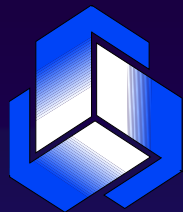


---

# **Report from Module Development Committee April 2010**

**Colin Johnson,  
Ken Cornelissen, Sheila Sanderson,  
EORTC Quality of Life Group,  
EORTC Quality of Life Department**

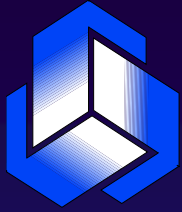
---



# Review procedures

---

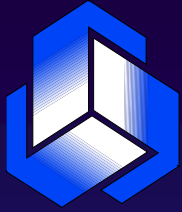
- Initial proposal: presentation to MDC and 1 page outline to Chair of MDC
  - MDC review **after Phase 2**, after Phase 3, after Phase 4
  - Review process:
    - Aim to review Phase 1&2 reports within 8-12 weeks of submission
    - 4 week deadlines for reviews of papers describing Phase 3 or 4;
    - Quick review of finished manuscripts – MDC chair and previous reviewers within 2 weeks
    - Papers published “on behalf of the EORTC Quality of Life Group” require approval of MDC Chair/EC before submission
    - **Acknowledge reviewers in publications – ask Colin if names not known**
  - Only completed Phase 3 modules to be distributed by QLD/added to Item Bank
  - send approved Phase 3 modules to Ken / check module entry on QOL website
-



# Module Development Guidelines

---

- Working group shared the tasks
- Focus on:
  - Statistical requirements
  - Translation
  - Revision/update and module merging
  - Overall revision of text
- Main points summarised



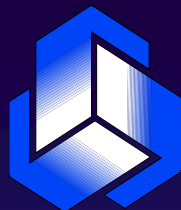
---

# Revision of Module Development Guidelines

*First full draft*

**Colin Johnson**

**Neil Aaronson, Jane M Blazeby, Peter Fayers,  
Michael Koller, John Ramage, Galina Velikova,  
Teresa Young**



# Phase 1

---

## Starting a new module

identification of research question and target population –  
approval by MDC  
language – English

## Phase 1: generation of QoL issues

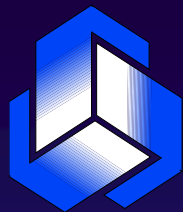
literature (including existing questionnaires),  
**patients – by semistructured interviews – key element**  
health care professionals (HCPs; e.g., physicians, nurses,  
radiographers, dietitians etc) **with clinical expertise in the area  
of the module (complement patient data)**

Adaptations are permissible provided they can be justified

Phase 1 should describe issues and their

Relevance  
Breadth of coverage  
Relative importance

---



## Phase 2

---

### **PHASE 2: Construction of the item list**

#### **Item construction**

**Follow standard wording, timeframe**

**Avoid double question**

**Avoid double negative**

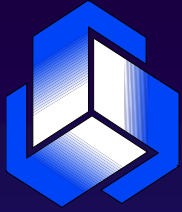
**What is the question? Symptom or interference?**

#### **Use the Quality of Life Group Item Bank**

**Avoids duplication and redundancy**

**Translations already exist**

**Consultation of health care professionals – final approval**



## Phase 3 structure

---

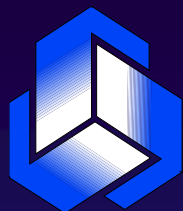
### PHASE 3: PRE-TESTING

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 identify **missing or redundant issues**.

Preliminary psychometric testing and exploration of scales may be performed

Pre-testing consists of:

- Administering the core questionnaire and the provisional module to patients for **scoring, relevance and importance**
- Structured interviews with each patient after completion



## Phase 3 Sample and Analysis

---

A sample matrix may include relevant treatments

**treatment stage**

**disease stage**

Each cell should contain at least 15 patients

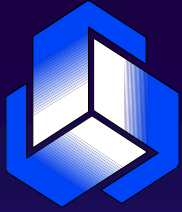
Retention/deletion of items

Difficulties in the wording upsetting or irrelevant

highlighted as important ranked to assess the most important/relevant

Clear decision rules **before** analysis

	Before Treatment	During Treatment	After Treatment	Palliativ Care
Localised Disease	15	15	15	-
Advanced Disease	15	15	15	-
Palliative Care	-	-	-	15



## Phase 3 Scale Structure

---

**Preliminary testing of hypothesized scale structure**

**In Phase 2, a number of scales will have been considered. These will be tested fully in phase 4**

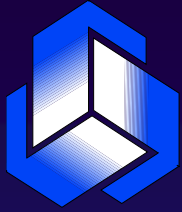
**Preliminary testing of hypothesized scales may include:**

**Reliability**

**Convergent validity**

**Exploratory factor analysis**

---



## Phase 4

---

### FIELD-TESTING

to determine reliability, validity, and cross-cultural applicability  
Scale structure and reliability

*Dispersion of scores*

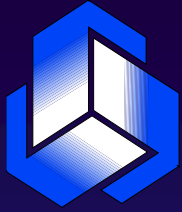
*internal consistency (Cronbach's alpha) of hypothesised scales*

recent approaches include *item-response theory* and *differential item functioning* or item bias analysis

*Validity*

known-groups comparison  
responsiveness over time

*Test-retest reliability*



# Description of modules

---

**In Phase 1 and 2. Module has been approved by MDC. Developer demonstrated**

**need for such a module,  
no overlap with existing modules**

**Completed Phase 2. has completed phases 1 and 2**

**includes approval of a Report of phases 1 & 2**

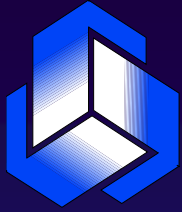
**Completed Phase 3. has completed phase 3 as described in the Guidelines**

**approval by the MDC**

**Validated. completed phase 4 successfully**

**approval of the MDC based on its cross-cultural, psychometric performance**

**A module which has completed phase 3 and is undergoing validation testing may be described as “*in phase 4 testing*”**



# Availability

---

**Modules that have completed Phase 3 are available for general use**

**tested for acceptability with patients,**

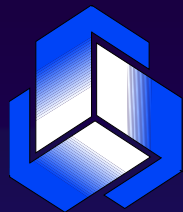
**have not undergone psychometric testing in a large international group of patients**

**scales for those modules are hypothetical and may change after psychometric analysis.**

**Validated modules have undergone formal psychometric testing in a large international group of patients**

**scale structure has been confirmed.**

**can be used in clinical trials and other studies without the need for extensive psychometric analysis.**



## Update modules

---

**Important changes and advances in treatment may affect QoL evaluation.**

**New chemotherapeutic drugs**

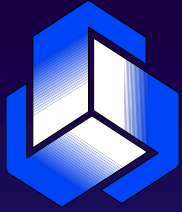
**Biological agents,**

**Radiotherapy protocols**

**Changes in surgical approach and extent**

**Questionnaires to assess PROs may become obsolete or require additional items**

---



# Update Modules

---

## Four phases:

- 1: generation of new issues related to the new treatments  
identification of problematic items and/or scales
- 2: create new item list  
change the wording of problematic items,
- 3: pre-testing the new module and
- 4: international validation field testing

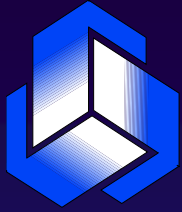
## Literature searches

- update the original literature review
- Identify issues associated with new treatments
- identify all studies that have used the EORTC module

## Interviews with patients and HCPs

## Phases 2, 3 and 4 follow standard guidance

- Create item list
  - pre-testing
  - validation of the updated module
-



# Merge modules

---

**Approval of the MDC required.**  
demonstrate the need  
combined module appropriate

## ***Phase 1***

literature search

existing modules combined into a single set of logical clinical groups (corresponding to scales)

new issues included from the literature search

new issues converted to questions/items at this stage, if possible using items from the Item Bank *Phase 2*

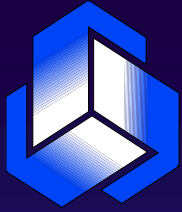
**Phase 2 is relatively straightforward**

Because majority of items derived from existing questionnaires

additional issues already framed as items

**Phases 3 and 4 as per Guidelines**

---



# Translation

---

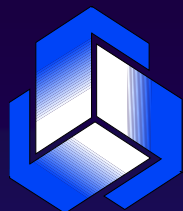
**Full revision of Translation Guidelines 2009**

**Summary of procedure in Mod Dev GL**

**2x forwards – agree – 2 x back – agree**

**Repeat if necessary**

**Document all stages – report to Data Center**



# Statistical aspects

---

## Scale structure and reliability

- multi-trait scaling analysis

- internal consistency of scales (Cronbach's alpha)

- item-response theory

- differential item functioning

## item bias analysis

## module's test-retest reliability or stability

- Intra-Class Correlation Coefficients can be calculated between the two assessments.

## score distributions

- skewness, floor and ceiling effects

## known-groups comparison (One-way analysis of variance)

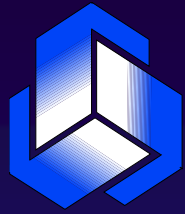
## responsiveness

- patient groups having different disease or treatment courses

- Changes with time/clinical condition

## Sample size and sample matrix

---

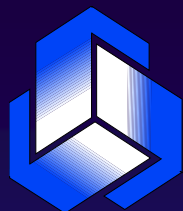


# Module Development Guidelines progress

---

## Still to do:

- Collate comments (end April)
- circulate to whole group
- Final document for approval (Summer 2010)



## Publications since September 2009

---

OV28 in Taiwan. Wei-Chu Chie. *Psycho-Oncology in press*

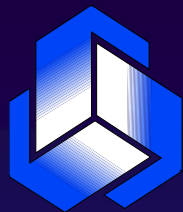
Revision of CR29. *RN Whistance, T Conroy, W Chie, A Costantini, O Sezer, M. Koller, CD Johnson, SA Pilkington, J Arraras, E Ben-Josef, AM Pullyblank, P Fayers, JM Blazeby, on behalf of the EORTC Quality of Life Group EJC 45 (2009) 3017–3026*

Brain BN20 Phase 4 MJB Taphoorn, L Claassens, NK Aaronson, C Coens, M Mauer, D Osoba, R Stupp, RO Mirimanoff, MJ van den Bent, A Bottomley, On behalf of the EORTC Quality of Life Group, and Brain Cancer, NCIC and Radiotherapy Groups. *EJC 46 (2010) 1033–1040*

INFO25 submitted EJC

ELD15 submitted EJC

---



# Validated modules

*no changes*

---

Head and neck cancer HN35 - (update in progress – Suzanne Singer)

Ovarian OV28

Breast cancer

Lung LC13 - modifications suggested, but no report to MDC

Satisfaction with care

Oesophageal

Gastric cancer

Cervix CX24

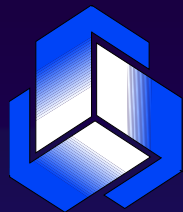
Multiple myeloma MY20

Prostate PR25

Liver metastases from colorectal cancer LMC21

Brain tumours BN20

Colorectal revision CR29



## Modules in Phase IV

---

**Pancreatic cancer - scaling analysis in progress, translations in 33 languages (complete 21)**

**Peripheral Neuropathy –used in Phase 3 trial for validation, data now ready for analysis**

**Information module –Ph4 closed, report awaited. Presentation IPOS INFO25 new translation Russian. One paper submitted, CCA in progress**

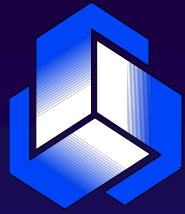
**GI NET module – *closed: 250 entered, 12 translations***

**Hepatocellular Carcinoma (HCC18) recruited 225 patients, to close April 2010**

**Bone metastases BM22 8 countries, 223 pts (PAL15). Now testing with C30. New translations Portuguese**

**Endometrial cancer – EN24 Report with authors after review. 8 translations**

---



## Completed Phase III

---

EORTC QLQ-C15 PAL – SF for palliative care; validation study has been completed but awaits analysis

High-dose chemotherapy (HDC29) published. No plan for phase 4

Ophthalmic cancer

Bladder cancer

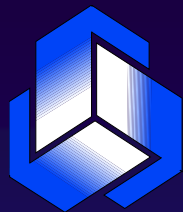
Chronic Lymphocytic Leukemia – **additional work to update and complete will start soon**

Combined oesophago-gastric OG25 PAPER PUBLISHED  
Phase 4 will be in use analysis. Translation x 8

Radiation proctitis –PR21 Grant awarded for phase 4

Fatigue

**ELD15 revised paper with EJC**



## In Phase III

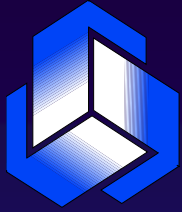
---

**Spiritual well-being – closed. Report awaited**

**Nasopharyngeal cancer NPC42 – report awaited**

**Cholangiocarcinoma – combine LMC21 and PAN26,  
recruitment completed – report with reviewers  
patients UK, Taiwan, Germany and Italy**

**Testicular cancer, recruitment in progress**



## In Phase II

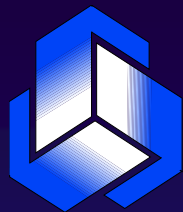
---

**Breast reconstruction –Ph2 report approved.**

**Social Support – on hold**

**Validation of C15PAL + BN20+2 for brain mets. 6 countries, 36 patients. 2 further translations**

**Oral health phase 1-2 report reviewed, with developers for response**



# In Phase 1

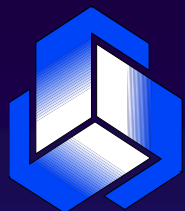
---

## New modules

- Vulva
- Pleural effusion - ??
- Children and adolescents
- Neuropathy
- Communication

## ● Update

- H&N35 –63 HCP interviews and 25 patient interviews. plan to finish phase II by September 2010. 3 translations
  - CML
  - Melanoma : literature review. 22 patients 10 relatives, 10 HCP
  - Nutrition status/symptoms - development group preparing grant
  - Spinal cord compression 70 HCP and 26 patients
-

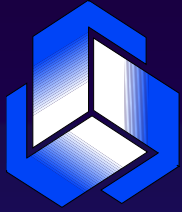


# Summary of modules in development

---

New proposals	4
Phase 1 & 2	7 + update H&N
In phase 3	5 + update CLL
Completed phase 3	8
In phase 4	7
Validated modules	13

**28 modules for use in clinical trials**



# Many thanks to

---

- To Sheila, Ken, Galina
- *To the reviewers of modules: Fatigue, BN20, EN24*

Thank You!

