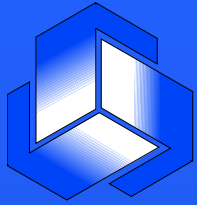


Cervical Cancer Module Update EORTC QLQ-CX

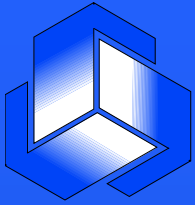
Project Coordinator: Eva Greimel

Quality of Life Group Meeting
November 24 - 25, 2005
Copenhagen



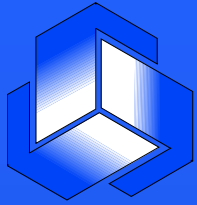
Cervical Cancer

- Second most common cause of cancer mortality amongst women worldwide
- The incidence is dropping in developed countries due to effective screening programs
- The five year survival rate for early stage disease (stage I) is 90 % for advanced stage below 10 %



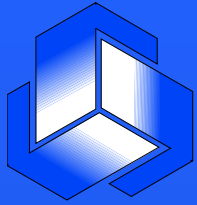
Cervical Cancer: Treatment

- Pelvic surgery
- Radiotherapy
- Concomittant chemo/radiotherapy
- Different treatment modalities have an impact on QoL



Development of the Cervical Cancer Module

- Symptoms related to cervical cancer
 - Treatment related issues for patients undergoing pelvic surgery and/or concomittant chemo/radiotherapy
 - Additional QoL issues (sexuality, body image, menopausal symptoms)
 - Supplement to the core questionnaire
-



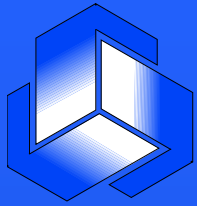
QLQ-CX Module Development

Project start: May 2002

Cooperating Group: EORTC GCG, ANZ GOG

Phase I/II: Generation of QOL Issues/Operationalization
Phase I,II report (MDC accepted Dec 2003)

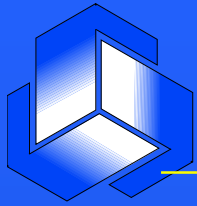
Phase III: Pre /pilot testing of the CX module
Patient interviews in 11 countries
Phase III report (MDC accepted April 2004)
Pilotsample N=37
N=346 (2 subsamples)



Country	Collaborator	Sample1	Sample 2
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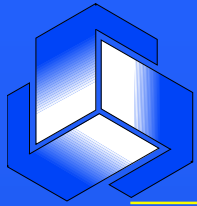
Australia	Duric/Hacker	7	17
Austria	Mautner/Bjelic/Greimel	15	11
Brazil	deSouza	5	14
Croatia	Kuljanic Vasic	15	13
Denmark	Jensen	14	8
Germany	Singer	9	39
	Fehlauer	4	--
Korea	Yun	13	10
NL	Incrocci	21	--
	Creutzberg	6	6
Poland	Wydra	31	10
Sweden	Waldenström	8	9
	Bergmark	11	0
Taiwan	Chie	11	15
UK	Nordin/Swift	1	12
	Routledge/Burns	7	3

Total		179	167
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Patient characteristics N=364

		N	%
Age:	Mean 52 yrs (SD 14)		
Stage:	FIGO I	177	52
	FIGO II	102	30
	FIGO III	53	16
	FIGO IV	8	2
Treatment:	Surgery	227	66
	Radio Chemotherapy	134	39
	Brachytherapy	148	43
	External Beam	106	37
	Other	10	3
	On Treatment	135	42
	Off Treatment	197	58



Hypothesised Scale Structure

Multi-item scales

- Gastrointestinal symptoms
- Genitouriological symptoms
- Vaginal symptoms
- Body image
- Sexual functioning

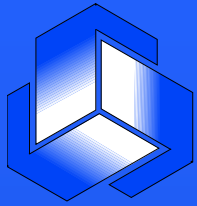
Single item scales

- Menopausal symptom
- Lymphoedema
- Lower back pain
- Peripheral neuropathy



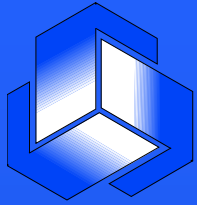
Multi-trait scaling analyses (N=179)

Scale	M	SD	Cronbach's Alpha	Scaling Error
Gastro intestinal Items 31 33	14.40	16.51	0.39	5 (16.7%)
Genitological Items 34 37	21.69	19.41	0.51	1 (2.5%)
Vaginal Items 41 43	16.39	20.41	0.52	6 (20.0%)
Body Image Items 45 47	22.19	27.83	0.81	0 (0.0%)
Sexual Functioning Items 50 54	29.39	21.31	0.67	7 (14.0%)



Multi-trait scaling analyses (N=167) Revised Scale Structure

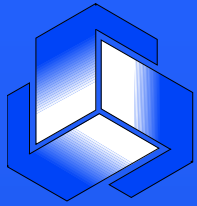
Scale	M	SD	Cronbach's Alpha	Scaling Error
Symptom Experience 31 33, 39, 41 43	14.06	13.05	0.72	2 (2.3%)
Body Image Items 45 47	27.61	29.49	0.86	0 (0.0%)
Sexual Functioning Items 50 53	25.98	27.98	0.87	0 (0.0%)



Clinical validity: Known-group comparison

QLQ-CX24 discriminates well between patients subgroups

- > Karnofsky Performance Status
 - > Stage of disease
 - > Treatment modalities
 - > On /off treatment
-



EORTC QLQ CX-24

- Psychometric analyses support
 - content validity
 - construct validity
 - reliability
- QLQ CX-24 cross culturally tested in 12 countries

**It has been accepted as validated phase IV module
by the MDC and the Executive Committee**