

EORTC QUALITY OF LIFE GROUP

Guidelines for Developing Questionnaire Modules

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The EORTC Quality of Life Group (QLG) guidelines for module development have proven to provide a useful tool for questionnaire development. Modules that have been produced have exhibited good levels of psychometric and cross-cultural validity. The guidelines also allow those who use modules (individuals and industry) to understand the rigorous methodology of module development. Experience with module development over the past three years, however, has highlighted areas where the guidelines require further development. These areas include: (i) alternative methods of identifying quality of life (QL) issues for psychosocial modules (ii) links to the newly developed Item Bank at the EORTC Quality of Life Unit at the EORTC Data Center, (iii) translation of modules and (iv) changes to the methods used to produce phase 4 modules. These amendments are included in the current version.

We would like to thank all members of the EORTC QLG who have contributed to this document.

We hope that these updated guidelines will continue to ensure uniformly high quality across modules. Users who have comments or questions, are encouraged to contact the authors to enable them to further improve the guidelines.

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An essential aspect of the "modular" approach to QL assessment adopted by the EORTC QLG is the development of modules specific to tumour site, treatment modality, or a QL dimension, to be administered in addition to the core questionnaire (the EORTC QLQ-C30). The modules, like the core questionnaire, will be designed for use in cancer clinical trials.

Since individual members or subgroups of the Quality of Life Group will be involved, guidelines are needed to standardise the module development process in order to ensure uniformly high quality across the modules.

The term "module" will be defined, the composition of modules will be sketched, the attributes of modules will be specified, and the module development process will be described in detail. Finally, issues related to cross-cultural aspects, the need for monitoring the module development process from within the EORTC QLG, the storage of relevant information, ownership, and publication rights, will be discussed.

A module is defined as a set of items assessing QL issues not (sufficiently) covered by the core questionnaire and considered to be relevant for the target population and the research question.

This set of items may refer to:

- > a. Disease symptoms related to tumour site (e.g., lung cancer, breast cancer, colorectal cancer) or stage within tumour site (e.g., local vs metastatic);
- > b. Side effects and other issues related to treatment (e.g., skin changes resulting from radiotherapy, chemotherapy-induced neuropathy); or
- > c. Additional QL dimensions that are relevant across diagnoses and treatment modalities (e.g., fatigue, sexuality, body image, and fear of recurrence).

The matrix in Appendix 1 illustrates QL issues of potential relevance for two tumour sites. The columns refer to stages within tumour sites, and the rows refer to potentially relevant aspects (i.e., disease symptoms, treatment-related issues, and relevant QL dimensions not covered by the core questionnaire).

Each cell in this matrix represents a "module element". These module elements may be considered the "building blocks" of the module. Depending on the research question, the module to be developed may need one element (e.g., items related to symptoms of metastatic breast cancer) or more elements (e.g., items related to metastatic breast cancer symptoms and to chemotherapy, sexuality, and body image).

A "module element" is a set of questionnaire items, which refers to one cell in the matrix. Theoretically, it could consist of a single item, but for psychometric reasons this is not desirable. More usually, a module element will consist of a set of single items, one or more sub-scales, or some combination of items and (sub) scales to assess the QL domain represented by the cell in the matrix. The final questionnaire, to be administered in addition to the core questionnaire, will be referred to as a "module", irrespective of the number of module elements it contains.

> > > 3 • CRITERIA FOR MODULES AND THEIR CONSTITUENT ELEMENTS

The modules and their constituent elements to be developed by the group should meet the following criteria:

- > 1. The items must cover relevant areas of quality of life that are not (sufficiently) covered by the core questionnaire (EORTC QLQ-C30).
- > 2. The format of the items should be compatible with the EORTC QLQ-C30: items should preferably employ four-point Likert scales (from "not at all" to "very much"), or alternatively, seven-point linear analogue scales.
- > 3. The items should employ the same time frame as the EORTC QLQ-C30 (i.e., the previous week), unless a week time frame is unsuitable for a particular (set of) item(s).
- > 4. They should be easy to understand, and easy to respond to. Additionally, they should be relatively brief: the number of questions composing the module (i.e., the sum of the items of the module elements included) should not exceed that of the core questionnaire.
- > 5. They should be compatible with existing modules. Wherever possible, identical wording is to be used across modules for those items that are similar in content (see section 4.3 for use of the Item Bank). Where alternative wording is proposed this must be explicitly justified.
- > 6. Preferably, they should be comprised of multiple item scales.
- > 7. A final, critical requirement is that the module (element) should exhibit adequate levels of reliability and (cross-cultural) validity. Additionally, it should be responsive to clinically important changes in health status over time.

1 • IDENTIFICATION OF RESEARCH QUESTION AND TARGET POPULATION

Module construction begins with clearly specifying the research question and the target population for which the module will be designed on the basis of which the relevant module elements can be identified. The selection of elements for a specific module may be made on theoretical and/or clinical grounds. Consequently, for each disease site, the relevant cells should be tapped that need to be developed into a module element. Matrices such as the one depicted in Appendix 1 can provide a heuristic for this module element selection.

The actual module development process consists of four phases: (1) generation of relevant QL issues, (2) operationalisation of the QL issues into a set of items, (3) pre-testing the module questionnaire, and (4) large-scale international field-testing. These phases will be described in detail. The cross-cultural aspects of module development will be described later.

2 • PHASE 1: GENERATION OF QL ISSUES

> *Aim*

This phase is aimed at compiling an exhaustive list of relevant QL issues that cover the domain(s) of interest. In the process of compiling this list, three sources are consecutively tapped: (i) literature (i.e., including existing questionnaires), (ii) health care providers (e.g., physicians, nurses), and (iii) patients.

> (i) *Literature searches*

Literature searches need to be conducted on MEDLINE and eventually on PSYCHINFO or other relevant databases to ensure that one has identified the relevant QL issues. From this and other sources (see section 4.2) existing, relevant questionnaires should be reviewed (i.e., general quality of life questionnaires and disease-specific questionnaires). A list of all questionnaires identified and finally a list of all potentially relevant QL issues should be derived.

> (ii) *Interviews with health care providers*

This provisional list and the core instrument should then be presented to a number of health care providers (e.g., 3 to 5) for feedback on appropriateness of content and breadth of coverage. The health care providers may be specialist physicians and/or nurses who are involved in the treatment of patients belonging to the target population. Depending on the QL issues, other health care providers could be consulted (e.g., psychologists, psychiatrists, and social workers). It is advisable to consult the Chairman or other members of the relevant EORTC Group(s) as well.

This list of QL issues may be "administered" in the form of a structured, personal interview in which basically two questions are posed: (a) are issues included which the specialists consider irrelevant for this patient group, and if so, why do they consider these issues irrelevant?; and (b) are there issues missing

from this list that the specialists consider relevant, and if so, why do they consider these issues relevant?

To establish the relative importance of the QL issues, the specialists should be asked to identify a subset (e.g., 5 to 10) of issues that, in their opinion, affect patients' QL most profoundly and should definitely be included in the final questionnaire. Appendix 2 provides an example of a detailed interview protocol. On the basis of the comments of these specialists, the list of QL issues may be revised (e.g., issues may be deleted, reworded, or added).

> *Footnote*

Phase 1 aims at identifying an exhaustive list of issues, i.e. to achieve content validity. When applying the Guidelines to new modules on topics that are more abstract than symptoms (e.g. psychological or sociological concepts), careful attention must be given to the theoretical literature, when available. It may not be sufficient to assume that relevant issues are covered: issues may also need to be selected based on their ability to reflect an accepted theoretical conceptualisation of the phenomenon. If, for example, a module to assess coping had to be made, it would not be sufficient to identify issues assumed to reflect coping. A useful coping module would have to relate to current theories about coping. Therefore, if modules aimed at assessing more abstract concepts are to be made, Phase 1 will have to include a thorough review of the existing theoretical literature, and this literature may play a more central role in item construction than seen when modules on symptoms are made.

> *(iii) Patients' interviews*

This adapted list and the core questionnaire will then be administered to a limited number of patients. Since relatively few patients will be interviewed during this phase, the selection of subjects is crucial. Strict eligibility criteria should be adopted to ensure that subjects adequately represent the target population for which the module is being devised. It is recommended that samples of 5 to 10 patients from each different treatment group or disease stage are interviewed.

Interviews should be conducted to determine the extent to which patients have experienced the problems, limitations, or positive experiences during the period of their disease and to check for any significant omissions. Furthermore, patients may be asked to choose a limited number (e.g., 5 to 10) of the negatively phrased issues that troubled them the most (or caused the greatest problems/nuisance/distress). Alternatively, for capacities and positive experiences, patients may be asked to select a limited number that they value particularly highly. An example of a detailed, personal interview protocol is provided in Appendix 3.

> *Adaptation of the list*

On the basis of these responses the list of QL issues may require further adaptation. An example of decision rules for adaptation is also included in Appendix 3. Additionally, the list of items should be reviewed for overlap. Moreover, issues brought up by health care providers and/or patients that are common to patients with cancer in general and

that are included in the core questionnaire, should be reviewed for redundancy and be eliminated where possible.

> *Room for variation*

On the basis of the literature searches and the interviews with health care providers and patients, additional domains of interest may be identified that need to be included in the module. Clearly, such module elements that were not identified at the start of the module development process need to be added.

In practice it may be advantageous to elicit health care providers' and patients' opinions in slightly different ways. The following variations in the conduct of the interviews are acceptable:

- > 1. With respect to the order of the interviews, health care providers and patients may be consulted simultaneously or in reverse order. However, to make optimal use of these sources of information and to reduce patient burden, we strongly recommend consecutive consultation in the order presented.
- > 2. With respect to the format, (a) focus group interviews can be conducted instead of individual interviews, provided that one has the required skills and is able to bring 10 to 15 patients belonging to the target population together.
(b) dependent on the novelty of the module to be constructed, one may opt for interviewing health care providers and patients in an open rather than in a pre-set way, and ask them to describe their opinion with regard to the relevant dimension, prior to administering the list of QL issues (see Groenvold, 1997). If they describe additional aspects these should be included in the list.
- > 3. In some instances it may be relevant to consult self-help Groups in eliciting patients' experiences in addition to or instead of consulting patients in hospital clinics or outpatient departments.

3 • PHASE 2: OPERATIONALISATION

The list of QL issues is then ready to be operationalised into questions with the format and time frame being compatible with the QLQ-C30.

> The EORTC Quality of Life Group Item Bank

At this stage, it is important to consult existing EORTC questionnaire modules for their wording (by using the Item Bank), in order to avoid duplication of effort and to ensure uniformity across modules. Issues included in modules that have been developed under the auspices of the EORTC QLG should be operationalised into items to be included in subsequent modules, unless there are strong arguments not to do so (e.g. when these items appear to perform poorly). If the modules from which items are extracted are still under development, then the explicit permission and co-operation of the author(s) should be sought first.

The Item Bank based at the EORTC Quality of Life Unit within the EORTC Data Center should be consulted. The issues from the phase 1 list should be searched for in the Item Bank. This may yield several items that cover the same issue. The most appropriate item for the module under development should be chosen. If several items addressing similar issues are identified, it may be necessary to test these in samples of patients from the target population. Developers of EORTC QLG Modules have access to the Item Bank, which is available through the Internet. Further information about the purpose and methods of using the Item Bank are published in the EORTC QLG Item Bank blue book or, details may be obtained directly from the EORTC Quality of Life Unit.

Additionally, in order to save time and effort, existing questionnaires, developed by other research groups, may be consulted for their wording. The format of “existing” questionnaire items may require adaptation to achieve compatibility with the core questionnaire. Again, the explicit consent of the questionnaire constructors should be obtained prior to including the items in the module.

> Item construction

If a new item is needed for the new module, it is important to be aware of the major caveats in item construction. Litanies of cautions may be found in the majority of relevant textbooks (see also References). Additionally, when the module elements of interest cover positive spectra (e.g., sexuality and body image), one may want to include items that are positively phrased (i.e., in terms of abilities, capacities, and positive experiences) in addition to items that are negatively worded (i.e., in terms of problems, limits in functioning, and negative experiences). In these cases one should be alert to avoid confusion and biased responses due to differences in items' evaluative content (i.e., negative versus positive). For example, one should draw patients' attention to these differences (e.g., by underlining). Further, the forming of multiple item scales should be anticipated by including several items pertaining to similar constructs.

The resulting list of items should be reviewed for clarity and overlap, preferably by persons other than those who were involved in step 1 (e.g., colleagues). These reviews should then be combined to give the final list of items.

> *Consultation of health care providers*

At the end of this stage it may be advisable to present the provisional module to one or two additional consultants (e.g., some of whom may have been involved in phase 1) for review. It may be appropriate to consult other health care providers as well, e.g., the study co-ordinator of the given trial or the Chairman of the relevant EORTC Group. On the basis of these final comments the list of items may require further adaptation, before it is administered to patients in the pre-testing phase.

4 • PHASE 3: PRE-TESTING

> *Aim*

The aim of pre-testing the module is to identify and solve potential problems in its administration (e.g., the phrasing of questions, the sequence of questions), to determine the need for additional questions or the elimination of others, and to determine the overall degree of eliciting attention and interest.

If items from existing questionnaires are included in the provisional module (see section 4.2) there is still an obligation to pre-test them. There are several reasons for pre-testing these tried items, some of which may have proven psychometric quality. First, the meaning of questions can be affected by the context of their neighbouring questions (see also Converse and Presser, 1986). Second, these items have been devised primarily in one language and region and may require adaptation when used in different languages and cultural settings. Third, questions developed originally for a particular target group may perform differently when applied in a new setting.

> *Pre-testing consists of:*

- > 1. Administering the provisional module and the core questionnaire to a number of patients (e.g., 10 to 15), belonging to the target population, but who were not involved in phase 1, and...
- > 2. Conducting structured interviews with each patient individually (or, possibly, to conduct focus group interviews) after completion of the module.

> *Patient sample*

Since relatively few patients will be interviewed, the selection of subjects is crucial. Again, strict eligibility criteria should be adopted to ensure that subjects adequately represent the target population for which the module is being devised. Dependent on the scope of the module, more subjects may need to be consulted during the pre-testing phase. For example, if a module includes side-effects

of three different treatment modalities (e.g., surgery, radiotherapy, and chemotherapy), the pre-testing sample should include at least three times 10 to 15 patients, each group receiving one of the three treatment modalities.

> *The structured interview*

The interview should, in principle, be directed to each module item separately and should invite further comments to: (1) the particular experience to which the item refers (e.g. is this experience related to your disease or treatment?); and (2) the wording of the item itself (e.g. was the item difficult to respond to? was the item annoying, confusing or upsetting? and how would you have asked this question?).

If modules contain a large number of items (e.g. more than 20), the time involved in inquiring about each individual item may be prohibitive. In those cases the questions may be directed towards the entire module (e.g. were there questions that you found difficult to answer? were there questions that you found annoying, confusing or upsetting? and do you have other comments about these questions?). These general questions may then be supplemented by the further probing of selected module items that are expected to cause some difficulty (e.g., positively phrased questions and double negatives) or items that appear to be troublesome during the interview.

The pre-testing interview should be completed with two questions directed to the entire questionnaire (i.e., core questionnaire plus module): (1) Were there questions that you found irrelevant? (2) Can you think of additional issues that are relevant for you but are not included in this questionnaire?

On the basis of this pre-testing phase, the provisional questionnaire may require adaptation. Examples of a detailed interview protocol as well as decision rules for deletion, addition, and rewording of items are provided in Appendix 4.

5 • PHASE 4: FIELD-TESTING

> *Aim*

The module questionnaire should finally be field-tested in a larger, (international) group of patients in order to determine its reliability, validity, and cross-cultural applicability (see section 3, criterion 5).

In order to determine the acceptability of the module, it is advisable to administer the debriefing questions that accompanied the EORTC QLQ-C30: (a) how long did it take you to complete the questionnaire; (b) did anyone help you to complete the questionnaire, and if so, what kind of help and how much help was provided; (c) were there questions that you found confusing or difficult to answer; (d) were there questions that you found upsetting; and (e) please use the space below if you have other comments about the questionnaire.

> *Scale structure and reliability*

In some cases, it is advantageous to combine items into scales. The construction of scales is warranted when the items constituting that scale pertain to the same clinical or psychosocial concept. A range of analyses can be conducted to test empirically the module's hypothesised scale structure and to establish scale reliability. For example, multi-trait scaling analysis can be used to examine the extent to which the items of the module can be combined into the hypothesised multi-item scales. The technique is based on an examination of item-scale correlations (Hays et al., 1988). The internal consistency of the multi-item scales can be assessed by Cronbach's alpha coefficient (Cronbach, 1951) where estimates of a magnitude of .70 need to be sought for group comparisons (Nunnally and Bernstein, 1994). However, aggregating symptoms or side effects (so called 'causal' indicators in relation to overall quality of life) into a summated scale should be exercised with greater caution than other aspects, such as depression (for which items may be 'effect' indicators in relation to overall quality of life) (Fayers and Hand, 1997; Fayers et al., 1997). More recent approaches to scale construction could also be adopted, including those based on item-response theory (Nunnally and Bernstein, 1994) and differential item functioning or item bias analysis (Nunnally and Bernstein, 1994; Groenvold et al. 1995). If the design allows for assessing the module's test-retest reliability or stability, Intra-Class Correlation Coefficients can be calculated between the two assessments. Finally, score distributions (i.e.skewness, floor and ceiling effects) of the multi-item scales and single items can be examined.

> *Validity*

For the purpose of external validation of the modular questionnaires, additional information should be collected. Dependent on the QL dimensions assessed, this information could include socio-demographic data, clinical data, and additional instruments assessing relevant QL dimensions. Since the module will contain items specific to certain groups of patients and/or QL dimensions, external validation criteria should be more specific than those selected for the validation of the core questionnaire (e.g., breast conserving therapy versus mastectomy to validate a body image scale included in a breast cancer module). Additionally, the assessment of the module questionnaire at more than one point in time may permit the evaluation of its responsiveness to (clinical) changes over time.

A range of analyses is available to evaluate the validity and responsiveness of the questionnaire scales and single items. For example, the method of known-groups comparison (Kerlinger, 1973) can be used to evaluate the extent to which the module is able to discriminate between subgroups of patients differing in clinical status. Examples of clinical parameters that can be used to form mutually exclusive patient subgroups include disease stage, previous treatment (if relevant), current treatment modality, and/or performance status. One-way analysis of variance (or a non-parametric pendant) can be used to test for the statistical significance of group differences. Second, the responsiveness of the module can be evaluated by examining changes

in scale score patterns over time of patients groups having specific disease or treatment courses (e.g., comparing scores obtained prior to chemotherapy with those obtained during chemotherapy). Additionally, changes in the module scores over time may be examined in relationship to changes in a criterion parameter (e.g. performance status). In the latter two instances, repeated measures ANOVA (or a non-parametric pendant) can be used to test for statistically significant changes in module scores over time.

Examples of international validation studies include those of the EORTC QLQ-C30 (Aronson et al., 1993), the lung cancer module (Bergman et al., 1994), the breast cancer module (Sprangers et al., 1996) and the head and neck cancer module (Bjordal 1999).

> *Item reduction*

Since the number of patients consulted during phase 1 (generation of QL issues) and 3 (pre-testing the provisional module questionnaire) is rather limited, the basis on which to eliminate issues/items during these phases, is quite narrow. The module to be field-tested may therefore contain more items than is actually desirable (see also section 3, criterion 4). On the basis of the data collected in the larger sample of patients, elimination of items may be warranted on psychometric grounds. Additionally, on the basis of psychometric analyses it may be possible to construct long and short forms of the modules.

> *Minimal requirements for psychometric validation of the module*

The above describes the standards that have been applied to all published EORTC QLG modules at present. Until this time all phase 4 studies have been conducted from the EORTC QL Unit at the Data Center. Future modules may undergo psychometric testing in a stepwise manner, so that reliability and scaling tests are carried out at an international level and further validation (including sensitivity to change over time) may be undertaken in a separate study. The EORTC QLG is currently investigating alternative ways of field testing phase 4 modules and whether it is possible to test them outside of the EORTC QL Unit.

1 • COLLABORATION

Ideally, module development should be conducted simultaneously in a range of languages and countries. Moreover, consensus should be achieved at each of these steps to ensure cross-cultural comparability. This approach, however, may not always be feasible. There are at least two different approaches, here presented in increasing order of practical applicability (and in decreasing order of scientific rigour).

First, the construction process should be limited to three languages and countries representing for example the groupings used in the analysis of the QLQ-C30: (a) Anglo-Saxon countries (i.e., Australia, Canada, United Kingdom, United States); (b) Northern Europe (i.e., Denmark, Germany, The Netherlands, Norway, Sweden); and (c) Southern Europe (i.e., French-speaking part of Belgium, France, Italy, Spain). Second, the construction process may be limited to representatives of Anglo-Saxon countries and non-Anglo-Saxon countries, thus involving two languages and regions. Needless to say the involvement of three or more languages in the construction process simultaneously is preferable and strongly recommended.

When module construction will be restricted to a limited number of languages, constructors are strongly encouraged to consult group members from various countries at each step. Specifically, input needs to be sought at the end of the operationalisation phase prior to pre-testing the provisional module. The English module (or in the case the module has been devised in a language other than English, its provisional English translation) should be sent to all national co-ordinators for direct feedback on the translatability of the items.

Ideally, members of the EORTC QLG who are willing to participate in the development of a particular module should proceed as follows. They should work independently, and should seek to achieve consensus after each crucial step, and should agree upon:

- > 1. The formulation of the QL domains;
- > 2. The list of QL issues derived from the literature (i.e., the same list of QL issues should be put to the health care providers);
- > 3. The list of QL issues they want to administer to the patients (i.e., adapted on the basis of the health care providers' interviews);
- > 4. The final list of QL issues that need to be operationalised (i.e., on the basis of the patients' interviews);
- > 5. The provisional list of items that will be administered to patients in the pre-testing phase;
- > 6. Final list of items that will be field-tested.

2 • TRANSLATION

The questionnaire modules should be submitted to a rigorous translation process, based on iterative forward-backward procedures. The aim of translation is to produce modules which are clear, expressed in language in common use, and conceptually equivalent to the original module. The English version should be used as the standard from which all other translations are prepared.

Rigorous translations need to be conducted both before and after pre-testing. The processes of translation and pre-testing are necessarily iterative. If translation has not been done sufficiently rigorously before pre-testing, issues may arise during pre-testing which require better translation and further pre-testing. Additionally, pre-testing may necessitate adaptations of existing items or the inclusion of new ones which need to be translated and further tested.

The acceptability of the translations should be pilot-tested in each respective language. Translated modules should be administered to a number of patients (e.g., 10 to 15) belonging to the target population to identify potential problems in the phrasing of questions and be revised accordingly. If modules include sections which apply to subgroups of the target population (e.g. specific sections for males and females), the sample size needs to be increased to ensure that each item can be pilot-tested with at least 10 patients.

If items are taken from existing modules, then the existing translations of these items need to be adopted (translation available in the Item Bank). Thus, additional forward-backward translation is not needed, unless the co-ordinator feels that the translation can be substantially improved. In that case, the standard translation procedure should be adopted. The resulting translation should be discussed with the co-ordinator of the translation of the original module and consensus should be achieved about the 'best' translation.

Clearly, the aim of translation is to create equivalent modules across languages and cultures, but wherever cultural and local differences necessitate the inclusion of "idiosyncratic" items (e.g., when standard treatment protocols differ, when symptom perception is culturally bound), these could be added to the module, provided that the remainder of the module is equivalent across languages. These idiosyncratic items should appear at the end of the module questionnaire.

Translations will be co-ordinated from the EORTC QL Unit at the Data Center after completion and approval of phases 2 and 3 of module development. All modules will be translated into eight European languages (Danish, Dutch, French, German, Italian (mixed), Norwegian, Spanish (mixed) and Swedish. Pilot testing of the translations in an appropriate sample of patients should be performed in each country to ensure that the items are well understood and have the same meaning as originally intended. The module developer in conjunction with the EORTC QL Unit is responsible for reviewing the results of the pilot tests. Details of the procedures on translation and pilot testing are provided in a separate document: "EORTC Quality of Life Group Translation Procedure" (Cull et al., 1998).

6 • CO-ORDINATING AND MONITORING < < < THE MODULE DEVELOPMENT PROCESS

1 • AIM

To ensure uniformly high quality in questionnaire modules, the entire developmental process should be the subject of rigorous peer review within the EORTC QLG. The purpose of such a review is five-fold: (1) to avoid unintended duplication of effort and variation across modules; (2) to monitor the progress made; (3) to provide advice whenever needed during the course of module development and translation; (4) to evaluate the process, i.e., whether any deviations from the standard procedures were justified and whether any alternative procedures followed were sufficient to meet the standards set; and (5) to evaluate the quality, suitability, and compatibility of the provisional and final questionnaire modules and their translated versions.

2 • MONITORS

> *The Module Development Committee*

The members of the Module Development Committee (MDC) are appointed by the EORTC QLG. They are chaired by the Module Development Co-ordinator. The task of the MDC is to co-ordinate module development through: (1) reviewing proposals for modules to be developed (to avoid duplication), reviewing items generated in phase 2 (to avoid unintended variation across modules), and reviewing written documentation describing phases 1 through 4; (2) being available throughout the process for advice; and (3) keeping the guidelines for module development up to date by making revisions when needed. All module developers are advised to contact the MDC in an early stage. Especially, if deviations from the Guidelines are anticipated or are being made, it is highly recommended to consult the MDC in order to be able to proceed smoothly.

> *Reviewers*

Each review of the module construction process and the suitability of the resulting module is undertaken by at least two members of the EORTC QLG. These reviewers will be chosen by the MDC. At least one reviewer is also a member of the MDC. Reviewers are identified on a case-by-case basis, provided that they have not been involved in the specific module development project. However, they may have been consulted for advice. It may be appropriate to consult other individuals as well, e.g., the Chairman of the relevant Co-operative Group (see also sections 4.2 and 4.3).

The review of the translation processes and resulting translated versions is co-ordinated by the EORTC QL Unit. The module developer and translation co-ordinator at the EORTC QL Unit are required to review the pilot testing results to ensure the appropriateness of the translated version.

3 • PREPARATION OF DOCUMENTS

The availability of detailed documentation of the module construction process serves two purposes: (1) informing all interested members; and (2) independent peer review. Module construction is a sequential, step-wise process where a new phase cannot be entered unless the previous has been successfully completed. Since permission to proceed to the next step is based on the approval of the previous steps, several documents need to be prepared. All documentation should be written in English.

First, before initiating the development of a module, the EORTC QLG (by means of the MDC) needs to review and approve the project on the basis of a proposal including the objectives of the planned module and the multi-disciplinary and multi-cultural involvement of contributors. This proposal should also be flagged at the subsequent meeting of the EORTC QLG to ascertain that it does not overlap with other module development projects. If this is the case, the work needs to be co-ordinated to avoid duplication of effort.

Second, the multi-national, cross-cultural, and multidisciplinary composition of the EORTC QLG enables important scientific and cultural input for the development of modules. Moreover, the experience in questionnaire development accumulated by its group members is invaluable. Therefore, for each bi-annual meeting of the EORTC QLG, a brief written report is required describing the progress since the last meeting, possible deviations from the guidelines and the problems that may have been encountered. This report is briefly presented in the plenary meeting of the EORTC QLG, by the chair of the MDC. The written report and a summary of these discussions will be circulated in the minutes of the EORTC QLG's meetings.

Third, after the operationalisation phase (phase 2), the provisional module needs to be submitted to the MDC for review. This is to ensure that identical wording is used across modules for those items that are similar in content.

Fourth, the first three phases (generation of QL issues, operationalisation and pre-testing) should be summarised in a report. Deviations from the protocol and the reasons for deviations should also be reported. Appendix 5 provides a detailed enumeration of the topics to be included in such a report.

Fifth, a summary of the pilot testing of the translations should be documented separately for each language (see section 5.2). Details on the content of such reports are provided in the EORTC Quality of Life Group Translation Procedure (Cull et al., 1998).

Sixth, the final international field-testing phase needs to be written up in a report for the MDC or alternatively in a paper to be submitted to a peer-reviewed, international journal. The MDC requires a copy of published papers for information only.

CO-ORDINATING AND MONITORING < < < THE MODULE DEVELOPMENT PROCESS

Reports or papers need to include information about the sample (in- and exclusion criteria, recruitment procedures), data collection procedure, and results (e.g., scale structure, internal consistency reliability, stability, clinical validity, and responsiveness).

Finally, at each phase, reviewers of the module development or translation process are asked to document their comments as well. Dependent on the nature and scope of these comments, the original document may need revision. When this is deemed impractical, a separate reply that is sensitive to the issues raised by the reviewers should be prepared by the module constructors or translation co-ordinators.

The documentation of the entire construction process for each module will therefore include: (a) a proposal of the planned module including its objectives and the multi-disciplinary and multi-cultural involvement of contributors; (b) a brief written report for each bi-annual meeting of the EORTC QLG describing the progress since the last meeting; (c) the provisional module after the operationalisation phase; (d) a report on the construction process (including phase 1 through 3); (e) reports on the translation and pilot-testing of the module in each language separately; (f) reports on the procedures and results of large-scale field-testing (preferably scientific papers); and (g) reviewers' comments at each of the four stages of module development and translation and the co-ordinators' reply.

All steps that need to be taken in the module development process are described in a flow chart, which is included in Appendix 6.

4 • DETAILED CRITERIA FOR PHASE 1 TO 4 MODULES

Since modules are in different stages of development, they are referred to by the developmental stage that they are either in or have successfully completed. The term phase 1 module is reserved for modules that are in the process of compiling a list of QL issues and for those modules which have completed phase 1 successfully. Phase 2 modules have completed operationalisation, but await completion of the international pre-testing, while phase 3 modules have gone through the first three developmental phases and are awaiting completion of the international field-testing. Phase 4 modules have passed the phase of international field-testing, have been published either as internal reports or in peer-reviewed journals, have received the final approval of the EORTC QLG and are available for general use. More detailed criteria are provided below.

> > > CO-ORDINATING AND MONITORING THE MODULE DEVELOPMENT PROCESS

- > 1. An EORTC Phase 1 Module is a module under development
 - > Which is accepted as such following review for overlap with existing modules by the MDC and is being flagged as such at the subsequent meeting of the EORTC QLG;
 - > Which involves at least one member of the EORTC QLG;
 - > Which is carried out according to the Guidelines (see section 4.1, 4.2 and 5); and
 - > Whose progression is being presented during the meetings of the EORTC QLG.
- > 2. An EORTC Phase 2 Module is a module under development
 - > Which fulfils the criteria in 1;
 - > Which has completed phases 1 and 2 of the Guidelines (see section 4.3 and 5), and
 - > Whose list of items has been approved by the MDC after review of its compatibility with other modules (via the Item Bank).
- > 3. An EORTC Phase 3 Module is a module under development
 - > Which fulfils the criteria in 1 and 2; and
 - > Which has additionally completed phase 3 of the Guidelines (see sections 4.4 and 5) and has received the formal approval of this work by the MDC.
- > 4. An EORTC Phase 4 Module is a module
 - > Which fulfils the criteria in 1 through 3;
 - > Which has additionally completed phase 4 successfully (see sections 4.5 and 5), and
 - > Has received the formal approval of the MDC on the basis of generally accepted criteria with regard to its cross-cultural, psychometric performance.

The term 'EORTC (Phase...) Module' is therefore to be reserved only for those modules which fulfil these criteria.

Researchers who develop modules to supplement the QLQ-C30 that do not meet these criteria, are not allowed to use the terms 'EORTC (Phase...) Module' and need to explicitly state that the resulting module cannot be regarded as an official EORTC module.

Translated modules have to meet the following criteria:

- > The module from which they are to be translated has to be approved by the EORTC QLG;
- > Translations should be done according to the procedures described in Cull et al. (1998); and
- > The translated version should be approved by the EORTC QLG after independent review.

CO-ORDINATING AND MONITORING < < < THE MODULE DEVELOPMENT PROCESS

Only phase 3 and 4 modules may carry names. These modules should be referred to in a standard way. The names will be comprised of 'QLQ' followed by two or three letters that will denote the relevant tumour site (e.g. BR for breast cancer, OES for oesophageal cancer), treatment modality (e.g., RT for radiotherapy, CT for chemotherapy), or QL dimension (e.g., BI for body image, and SX for sexuality) followed by 1 or 2 integers that pertain to the number of items included (e.g., the QLQ-BR23, the QLQ-OES24).

As a means of facilitating communication and co-operation within the EORTC QLG, two additional, ongoing activities are being undertaken.

First, position papers reviewing the literature and the available questionnaires on several quality of life domains have been written by group members, e.g., on body image (Hopwood, 1993) and sexuality (Cull, 1992). These papers clarify issues to be included in potential modules and, in some cases, may generate possible items.

Second, phase 2, 3 and 4 modules and their translated versions are stored in a central EORTC database (the Item Bank). The purpose of maintaining this database is to facilitate communication and retrieval of information about available modules, to avoid duplication of effort, and to ensure compatibility in module construction. All module developers are required to send phase 2 and 3 modules to the MDC and the Item Bank at the EORTC QL Unit. Phase 4 modules need to be sent to both the MDC and the EORTC QL Unit at the Data Center. Any changes in the modules or their translated versions also need to be sent immediately to the MDC and Item Bank at the EORTC QL Unit. All phase 4 modules are distributed from the EORTC QL Unit.

Information regarding these issues can be obtained from the MDC and the EORTC QL Unit at the Data Center.

1 • RULES FOR USING MODULES

Phase 1 and 2 modules will not be shared with others. However, information about the developmental process can be obtained directly from the principal investigators.

Phase 3 modules are the property of the EORTC QLG. They are not freely available, but may be obtained via the principal investigators or the EORTC QL Unit. If researchers want to use Phase 3 modules, they may do so only, if:

- > 1. They have received the explicit permission of the principal investigator.
- > 2. They leave the module's integrity intact and will not revise items. However, if they want to add items at the end of the module they may do so after consulting the first author.
- > 3. They provide the first author with a copy of the module as used in the study and the study protocol. When the study is finished they should report back to the first author.
- > 4. They contribute to the psychometric/clinical validation of the module.
- > 5. They respect the publication rights.

Phase 4 modules are the property of the EORTC QLG and can be obtained from the EORTC QL Unit at the Data Center.

2 • PUBLICATION RIGHTS OF MODULES

Phase 2 modules may, in principle, not be published. Phase 3 modules should preferably not be published unless this is specifically agreed upon with the MDC. No restrictions are made with respect to the publication of Phase 4 modules. Publications of EORTC Phase 3 or 4 modules should be on behalf of the EORTC QLG.

When researchers, other than the module constructors, use Phase 3 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. However, if that is unfeasible, publications should be negotiated on a case by case basis.
- > 3. Collaboration between the principal investigator(s) of the module and its users is required 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.

- > 5. The module constructors should have limited access to the data derived from the module, and such socio-demographic/clinical data as would be necessary solely for the purpose of psychometric/clinical validation.

Appendix 7 enumerates the rules and publication rights of modules under development. This information may be sent to (potential) users of such modules to fully inform them about the conditions under which the modules may be used.

3 • OWNERSHIP

The modules to be devised under the auspices of the EORTC Quality of Life Group are the property of the Group. Users' agreement and copyright procedures will follow those drawn up for the core questionnaire.

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1 • MATRIX OF MODULE ELEMENTS: AN EXAMPLE

Stage	Disease Sites			
	Lung		Breast	
	local/ regional	distant	local/ regional	distant
> Disease symptoms	X	X	X	X
> Treatment-related issues				
* Surgery	X	—	X	X
* Chemo therapy	X	X	X	X
* Radio therapy	X	X	X	X
* Hormonal therapy	—	—	X	X
> QL-dimensions				
* Sexuality				
Female	—	—	X	X
Male	—	—	—	—
* Body image				
Female	—	—	X	X
Male	—	—	—	—
* Fear of recurrence	X	—	X	—

> **Note 1:** X is potentially relevant; — is irrelevant.

> **Note 2:** The point can be made that sexuality is compromised by cancer and its treatment even when the reproductive apparatus is not involved. Therefore, sexuality may also be relevant to lung cancer patients. Additionally, fear of recurrence (or fear of death) may also be of interest to patients with metastatic disease.

2 • GENERATION OF RELEVANT QL ISSUES: EXAMPLE OF HEALTH CARE PROVIDERS' INTERVIEWS

> Part 1: *Relevance of issues*

We already have a questionnaire assessing quality-of-life aspects of cancer patients, in general. Quality-of-life aspects relevant to specific diagnostic patient groups are not included in this questionnaire.

We are asking your help in devising a questionnaire which will be used to assess the quality of life of patients who have (fill in specific disease or treatment).

(Place list with issues before consultant)

Here you can see a list with issues relevant to cancer patients with (fill in specific disease or treatment).

- > 1. Could you please indicate for each issue separately the extent to which you find it relevant for this patient group (response categories may range from (1) "not at all relevant" to (4) "very relevant"). "Relevance" refers to the frequency with which a specific complaint occurs and, when it occurs, the trouble it may cause. Thus, the more frequently a complaint occurs and the more trouble it causes, the more relevant it will be for this patient group.

(After completion, the interviewer asks:)

- > 2. Could you please tell me for each issue for which you circled a 1 ("not at all relevant") or 2 ("a little relevant") why you consider it not or only a little relevant?

(Interviewer notes down reasons).

> Part 2: *Breadth of coverage*

(Place the EORTC QLQ-C30 before the consultant).

This is the existing questionnaire that assesses the quality of life of cancer patients in general. Could you please read these questions?

You may have thought of other things that are not included in this questionnaire nor in the previous list of issues you have just rated.

- > 1. Can you think of anything else that may be of relevance to this patient group and is not included in these two questionnaires?
- > 2. If yes: Please name each of these issues so I can write them down.
- > 3. For each additional issue: Could you tell me about this?.

> *Part 3: Relative importance of issues*

The list of issues (including the issues mentioned by the consultants themselves) is too long to be administered to patients. Therefore, a subset of items must be chosen.

- > 1. Could you please point out those issues that, in your opinion, affect the quality of life of these patients most profoundly, and that we should definitely include in the final questionnaire. You may choose a limited number of issues (name the exact number) that you consider to be most relevant. Please indicate for each issue separately whether it should definitely be included in the final questionnaire or not (Yes/No response categories).

> *Example of decision rules for adapting the list of QL issues:*

With respect to deletion of issues:

At this stage, one should feel reluctant to delete issues. However, issues that have a low mean relevance score (e.g. mean < 2) and have not received priority ratings by any of the health care providers may be deleted, provided that the amplification is plausible.

With respect to adding issues:

In principle, if one or more health care providers mention an additional issue, it should be included, provided that the motivation is plausible.

3 • GENERATION OF RELEVANT QL ISSUES: EXAMPLE OF PATIENTS' INTERVIEW

> Part 1: *Relevance of issues*

We are asking your help in devising a questionnaire which will be used to monitor the experiences of patients who have (fill in specific disease or treatment).

Here you see a list of experiences related to.... (Fill in when the module is concerned with an additional QL dimension) which a patient who is.... (Fill in relevant characteristics) may have.

- > 1. Could you please indicate for each experience separately, the extent to which you have had it during your illness?

> Part 2: *Breadth of coverage*

(Place the QLQ-C30 before the patient).

This is an existing questionnaire that asks about you and your health. These questions may be of value for all those patients who are ill (if possible, fill in: patients who have cancer). Could you please read these questions?

You may have had some other experiences that are not included in this questionnaire or in the previous questionnaire (that is the list of issues you have just rated).

- > 1. Can you think of anything else that you have had (experienced/had to cope with) during your illness but is not included in these questionnaires?
- > 2. If yes: please name each of these experiences so I can write them down
- > 3. For each additional issue: could you tell me about this?

> *Alternative part 1 and 2*

One may begin the interview with an open question, asking about patients' experiences with their health and then proceed with part 1. If patients mention issues not included in the list or core questionnaire, these should be added. Part 2 may then not be required. We recommend this alternative approach when the information in the literature is limited. For example:

() I would like to ask you a few things about your health. Can you tell me about the experiences you may have had as a result of your disease (or treatment)?*

(Neutral probes, e.g.: Can you tell me more about that? Can you think of additional experiences?)

> *Part 3: Relative importance of issues*

(Two lists could be prepared in advance: one including all the problem statements (i.e., the negatively worded items), the other including all the functioning items (i.e., the positively phrased items). The issues added by the patient should be filled in on the appropriate list).

> *For problem statements:*

Here you can see a list comprising all the problems that were included in the two questionnaires (and problems you have added yourself). These problems are probably not equally important to you. You may consider some problems more important than others.

- > 1. We would like to ask you which of these problems, including the problems you have mentioned yourself, troubled you the most. Please, read these two questionnaires carefully, and pick out the 5 (to 10) problems that caused you the greatest trouble (nuisance, distress).

(Interviewer notes down problems)

- > 2. For each chosen problem separately: Can you tell me about that?

> *For capacities, abilities, and positive experiences:*

The same, but the wording will be conform page 5, first paragraph: patients will be asked to select 5 (to 10) items that they value particularly highly.

> *Follow-up questions*

The use of follow-up questions or "probes" will be required in the majority of interviews. The appropriate wording is dependent on the topic at hand, but should always be in an open, non-judgemental way. For example:

* If the answer is too general and indefinite, the follow-up may be "In what way?"
"Just how do you mean?" "Can you give me an example?"

* If the answer is incomplete, the questions may be "Any other reasons?"
"Would you tell me a little more about that?"

Other follow-ups could ask: "What makes you think this?" "What was there in the question that made you feel that way" (Kornhauser and Sheatsley, 1976, p. 544).

> *Example of decision rules for adapting the list of QL issues:*

With respect to deletion of issues:

At this stage, one should feel reluctant to delete issues. However, issues rated to be least important by a number of patients (e.g. a quarter) may be deleted, provided that the amplification is plausible, and that these issues are not rated to be most important by a number of other patients.

With respect to adding issues:

In principle, if a number of patients (i.e. at least two) mention an additional issue, it should be included, provided that the motivation is plausible. In some cases, an issue mentioned by only one patient may warrant inclusion.

4 • PRE-TESTING THE MODULE: EXAMPLE OF PATIENTS' INTERVIEW

> *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 (if possible, fill in: patients who have cancer).

As a result of your (illness/treatment) you may have experiences in common with other patients who have the same (illness/treatment). These particular experiences are not covered by this more general questionnaire. We want to add some extra questions to take account of those things which may be important to you and other patients who have (disease/treatment/characteristics). We are now asking your help in devising these additional questions.

> *Administration of EORTC QLQ-C30 and the module*

(Place EORTC QLQ-C30 and the module before the patient)

I will ask you first to complete the original questionnaire and the additional, special questions. After you have completed them, I will interview you to make sure we asked the right questions in the right way. We want to be sure that we cover the most important aspects of patients' experience of (disease/treatment/QL dimension).

> *Interview directed to each module item separately*

The wording of the interview questions will be dependent on whether the module item refers to a problem or an ability, and how the respondent has filled out the particular item (i.e., no problem at all versus a problem to some degree).

> For items referring to problems respondents have indicated they have, they will be asked the following questions:

I see that you have this problem (fill in particular problem) to some degree (fill in the degree tapped).

- > *a.* Is this correct?
- > *b.* Can you tell me about this problem?
- > *c.* Do you think that this problem is related to... (fill in disease or treatment)?
- > *d.* Did you have difficulty in replying to this question?
- > *e.* Did you find this question annoying?
- > *f.* Did you find this question confusing?
- > *g.* Did you find this question upsetting?
- > *h.* How would you have asked this question?

- > For problems the respondent did not endorse, they will be asked the following questions:

I see that you did not have this problem during the previous week.

- > *a.* Is this correct?
- > *b.* Have you ever experienced this problem before last week?
If not, skip to (e)
- > *c.* If yes, do you have any idea if that had something to do with your disease (or treatment)?
If not, skip to (e)
- > *d.* If yes, can you tell me about this problem?
- > *e.* Did you have difficulty in replying to this question?
- > *f.* Did you find this question annoying?
- > *g.* Did you find this question confusing?
- > *h.* Did you find this question upsetting?
- > *i.* How would you have asked this question?

- > For abilities and functioning which the respondent indicated to be limited in to some extent, they will be asked the following questions:

I see that you were able to... (fill in exact ability) to some degree (fill in degree tapped) during the previous week.

- > *a.* Is this correct?
- > *b.* Can you tell me about this (ability)?
- > *c.* Do you think that your disease (or treatment) has affected in any sense your ability to (fill in ability)?
- > *d.* Did you have difficulty in replying to this question?
- > *e.* Did you find this question annoying?
- > *f.* Did you find this question confusing?
- > *g.* Did you find this question upsetting?
- > *h.* How would you have asked this question?

- > For abilities and functions the respondent is completely able to perform, they will be asked the following questions:

I see that you are completely able to.... (fill in ability) during the previous week.

- > *a.* Is this correct?
- > *b.* Can you tell me about this ability?
- > *c.* Were you limited in your capacity to do this before last week?
If not, skip to (e)
- > *d.* If yes, do you have any idea if that had something to do with your disease (or treatment)?
- > *e.* Did you have difficulty in replying to this question?
- > *f.* Did you find this question annoying?
- > *g.* Did you find this question confusing?
- > *h.* Did you find this question upsetting?
- > *i.* How would you have asked this question?

> *Interview directed to the entire module*

If modules contain a large number of items (e.g., over 20), the time involved in questioning about each individual item would be prohibitive. In those cases the questions may be directed towards the entire module. For example:

- > *1.* Were there questions that you found difficult to answer?
- > *2.* Were there questions that you found annoying?
- > *3.* Were there questions that you found confusing?
- > *4.* Were there questions that you found upsetting?
- > *5.* Were there questions that you found intrusive?
- > *6.* Do you have other comments about these questions?

These general questions may then be supplemented by the further probing of selected module items. For example, questions (a) to (c or d) and (h) may be posed to items that are expected to cause some difficulty (e.g., positively phrased questions and double negatives) and items that appear to be troublesome during the interview.

> *Completion of the interview*

The pre-testing interview should be completed with two questions directed to the entire questionnaire (i.e., the core questionnaire and the module):

- > a. Were there questions that you found irrelevant?
- > b. Can you think of additional issues that are relevant for you but are not included in this questionnaire?

> *Example of decision rules for module adaptation*

> With respect to deletion of items:

Problems (e.g., symptoms) that relatively few patients reported to have, and abilities that relatively few patients were limited in, may be of little relevance for inclusion in the final module. These are candidate items for deletion.

Parameters to be considered are: the mean, the prevalence ratio (i.e. the number of patients who has the particular complaint divided by the total number who has completed the item), and the range of responses. Additionally, the relevance and priority ratings provided by patients as well as physicians during the first phase, may again be considered, provided that items and issues coincide. Finally, verbal comments provided by patients are important, additional considerations. For example, after re-scaling the positive items, with response categories ranging from 1 "not at all" (no problems)" to 4 "very much" (many problems) the following cut-off points may be chosen:

- > 1. Mean score: < 1.5 versus ≥ 1.5 ;
- > 2. Prevalence ratio: < 30% versus $\geq 30\%$;
- > 3. Range: < 2 points versus ≥ 2 points;
- > 4. Priority patients: < a third versus \geq a third; and
- > 5. Priority consultants: < a third versus \geq a third.

Items that meet at least 3 of these 5 criteria may be retained in the list, unless the answers to the open interview questions provide counter-information (e.g., for the majority of subjects, the issues are not related to the disease, the question meant something different, etc.).

Items that meet 2 or less criteria could be deleted, unless the interviews provided strong arguments for retaining them in the list (e.g., when the importance was stressed in a considerable number of interviews).

We would like to emphasise that these cut-off points serve as an example. Depending on the number of items pre-tested, the number of items that are allowed to be identified as having a high priority, and the sample size, the cut-off points may need to be adapted.

> With respect to addition of items:

At this stage, the barrier to any new questions should be kept high (see also Converse and Presser, 1986). Additional issues that are mentioned by a considerable number of patients (e.g., at least a third of the patients) and that are related to the disease or treatment, should be operationalised into questions and added to the list.

> With respect to rephrasing items:

On the basis of the interviews, questions may be identified that troubled (some of the) patients. This information should be taken seriously. Even when a small number of patients had difficulty answering the questions, these should be rewritten (e.g., rephrased, subdivided etc.). Additionally, items that have limited variance are suspicious and may require rewriting.

5 • REPORT ON MODULE CONSTRUCTION (PHASE 1 THROUGH 3)

This report, written in English, should be organised according to the following subheadings and should include the following information:

> CONTENTS

> 1. Research objective

Research question, purpose or patient population for which the module was developed.

> 2. Identification of relevant module elements

i.e. the list of QL domains

> 3. Phase 1: Generation of quality of life issues: literature searches

> 3.1 Literature search

Use of "MesH" headings and databases

List of references included in the literature search (see Appendix A)

> 3.2 Existing questionnaires

List of available questionnaires consulted

> 3.3 Selection of issues

Final list of QL issues (see Appendix B)

> 4. Phase 1: Generation of quality of life issues: interviews with health care providers

> 4.1 Health-care providers

Number of consultants and their specialities

> 4.2 Organisation of the issues

E.g. according to disease symptoms, treatment-related side effects etc.

> 4.3 Interviews

The interview instructions (see Appendix B)

> 4.4 Results of health care providers' interviews

> 4.4.1 Quantitative results

Individual ratings, average ratings, priority ratings
(See Appendix C)

> 4.4.2 Qualitative results

Comments leading to adaptations (e.g., irrelevance of issues,
Rewording, combining or splitting up of issues, omissions)

> 4.4.3 Resulting list of issues (see Appendix D)

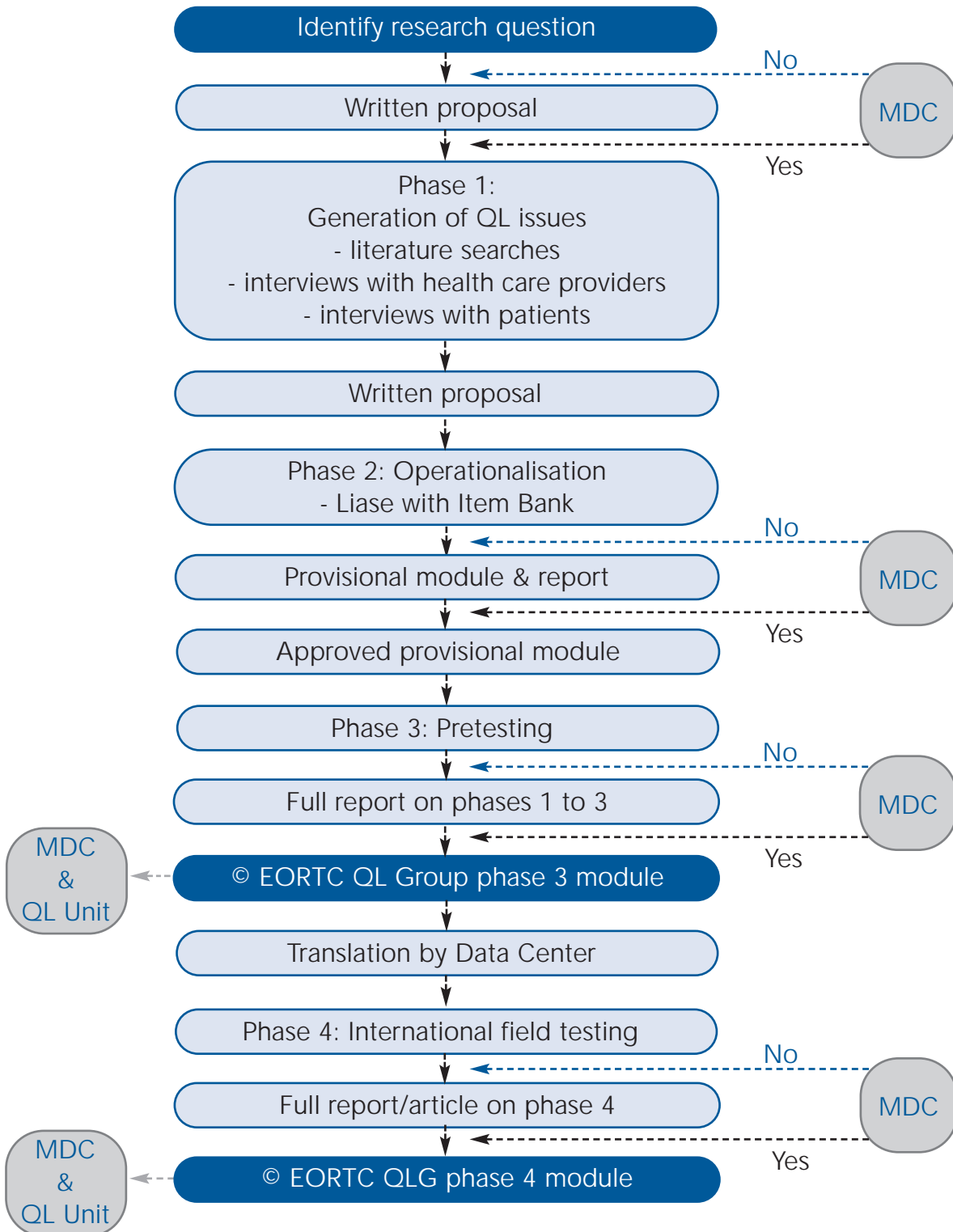
- > 5. Phase 1: Generation of quality of life issues: patients' interviews
 - > 5.1 Patients
 - Number of patients and relevant background characteristics
 - > 5.2 Interviews:
 - The interview instructions (see Appendix E)
 - > 5.3 Results of patients' interviews
 - > 5.3.1 Quantitative results
 - Individual ratings, average ratings, priority ratings
 - (See Appendix F)
 - > 5.3.2 Qualitative results
 - Comments leading to adaptations (e.g., irrelevance of issues, Rewording, combining or splitting up of issues, omissions)
 - > 5.3.3 Resulting list of issues (see Appendix G)
- > 6. Phase 2: Operationalisation
 - > 6.1 Criteria
 - Criteria for operationalisation
 - > 6.2 Operationalisation
 - > 6.2.1 Construction of new items (not in the Item Bank)
 - > 6.2.2 Inclusion of existing items from the Item Bank
 - > 6.2.3 List of new items not included from the Item Bank
 - > 6.3 The resulting questionnaire
 - Description of the questionnaire (see Appendix H)
- > 7. Phase 3: Pre-testing
 - > 7.1 Patients
 - Number of patients and their relevant characteristics
 - > 7.2 Interviews
 - The interview instructions (see Appendix I)
 - > 7.3 Procedure for item selection
 - > 7.3.1 Quantitative information
 - (Per item: e.g. mean scores, prevalences, standard deviations, Range of scores and priority ratings)
 - > 7.3.2 Quantitative criteria for item selection
 - > 7.3.3 Qualitative information
 - (I.e. summary overviews of the comments provided by patients)

- > 7.4 Results
 - > 7.4.1 Quantitative (see Appendix J)
 - > 7.4.2 Qualitative
- > 8. Resulting module to be field-tested
 - > 8.1 Description
 - > 8.2 Hypothesised questionnaire structure
 - > 8.2.1 Sub-scales
 - > 8.2.2 Single items (see Appendix K)
- > *References*

Note on researchers involved
- > *Appendices*
 - > a. References
 - > b. Generation of QL issues: Interviews with health care providers plus subsequent list of issues
 - > c. Generation of QL issues: Quantitative results of interviews with health care providers
 - > d. List of issues to be presented to patients
 - > e. Generation of QL issues: Interviews with patients
 - > f. Generation of QL issues: Quantitative results of interviews with patients
 - > g. List of issues to be operationalised into items
 - > h. Provisional module to be pre-tested
 - > i. Pre-testing: patients' interview
 - > j. Pre-testing: overview of quantitative results
 - > k. Resulting module to be field-tested

>>> **NOTE:** Depending on the number of languages involved in the module development process, appropriate paragraphs and appendices should be added.

6 • FLOW CHART OF MODULE DEVELOPMENT PROCESS



>>> **N.B.** Bi-annual update report to MDC (and minutes) required
Send revisions of phase 3 and 4 modules to MDC and EORTC QL Unit.

7 • RULES AND PUBLICATION RIGHTS FOR MODULES UNDER DEVELOPMENT

> Rules for using EORTC Phase 3 modules

- > 1. Such modules are not freely available, but may be obtained from the EORTC QL Unit or the principal investigator.
- > 2. If researchers want to use such modules, they may do so only if:
 - > a. They have received the explicit permission of the first author (via the EORTC Quality of Life Unit).
 - > b. They leave the module's integrity intact and will not revise items. However, if they want to add items at the end of the module they may do so after consulting the first author.
 - > c. They provide the first author with a copy of the module as used in the study and the study protocol. When the study is finished they should report back to the first author.
 - > d. They contribute to the psychometric/clinical validation of the module.
 - > e. They respect the publication rights.

> Publication rights of EORTC modules under development

- > 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. However, if that is not feasible, publication should be negotiated on a case by case basis.
- > 3. Dependent on the stage of module development, collaboration between the (first) author(s) of the module and its users may be required 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 psychometric information of the module.
- > 5. The module constructors should have limited access to the data derived from the module, and such socio-demographic/clinical data as would be necessary solely for the purpose of psychometric/clinical validation.