

EORTC Quality of Life Group

Revised Guidelines for Translation of Phase II Modules

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Background

Recently, the translation procedure of Phase II modules has been reorganised and is currently co-ordinated by Karen West at the Quality of Life Unit. An overlap was noticed between the Pilot-testing of translations (see page 13 of Translation Procedure) and the subsequent Pre-testing of modules during Phase III (see page 11 of Guidelines for Developing Questionnaire Modules). Both procedures require participation of 10-15 patients belonging to the target population, who then complete the module and semi-structured interviews (conducted with each patient). The questions in the semi-structured interviews are identical for the Pilot- testing of translation and Pre-testing of modules at Phase III. The purpose of the semi-structured questionnaires is different. In the case of Pilot- testing of translations, the aim is to identify any problems with the translation. In the case of module Pre-testing, the aim is to identify and solve potential problems in the administration (phrasing of questions, sequence of questions) and to determine the need for additional questions or the elimination of others.

This was felt to be an unnecessary repetition. Therefore, in the case of translation of Phase II modules, when Phase III pre-testing of the modules follows, a revised procedure is suggested.

Revised Guidelines

1. Translation of Phase 2 module

a. The translation of Phase II modules will be co-ordinated by the Quality of Life Unit, Karen West. Up to the Pilot-testing phase, the translation process should follow the procedure specified in EORTC Quality of Life Group translation procedure, February 2002.

b. The resulting translated questionnaire should then be reviewed by at least 2 native speakers of the language who have experience in working with patients (physicians, nurses, psychologists or other members of the healthcare profession). This is necessary in order to ensure that the words used are appropriate for the patient population. In addition, the questionnaire should be administered to not more than 3-5 patients, in order to identify any obvious problems in translations. Patients should be asked to complete the module and then participate in a brief structured interview, as in the Translation Guidelines. They will be asked whether any of the items were difficult to answer, confusing, difficult to understand, upsetting or whether the patient would have asked the question in a different way.

c. At the end of this process, a brief report should be submitted to Karen West and to the Module Development Committee Chair. The report should include

- All forward and backward translations;
- All key memoranda relevant to the process, relating to how decisions were made regarding any difficulties, disagreements and justification of deviations.

- The comments from the 2-3 healthcare professionals and 3-5 patients who commented on the translation.

2. Pre-testing in Phase III.

The resulting translation can then be used in Phase III pre-testing of the module according to the guidelines for developing questionnaire modules. These state that the pre-testing should include 10-15 patients, who will complete the module and will then participate in a structured interview. The same de-briefing questionnaire as in the Guidelines for Developing Questionnaire Modules will be used. However, if any problems are identified, these should be discussed both in terms of wording of the item in the original language, but also as potentially due to translation. Therefore, the aim of the Phase III testing will be two-fold:

- the first is to test the questionnaire in the target population with the aim of identifying items that are unnecessary or adding items;
- the second is to identify any potential problems with the translation of the items.

The final questionnaire after Phase III may be different from the provisional module. Any new items have to be translated and the final questionnaire given to 3-5 patients to see if there are any problems.

3. Report on Phase III modules and translation.

The development and pre-testing of Phase III modules should be reported as usual. An appendix should be included describing the translation of Phase II module. This appendix should include:

- any qualitative and quantitative data related to translation issues from the larger patient sample of 10-15 patients who participated in the Phase III pre-testing of the module. Characteristics of these patients will be already described in the main report of Phase III pre-testing of the module.
- The final versions in each language used in Phase III.

Phase II module

