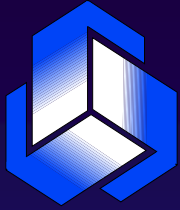


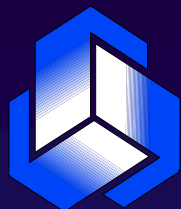
**Report from Module
Development
Committee
September 2008**

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



Agenda

- **Revision of module development and scoring guidelines**
- **Report from Chair**
 - update on Module Development
 - website: keeping module information up to date
 - Publications
- **Presentations from Module Developers**
 - Juan – information; Rob CR29;
- **Possible new modules**
 - Spinal cord compression
 - Paediatric
 - Nutrition



Scoring manuals – Peter

Body image scales in different modules + or –

Is this a problem?

Should we standardise?

Sexual function

Variable components of scale

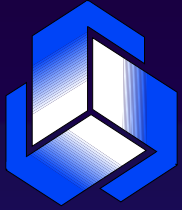
How to handle items not scored? –

Not applicable

Zero score

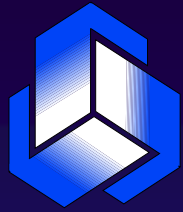
Missing data

Small working group to consider



Module Development Guidelines

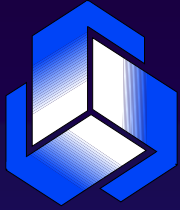
- **Revision now needed**
- **Working group to share the tasks**
- **Focus on:**
 - **Statistical requirements**
 - **Translation**
 - **Revision/update and module merging**
 - **Overall revision of text**



Module Development Guidelines

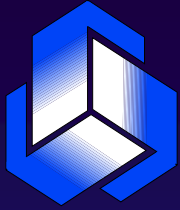
progress

- **Sections allocated**
 - **Some completed**
 - **All revisions first draft end September**
 - **Collate all sections and circulate to revision group November**
 - **Final document for approval end December**
 - **Update modules – need to consider why and when as well as how - ? Discussion paper**
-



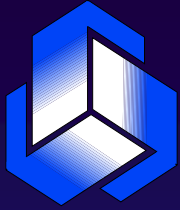
Review procedures

- MDC review **after Phase 2** and Phase 3
- Phase 3 report / manuscript
 - Aim to review module reports within 8-12 weeks of submission
 - 4 week deadlines for reviews;
 - **Acknowledge reviewers in publications – ask Colin if names not known**
- Quick review of finished manuscripts – MDC chair and previous reviewers within 2 weeks
- Only completed Ph3 modules to be distributed by QLD/added to Item Bank
- send approved Ph3 modules to Ken / check module entry on QOL website
- MDC chair sends all reports reviews and responses to Sheila for archive



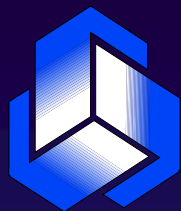
Validated modules

- **Head and neck cancer**
(proposal to update – Suzanne Singer)
 - **Ovarian**
 - **Breast cancer**
 - **Lung**
 - **modifications suggested, but no report to MDC**
 - **Satisfaction with care**
 - **Oesophageal**
 - **Gastric cancer**
 - **Cervix CX24**
 - **Multiple myeloma MY20**
-



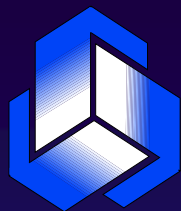
Modules in Phase IV

- Prostate cancer- Final version of MS (accepted EJC)
- Liver metastases from colorectal cancer (LMC21) – study closed, **paper submitted**
- Pancreatic cancer - scaling analysis in progress, translations in 33 languages (complete 21)
- Brain tumours –analysis of data from clinical trial for validation presented – awaiting final phase 4 report
- Peripheral Neuropathy –used in Phase 3 trial for validation, data now ready for analysis
- Information module –Ph4 started **509 patients 9 centres will finish end 08**
- **GI NET module – open: 150 entered, slow recruitment ?revise target 12 sites. End 2009**
- **Colorectal cancer CR29 now closed. TransIn x 8**
- **Hepatocellular Carcinoma (HCC18) recruited 79 pts (4 centres), on schedule for end November 09**



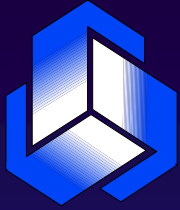
Completed Phase III

- 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 – ready for publication
- Combined oesophago-gastric OG25 PAPER PUBLISHED
Phase 4 will be in use analysis. Translation x 8
- **Bone metastases BM22 phase 3 report approved May 08.
Translation x 12**
- **Endometrial cancer – EN34 Phase3 completed Sept 08.
Translations x 7 +3**



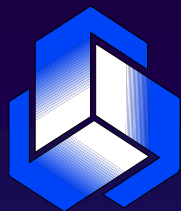
In Phase III

- **Spiritual well-being -98 patients in 8 countries**
 - **Fatigue- 320 patients from 7 countries closed. report September 2008. Translations x 5**
 - **Radiation proctitis –PR21 translations (F, D, N, S) for Europe, Phase 3 aims to close during 2008. Phase 1,2 report **published** International Journal of Radiation Oncology, Biology and Physics (Spry, Halkett, Aoun et al., 2008)**
 - **Nasopharyngeal cancer NPC42 – report awaited**
 - **Cholangiocarcinoma – combine LMC21 and PAN26, recruitment closed in UK, other centres needed**
 - **Cancer in Elderly recruited n = 110 from 5 countries**
-



In Phase II

- **Breast reconstruction –Ph2 report in preparation, expected September 08. More interviews needed. Translations in progress**
- **Testicular cancer Phase 2 report revised following review. Awaited**
- **Social Support – on hold**
- **Proposal to validate C15PAL + BN20 for brain mets. Protocol to be reviewed**



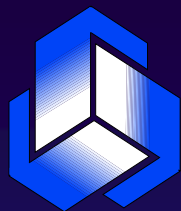
In Phase 1

Oral health (Marianne Hjermsstad)

- Literature review done updated March 08 and list of issues finalised
- Interviews professionals done
- **Patient interviews: 88 patients in 5 countries, to finish October 08, start phase 3 early 2009**

Proposals for discussion

- Nutrition status/symptoms
- Paediatric
- Spinal cord compression

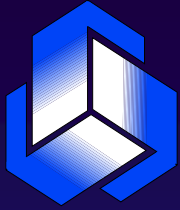


Publications since November 2007

**Proctitis International Journal of Radiation
Oncology, Biology and Physics 2008 Oct
1;72(2):522-8 (and online).**

PR25 phase 4: Eur J Cancer (epub 2008).

ELD systematic review: Eur J Cancer (epub 2008)



Many thanks to

- To Sheila and Ken
- To the reviewers of modules: BM22; EN34
- And to Galina, for continued help and advice

Colin

