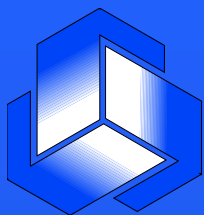


Endometrial Cancer Module EORTC QLQ-EN24

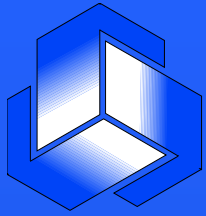
Project Co-ordinators
Phase I/II Andy Nordin
Phase III/IV Eva Greimel

Quality of Life Group Meeting
Rome 8-9, 2010



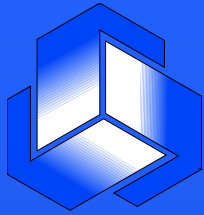
Endometrial Cancer

- Endometrial cancer is usually diagnosed in an early stage
- Pelvic surgery alone is effective in early stage disease
- 15% present disease progressed beyond the uterus
- High risk cases are treated with lymphadenectomy and adjuvant pelvic radiotherapy and chemotherapy



Relevant QoL Issues

- Symptoms related to endometrial cancer
- Treatment related issues: pelvic surgery, pelvic radiotherapy, chemotherapy
- Additional QoL issues: sexuality, body image, menopausal symptoms



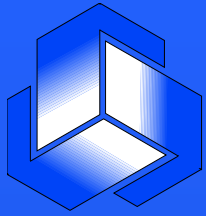
QLQ-EN Module Development

Project start: Feb 2006

Phase I/II: Generation of QOL Issues/Operationalization
Phase I,II report (MDC accepted Sept 2007)

Phase III: Pre-/pilot-testing of the EN-module
Phase III report (MDC accepted Sept 2008)

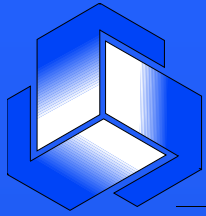
Phase IV: Field study
Patient recruitment completed June 2009
Phase IV report submitted and accepted with minor revisions



Phase 4: Field-testing

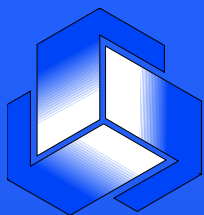
Aims

- to test the psychometric properties
- to confirm the hypothesized scale structure
- to determine the cross-cultural applicability



Patients / Collaborators

Country	Collaborators	N	%
Australia	E Barlow	23	8.6
Austria	V Bjelic/E Greimel	27	10.1
Croatia	K Kuljanic-Vlasic	12	4.5
Denmark	P Jensen	22	8.2
Germany	R Galalae, C Schmalz, D Könsgen-Mustea	27	10.1
Italy	A Costantini	6	2.2
Netherlands	C Creutzberg, L van de Poll-Franse	38	14.2
Sweden	A Waldenström/K Bergmark	20	7.5
Taiwan	W Chie	19	7.1
UK	A Lanceley/A Nordin	74	27.6
Total		268	100.0



Sample characteristics (N=268)

		%
Stage of disease:	FIGO I	56.2
	FIGO II	18.5
	FIGO III	21.1
	FIGO IV	4.2
Menopausal Status:	Pre-menopausal	12.3
	Post-menopausal	85.4
	Unknown	2.2
Surgery:	Laparotomy	87.1
	Laparoscopy	9.1
	Vaginal surgery	3.8
Radiotherapy:	Exernal beam	32.1
	Brachytherapy	29.9
	Exernal beam + Brachytherapy	38.1
Sexual Partner:	Yes	53.3
	No	46.7

Hypothesized scale structure

Body image **2**

Reduced attractiveness
Reduced femininity

Sexuality **6**

Vaginal dryness
Worried sex will be painful
Reduced interest in sex
Reduced enjoyment
Reduced activity
Vaginal shortening/tightening

Climacteric **2**

Hot flushes/sweats
Mood changes

Urological **5**

Pain/soreness
Frequency
Leakage
Problems emptying bladder
Urgency

Chemotherapy related **6**

Muscular pain
Hair loss
Tingling/numbness
Skin rashes
Hearing problems
Taste changes

Gastro-intestinal symptoms **6**

Cramps
Faecal leakage
Urgency to open bowels
Flatulence
Bloated
Blood in stools

Atrophic Vaginal Changes **2**

Vaginal bleeding
Irritation & soreness

Lymphoedema **2**

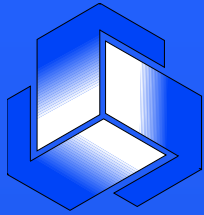
Swelling in legs
Heaviness in legs

Single items **3**

Weight gain

Pain in back & pelvis

Pain around surgical scar



Scale structure

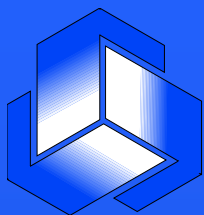
Number of items

5 Multi-item scales

Lymphoedema	2
Urological symptoms	4
Gastrointestinal symptoms	5
Body Image problems	2
Sexual/Vaginal problems	3

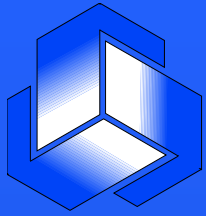
8 Single-item scales

Back and Pelvic pain	1
Tingling/Numbness	1
Muscular Pain	1
Hair Loss	1
Taste Change	1
Sexual Interest	1
Sexual Activity	1
Sexual Enjoyment	1



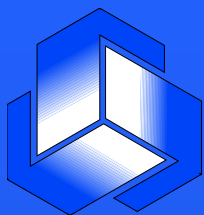
Multi-trait scaling analyses

Multi-item Scales	Number of items	Mean	SD	Cronbach's alpha
Lymphoedema	2	20.8	26.5	0.80
Urological Symptoms	4	21.9	21.4	0.75
Gastrointestinal Symptoms	5	18.6	18.8	0.74
Body Image Problems	2	13.3	22.6	0.86
Sexual/Vaginal Problems	3	22.8	27.9	0.86



Test-retest validity

	r
Lymphoedema	0.87**
Urological Symptoms	0.92**
Gastro-intestinal Symptoms	0.81**
Body Image	0.84**
Sexual/vaginal Symptoms	0.88**
Back/Pelvic Pain	0.88**
Tingling/Numbness	0.72**
Muscular/Joint Pain	0.87**
Hair Loss	0.97**
Taste Change	0.85**
Sexual Interest	0.84**
Sexual Activity	0.83**
Sexual Enjoyment	0.77**



Debriefing Questions

Time required

< 15 minutes	89 %
> 15 minutes	11 %

Assistance required

No help	88 %
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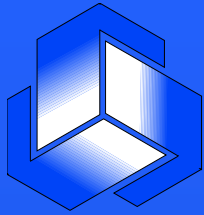
Questions

Clear/easy to understand	89 %
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Item Compliance

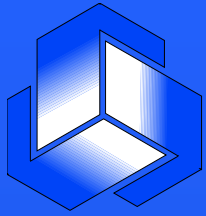
Missing values	2 %
Sexuality items missing values*	13 %

*of those who where sexually active (26%)



EORTC QLQ EN-24

- Psychometric analyses support
 - content validity
 - construct validity
 - reliability
- QLQ-EN24 cross-culturally tested in 12 countries
8 languages: Croatian, Danish, Dutch, English, German,
Italian, Mandarin, Swedish



Acknowledgements

The module development (phase III and IV) was funded by the EORTC Quality of Life Group

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