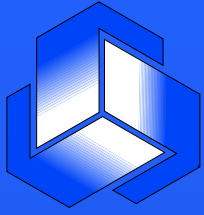


Cervical Cancer Module EORTC QLQ-CX

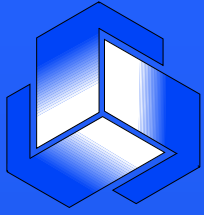
Coordinator: Eva Greimel

Quality of Life Group Meeting
18th-19th November 2004
Freiburg, Germany



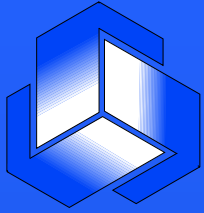
Cervical Cancer

- Second most common cause of cancer mortality amongst women worldwide
 - The incidence in developed countries is higher in countries without effective screening programs
 - The five year survival rate for early stage disease (stage I) is 90 % for advanced stage below 30 %
-



Cervical Cancer: Treatment

- Curative treatment for earlier stages: pelvic surgery or radiotherapy
 - Radiotherapy is the standard treatment for locally advanced or for recurrent disease
 - Concurrent chemotherapy to radiotherapy and surgery has demonstrated promising results in terms of survival
 - Different treatment modalities have an impact on Quality of Life
-



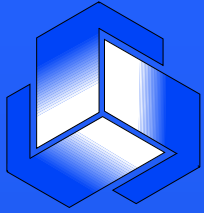
CX Module Development

Objective

To develop a questionnaire module to assess the QOL of patients with cervical cancer for use in clinical trials

To include issues related to

- symptoms of cervical cancer
 - treatment (pelvic surgery, radio-/chemotherapy)
 - other QOL aspects specific to cervical cancer not covered in the QLQ-C30 (sexuality, menopausal issues, vaginal symptoms...)
-



CX Module Development

Project start: May 2002

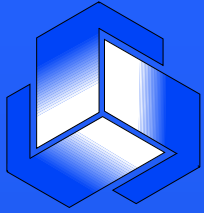
Cooperating Group: EORTC GCG, ANZ GOG

Phase I/II: Generation of QOL Issues/Operationalization

- Literature search
- HCP and patient interviews
- Provisional CX-Module

Phase I,II report

- submitted to MDC October 2003
 - accepted December 2003
-



Phase III: Pre-/pilot-testing of the CX-module

Aims

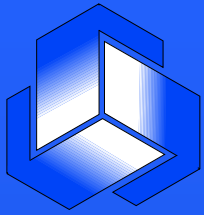
- to identify items that are irrelevant or adding items
- to identify and solve problems with the translations (difficult wording, confusing, upsetting...)

Provisional QLQ-CX Module

26 items

16 languages

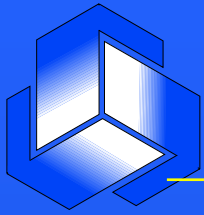
Translations have been approved



Country	Collaborator	Patients
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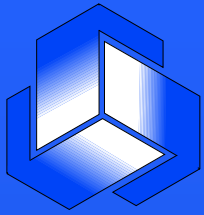
Australia	Duric/Hacker	7
Austria	Greimel/Bjelic/Mautner	15
	Holzner	0
Croatia	Kuljanic-Vlasic	10
Denmark	Jensen	17
Germany	Singer	13
	Fehlauer	5
Korea	Yun HY	21
NL	Incrocci	29
	Creutzberg	6
	Visser	0
Poland	Wydra	31
Sweden	Waldenström	0
Taiwan	Chie	27
UK	Nordin/Swift	9
	Routledge/Burns	7

Total		197
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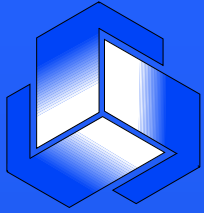
Patient characteristics

		N	%
Age:	Mean 52 years (SD 14)		
Education:	Compulsory or less	68	45
	Post-compulsory	68	45
	University level	16	10
Employment:	Full/part time	53	35
	Homemaker	34	23
	Retired	34	23
	Unemployed/other	31	19
Living:	Alone	25	17
	With partner/family	116	77
	With others/unknown	8	6



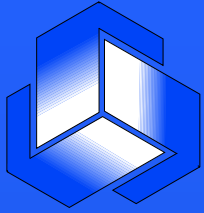
Cross-cultural distribution

Country	FIGO Stage				Active Treatment	
	I	II	III	VI	Yes	No
Australia	4	-	1		4	3
Austria	9	6	-		2	11
Croatia	6	3	1		2	8
Danmark	5	8	4			17
Germany	2	4	5	2	11	2
Korea	7	5	-	1	4	4
NL	3	7	16		6	21
Poland	23	7	1		31	
Taiwan	7	3	1		2	9
UK	2	4	1		7	1
Total	69	47	30	3	74	76



Cross-cultural distribution

Country	Menopausal Status			HRT	
	Pre-MP	Post-MP	Tx-related	Yes	No
Australia	4	3		1	5
Austria	7	6	1	2	12
Croatia	2	5	3	1	9
Danmark	4	1	12	9	8
Germany	7	3	2	1	12
Korea	6		7		11
NL	4	16	5		26
Poland	15	16		5	26
Taiwan	1	5	5	3	8
UK	4	4		2	6
Total	54	59	35	24	123



Patient responses

QUANTITATIVE RESULTS

Criteria for inclusion:

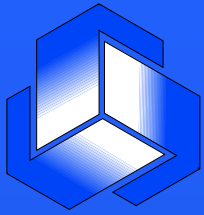
Mean rating ≥ 1.5

Range ≥ 2

Most items met the criteria (3 items mean score < 1.5)

Completion time (QLQ-C30, CX26):

< 10 min	76	50 %
11-15 min	47	31 %
16-20 min	24	16 %
> 20 min	5	3 %



Patient responses

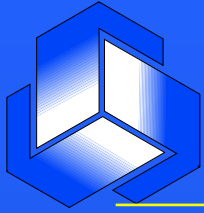
QUALITATIVE RESULTS

109 patients (72 %) made no comments
43 patients (28 %) made comments

Difficult to understand	17
Confusing items	20
Difficult wording	4
Upsetting	2

Sexuality items:

36 % completed the sexuality items
64 % not relevant (missing data)



EORTC QLQ-CX26 Module

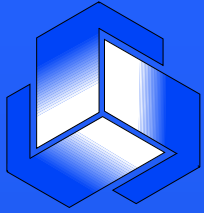
Provisional Scale Structure

5 Multi-item Scales

- GI:** Gastrointestinal symptoms (3 items)
- URO:** Urological symptoms (4 items)
- VA:** Vaginal symptoms (3 items)
- BI:** Body image (3 items)
- SF:** Sexual functioning (9 items)

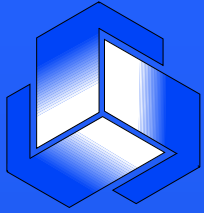
4 Single-item Scales

- MS:** Menopausal symptom (single item)
- LY:** Lymphoedema (single item)
- BP:** Back pain (single item)
- PN:** Peripheral neuropathy (single item)



Timeline

- Nov-Dec 04:** Completion of Phase III patient interviews
- Jan-Feb 05:** Data analysis - preparing phase III report for MDC
Manuscript for publication
- 2005:** Phase IV
-



Phase IV: Testing psychometric properties

UK Phase II cervix trial: A Phase II study of Docetaxel and Gemcitabine as second line chemotherapy in cervical cancer

EORTC protocol 55994: Randomized phase III study of neo-adjuvant chemotherapy followed by surgery versus concomitant radiotherapy and chemotherapy in FIGO stage IIB

Open trial (amendment?)

Other trials?
