



The development and utilisation of the European Organisation for research and treatment of cancer quality of life group item bank

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Abstract

One of the problems in assessing patients' quality of life (QL) is the availability of good robust measures that have demonstrated validity, reliability and sensitivity for changes over time, but also have been validated across a large group of culturally diverse nations. The European Organisation for Research and Treatment of Cancer (EORTC) Quality of Life Group (QLG) has recognised this and has established a substantial research programme with the aim of developing such tools, with particular relevance to cancer clinical trials. However, the management of a large set of items in multiple languages is difficult and very labour-intensive. Thus, to support the EORTC QLG research agenda, a computerised web-based database of all EORTC QLG measures and individual questionnaire items was developed. This database allows access to a pool of over 500 validated items in some 6000 translated versions. The database speeds up module development, ensures that questionnaires items have similar wording and provides rapid access to multiple translations. © 2002 Elsevier Science Ltd. All rights reserved.

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1. Introduction

Quality of life (QL) is a multidimensional construct, generally regarded as encompassing clinical subjective perceptions of positive and negative aspects of cancer patient domains, including physical, emotional, social and cognitive functions, and, importantly, disease symptoms and treatment [1]. Some 20 years ago, scant literature reporting QL in cancer research existed. However, over recent years a significant increase is noted in studies reporting the assessment of QL in peer-reviewed publications. A recent review of the published literature indicates that the number of QL studies supports this substantial increase. Furthermore, at present

some 10% of all randomised cancer clinical trials include QL as a main endpoint [2].

However, introducing QL into the medical area has not been without numerous difficulties. There are several conceptual, methodological, practical and attitudinal explanations for the challenges which have faced QL researchers [3–5]. Some of these are being slowly overcome [6,7].

Choosing the appropriate, valid and reliable QL tool is a challenge for clinicians who have only a little knowledge of how to select such tools [8]. Unfamiliarity with analysis and interpretation of data are examples of problems encountered by clinicians [9]. While some investigators have systematically set out to develop a programme of QL tools (e.g. Ref. [10]), usually such QL measures have been developed by a single investigator or with a single centre producing single measures within one cultural group [11]. Clearly, there exists a significant resource barrier to such large-scale initiatives, and we

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believe there are few organisations that attempt to develop several measures concurrently according to the highest standards in psychometrics, and following a consistent and coherent approach, in order to make it applicable across many cultural groups.

Therefore, in the following paper, we report our progress in developing a database of items which will serve as a research aid for the standardisation of future European Organisation for Research and Treatment of Cancer (EORTC) QL instruments, thereby reducing any possible redundancy of questionnaire items, and speeding up the process of developing new modules. The EORTC Quality of Life Group (QLG) Item Bank may also be used for EORTC trial-specific items in particular circumstances.

1.1. The EORTC QLG approach to measuring quality of life

The EORTC QLG has adopted a modular approach to QL measurement. The core questionnaire, the EORTC Quality of Life-Core 30 (QLQ-C30) is used to assess QL in any patient with cancer and it is often chosen for EORTC clinical trials. The QLQ-C30 is designed to be supplemented with disease- or treatment-specific modules. These are developed by a strict rigorous

process described by Blazeby and colleagues [12]. The modules produced by the QLG are listed in Table 1. All of these amount to a total of 500 questions that are also available in many different languages. There are now over 6000 translations of questionnaire items. In general, all questionnaire modules and respective questionnaire items are translated from English into eight major European languages: Danish, Dutch, French, German, Italian, Norwegian, Spanish and Swedish, plus various other languages such as Bulgarian, Hebrew and Indian [13]. However, our translation programme is ongoing and many more are being produced on a regular basis.

2. Patients and methods

Because of the number of challenges highlighted by the success of the development of an increasing number of various EORTC QL Modules and the potential use for additional specific questionnaires, we developed a web-based computerised database which would continue to improve the standard of EORTC QL instruments. The 'EORTC QLG Item Bank' project was initiated and funded in November 1998 by the EORTC QLG and is managed by the EORTC Quality of Life

Table 1
Status of development of EORTC QL modules^a

Phase of development	Questionnaire/modules	Number of items	Languages available
Completed phase IV	General—QLQ-C30	30	43
Completed phase IV	Breast—QLQ-BR23	23	31
Completed phase IV	Head and neck QLQ-H&N35	35	20
Completed phase IV	Lung—QLQ-LC13	13	24
Completed phase IV	Oesophageal—QLQ-OES24	24	12
Completed phase IV	Ovarian—QLQ-OV28	28	14
Currently in phase IV	Gastric—QLQ-STO22	22	13
Currently in phase IV	Satisfaction with care—QLQ-SAT32	32	8
Currently in phase IV	Prostate—QLQ-PR25	25	17
Completed phase III	Bladder (muscle invasive)—QLQ-BLM30	30	16
Completed phase III	Bladder (superficial)—QLQ-BLM28	24	16
Completed phase III	Brain—QLQ-BN20	20	25
Completed phase III	Colorectal—QLQ-CR38	38	12
Completed Phase III	Multiple myeloma—QLQ-MY24	24	11
Completed phase III	Pancreatic—QLQ-PAN26	26	10
Currently in phase III	Ophthalmic—QLQ-OPT37	37	5
Currently in phase III	High-dose Chemotherapy- QLQ-HDC49	49	1
Currently in phase III	Chronic lymphocytic leukaemia—QLQ-CLL25	25	5
Currently in phase III	Peripheral neuropathy		
Phase I	Colorectal liver metastases		
Phase I	Carcinoid		
Phase I	Fatigue		
Phase I	Information		
Phase I	Primary liver tumours		
Phase I	Social support		
Phase I	Spirituality		

EORTC QL, European Organisation for Research and Treatment of Cancer Quality of Life; QLQ-C30, Quality of Life-Core 30.

^a Module development consists of four phases: I, identification of relevant QL issues; II, operationalisation of the issues; III, pretesting of the provisional module; IV, field testing.

Unit (QLU). After 3 years of development, the database now includes all the questionnaire items from the QLQ-C30 and all the EORTC QL Modules. Our aim was to ensure that the database improved consistency by harmonising the wording of existing items and their translations. We also wanted to improve the speed of development of future modules to rapidly compensate for the lack of available modules, by using existing Items wherever possible, to ensure a standard quality.

2.1. History and development of the EORTC QLG Item Bank

The development of the EORTC QLG Item Bank followed a detailed analysis of the literature, to gain an understanding of how this issue had been addressed by other research organisations. It was apparent that there was no evidence of an existing 'Item database', although the National Cancer Institute of Canada (NCI-C) had initiated a project where items were held within a stand-alone, simple non-web database. Our approach to development was a simple methodology: The first step of the development was to review all EORTC QL Module development reports, as well as published

papers, in order to make a list of all pertinent points that should appear in the database. This was conducted in close collaboration with EORTC QL Module developers. As a result, the EORTC QLG Item Bank includes not only questionnaire items, but also information pertaining to each questionnaire item and to existing EORTC QL Modules. Explanation of information given for each Item of each module is available in Table 2. Once the various fields had been decided, the next step was to introduce lists of all the data. At this stage of development, EORTC module developers checked the data to be entered into the database. Translated modules were scanned and each translated Item was entered into the database. All the wording and translations were checked by two independent researchers, the EORTC QLG Item Bank developer and a lay person. The final check was an audit of the system's functioning and contents.

3. Results

To date, the EORTC QLG Item Bank has been used with success for developing seven new modules. The

Table 2
Information displayed for each Item

EORTC Quality of Life Group ITEM BANK	
Item Name	H&N41
Item Wording	Have you had a dry mouth?
Answer Type	Four point Likert scale
Underlying Issue	Dryness in the mouth
Origin	Head and Neck
Keyword	Thirsty, parched, xerostomia
Scale	Dry mouth
Similar / Related to	BR31 CR40 PAN43
Identical to	MY40 OES40 STO44
Module	Head and Neck
Phase	4
Contact Person	Vachalec Stephanie
Target Population	A wide range of patients with head & neck cancer, varying in disease stage and treatment modality (i.e. surgery, radiotherapy and chemotherapy)
Testing	Pretested on patients from Norway, Sweden, Denmark UK and French-speaking Belgium. Field tested in Norway Sweden and the Netherlands and in a large cross-cultural study involving more than ten countries (protocol 15941).
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Used in trials	15941
Final translation	Chinese (Taiwanese) Dutch English Finnish French German Italian Lithuanian Norwegian Polish Portuguese Russian Slovenian Spanish

CT, chemotherapy; RT, radiotherapy.

EORTC QLG Item Bank is also used for EORTC clinical trials where disease- or symptom-specific assessment is required, in addition to a general QL assessment and when no existing EORTC QL module is available. Additional EORTC trial-specific questionnaire items would need to be analysed as informative items only. The EORTC QLG strongly caution the use of items in this manner, because using individual items or QL scales (without reliability and validity data) renders the results open to criticism. Two EORTC trials have used the EORTC QLG Item Bank in this perspective. Over the next 2–3 years, we hope to explore this work further.

4. Discussion

The EORTC QL Item Bank currently provides a research tool for rapid access to EORTC QL items and their translations. This standardises the consultation of existing Items, as well as their translations, and any information about EORTC QL Items or Modules. This reduces the time spent by EORTC QLG module developers and it increases the quality of the module development. In addition, we hope to enlarge the future use of the EORTC QLG Item Bank with the introduction into the database of psychometric and statistical properties of each item which will make analysis of specific items easier, especially when they are used in addition to the QLQ-C30 and/or an EORTC QL Module for specific clinical trials. The EORTC QLG Item Bank may allow a link to real time data from clinical trials to the EORTC QLG Item Bank, thereby providing a dynamic tool, which could be used for providing data on norms for items. With such data, we could also see this as a valuable tool for calculating sample size.

We also face the challenge of access to the EORTC QLG Item Bank. At present, we have made user access to the EORTC QLG Item Bank via the public domain internet, on the EORTC web site, aimed predominantly at EORTC module developers, and members of the EORTC QLG who are interested in progressing with QL assessments within clinical trials. Of course, such a tool could also be relevant to other academic research-

ers seeking access to develop either 'ad-hoc' trial specific items, or conceivably develop treatment- or symptom-related questionnaires from existing items. At present, however, we are cautious in adopting such an approach given that this could lead to the abuse of instrument items. Careful use and selection must be imperative when using the EORTC QLG Item Bank.

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