who is fluent both in the mother language and the language of translation.
   a) Where there is agreement between the back translation and the mother language then these items may be considered semi-final, i.e. ready for pilot-testing.
   b) Where there are differences the coordinator should attempt to resolve these by discussion. Where agreement can be reached these items may be regarded as semi-final, i.e. ready for pilot-testing.
   c) Where agreement cannot be reached the adequacy of the translation of those items in the mother language should be checked with the principal author of the questionnaire. If the version of the questionnaire in the mother tongue was unsatisfactory some revision (through the standard translation procedure) may be indicated. If the translation in the mother language has proved satisfactory and difficulties in agreeing a single version of item(s) in the required language persist then alternative wording may be offered to patients on pilot-testing.
5. The cultural adaptation process should be fully documented. The coordinator should record the stance of each translator in sufficient detail to explain any difficulties encountered and the rationale for the solution reached. Copies of all interim forward and backward translations should be included in the translation report.

6. The culturally adapted version of the questionnaire, which emerges from this process, should be rigorously pilot-tested in its entirety in the country in which it is to be used. (see Section IV).
SECTION IV: PILOT-TESTING

Each translated item should be pilot-tested on between 10 and 15 patients before being field-tested on a larger sample. (See Guidelines for Module Development, Sections 4.3 and 5.2).

**Note:** where items that pertain to a subsample of patients (e.g. men or women) the total sample size for pilot-testing will have to be increased to include adequate numbers of respondents to represent these subsamples.

It is essential that pilot-testing should be carried out on patients who are adequately representative of those for whom the questionnaire was designed in terms of their sociodemographic (sex, age and education) and clinical characteristics. They should also be native speakers of the language of the translation.

The aim is to identify and solve any potential problems in translation (e.g. wording which is confusing or difficult to understand). The objective of pilot-testing is not to change the wording of the original item but to express it clearly in the language of translation.

**Pilot-testing consists of:**

1. Administering the translated questionnaire to 10-15 patients belonging to the target population, and afterwards;

2. Conducting structured interviews with each patient individually (or as a focus group interview).

**The structured interview**

The interview should be directed to each module item separately to determine whether the wording used made any of the translated items:

a) Difficult to answer;

b) Confusing;

c) Difficult to understand;

d) Upsetting/offensive and/or

e) Whether the patient would have asked the question in a different way.

An example of the interview protocol is given in Appendix IV. On the basis of the interview the provisional translation may require adaptation.

When patients report finding an item problematic and/or where they suggest the item would be improved by alternative wording (see structured interview, Appendix IV), this item should be recorded on the patient response sheet (1) together with the patient’s comments on the nature of the difficulty with the item. For ease of administration there is no need to complete this form for items which the patient found acceptable. The record of the interview therefore consists of a list of the problem items with the comments evoked and the patient’s suggestions for improved wording.

This information can be summarised on a sheet of the questionnaire (2). There is no need to file sheets for items which attracted no adverse comment on pilot-testing. For those items
which did cause problems all the associated comments/suggestions can then be drawn together for communication in the report.
SECTION V: REPORTING AND REVIEW PROCEDURES

A. THE TRANSLATION REPORT

The report should be written in English and will consist of 2 sections concerning the translation process and the results of pilot-testing which may be reviewed separately or together. Examples of approved reports may be obtained on request from the QL Unit. Those new to the translation process may find it helpful to have the translation process reviewed before proceeding to pilot-testing.

1. The Translation Process

The report should include:

   a) All forward and backward translations. It is very important for the review process that the final version of both the forward and the backward translation should be included and clearly labelled in the report.

   b) Any key memoranda relevant to the process, i.e. relating to how decisions were made regarding any difficulties/disagreements; justification of deviations. For example a literal translation may not be possible in a certain language. If this is the case this should be explained with the rationale for choosing a particular translation as closest to the original.

   c) Information about the qualifications of the translators.

2. Pilot-testing

The report should include:

   a) An account of the procedure followed, including the characteristics of the sample, and details of any deviation from the standard interview

   b) Qualitative and quantitative data from the pilot-testing to justify the final translation. (See Appendix IV)

B. REVIEW PROCEDURE

Reports of the translation process and pilot-testing of EORTC QLQ-C30, Phase IV and Phase III modules should be sent to Translation Coordinator, QL Unit, to be reviewed. Where the Translation Coordinator has concerns about the translations these may be discussed with the Chair of the Module Development Committee.

Reports of the translation process and pilot-testing for phase I and II modules, should be sent to the principal author of the module for review. Where there has been a deviation from standard procedures and/or where the reviewer has doubts or difficulties about the translation arrived at, these may be discussed with the Chair of the Module Development Committee.
Committee who may recommend that the report of the translation process be independently reviewed.

It is recommended that the translation process be reviewed before pilot-testing is undertaken.

The reviewer of the translation process is responsible for checking that appropriate procedures have been followed:

a) in the case of items which overlap across modules

b) to resolve difficulty in the translation of new items.

The reviewer will be responsible for recommending action to be taken, e.g. further translation, or inclusion of additional questions for use in pilot-testing, to resolve any difficulties or shortcomings identified in the translation report.

It is intended that this review process be sufficiently rigorous to assure the quality of the translations resulting from this process without being unduly bureaucratic. The aim at this stage is to resolve any obvious difficulties before time and effort is invested in pilot-testing. In particular the two step process may be of help to inexperienced module developers.

The full report, i.e. of the translation process and the results of pilot-testing should be submitted to Translation Coordinator, QL Unit for EORTC QLQ-C30 for Phase III and Phase IV modules or for Phase I and II, to the principal author of the module. That person will then contact a nominated EORTC QL Group Member who was not involved in the translation process to review the full report. Wherever possible the reviewer should be fluent in the language of translation.

The purpose of this review is to confirm that satisfactory procedures were followed and to ensure that the provisional translation was adequately tested and found to be appropriate for use in the target population. Where translation reports are not approved the reviewer is responsible for giving specific recommendations about the steps to be taken to remedy this.
APPENDICES
Appendix I: Names and Contact Information

1. **EORTC QL Unit**
   Dr Andrew Bottomley/Ms Karen West, Translation Coordinator, EORTC Data Center, Quality of Life Unit, Avenue E Mounier 83, Bte 11, 1200 Brussels, Belgium.
   Tel: +32 2 774.1667; Fax: +32 2 779.4568; e-mail kwe@eortc.be

2. **Chair of Module Development Committee**
   Dr. Jane Blazeby, Dept. of Surgery, Level 7, Bristol Royal Infirmary, Marlborough St. Bristol BS2 8HW, United Kingdom.
   Tel: +44.1179.230.000 or Fax: +44.1179.252.736, e-mail: j.m.blazeby@bristol.ac.uk

3. **Principal authors of existing modules**

   **Anorexia and Cachexia Module - Phase I module:**
   Dr. Jane Blazeby, Dept. of Surgery, Level 7, Bristol Royal Infirmary, Marlborough St. Bristol BS2 8HW, United Kingdom.
   Tel: +44.1179.230.000 or Fax: +44.1179.252.736, e-mail: j.m.blazeby@bristol.ac.uk

   **Bladder Cancer Module (Superficial and Muscle Invasive) - Phase III module:**

   **Brain Cancer Module - Phase III module:**
   Contact the EORTC QL Unit in the first instance.
   Dr David Osoba, Quality of Life Consulting, 4939 Edendale Court, West Vancouver BC, Canada V7W 3H7.
   Tel: +1.604 921.7793; Fax: +1.604 921.7794; e-mail: david_osoba@telus.net.

   **Breast Cancer Module - Phase IV module:**
   Contact the EORTC QL Unit in the first instance.

   **Carcinoid Module - Phase III module:**
   Dr. John Ramage, North Hamptonshire Hospital, Aldermaston Road, Basingstoke, Hampshire RG24 9NA, United Kingdom
   Tel: 01256 313 637, Fax: 01256 313 634, e-mail johnramage1@compuserve.com

   **Chemotherapy Module - Phase I module:**
   Prof. Alexander de Graeff, Universitair Medisch Centrum - Academisch Ziekenhuis, Internal Med.-F.02.116, P.O. Box 85500, Heidelberglaan 100, 3508 GA Utrecht, The Netherlands
   Tel +31 30 2506308, Fax +31 30 2521779, e-mail a.graeff@digd.azu.nl

   **Choice and Decisions Module - Phase I module:**
   Mr. Martin Eisemann, Umea Universitet, Dept of Psychiatry, S-901 87 Umea, Sweden
   Tel +46 90 7856320, Fax +46 90 135324, e-mail martin.eisemann@psychiat.umu.se

   **Colorectal Cancer Module - Phase III module:**
   Contact the EORTC QL Unit in the first instance.
   Dr. Jane Blazeby, Dept. of Surgery, Level 7, Bristol Royal Infirmary, Marlborough St. Bristol BS2 8HW, United Kingdom.
   Tel: +44.1179.230.000 or Fax: +44.1179.252.736, e-mail: j.m.blazeby@bristol.ac.uk
Fatigue Module - Phase I module:
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Tel + 49 761 2062220, Fax + 49 761 2062299, e-mail jowe@tumorbio.uni-freiburg.de

The Gastric Module - Phase III module:
Contact the EORTC QL Unit in the first instance.
Dr. Jane Blazeby, Dept. of Surgery, Level 7, Bristol Royal Infirmary, Marlborough St.
Bristol BS2 8HW, United Kingdom.
Tel: +44.1179.230.000 or Fax: +44.1179.252.736, e-mail: j.m.blazeby@bristol.ac.uk

Head and Neck Cancer Module - Phase IV module:
Contact the EORTC QL Unit in the first instance.

High Dose Chemotherapy Module - Phase III module:
Dr. Galina Velikova, ICRF Cancer Medicine Research Unit,
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Information Module - Phase III module:
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31008 Pamplona, Spain
Tel +34 948 422169, Fax +34 948 422303, e-mail jiarraras@correo.cop.es

The Chronic Lymphocytic Leukaemia - Phase III module:
Mrs. Shirley Crofts, Haematology Dept., Royal South Hants Hospital, Brintons Terrace
(off St. Mary’s Road), Southampton SO14 0YG, United Kingdom.
Tel: +44.2380.825.811 or Fax: +44.2380.823.338.

Liver Metastasis – Colorectal Module - Phase III module:
Dr. Jane Blazeby, Dept. of Surgery, Level 7, Bristol Royal Infirmary, Marlborough St.
Bristol BS2 8HW, United Kingdom.
Tel: +44.1179.230.000 or Fax: +44.1179.252.736, e-mail: j.m.blazeby@bristol.ac.uk

Liver – Hepatoma Module - Phase II module:
Dr. Jane Blazeby, Dept. of Surgery, Level 7, Bristol Royal Infirmary, Marlborough St.
Bristol BS2 8HW, United Kingdom.
Tel: +44.1179.230.000 or Fax: +44.1179.252.736, e-mail: j.m.blazeby@bristol.ac.uk

Lung Cancer Module - Phase IV module:
Contact the EORTC QL Unit in the first instance.

Myeloma Module - Phase III module:
Contact the EORTC QL Unit in the first instance.
Ms. Maxine Stead, Yorkshire Clinical Trials & Research Unit, Yorkshire Cancer
Tel: +44.113.292.4411, Fax: +44.113.292.4132, e-mail: mls@yco.leeds.ac.uk.

Oesophageal Cancer Module - Phase III module:
Contact the EORTC QL Unit in the first instance.
**Ophthalmic Module - Phase III module:**
Dr Yvonne Brandberg, Psychosocial Unit, Dept. of Oncology, Karolinska Hospital, 171 76 Stockholm, Sweden.
Tel: +46.872.92422 or Fax: +46.831.1585, e-mail: yvonne.brandberg@ce.ks.se,

**Ovarian Cancer Module - Phase III module:**
Contact the EORTC QL Unit in the first instance.

**Pancreatic Cancer Module - Phase III module:**
Contact the EORTC QL Unit in the first instance.
Dr. Deborah Fitzsimmons, University Surgical Unit (816), F Level Centre Block, Southampton General Hospital, Tremona Road, Southampton SO16 6YD, UK.
Tel: +44.1703.798860 or Fax: +44.1703.794020, e-mail: d.fitzsimmons@soton.ac.uk.

**Peripheral Neuropathy Module - Phase II module:**
Professor Neil Aaronson, Netherlands Cancer Institute, Department of Psychosocial Research and Epidemiology, Plesmanlaan 121, 1066 CX Amsterdam, The Netherlands, Tel: +31 20 512 2480; Fax: +31 20 617 2625; e-mail: naaron@nki.nl.

**Prostate cancer module - Phase III module:**
Contact the EORTC QL Unit in the first instance.

**Satisfaction with Care Module - Phase III module:**
Contact the EORTC QL Unit in the first instance.
Dr. Anne Brédart, Institut Curie, Psychiatry and Psycho-Oncology Unit, 26 rue d’Ulm, 75246 Paris Cedex 05, France.
Tel: +33.1.4432.4033, Fax: +33.1.4432.4017, e-mail: anne.bredart@curie.net.,
Appendix II : PREPARATORY CHECKLIST

For EORTC QLQ-C30, Phase III and Phase IV modules contact the QL Unit. For modules under development contact the principal author. Check the following:

1. Has the questionnaire been translated into the language you need and tested in the country you want to use it in?

   If Yes: Use the approved translation
   If No: Continue

2. Has the questionnaire been translated in the language you need but not yet pilot-tested in the country you want to use it in?

   If Yes: Do you want to use the translation in the mother country or another country where the same language is spoken?

   Mother country: contact principal author about status of pilot-testing. You may have to undertake this yourself, join an ongoing pilot-test or wait for their results.

   Another country: you will need to undertake a cultural adaptation (Section III) and pilot-test (Section IV)

   If No: Continue

3. Is there a translation in preparation in the language you require?

   If Yes: Do you want to use the translation in the mother country or another country where the same language is spoken.

   Mother country: contact principal author about status of translation/pilot-testing. You may have to undertake pilot-testing yourself, join an ongoing pilot-test or wait for their results.

   Another country: you will need to undertake a cultural adaptation (Section III) and pilot-test (Section IV)

   If No: Continue - you will now need to initiate translation of the questionnaire
4. Do the questionnaire’s instructions/response categories conform to QLQ-C30 or existing modules?

If Yes: Check with the QL Unit about availability of translations of EORTC QLQ-C30 and modules in language you require. Use existing translations of instructions/response categories where possible.

If No: Start from the English version of the questionnaire if available and use standard forward-backward translation procedures (Section I). If the questionnaire is only available in a language other than English it should first be translated into English using the standard procedure (Section II) and only then translated into the language you require (Section I).

5. Do any of the items of the questionnaire overlap with existing EORTC modules?

The EORTC QL Group has developed an Item Bank which is an efficient way of checking overlapping items. To consult the Item Bank please contact the Module Development Manager of the QL Unit.

If Yes: Having identified modules with areas of overlap contact the principal authors of those modules. Check the wording of those items in the English version is the same as the wording used in the questionnaire you are interested in. If so, check whether those identical overlapping items have already been translated into the language you want. Use existing translations where possible unless they are seriously flawed (this should be discussed with the authors of the modules with the overlapping items).

If No: Start from English version of the questionnaire if available and use standard forward-backward translation procedures (Section I). If the questionnaire is only available in a language other than English it should first be translated into English using the standard procedure (Section II) and only then into the language you require (Section I).
APPENDIX III: 1. PROCEDURE FOR ENGLISH QUESTIONNAIRES
Translation From English -> Language X

English original

IA Forward Translation

Provisional Forward Translation

± Additional Translator

IB Backward Translation

English Translation

Good Approximation to Original?

NO

YES

Semi-Final Forward Translation

Interim Report OK?

NO

YES

Pilot-Testing OK?

NO

Minor Revision to Pilot-Testing OK?

NO

YES

Report for Peer Review OK?

NO

Minor Revision to Report OK?

YES

Final Translation in X
© EORTC
Quality of Life Group
APPENDIX III: 2. PROCEDURE FOR QUESTIONNAIRES IN OTHER LANGUAGES
Translation From Language X -> English

Document in Language X

IIA Translate into English

Provisional English Translation

± Additional Translator

± Additional Translator

Translation in X Good Approximation of Original?

YES

Semi-Final English Translation

NO

Interim Report OK?

YES

Pilot-Testing OK?

NO

Minor Revision to Pilot-Testing OK?

NO

Report for Peer Review OK?

NO

Minor Revision to Report OK?

YES

Final Translation in English

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APPENDIX IV: PILOT-TESTING THE TRANSLATED MODULE

Example of the patients’ interviews

Instruction

This is a questionnaire that asks about you and your health. We know that this questionnaire is of value for patients who are ill.

The questionnaire has originally been devised in .......(fill in appropriate language) and is now translated in ...... (fill in appropriate language). We want to be sure that this translated questionnaire asks the right questions in the right way. For that purpose, we are now asking for your help.

I will ask you first to complete the questionnaire. After you have completed it, I will interview you to make sure we asked these questions in the proper way.

The Structured Interview

The interview should be directed to each module item separately. For example:

a. Did you have difficulty in replying to this question?
   (probe: can you tell me what you found difficult?)

b. Did you find this question confusing?
   (probe: can you tell me what you found confusing?)

c. Have words been used that you found difficult to understand?
   (probe: can you tell me which words you found difficult to understand?)

d. Did you find the way this question was worded to be upsetting or offensive in any way?
   (probe: can you tell me which words you found upsetting/offensive?)

e. How would you have asked the question?

When patients report finding an item difficult to respond to, confusing or difficult to understand, or where they suggest an alternative wording (see structured interview, Appendix II), this item should be recorded on the patient response sheet (1) together with the patient’s comments on the nature of the difficulty with the item. For ease of administration there is no need to complete this form for items which the patient found acceptable. The record of the interview therefore consists of a list of the problem items with the comments evoked.

This information can be summarised on a sheet of the questionnaire (2). There is no need to file sheets for items which attracted no adverse comment on pilot-testing. For those items which did cause problems all of the associated comments can then be drawn together for communication in the report.
**Pilot-testing : Sample of a patient response sheet**  
*completed by interviewer*

<table>
<thead>
<tr>
<th>Question number -----</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. Difficulty? Yes ☐</td>
<td></td>
</tr>
<tr>
<td>b. Confusing? Yes ☐</td>
<td></td>
</tr>
<tr>
<td>c. Difficult words? Yes ☐</td>
<td></td>
</tr>
<tr>
<td>d. Upsetting? Yes ☐</td>
<td></td>
</tr>
<tr>
<td>e. How would you ask this question?</td>
<td></td>
</tr>
</tbody>
</table>

**Question number --**

<table>
<thead>
<tr>
<th>Question number --</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. Difficulty? Yes ☐</td>
<td></td>
</tr>
<tr>
<td>b. Confusing? Yes ☐</td>
<td></td>
</tr>
<tr>
<td>c. Difficult words? Yes ☐</td>
<td></td>
</tr>
<tr>
<td>d. Upsetting? Yes ☐</td>
<td></td>
</tr>
<tr>
<td>e. How would you ask this question?</td>
<td></td>
</tr>
</tbody>
</table>
Pilot-testing: Summary of patient responses by item

(Total no. of patients interviewed = N)

Question number ----

<table>
<thead>
<tr>
<th>Number of patients answering Yes</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. Difficulty?</td>
<td></td>
</tr>
<tr>
<td>b. Confusing?</td>
<td></td>
</tr>
<tr>
<td>c. Difficult words?</td>
<td></td>
</tr>
<tr>
<td>d. Upsetting?</td>
<td></td>
</tr>
<tr>
<td>e. Alternative wording suggested by patients</td>
<td></td>
</tr>
</tbody>
</table>
APPENDIX V: RULES FOR USING EORTC MODULES UNDER DEVELOPMENT

Phase III modules are the property of the QL Group. They are not freely available but can be obtained via the principal investigators. If researchers wish to use Phase III modules they may do so only if:

1. They have received the explicit permission of the principal investigator.

2. They note that the module is designed to be used in conjunction with the EORTC QLQ-C30.

3. They leave the modules integrity intact and will not revise items. Additional items may be added at the end of the module.

4. They provide the first author with a copy of the module as used in the study and the study protocol, if requested to do so. When the study is finished they should report back to the first author.

5. They are willing to contribute to the psychometric/clinical validation of the module.

6. They respect the publication rights.

Publication rights of EORTC Modules

When researchers other than the module constructors use Phase III modules, then the following rules for publication apply:

1. The module itself may not be published by others than its constructors.

2. The module constructors should in principle have the right to publish their data first. If that is unfeasible, publications should be negotiated on a case by case basis.

3. Collaboration between the principal investigator of the module and its users is expected with respect to the scoring and scale structure of the module.

4. At least one constructor of the module should be a co-author on publications that include information on the psychometric performance of the module.