

EORTC QUALITY OF LIFE GROUP

TRANSLATION PROCEDURE

**Linda Dewolf, Michael Koller,
Galina Velikova, Colin Johnson, Neil Scott, Andrew Bottomley
on behalf of the EORTC Quality of Life Group**

March 2009
Third Edition

**EORTC Quality
of Life Group**



AISBL International Non-Profit Association under Belgian law IVZW

Copyright EORTC, Brussels, 1998, 2002, 2009
D/2009/6136/001
ISBN 978-2-930064-38-3

CONTENTS

EXECUTIVE SUMMARY	4
INTRODUCTION	6
A. AIM	6
B. UPDATE OF THE MANUAL	6
SECTION I: TRANSLATION PROCEDURE	7
A. ROLES AND RESPONSIBILITIES	7
B. PREPARATION	9
C. FORWARD TRANSLATIONS ENGLISH → LANGUAGE X (FWT)	9
D. RECONCILIATION OF THE TWO FORWARD TRANSLATIONS	10
E. BACKWARD TRANSLATIONS LANGUAGE X → ENGLISH (BWT)	10
F. PILOT-TESTING	11
SECTION II: CULTURAL ADAPTATION	13
SECTION III: REPORTING AND REVIEW PROCEDURES	14
A. THE TRANSLATION REPORT	14
B. REVIEW PROCEDURE OF THE REPORTS	15
C. ARCHIVING	15
SECTION IV: TRANSLATION QUALITY ASSESSMENT PROCESS	16
REFERENCES	18
APPENDICES	20
APPENDIX I: TRANSLATION PROCESS FLOWCHART	21
APPENDIX II: COMPUTERIZED DATABASES AND TOOLS	22
ITEM BANK	22
TRANSLATION MEMORY (TM)	22
APPENDIX III: PILOT-TESTING THE TRANSLATED MODULE	24
APPENDIX IV: TABLE OF AVAILABLE TRANSLATIONS	27

EXECUTIVE SUMMARY

The following guidelines were developed to provide guidance for investigators and/or organizations involved in translating EORTC Quality of Life Questionnaires (QLQ).

Translations must be undertaken in consultation with the Translation Coordinator at the EORTC Quality of Life Department (QLD). The EORTC Quality of Life Department should be contacted for permission to translate the core questionnaire or any of the modules. Only projects which have been logged onto the Translation Coordinator's project plan will receive approval from the Quality of Life Group.

Before translating the instrument or sending it out to be translated, the Translation Coordinator will pre-process the files by using two computerized tools, the Item Bank and the Translation Memory.

These files are then sent to the Project Manager (either an investigator or a staff member of a professional translation agency) who is in charge of overseeing the translation and pilot testing of a particular questionnaire. The Project Manager cooperates closely with and reports back to the Translation Coordinator at the QLD.

The questionnaire is translated from English into the target language. Two Forward-Translators, native speakers of the target language and fluent in English, provide translations independently.

Any disagreements are resolved via a reconciliation process, resulting in a single provisional forward translation. This translation is back-translated by two independent Backward-Translators (fluent in both, the target language and English, and different from the Forward-Translators) in order to ensure that the provisional forward translation is an adequate representation of the English original.

The forward translation is then ready for pilot-testing on 10 to 15 patients of the target population.

At each step, the Project Manager should record decisions and changes in a report. The whole translation procedure should be traceable through the appropriate documents. Documentation should include:

1. the two initial forward translations (FWT1, FWT2);
2. the reconciled version (FWT12);
3. the two backward translations (BWT1, BWT2);
4. the interim translation (before pilot testing);
5. an interim report before pilot testing;
6. the pilot testing and a report after pilot testing;
7. the final translation.

All these documents need to be sent to the Translation Coordinator who will review the report and store the documents in hard copy and in electronic form, for up to a maximum of twenty years to comply with ICH-GCP and FDA regulations on the conduct of good clinical trials.

The policy on cultural adaptations applies if a questionnaire is already available in a language (e.g. German for Germany; Spanish for Spain) and is required for use in another country where this language or a variant of this language is spoken. Cultural adaptations will be supported and approved by the EORTC QLD only if requesters provide evidence that an existing translation is insufficient and that a clinical study can be carried out only with a culturally appropriate version.

All efforts will be made in the questionnaire development and in the translation process to provide versions that are generic and applicable across different countries in which the target language is spoken.

The Translation Quality Assessment (TQA) Process becomes relevant once a questionnaire has been translated and made available to users. Its aim is to be responsive to and fix problems reported by users in a timely manner.

The translation work at the EORTC QLD is a dynamic and growing endeavour. The current list of existing translations can be viewed at the EORTC QLG website page <http://groups.eortc.be/qol/translations.htm>.

INTRODUCTION

A. AIM

The aim of this document is to outline translation procedures that generate translations which are:

1. Clear, i.e. written at an appropriate reading level for the target cancer population;
2. Expressed in language in common use;
3. Conceptually equivalent to the original.

The translation procedures described apply to the translation of the European Organization for Research and Treatment of Cancer Quality of Life Core Questionnaire (EORTC QLQ-C30) and its disease and symptom-specific modules. The translation methodology follows a rigorous iterative forward-backward format and strives to maintain the *conceptual, functional, linguistic and cultural equivalence* between the original questionnaire and the translated form (Brislin, 1970; Hambleton, 1993, 1994, 1999). The EORTC translation procedure is graphically summarized in Appendix I.

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

B. UPDATE OF THE MANUAL

This update is the third edition of the Translation Manual and is based on the previous version, the second edition (Cull et al., 2002). This update contains a reorganisation of the original text and numerous new elements, such as specifying roles and responsibilities, computerized translation support tools, reconciliation of competing translation attempts, scope of and limitations to cultural adaptations, reviewing procedures, the quality assessment process, and archiving.

SECTION I: TRANSLATION PROCEDURE

A. ROLES AND RESPONSIBILITIES

The following individuals and institutions are involved in the translation process. Their roles and responsibilities are laid out in the following table.

Roles	Responsibilities
Translation Coordinator (TC)	The TC at the QLD in Brussels is the initial person to contact for all individuals or organizations wishing to undertake a translation of the questionnaires. The TC is responsible for coordinating and overseeing compliance with the whole translation process. The TC monitors and keeps track of the translation requests, the status of each ongoing translation, and the deadlines. The TC is also the person to whom translation reports have to be sent.
Assistant to the Translation Coordinator	Person assisting the TC with administrative procedures. The Assistant to the TC provides the back-end support and the preparation of daily translation tasks such as file management (including file alignment, conversion transfer and updating in databases).
Requester/Sponsor	Individual or organisation (most likely pharmaceutical company) requesting and usually also financing the translation process.
Project Manager	Individual (can be an investigator or a translation agency staff member) managing a particular translation project, writes the translation report, coordinates the pilot testing and reports to the Translation Coordinator. During the module development phase, the Module Developer and the Chairman of the Module Development Committee can act as Project Manager (see Module Development Manual for further details).
Forward-Translator	Individual who is a native speaker of the target language who also has a very good command of English and medical terminology. Two independent forward translators are needed.
Backward-Translator	Individual who is a native English speaker and also has a very good command of the target language. Two independent translators are needed.

Roles	Responsibilities
Third Translator	Individual who is brought into the process in case no consensus can be found regarding the two forward translations
Translations Agency	Most translations are performed by professional translation agencies. These agencies are responsible for choosing Forward and Backward Translators and for reporting to the Translation Coordinator.
Translation Committee	Committee formed by members of the Quality of Life Group and chaired by a Chairperson elected for 3 years. The Committee meets bi-annually (during QLG meetings) to discuss translation issues and help the TC resolving these.

B. PREPARATION

The EORTC Quality of Life Department should be contacted for permission to translate the core questionnaire or any of the modules. Only projects which have been logged onto the Translation Coordinator's project plan and which follow the strict EORTC translation workflow (for an overview see Appendix I) will receive approval from the Quality of Life Group.

Before translating the instrument or sending it out to be translated, the Translation Coordinator will prepare the translation by:

- 1) Consulting the Item Bank
- 2) Pre-processing the files using the Translation Memory software.

(Both computerized tools are described in more detail in Appendix II).

Where an approved translation of the instructions and/or response categories for a questionnaire already exist in the language required, these do not need to be translated again. The existing translation of instructions and response categories should be adopted. If items are taken from existing modules, then the existing translations of these items need to be adopted.

C. FORWARD TRANSLATIONS ENGLISH → LANGUAGE X (FWT)

1. A distinction is made between the source language (which is English in the case of EORTC questionnaires) and the target language, i.e. the language into which a questionnaire is translated. When, on the basis of pre-processing, it has been established whether the entire questionnaire or only a selected number of items require to be translated, two translators, native speakers of the target language of translation (X) who have a high level of fluency in English, will be required.
2. The two translators should independently translate the questionnaire into the required target language (X).
3. The person responsible for coordinating the translation process (i.e., the Project Manager) should then compare the translations.

D. RECONCILIATION OF THE TWO FORWARD TRANSLATIONS

The first and the second translators' versions (FWT1 and FWT2) are merged into one single forward translation (FWT12) and this reconciliation process is coordinated by the Project Manager. The Project Manager discusses any problems identified in the provisional forward translations with the translators, and produces a reconciled version of the translations. The Project Manager may contact the EORTC Translation Coordinator to request additional guidance where needed.

The following reconciliation scenarios may appear in practice:

- a) Where there is *agreement* between the two forward translations, this translated version is accepted for further processing.
- b) Where there are *differences* between the two forward translations the Project Manager should attempt to resolve these by discussion with the translators. The aim is to come up with one single version which is accepted by the two Forward Translators and the Project Manager and is then ready for further processing.
- c) Where *disagreement* is difficult to resolve on a few items, alternative wording may be suggested in the provisional forward translation for resolution through the backward 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 into the discussion. The disagreement may be resolved by discussion with the translators or by proposing alternative wording for the backward translation.

E. BACKWARD TRANSLATIONS LANGUAGE X → ENGLISH (BWT)

1. Two translators, native English speakers with a high level of fluency in language X, will be required.
2. The translators should independently and without knowledge of the English original translate the relevant sections (of the questionnaire) from the provisional forward translation back into English.
3. The Project Manager should compare the English translations with the original questionnaire following a workflow that is consistent with the reconciliation process described under D.
 - 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 in common use; conceptual equivalence to original).

F. PILOT-TESTING

Each translated item should be pilot-tested on 10 to 15 patients before being field-tested on a larger sample. Where items 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 socio-demographic (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 focused on 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.

The template of the interview protocol is given in Appendix III. 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 III), this item should be recorded on the patient response sheet (Appendix III, 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 patients find acceptable. The record of the interview thus 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 form sheet (Appendix III, 2). There is no need to file sheets for items which attracted no adverse comments 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 II: CULTURAL ADAPTATION

Translation/cultural adaptation for a language spoken in several countries

The following procedures apply when the questionnaire is already available in the target 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).

All efforts are being made during the development of questionnaire modules to anticipate and, whenever possible, avoid potential translation and cultural adaptation problems. The group of researchers developing questionnaires is international, representing many different languages. This facilitates the choice of item content and wording for the source or parent (i.e., English-language) versions that can be relatively easily translated into other target languages, thus yielding translations that are acceptable to (ideally) all countries/regions in which a particular language is spoken. Furthermore, the Translation Coordinator will participate in module development sessions at the Quality of Life Group's biannual meetings and may provide input.

1. The English version of the core questionnaire, the EORTC QLQ-C30, should be regarded as a generic standard that can be used internationally - this means across English-speaking countries, including Australia, Canada, Ireland, the United States, Singapore, etc. In principle, no cultural adaptations of the English version of the questionnaire should be required.
2. Questionnaire modules (particularly Spanish, French or Chinese) may require cultural adaptation under restricted and very specific circumstances. The individual, pharmaceutical company or translation agency requesting a cultural adaptation should contact the Translation Coordinator of the EORTC QL Department in Brussels prior to undertaking such a cultural adaptation. The requester must provide convincing evidence that a cultural adaptation is necessary for a particular country, region or context. Specifically, the following evidence has to be presented (one or more):
 - a. Results of a pilot test of the current language version X questionnaire in the target country/region showing that a considerable percentage of respondents do not understand the meaning of specific items in that country/region;
 - b. Results of a survey of health care providers in country Y indicating that the standard translation of the questionnaire is not appropriate for denoting a particular symptom or health issues in that country;
 - c. A reference to an Academy (for example, *Real Academia de la Lengua Española*, *Nederlandse Taalunie*, *Académie française*), a dictionary or linguistic reference describing the inappropriateness of a particular word or phrase that would necessitate a cultural adaptation.
3. If the decision is made (involving the Translation Coordinator, the Module Development Chair and the Module Developer) that a cultural adaptation of a given module is justified on the basis of the presented evidence, the cultural adaptation should comply with the procedure spelled out in the Translation Procedure (see Section I – A to F).
4. Cultural adaptations created by third parties that do not follow this EORTC QLQ policy will not receive the Group's approval and should not be used.

SECTION III: REPORTING AND REVIEW PROCEDURES

A. THE TRANSLATION REPORT

The Project Manager is responsible for writing the translation report. The report should be written in English and should consist of two 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 Department.

The translation 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, particularly reconciliation regarding the forward translations and the comparison between backward translations and the English original. These descriptions should make clear how decisions were made in order to resolve discrepancies and how, in complicated cases, a particular translation was accepted that deviated in some way but came closest to the original.
- c) Information about the qualifications of the translators (ideally a short CV).

The pilot testing 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) The original pilot testing forms with handwritten legible comments by the interviewer. If the interviewer's comments are in a language other than English, then a summary of the comments in English is required.
- c) A summary of qualitative and quantitative data from the pilot-testing to justify the final translation.

B. REVIEW PROCEDURE OF THE REPORTS

The reports of the translation process and pilot-testing should be sent to the EORTC Quality of Life Department and are reviewed by the Translation Coordinator.

It is recommended that the translation process be reviewed before pilot-testing is undertaken (1st Report, see translation flow chart in Appendix I). After pilot-testing the second and final report have to be sent to the Translation Coordinator (2nd Report, Appendix I).

The whole translation procedure should be traceable through the appropriate documents. Documentation should include:

1. the two initial forward translations (FWT1, FWT2);
2. the reconciled version (FWT12);
3. the two backward translations (BWT1, BWT2);
4. the interim translation (before pilot testing);
5. an interim report before pilot testing;
6. the pilot testing and a report after pilot testing;
7. the final translation.

The purpose of this review procedure is to confirm that documentation is complete, 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 Translation Coordinator will give specific recommendations about the steps to be taken to remedy this.

C. ARCHIVING

All documents describing a translation process are to be stored in hard copy and in electronic form at the EORTC Quality of Life Department in Brussels. The Translation Coordinator is responsible for this. In compliance with ICH-GCP and FDA regulations on the conduct of good clinical trials, all documents will be stored for up to a maximum of 20 years and should be retrievable within 48 hours.

SECTION IV: TRANSLATION QUALITY ASSESSMENT PROCESS

The Translation Quality Assessment (TQA) Process becomes relevant once a questionnaire has been translated and made available to users (Appendix IV). The aims of this process are:

- to be responsive to problems (e.g., translation errors) that have been detected by users;
- to correct these problems in a timely manner;
- to systematically document problems encountered;
- and to report on problems at the biannual meetings of the Quality of Life Group.

Once a problem has been detected by a user, the following problem solving algorithm unfolds:

Step	Agent(s)	Action
0	User	Reports the problem.
1	Translation Coordinator (TC)	Logs the problem identified using a standardized form bearing the following information: <ul style="list-style-type: none"> - module/version - language - item - type of problem (punctuation, spelling, wording, style, mistranslation).
2	Translation Coordinator User	TC gets back to the person who identified the problem in order to clarify that the problem has been correctly identified. Particularly, in the case of “wording” or “style” issues the person who identified the problem has to specify whether the reported anomaly/proposed change is purely stylistic or that it may have serious consequences on how the patient will complete the questionnaire.
3	Translation Coordinator	TC makes a final assessment on whether the problem is minor/major. Examples of minor problems include wrong punctuation or misspelling. Major problems include the use of wrong terms or omissions, which seriously affect the meaning of the translation.

Step	Agent(s)	Action
4a	Translation Coordinator Module Developer Module Development Chair	<u>Minor problems</u> TC corrects the problem ad hoc and informs the Module Developer and the Module Development Chair. Both individuals should respond and indicate agreement with the change suggested.
4b	Translation Coordinator Module Developer Module Development Chair Translators Translation Agency	<u>Major problems</u> Modification process including all the individuals listed on the left. The original files should be checked in order to identify how the erroneous translation came into existence. An agreement should be reached about the best solution, most likely by obtaining a new translation for the item under question.
5	Translation Coordinator	To edit new version of questionnaire. Replace the old version by the new version in the EORTC questionnaire files. Send the new version to all current users of the questionnaire (in the case of major changes).
6	Translation Coordinator	Enters the whole process into the EORTC translation database.
7	Translation Coordinator	Reports regularly on TQA processes at the biannual QLG meetings.

The ultimate goal of the quality assessment process is to further improve the translation procedure.

THE CROSS-CULTURAL ANALYSIS PROJECT

The EORTC Quality of Life Group's Cross-Cultural Analysis (CCA) Project aims to explore the cross-cultural validity of the EORTC QLQ-C30 and to evaluate the item translations of the core questionnaire. A large database incorporating EORTC QLQ-C30 data from 125 separate studies was assembled and used to investigate the item response patterns for each translation of the questionnaire and for each cultural/geographic group. The results of statistical analyses using the method of differential item functioning (DIF) were compared with parallel interviews with bilingual people (Scott et al., 2006; Scott et al., 2007) and, based on these results, a number of item translations have been targeted for review. The project has also explored the relative contribution of the QL domains for each geographic group of respondents (Scott et al., 2008) and will also examine the translation of the four item response choices.

The CCA project can be regarded as a novel and empirical method in order to explore the quality of translations.

REFERENCES

Blazeby JM, Sprangers MAG, Cull A, Groenvold M, Bottomley A on behalf of the EORTC Quality of Life Group. *EORTC Quality of Life Group Guidelines for Developing Questionnaire Modules* (2nd edition). EORTC Quality of Life Group Publication, Brussels, August 2002. (ISBN2-930064-24-2)

Brislin RW. Back translation for cross-cultural research. *Journal of Cross-Cultural Psychology*, 1:185–216, 1970.

Cull A, Sprangers MAG, Bjordal K, Aaronson NK, West K and Bottomley A on behalf of the EORTC Quality of Life Group. *EORTC Quality of Life Group Translation Procedure* (2nd edition). EORTC Quality of Life Group Publication, Brussels, April 2002. (ISBN 2-930064-28-5)

Hambleton RK. Translating achievement tests for Use in cross-national studies *European Journal of Psychological Assessment*. 9: 57–65, 1993.

———, Guidelines for adapting educational and psychological tests: A progress report. *European Journal of Psychological Assessment*, 10: 229–44, 1994.

Hambleton RK, Patsula L. Increasing the validity of adapted tests: Myths to be avoided and guidelines for improving test adaptation practices. *Applied Testing Technology Journal*. 1: 1-16, 1999.

Koller M, Aaronson NK, Blazeby J, Bottomley A, Dewolf L, Fayers P, Johnson C, Ramage J, Scott N, West K, on behalf of the EORTC Quality of Life Group. Translation procedures for standardised quality of life questionnaires: The European Organisation for Research and Treatment of Cancer (EORTC) approach. *European Journal of Cancer*, 43: 1810-1820, 2007.

Scott NW, Fayers PM, Bottomley A, Aaronson NK, de Graeff A, Groenvold M, Koller M, Petersen MA, Sprangers MAG on behalf of the EORTC and the Quality of Life Cross-Cultural Meta-Analysis Group. Comparing translations of the EORTC QLQ-C30 using differential item functioning analysis. *Quality of Life Research*, 15: 1103-1115, 2006.

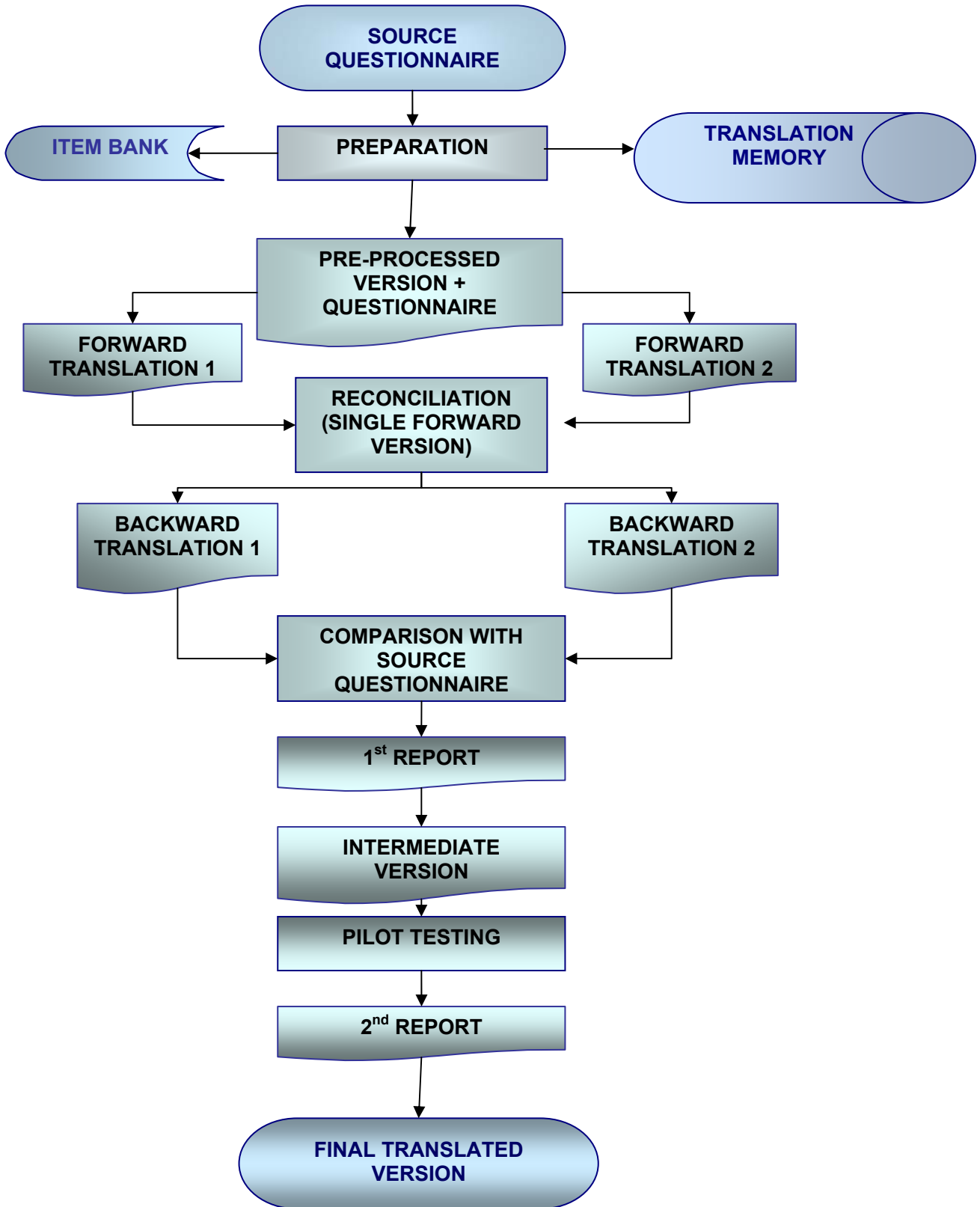
Scott NW, Fayers PM, Aaronson NK, Bottomley A, de Graeff A, Groenvold M, Koller M, Petersen MA, Sprangers MAG on behalf of the EORTC and the Quality of Life Cross-Cultural Meta-Analysis Group. The use of differential item functioning analyses to identify cultural differences in responses to the EORTC QLQ-C30. *Quality of Life Research*, 16:115-129, 2007.

Scott NW, Fayers PM, Aaronson NK, Bottomley A, de Graeff A, Groenvold M, Koller M, Petersen MA, Sprangers MAG on behalf of the EORTC Quality of Life Group and the Quality of Life Cross-Cultural Meta-Analysis Group. The relationship between overall quality of life and its subdimensions was influenced by culture: analysis of an international database. *Journal of Clinical Epidemiology*. 61: 788-795, 2008.

Vachalec S, Bjordal K, Bottomley A, Blazeby J, Flechtner H, Ruyskart P, *EORTC Item Bank Guidelines*. EORTC Quality of Life Group Publication, Brussels November 2001. (ISBN 2-930064-32-3)

APPENDICES

APPENDIX I: TRANSLATION PROCESS FLOWCHART



APPENDIX II: COMPUTERIZED DATABASES AND TOOLS

ITEM BANK

The Item Bank is a database of more than 6,000 translations of items from the EORTC questionnaires. Detailed instructions for its use can be found in the EORTC Item Bank Guidelines (Vachalec et al. 2001) available from the QL Department.

The aim of the Item Bank is to facilitate the development and use of the EORTC core questionnaire and modules in QOL research in clinical trials. More specifically:

- To store information about the development of module items, the wording and translations of the various items and subscales.
- To store information about results from pre-testing and field-testing including psychometric properties when available.
- To compare items and subscales in new modules with those that are already approved.
- To speed up item construction in phase II of the module development procedure.
- To act as a data bank for items to be used in ad hoc questionnaires in conjunction with an existing module for specific EORTC trials.

The Item Bank aims at improving the speed of translations by facilitating the reviewing of the items in a new module. When using existing translations for identical items from other modules, the translations are limited to new items that are not used in other modules.

TRANSLATION MEMORY (TM)

The TM is a database integrated into a Microsoft Word environment. The principle behind using a TM is to support translators by ensuring that items that have already been translated do not need to be translated again. Previous translations can be recycled and re-used for future translations, increasing efficiency and consistency across all translated questionnaires. Translators may be provided with pre-processed questionnaires containing items that have been previously translated for all above-mentioned languages where there are existing translations stored in the TM.

The EORTC Translation Memory is currently available in 10 languages and can support up to 100 languages.

An empirical test involving more than 1,300 items of the EORTC QLQ-C30 and of 16 disease-specific modules in Danish, Dutch, French, German, Italian, Japanese, Slovak, Norwegian, Spanish and Swedish suggests that average content reuse rates over 50% can be achieved.

The value of using a TM grows with its size and with the number of languages for which translations exist.

Difference between the Translation Memory tool and the Item Bank

The Translation Memory tool and the Item Bank have in common that both enhance consistency in the use of well proven expressions across the various EORTC modules. The difference, however, lies in the function for the users. The TM is a daily translation tool used by the Translation Coordinator and translators in translation agencies, whereas the Item Bank is primarily aimed at module developers, not to "create new or recycle existing translations".

APPENDIX III: PILOT-TESTING THE TRANSLATED MODULE

Example of 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 into (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:

1. Sample of a patient response sheet (completed by interviewer)

Question number -----

Comments

- a. Difficulty? Yes _____

- b. Confusing? Yes _____

- c. Difficult words? Yes _____

- d. Upsetting? Yes _____

- e. How would you ask this question? _____

Question number --

Comments

- a. Difficulty? Yes _____

- b. Confusing? Yes _____

- c. Difficult words? Yes _____

- d. Upsetting? Yes _____

- e. How would you ask this question? _____

Pilot-testing:

2. Summary of patient responses by item (completed by interviewer)

(Total no. of patients interviewed = N)

Question number ----

		Number of patients answering Yes	Comments
a.	Difficulty?	<input type="checkbox"/>	<hr/> <hr/> <hr/> <hr/>
b.	Confusing?	<input type="checkbox"/>	<hr/> <hr/> <hr/> <hr/>
c.	Difficult words?	<input type="checkbox"/>	<hr/> <hr/> <hr/> <hr/>
d.	Upsetting?	<input type="checkbox"/>	<hr/> <hr/> <hr/> <hr/>
e.	Alternative wording suggested by patients		<hr/>

APPENDIX IV: TABLE OF AVAILABLE TRANSLATIONS

Translations available (last updated March 2009): QLQ-C30+validated modules.
For regular updates visit <http://groups.eortc.be/qol/translations.htm> .

Languages	Language identifier	QLQ-C30	BR23	C15-PAL*	CX24	H&N35	IN-PATSAT32	LC13	MY20	OES18	OG25	OV28	PR25	STO22
Afrikaans	af	T	T	T		T		T						
Arabic	ar	T	T					T						
Arabic (Egypt)	ar_EG	T												
Arabic (Israel)	ar_IL	T		T		T								
Arabic (Jordan)	ar_JO	T												
Bengali (India)	bn	T				T		T						
Bosnian	bs	T						T						
Bulgarian	bg	T	T	T				T					T	
Burmese (Myanmar)	my	T												
Catalan	ca	T		T									T	
Chinese Mandarin (China)	zh_CN	T	T	T		T	T	T		T		T		T
Chinese (Malaysia)	zh	T		T				T						
Chinese M. (Singapore)	zh_SG	T		T				T						
Chinese Cantonese(HK)	zh_HK	T		T		T		T				T		
Chinese (Taiwan)	zh_TW	T	T	T	T	T	T	T	T	T		T	T	T
Croatian	hr	T	T	T	T	T		T				T		
Czech	cs	T	T	T		T		T	T				T	
Danish	da	T	T	T	T	T	T	T	T	T		T	T	T
Dutch	nl	T	T	T	T	T	T	T	T	T		T	T	T
Estonian	et	T								T				T
Finnish	fi	T	T	T		T		T	T	T		T	T	T
French	fr	T	T	T	T	T	T	T	T	T	T	T	T	T
French (Canada)	fr_CA	T		T				T	T					T
German	de	T	T	T	T	T	T	T	T	T		T	T	T
German (A)	de_AT												T	
Greek	el	T	T	T		T		T	T				T	T
Guajarati (India)	gu	T	T	T		T		T						
Hebrew	he	T	T	T		T		T	T				T	
Hindi (India)	hi	T	T	T		T		T		T			T	T
Hungarian	hu	T	T	T		T		T					T	T
Icelandic	is	T		T			T							
Indonesian	id													
Italian	it	T	T	T	T	T	T	T	T	T		T	T	T
Japanese	ja	T	T	T		T		T						T
Kannada (India)	kn	T		T		T		T						
Kiswahili (Africa)	sw	T												
Korean	ko	T	T	T	T	T		T		T		T		T
Latvian	lv	T												
Lithuanian	lt	T	T	T		T		T						

Languages	Language identifier	QLQ-C30	BR23	C15-PAL*	CX24	H&N35	IN-PATSAT	LC13	MY20	OES18	OG25	OV28	PR25	STO22
Malay (Bahasa Melayu)	ms_MY	T	T	T										
Malay (Myanmar)	ms	T	T			T								
Malay (Singapore)	ms	T						T						
Malayalam (India)	ml	T	T	T		T		T						
Marathi (India)	mr	T	T	T		T		T					T	
Norwegian	no_bk	T	T	T	T	T	T	T	T	T		T	T	T
Persian (Farsi)	fa	T	T							T				
Polish	pl	T	T	T	T	T	T	T		T		T	T	T
Portuguese	pt_PT	T	T	T	T	T	T	T	T			T	T	T
Portuguese (Brazil)	pt_BR	T	T	T	T	T		T	T	T			T	T
Punjabi (India)	pa	T				T		T						
Romanian	ro	T	T	T		T		T					T	
Russian	ru	T	T	T		T		T	T	T		T	T	T
Russian (Belarus)	be	T							T					
Russian (Georgia)	ru	T							T					
Serbian	sr	T	T	T		T		T						
Sinhala (Sri Lanka)	si	T	T	T	T	T	T	T		T				
Slovak	sk	T	T	T		T		T					T	
Slovenian	sl	T	T			T		T						
Sotho (Africa)	st	T				T								
Spanish (Europe)	es_ES	T	T	T	T	T	T	T	T	T	T	T	T	T
Spanish (Argentina)	es_AR	T		T		T		T					T	
Spanish (Chile)	es_CL	T	T	T										
Spanish (Colombia)	es_CO	T	T	T				T						T
Spanish (Costa Rica)	es_CR	T		T										
Spanish (Guatemala)	es_GP	T		T										
Spanish (Mexico)	es_MX	T		T		T	T		T		T		T	T
Spanish (Peru)	es_PE	T		T				T						
Spanish (Puerto Rico)	es_PR	T		T		T								
Spanish (USA)	es_US	T	T	T				T						
Swedish	sv	T	T	T		T	T	T	T	T		T	T	T
Swedish (Finland)	sv_FI	T						T			T			
Tagalog (Philippines)	tl	T	T	T				T						
Tamil (India)	ta_IN	T		T		T		T						T
Tamil (Malaysia)	ta_MY	T	T					T						
Telugu (India)	te	T	T	T		T		T						
Thai	th	T	T	T		T		T					T	

Languages	Language identifier	QLQ-C30	BR23	C15-PAL*	CX24	H&N35	IN-PATSAT 32	LC13	MY20	OES18	OG25	OV28	PR25	STO22
Turkish	tr	T	T	T	T	T	T	T	T				T	T
Ukrainian	uk	T	T	T		T		T	T	T			T	T
Urdu (Pakistan)	ur_PK	T		T										
Vietnamese	vi	T		T										
Xhosa (Africa)	xh	T		T		T								
Yoruba (Nigeria)	yo	T	T											
Zulu (Africa)	zu	T	T	T		T								

Table legend:

In this table the language identifier consists of a language code (ISO 639 tags) and (in cases where a language is spoken in more than one country) it is followed by a country code (ISO 3166 sub tag).

* As the QLQ-C15-PAL is an abbreviated version of the QLQ-C30, translations of the QLQ-C15-PAL are available for all languages where QLQ-C30 translations have been made. Please contact the QL Department if you need the QLQ-C15-PAL in one of these translations.

Translations available (last updated March 2009) – Modules under development
 For regular updates visit <http://groups.eortc.be/qol/translations.htm> .

Language	Language identifier	BLS24	BLM30	BM22	BN20	CIPN20	CLL16	CR29	CR38	FA-R15	GINET21	HCC18	HDC29	INFO26	LMC21	OPT30	PAN26	PRT21	SWB38
Afrikaans	af																		
Arabic	ar				T														
Arabic (Egypt)	ar_EG																		
Arabic (Israel)	ar_IL																		
Arabic (Jordan)	ar_JO																		
Bengali (India)	bn																		
Bosnian	bs																		
Bulgarian	bg																		
Burmese (Myanmar)	my																		
Catalan	ca																		
Chinese Mandarin	zh_CN											T							
Chinese (Malaysia)	zh																		
Chinese (Singapore)	zh_SG																		
Chinese Cantonese (HK)	zh_HK			T					T			T							
Chinese (Taiwan)	zh_TW	T	T		T	T	T	T				T	T	T	T	T	T		
Croatian	hr													T					
Czech	cs				T	T	T	T									T		
Danish	da	T	T		T	T	T	T			T						T		
Dutch	nl	T	T		T	T	T	T			T	T			T		T		
English (US)	en_US																	T	
Estonian	et																		
Finnish	fi				T											T			
French	fr	T	T		T	T	T	T				T		T	T		T		
French (Canada)	fr_CA				T	T													
German	de	T	T	T	T	T	T		T					T	T		T		
German (A)	de_AT																		
German (CH)	de_CH																	T	
Greek	el			T			T				T								
Gujarati (India)	gu						T												
Hebrew	he				T						T								
Hindi (India)	hi				T		T												
Hungarian	hu	T	T		T													T	
Icelandic	is																		
Italian	it	T	T		T	T	T	T	T	T		T	T				T		
Japanese	ja				T	T		T	T			T						T	
Kannada (India)	kn						T												
Kiswahili (Africa)	sw																		

Language	Language identifier	BLS24	BLM30	BM22	BN20	CIPN20	CLL16	CR29	CR38	FA-R15	GINET21	HCC18	HDC29	INFO26	LMC21	OPT30	PAN26	PRT21	SWB38	
Korean	ko				T				T			T						T		
Latvian	lv																			
Lithuanian	lt								T									T		
Malayalam							T													
Malay	ms																			
Marathi (India)	mr				T	T														
Norwegian	no_bk	T	T		T				T				T	T				T		
Persian (Farsi)	fa																		T	
Polish	pl	T	T		T		T				T	T			T			T		
Portuguese	pt_PT	T	T		T			T						T						
Portuguese (Brazil)	pt_BR						T													
Punjabi (India)	pa																			
Romanian	ro																			
Russian	ru	T	T		T		T		T										T	
Russian (Israel)	ru		T																	
Serbian	sr																			
Sinhala (Sri Lanka)	si																			
Slovak	sk	T	T								T									
Slovenian	sl																			
Sotho (Africa)	st																			
Spanish (Europe)	es_ES	T	T		T	T	T	T	T	T	T			T				T		
Spanish (Argentina)	es_AR			T																
Spanish (Chile)	es_CL																			
Spanish (Colombia)	es_CO							T												
Spanish (Costa Rica)	es_CR																			
Spanish (Guatemala)	es_GP																			
Spanish (Mexico)	es_MX						T													
Spanish (Peru)	es_PE																			
Spanish (Puerto Rico)	es_PR																			
Spanish (USA)	es_US				T															
Swedish	sv	T	T		T			T	T		T			T			T	T		
Tagalog (Philippines)	tl																			
Tamil (India)	ta						T													
Telugu (India)	te						T													
Thai	th						T													

Language	Language identifier	BLS24	BLM30	BM22	BN20	CIPN20	CLL16	CR29	CR38	FA-R15	GINET21	HCC18	HDC29	INFO26	LMC21	OPT30	PAN26	PRT21	SWB38
Turkish	tr	T	T						T										
Ukrainian	uk																		
Urdu (Pakistan)	ur																		
Vietnamese	vi																		
Xhosa (Africa)	xh																		
Yoruba (Nigeria)	yo																		
Zulu (Africa)	zu																		

Table legend:

In this table the language identifier consists of a language code (ISO 639 tags) and (in cases where a language is spoken in more than one country) it is followed by a country code (ISO 3166 sub tag).