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Quality of life research within the EORTC—the EORTC QLQ-C30

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Abstract

In forming its Quality of Life Group, the EORTC created one of the earliest and largest of such groups in Europe. The EORTC QLQ-C30 which this group developed has become the most widely used questionnaire in Europe for cancer patients, and is extensively used around the world. The Quality of Life Group continues to build upon this success, both by refining the QLQ-C30, whilst developing a range of additional modules, and by initiating research projects that explore aspects of quality of life assessment, evaluation and interpretation. We review the progress to date and indicate directions of further research and development.

Keywords: Quality of life; EORTC QLQ-C30; Patient questionnaire; EORTC Quality of Life Group

1. Introduction

One of the principal functions of the European Organisation for Research and Treatment of Cancer (EORTC) is the execution of large, prospective, randomised, multicentre cancer clinical trials, covering the full range of cancer sites and therapies. Quality of life (QoL) has always been an important aspect of the EORTC approach to treatment as stated in the aims of the organisation: "to conduct, develop, coordinate, and stimulate laboratory and clinical research in Europe to improve the management of cancer and related problems by increasing survival, but also patients' *quality of life*." Both cancer and its treatment are severely debilitating, and the need to consider their impact upon health-related QoL when making patient management or treatment decisions is nowadays well accepted. Given the current recognition of the importance of formal assessment of QoL, and the consequent proliferation of QoL questionnaires, it is interesting to note that as recently as 15 years ago there were hardly any validated instruments for patients' self-completion, and most of the few that were available focused narrowly upon the physical aspects of disease. Thus, the EORTC showed considerable foresight when creating the EORTC Quality of Life Group (QLG) in 1980 to advise the EORTC Data Center and the various cooperative groups on the design, implementation and analysis of QoL studies within selected phase III studies. The first major achievement of the EORTC QLG was in 1987, when the QLG developed its first generation core questionnaire, the EORTC Quality of Life Questionnaire-Core 36 (QLQ-C36). Throughout the years since then, the QLG has continued to build upon its initial successes, in particular taking advantage of its unique situation of having a multidisciplinary mix of members from diverse linguistic and cultural backgrounds.

The other crucial component in the EORTC strategy was the establishment in 1993 of the Quality of Life Unit (QLU) as a scientific and administrative unit within the EORTC Data Center. Initially, the creation of the QLU was a 2-year pilot project supported by the European Community, but the success led to its formal establishment in 1995. The main aim of the Unit is to advise on the design, implementation and management of QoL measurement across all EORTC clinical trials. The QLU supervises translations and undertakes distribution of the EORTC QoL instruments.

The EORTC QLG and QLU work in of close, daily collaboration, thus ensuring an optimal mix of scientific, business and administration activities.

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In this article, we review the achievements to date of the QLG and QLU, and describe our future directions in research and development.

2. Quality of Life Group

From its inception, the QLG had a formally defined mission statement. This was:

- To develop reliable instruments for measuring the quality of life of cancer patients participating in international clinical trials;
- To advise the EORTC about the assessment of the multidimensional aspects of patients' QoL as a measurable outcome of cancer treatment;
- To advise on the design, implementation and analysis of QoL studies within EORTC trials;
- To conduct basic research in the methodology of QoL assessment;
- To contribute to teaching/training initiatives to promote the EORTC approach to QoL assessment through preparation of teaching material, oral presentations, etc.

In addition, from the very beginning one of the strengths of the QLG has been its membership which consists of a broad range of professionals, including oncologists, radiotherapists, surgeons, psychiatrists, psychologists, social workers, nurses, statisticians and research methodologists. Furthermore, these members come from 15 European countries as well as Canada. This cultural mix of professional backgrounds, languages and geography, has shaped the QLG's approach to QoL assessment.

3. Quality of Life Unit, EORTC Data Center, Brussels

The aims of the QLU are three-fold. Firstly, to evaluate the importance of various factors that improves the QoL of cancer patients. Secondly, to supervise the evaluation of QoL in selected cancer clinical trials. Thirdly, to encourage physicians to pay greater attention to quality of life factors in the treatment of cancer by stimulating, enhancing and co-ordinating the evaluation of quality of life in cancer clinical trials. The QLU is staffed by a team of professionals with experience in psychometrics, psychology, statistics, data management, translations, and administration. Over 120 EORTC clinical trials have QoL components, and advising EORTC co-operative groups on the design, conduct and assessment of quality of life is a major activity of the QLU.

Many activities are carried out in close collaboration with the QLG. For example, the QLU manages the international QLG field studies that validate QLG modules, administers the translation programme for the QLQ-C30 and disease-specific modules, and serves as a central point for the dissemination of various QLG products such as the QLQ-C30 and support manuals. A number of research projects are also undertaken in collaboration with the QLG and conducted from the QLU, including cross-cultural analysis of the core QLQ-C30 questionnaire, and development and management of an Item Bank of all questionnaire items. Finally, the QLU is actively involved in education, training and providing support to academics and industry on all issues of design, conduct and analysis of quality of life studies.

The roles of the QLG and QLU are so intimately linked that many of the activities that we describe as 'QLG' in this paper are in fact 'QLG and QLU in collaboration'.

4. EORTC QLQ-C30 development

The first generation of the EORTC quality of life questionnaire (QLQ) was developed by 1987. It was designed to be:

- Cancer-specific;
- Multidimensional in structure;
- Appropriate for self-administration;
- Applicable across a range of cultural settings;
- Suitable for use with additional site- or treatment-specific modules.

The QLQ-C30 (version 1) incorporated five functional scales (physical, role, cognitive, emotional, and social), three symptom scales (fatigue, pain, and nausea and vomiting), a global health status/QoL scale, and a number of single items assessing additional symptoms commonly reported by cancer patients (dyspnoea, loss of appetite, insomnia, constipation and diarrhoea) and perceived financial impact of the disease. Subsequent versions were built upon the same basic principles, culminating in the 'core' 30-item EORTC QLQ-C30 (version 3.0) questionnaire, representing over 20 years of continuous development, refinement and validation (Fig. 1).

Development and validation of the QLQ-C30 has been published [1,2]. A Scoring Manual is available for the QLQ-C30 [3], and the Reference Values Manual provides values based upon international data sets from many countries [4].

The development continues. Currently, we are exploring the use of a shortened version of the QLQ-C30 for use in palliative care patients.

5. EORTC QLQ-C30 modules

From the beginning, an essential part of our philosophy has been that the EORTC QLQ-C30 is a brief core

EORTC QLQ-C30 (version 3)

We are interested in some things about you and your health. Please answer all of the questions yourself by circling the number that best applies to you. There are no "right" or "wrong" answers. The information that you provide will remain strictly confidential.

Please fill in your initials: ⌊_⌊_⌊_⌊_⌋

Your birthdate (Day, Month, Year): ⌊_⌊_⌊_⌊_⌊_⌊_⌊_⌊_⌋

Today's date (Day, Month, Year): 31 ⌊_⌊_⌊_⌊_⌊_⌊_⌊_⌊_⌋

		Not at All	A Little	Quite a Bit	Very Much
1.	Do you have any trouble doing strenuous activities, like carrying a heavy shopping bag or a suitcase?	1	2	3	4
2.	Do you have any trouble taking a long walk?	1	2	3	4
3.	Do you have any trouble taking a short walk outside of the house?	1	2	3	4
4.	Do you need to stay in bed or a chair during the day?	1	2	3	4
5.	Do you need help with eating, dressing, washing yourself or using the toilet?	1	2	3	4

During the past week:		Not at All	A Little	Quite a Bit	Very Much
6.	Were you limited in doing either your work or other daily activities?	1	2	3	4
7.	Were you limited in pursuing your hobbies or other leisure time activities?	1	2	3	4
8.	Were you short of breath?	1	2	3	4
9.	Have you had pain?	1	2	3	4
10.	Did you need to rest?	1	2	3	4
11.	Have you had trouble sleeping?	1	2	3	4
12.	Have you felt weak?	1	2	3	4
13.	Have you lacked appetite?	1	2	3	4
14.	Have you felt nauseated?	1	2	3	4
15.	Have you vomited?	1	2	3	4

Please go on to the next page

During the past week:		Not at All	A Little	Quite a Bit	Very Much
16.	Have you been constipated?	1	2	3	4
17.	Have you had diarrhea?	1	2	3	4
18.	Were you tired?	1	2	3	4
19.	Did pain interfere with your daily activities?	1	2	3	4
20.	Have you had difficulty in concentrating on things, like reading a newspaper or watching television?	1	2	3	4
21.	Did you feel tense?	1	2	3	4
22.	Did you worry?	1	2	3	4
23.	Did you feel irritable?	1	2	3	4
24.	Did you feel depressed?	1	2	3	4
25.	Have you had difficulty remembering things?	1	2	3	4
26.	Has your physical condition or medical treatment interfered with your family life?	1	2	3	4
27.	Has your physical condition or medical treatment interfered with your social activities?	1	2	3	4
28.	Has your physical condition or medical treatment caused you financial difficulties?	1	2	3	4

For the following questions please circle the number between 1 and 7 that best applies to you

29. How would you rate your overall health during the past week?

1	2	3	4	5	6	7
Very poor						Excellent

30. How would you rate your overall quality of life during the past week?

1	2	3	4	5	6	7
Very poor						Excellent

Fig. 1. EORTC QLQ-C30 (version 3). For permission to use, contact: Quality of Life Unit, EORTC Data Center, Avenue E Mounier 83-B11, 1200 Brussels, Belgium.

measure for general use with cancer patients, and that it should be supplemented by additional modules. These, when employed in conjunction with the QLQ-C30, provide more detailed information relevant to evaluating the QoL in specific patient populations. A module may be developed to assess: (1) symptoms related to a specific tumour site (e.g. urinary symptoms in prostate cancer, or problems with speech and eating in head and neck cancer); (2) side-effects associated with a given treatment (e.g. chemotherapy-induced neuropathy); or (3) additional QoL domains affected by the disease or treatment (e.g. fatigue, sexuality, body-image, fear of disease recurrence, etc.). By focusing on issues of particular concern in the different settings, clinically relevant information is collected concerning patients' reactions to treatment and progress over time, and also more sensitive comparisons may be made between treatment groups in clinical trials. This 'modular approach' has since been adopted by many other groups.

Rigorous procedures have been developed to ensure the quality of the modules developed [5], and these are defined in the Guidelines for Developing Questionnaire Modules [6]. In brief, four phases of development are recognised. Phase 1 generates QoL issues; phase 2 develops questionnaire items and scales; phase 3 pretests the provisional module and phase 4 examines the module in an international setting for reliability and validity. Phase 1 is entirely qualitative research, whilst phase 4 is predominantly quantitative and statistical. Phase 4 studies usually involve over 400 patients and up to 11 European countries. Module developers submit regular reports to the QLG, documenting their processes, and these undergo rigorous internal review and quality control. Developing modules to these standards is a lengthy and demanding process, requiring detailed clinical knowledge, as well as research skills. Modules developed in collaboration with the QLG frequently constitute the major part of a PhD project.

To date, 15 such modules have been developed, of which five have completed extensive large-scale international testing [7–18] (Table 1). Another seven modules are in the earlier stages of development (Table 1). Whereas early modules were predominantly for cancer sites, new modules are likely to focus increasingly upon QoL dimensions and issues, such as satisfaction with care, information giving, fatigue, choice and decision-making, anorexia/cachexia.

Modules are copyrighted and may only be used after written consent is obtained from the EORTC Data Center or the module developers.

6. EORTC QLQ-C30 translations

Another essential ingredient of our philosophy is that the QLQ-C30 and QLQ modules should be suitable for use in a wide range of languages and cultures, as found both within Europe and beyond. The QLQ-C30 (version 3) is currently available in 41 languages (Table 2), and each translation has been carefully developed and tested following strict and detailed guidelines that are documented in the QLG Translation Procedure Manual [19]. Any modules not initially developed in English are first translated into English, and then to other languages. All translations involve two native speakers of the target language who are also fluent in the original language; these independently translate the questionnaire. The resultant translation is then 'back translated' by two native speakers of the original language, with iterations between the forward and backward translation as necessary. The translated questionnaire is then field-tested on patients, to detect any ambiguities or other problems with the translated items. A formal report is submitted to the QLG, and is reviewed by at least two members before approval is given.

7. Using the QLQ-C30

Although the QLQ-C30 was primarily developed for use in clinical trials, it is now being used in a variety of other settings including cross-sectional surveys, longitudinal surveys, and individual patient management and monitoring.

7.1. Clinical trials

The QLQ-C30 is the most widely used questionnaire for patients in clinical trials in Europe, and is also used extensively in America and throughout the rest of the world. Over 12 000 patients in EORTC trials alone have completed the QLQ-C30 and modules. In addition, we have granted licenses for the QLQ to be used in over 3000 other studies, both by pharmaceutical companies and academic or other users.

There are many issues to consider when implementing an assessment of QoL into clinical trials, including deciding which trials benefit from evaluating QoL (not all do!), what QoL dimensions are relevant, frequency of assessment and flexibility around timing of assessments ('assessment windows'), compliance (in the past, many trials have been bedevilled by poor patient and/or clinician compliance), missing data (data will inevitably be incomplete, how can we avoid bias?), the use of proxy ratings for those unable to complete questionnaires themselves, training of staff, ethical issues, and so on. Analysis of QoL data from clinical trials, too, raises many issues—how to analyse multiple QoL outcomes, with assessments repeated at multiple timepoints, in the presence of incomplete or missing data, and when patients in the two or more treatment arms may have differing rates of death? How to interpret the

results? Many of these issues are discussed in Fayers and Machin [21].

Within the EORTC, to the best of our available resources, we try to improve the quality of QoL assessments by working on two fronts: firstly, the QLG encourages links with other EORTC groups by means of liaison members who belong to both groups; and secondly, the QLU also offers support to the other EORTC groups.

Table 1
Details of EORTC QLQ modules

EORTC QLQ phase 4 modules		Developed for (single or multi-modality)	Scales and items
Breast [7]	QLQ-BR23	Surgery, chemotherapy, radiotherapy, hormonal treatment	Side-effects of treatment, arm symptoms, breast symptoms, body image, sexual functioning, alopecia, future perspective
Head and neck [8–10]	QLQ-H&N35	Surgery, radiotherapy, chemotherapy, endoscopic laser therapy	Pain, swallowing, taste, smell, speech, eating, sexuality, teeth, mouth opening, dry mouth, sticky saliva, coughing, feeling ill, pain killers, nutrition supplements, feeding tube, weight loss or gain
Lung [11]	QLQ-LC13	Chemotherapy, radical or palliative radiotherapy, endobronchial brachytherapy, best supportive care.	Dyspnoea, pain, coughing, sore mouth, dysphagia, peripheral neuropathy, alopecia, haemoptysis
Oesophageal [12]	QLQ-OES24	Surgery, radiotherapy, chemotherapy, all methods of endoscopic palliation	Dysphagia, deglutition, eating, reflux symptoms, pain, emotional problems, coughing, dyspnoea, taste, talking, alopecia
Ovarian [13]	QLQ-OV28	Surgery, chemotherapy	Gastrointestinal symptoms, peripheral neuropathy, chemotherapy side-effects, hormonal symptoms, body image, attitudes to disease/treatment, sexuality
EORTC QLQ phase 3 modules		**Developed for**	**Scales and items**
Bladder (muscle invasive)	QLQ-BLmi30	Wide range	Urinary and bowel symptoms, sexual functioning, urostomy and catheter problems, body image
Bladder (superficial)	QLQ-BLsup24	Wide range	Urinary and bowel symptoms, sexual functioning, fever, malaise, convenience/worry of cystoscopies
Brain [14]	QLQ-BN20	Chemotherapy, radiotherapy	Future uncertainty, visual disorder, motor dysfunction, communication deficit and other disease symptoms, treatment toxicities
Colorectal [15]	QLQ-CR38	Wide range	Disease symptoms, side-effects of treatment (sphincter-saving resection, rectum extirpation, radiotherapy and chemotherapy), body image, sexuality, future perspective
Gastric [16]	QLQ-STO22	Wide range with adenocarcinoma	Disease and treatment-related symptoms and side-effects, dysphagia, nutritional aspects, items about emotional problems of gastric cancer
Multiple myeloma [17]	QLQ-MY24	Wide range	Pain, treatment side-effects, social support, future perspective
Opthalmic	QLQ-OPT37	Wide range	Vision impairment and functional problems, eye symptoms, worry about recurrent disease, problems with appearance, problems driving, headache, problems reading
Pancreatic [18]	QLQ-PAN25	Surgical resection, palliative surgical intervention, endoscopic palliation or palliative chemotherapy	Pain, dietary changes, jaundice, altered bowel habit, emotional problems related to pancreatic cancer, other symptoms
Prostate	QLQ-PR25	Localised and metastatic prostate cancer	Urinary symptoms, bowel symptoms, treatment-related symptoms, sexual functioning
Satisfaction with care	QLQ-SAT32	During hospital stay	Doctor and nurse technical and interpersonal skills; information provision and availability; personnel kindness, helpfulness and information giving; exchange of information between caregivers; waiting for medical tests/treatment/results; access, comfort/cleanliness, general satisfaction

EORTC QLQ phase 1 or 2 modules (modules in early development stages)	
Carcinoid	Information
Chronic lymphocytic leukaemia	Peripheral neuropathy
Fatigue	Primary liver tumours
Hepatic metastases	

Based upon our experience over the years, *Guidelines for Assessing Quality of Life in EORTC Clinical Trials* was written [20]. This manual provides guidance for standardising QoL assessment across EORTC randomised clinical trials, and acts as a reference source for 'Good Clinical Practice' where QoL is being assessed in a clinical trial.

One particular issue when designing a clinical trial in which QoL is the primary endpoint is the question of sample size. The Reference Values Manual [4] provides a basis for specifying the effect size of interest, and the manual also contains details for the calculations of sample size estimates together with worked examples.

7.2. Interpretation of QLQ scores

To those who are unfamiliar with the QLQ-C30 and modules, the clinical interpretation of the scores (which are presented on scales ranging from 0 to 100) may seem perplexing. A variety of methods have been proposed to aid interpretation of QoL scores in general [21], and several are reviewed in the QLG Scoring Manual [3]. The Reference Values Manual [4] tabulates values for the individual QLQ-C30 items and scales, according to the main cancer sites. The manual was developed to help familiarise researchers with the QLQ-C30 scores

Table 2
Currently available translations of the QLQ-C30 and modules[a]

Language	Gender	QLQ-C30 (version 3)	BR23	H&N35	LC13	OES24	OV28
African (Sotho)		✓					
African (Xhosa)		✓					
African (Zulu)		✓					
Arabic		✓	✓		✓		
Bulgarian		✓	✓				
Chinese		✓	✓	✓	✓	✓	✓
Chinese (Taiwanese)		✓					
Croatian		✓	✓				✓
Czech	m + f	✓	✓		✓		
Danish		✓	✓	✓	✓	✓	✓
Dutch		✓	✓	✓	✓	✓	✓
Dutch (Afrikaans)		✓					
English		✓	✓	✓	✓	✓	✓
Finnish		✓	✓	✓	✓	✓	
French	m, f, m + f	✓	✓	✓	✓	✓	✓
French (Canadian)		✓					
German		✓	✓	✓	✓		
Greek	m + f	✓	✓		✓		
Hebrew		✓	✓	✓	✓		
Hungarian		✓	✓				
Indian (Gujarathi)		✓	✓				
Indian (Marathi)		✓	✓				
Iranian		✓	✓				
Italian	m, f	✓	✓	✓	✓	✓	✓
Japanese		✓	✓			✓	
Korean		✓	✓		✓		
Lithuanian		✓	✓	✓			
Macedonian		✓		✓			
Norwegian		✓	✓	✓	✓	✓	✓
Polish	m + f	✓	✓	✓	✓	✓	✓
Portuguese	m + f	✓	✓	✓	✓		
Portuguese (Brazilian)	m + f	✓					
Russian		✓	✓	✓	✓	✓	
Serbian		✓					
Slovakian	m + f	✓					
Slovenian		✓	✓		✓		
Spanish	m, f	✓	✓	✓	✓	✓	✓
Spanish (American)	m, f	✓					
Spanish (Argentinian)	m + f	✓					
Swedish		✓	✓	✓	✓	✓	✓
Turkish		✓	✓		✓		

'm, f' indicates that separate male and female versions exist, and 'm + f' indicates a version suitable for both sexes (neutral).

[a] At the time of going to press, the EORTC QLQ-C30 (version 3) and the QLQ modules have been translated into the languages listed. The original English version has been tested for use with British, American, Australian and Canadian speakers of English. An up to date list of translations of the QLQ-C30 and its modules may be obtained from the Quality of Life Unit at the EORTC Data Center.

and thereby facilitate the interpretation of scores. This manual shows the scores that are typically seen in particular classes of patient, enabling identification of those patients with higher or lower scores than may be usually expected. It also shows the magnitude of the differences that may be seen when comparing different types of patient, and by relating this to clinical observation, allows clinicians to judge the clinical significance of similar changes within or between patients.

National population data has been collected independently from large random samples of the general population in Germany, Norway and Sweden, and females in Denmark [22–25]. Although these samples revealed some curious differences, their data provides a useful basis for interpreting QLQ-C30 scores [26].

King [27] used data from 14 published studies employing the QLQ-C30, grouping patients according to performance status, weight loss, toxicity, and extent or severity of disease. For each QLQ-C30 scale, analyses were made of the differences in mean scores between groups differing with respect to the clinical criteria. Osoba and colleagues [28] developed the Subjective Significance Questionnaire (SSQ). The SSQ asks patients about *perceived changes* in physical, emotional and social functioning and in global QL, using a 7-point scale ranging from 'much worse' over 'no change' to 'much better'. Patients filled in the QLQ-C30 at two occasions. At the second completion, they also filled in the SSQ. Patients who reported 'a little' change for better or worse on a particular scale (function or symptom) had QLQ-C30 changes approximately 5–10. Those reporting 'moderate' change had changed approximately 10–20, and 'very much' change corresponded to a change greater than 20.

The QLG is continuing research into change-scores and clinical significance, to answer such questions as: 'What is the smallest change in emotional functioning score that patients regard as discernable, or important?' In the absence of more concrete recommendations to date, it is interesting to note that various investigators, using a variety of QoL instruments, have found that an absolute change of approximately 10% in QoL scores corresponds on average to patients' description of 'a moderate change', and 5–10% represents a 'small change'. Osoba and colleagues [28] have shown that this applies to the QLQ-C30, too. This conclusion is also consistent with the results from other approaches, such as the use of Cohen's 'effect size' statistics [21]. However, we consider it unlikely that the same rule-of-thumb would apply to symptoms such as pain or nausea, and further research is needed.

7.3. Individual patient monitoring

An increasing number of clinicians also use the QLQ-C30 for assessing and monitoring patients in routine clinical practice. This is an area of growing interest, and QLG members have been exploring aspects of this, as well as the use of computer-aided data capture—for example, the use of touch-screens [29]. Early results have been extremely encouraging, and contrary to some expectations many researchers are finding that even elderly patients or those with terminal illness have little problem in using modern technology, provided suitable interfaces are provided.

8. Research

The continued development of the QLQ-C30 and an ever-increasing number of modules and translations remains a priority for the QLG. However, an equally important aspect of our programme is research into QoL assessment, analysis and interpretation. In addition to the topics already mentioned above (clinical significance and interpretation of QoL scores, use of touch-screens, and individual patient monitoring), the QLG and its members are working on a variety of 'state-of-the art' research issues.

8.1. Item response theory

The QLQ-C30, like most other currently available QoL instruments, was designed using rigorous, but traditional psychometric techniques. More recently, item response theory (IRT) models have become more widely available for scale development. These are statistical (probablistic) models for multi-item scales, and involve estimating 'difficulty' values for each question. For example, when measuring physical functioning, running is more 'difficult' than walking. Although the concept is simple, the models become quite complex and require special software for their implementation. They do, however, provide powerful tools for designing and evaluating new measurement scales, and for examining, altering and analysing existing QLQ scales. The QLG is funding two projects that use IRT methods.

8.2. Palliative care patients

We are funding a project to develop a shortened version of the QLQ-C30 for use with palliative care patients, because these patients frequently find the QLQ too lengthy and some of the items are less relevant in their situation. For example, the question about trouble doing strenuous activities is largely irrelevant to these patients. We are also using IRT to investigate whether some of the scales can be shortened without losing too much information. Early results suggest, for example, that when assessing these patients the emotional functioning (EF) scale can be shortened from four items to three or maybe only two; we find that IRT methods

enable the two-item version to provide a good 'prediction' of the score from the full scale.

8.3. Cultural issues

We are also funding a project that explores cultural and linguistic issues in assessing and reporting QoL. Because of its dominant place in European cancer trials, the EORTC is uniquely placed to evaluate cultural/linguistic differences. The EORTC collaborative groups are providing the QLG access to a database of over 10 000 patients from 11 countries, representing a correspondingly wide range of languages. This Cross-Cultural Analysis (CCA) project will be using a variety of analysis techniques, including IRT models, in order to make allowance for differing patient selection in different countries; if QoL scores are lower in one country than another, we have to explore whether this is due to patient selection or to translation/cultural differences.

8.4. Scale development

We are developing a fatigue module, building upon the work carried out by others who have designed fatigue instruments. In contrast to the site-specific modules that generally contain a number of single items representing disease-specific symptoms, this module is expected to comprise a few multi-item scales. This makes the use of IRT modelling particularly appropriate when deciding which items to include or remove, and when evaluating the scoring and performance of the scales.

8.5. Item Bank

The extensive and growing list of modules (Table 1) multiplied by the number of translations (Table 2) presents a huge task for organisation and maintenance. Some modules contain near-identical questions, and if a change is made to an item on one module, it is important to ensure accurate updating of all instances on all modules where that item is used. In addition, when designing new modules, it is important to re-use existing, validated items whenever appropriate, rather than developing a new item that may have inaccurate wording and which requires extensive validation. These considerations led the QLG to fund a project to build an Item Bank. Now, all items from all modules have been indexed and recorded in the Item Bank, and may be accessed by developers of new modules leading to a much faster development, consistency of items and scales across modules, and easier quality control. In addition, the Item Bank can serve as a centralised resource for EORTC clinical trials, where certain trial specific questions may be better addressed by using individual items, as opposed to complete modules, thereby creating greater flexibility in our general measurement approach.

8.6. Computer adaptive testing

We have already mentioned the growing interest in the use of computers as an alternative to paper-based questionnaires, including the application of touch-screens. This opens the doors to a whole new class of questionnaires, developed using IRT methods to provide computer adaptive testing (CAT) instruments. The concept here is that if, for example, we wish to evaluate physical functioning then we could ask an initial question about how easy it is to walk a short distance. For someone who responds 'no problem', we would then ask about, say, running—there would be little point in asking whether such a patient is confined to bed. Conversely, for someone who cannot walk a short distance, why ask about running? CAT techniques allow for a reduction in the number of questions presented to patients, yet at the same time by using closely targeted items it is possible to obtain a more-precise evaluation of patients' conditions. The QLG is considering a grant application to embark upon such a project.

9. Membership of the EORTC Quality of Life Group

Membership of the QLG is open to anyone who is willing to participate in and contribute to the Group's activities. The QLG holds meetings twice yearly, in April and November. The main plenary sessions on Friday and Saturday are open to visitors and new members, whilst on Thursday there are closed working sessions for the QLG's 'active members'. The plenary sessions discuss our ongoing research and development, and also offer scientific presentations of general interest. We encourage visitors to attend and, hopefully, subsequently become full members through active involvement with the Group's work. Information about joining the QLG is available from the QLU.

10. For more information

Detailed and up-to-date information on the products and activities of both QLG and QLU are available at our Website (www.eortc.be/home/qol/). Copies of QLG manuals may be obtained from the QLU by writing or visiting the website.

All users must register their studies with the EORTC Quality of Life Unit. The QLQ-C30 and modules are available free of charge to academic groups for non-profit making research. Permission to use the QLQ-C30 or the QLQ modules is available through the QLU.

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