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Assessing quality of life in patients with colorectal cancer: An update of the EORTC quality of life questionnaire

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ABSTRACT

The European Organisation for Research and Treatment of Cancer (EORTC) has a portfolio of questionnaire modules to supplement the QLQ-C30 to assess patient reported outcomes in cancer clinical trials. This study updated the module for colorectal cancer. A review of the literature identified 20 articles that used the EORTC colorectal module. Eight papers did not report data from scales addressing sexual function and 8 added additional scales to assess ano-rectal function. Interviews with patients ($n = 79$) and professionals ($n = 11$) informed item selection, reduction and modification. A new 29 item module was devised and further patient interviews ($n = 120$) examined its format and content validity. Patients found the new module acceptable with relevant content. The new module, the EORTC QLQ-CR29, is hypothesised as containing 6 scales and 11 single items. An international study examining its clinical and psychometric validity will be performed.

1. Introduction

The European Organisation for Research and Treatment of Cancer (EORTC) QLQ-CR38 is a disease-specific instrument used to supplement the widely used generic measure of quality of life (QOL), the EORTC QLQ-C30, to assess quality of life in patients with colorectal cancer (CRC).[1] Since its development in the 1990s, the QLQ-CR38 has been translated into several languages and is widely used in international trials in oncology.[2] During this time, however, the treatment for CRC has evolved to include the use of radiotherapy or chemoradiation before surgery, ultra-low anterior resection, minimal access surgery and new chemotherapy regimens. The QLQ-CR38, therefore, may no longer sufficiently cover the symptom side

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effects and/or functional advantages of current treatments. In addition, problems using the questionnaire have been reported relating to missing data and lack of specificity.[3,4] Another criticism that may complicate its use in clinical trials is that the QLQ-CR38 contains scales specific to particular patient subsets (e.g. patients with and without a stoma), and it is not possible to directly compare issues between these groups. Finally, the QLQ-CR38 was only tested for its psychometric performance in the Netherlands, but not internationally.[1] In order to address these issues, this study was undertaken to update and improve the QLQ-CR38 and prepare a module that could be validated internationally for use in clinical trials in CRC.

2. Methods

2.1. Study design

Guidelines for questionnaire development published by the European Organisation for the Research and Treatment of Cancer (EORTC)[5,6] were adapted for the purpose of updating the colorectal module (Table 1).

2.1.1. Update of the literature review (Phase I)

A literature review was undertaken to identify clinical studies reporting data from the QLQ-CR38 and to examine potential problems with the module. The review was performed in Medline, PubMed and EmBase. Keywords used were QLQ-CR38, quality of life, colorectal cancer, colon cancer and rectal cancer. Inclusion criteria incorporated English language original articles published from 1999 to April 2006, reporting clinical use of the QLQ-CR38 for patients with colon or rectal cancer. Articles quoting the use of the QLQ-CR38 for other cancers or diseases was excluded, as were articles only reporting results from the QLQ-C30.

2.2. Patients and interviews

Semi-structured interviews with patients and healthcare professionals using EORTC Quality of Life Group guidelines for Phase I and Phase II interviews were undertaken to identify new QOL issues. Eligible patients were required to have a histologically confirmed diagnosis of CRC, but were excluded if they had a concurrent malignancy or were unable to understand and complete the questionnaire. Following the literature review and interviews, the QLQ-CR38 was altered to produce a provisional new module that was compatible with EORTC format.[7] The provisional new module was then administered to a new set of patients to examine its acceptability and content validity. Patients were asked if the questions were relevant, upsetting or confusing, and they were asked if there were additional issues that should be included in the final module.

2.3. Data analyses

Mean item scores and the number of times prioritised for inclusion by patients and health care professionals were calculated. Items with mean scores of less than 25 were considered for deletion, but retained if either patients or professionals considered them sufficiently important to test further. In the pre-testing phase, patient response and reasons for non-response or comments about the questionnaire were tabulated. The gastrointestinal subgroup of the

Table 1 – Phases of EORTC Quality of Life Group module development and method for updating the QLQ-CR29 questionnaire

Phase	Standard module development	Modified process for updating QLQ-CR29
I	Generation of quality of life issues • Literature search • Interviews with patients • Interviews with healthcare professionals	Update list of quality of life issues • Literature search focusing on QOL issues related to new treatments • Literature review of papers using the QLQ-CR38 • Review of existing scale structure in questionnaire
	A list of relevant issues	Additional issues and new scale structure
II	Construction of a provisional module • Items identified from QOL issues • Items selected from EORTC item bank • New items created in EORTC format	Construction of a provisional new module • Interview patients and professionals with old module and new issues • Consult EORTC item bank and create new items
	Review by EORTC QOL Group Module Development Committee	Review by EORTC QOL Group Module Development Committee
III	Pre-testing of new module • Patients complete module and interview • Responses prevalence and variance analysed • Site specific module development group review results	Pre-testing of updated new module • Patients complete module and interview • Assess patient acceptability and response rates • Site specific module development group review results • Necessary amendments performed
	QOL Group Module Development Committee	QOL Module Development Committee Review
IV	International field testing • Testing for reliability, clinical and psychometric validity	International field testing • Testing for reliability, clinical and psychometric validity

Table 2 – Systematic review of clinical studies in colorectal cancer using the EORTC QLQ-CR38

Authors	Study design	N	Disease stage	Site	Intervention	QOL instruments	QLQ-CR 38 data reported
Allal et al.[18]	Cross-sectional	23	No active disease	R	AR or restorative procedure	EORTC QLQ-C30 EORTC QLQ-CR38 (+supplementary ano-rectal function questions)	All functional and symptom scales and items
Camilleri-Brennan and Steele[10]	Prospective observational	65	Local/locoregional and metastatic	R	AR or APR	EORTC QLQ-C30 EORTC QLQ-CR38 SF-36	All functional and symptom scales and items, except female sexual problems
Grumman et al.[13]	Prospective	73	No active disease	R	AR or APR	EORTC QLQ-C30 EORTC QLQ-CR38	All functional and symptom scales and items, except for sexual function and symptom scales
Guren et al.[17]	Cross-sectional Case-control	37	No active disease	R	AR, APR or Hartmann's and/or urinary diversion	EORTC QLQ-C30 EORTC QLQ-CR38 EORTC QLQ-BLM30 (parts)	All functional and symptom scales and items
Tjandra et al.[14]	Prospective	42	Local/locoregional	R	Neoadjuvant treatment and AR, APR or Hartmann's	EORTC QLQ-C30 EORTC QLQ-CR38	All functional and symptom scales and items from C30 (not financial) and selected CR38 scales (no sexual scales)
Camilleri-Brennan and Steele[11]	Matched cross-sectional	106	No active disease	R	AR or APR	EORTC QLQ-C30 EORTC QLQ-CR38 SF-36	All functional and symptom scales and items, except female sexual problems
Camilleri-Brennan and Steele [12]	Matched, cross-sectional	75	Local/locoregional and metastatic	R	AR or APR	EORTC QLQ-C30 EORTC QLQ-CR38 SF-36	All functional and symptom scales and items, except sexual enjoyment and male and female sexual function scales
Sailer et al.[15]	Randomised controlled trial	64	Local/locoregional and metastatic	R	Straight or J pouch after low AR	EORTC QLQ-C30 EORTC QLQ-CR38 GIQLI Ano-rectal function questions	All functional and symptom scales and items, except sexual enjoyment and male and female sexual function scales
Camilleri-Brennan et al.[23]	Prospective	33	Local/locoregional and metastatic	R	AR, APR, subtotal colectomy and colostomy alone	EORTC QLQ-C30 EORTC QLQ-CR38 SF-36 and PGI	Selected scales/ items dependent on patient preference, no female or male sexual problems
Engel et al.[3]	Prospective	329	Local/locoregional and metastatic	R	AR or APR	EORTC QLQ-C30 EORTC QLQ-CR38	All functional and symptom scales and items
Guren et al.[21]	Prospective	42	Local/locoregional	R	Neoadjuvant radiotherapy	EORTC QLQ-C30 EORTC QLQ-CR38 (and symptom diary)	All functional and symptom scales and items, except sexual scales

Table 2 – *continued*

Authors	Study design	N	Disease stage	Site	Intervention	QOL instruments	QLQ-CR 38 data reported
Rauch et al.[26]	Cross-sectional	121	No active disease	R	Transanal excision, colo-anal anastomosis and APR	EORTC QLQ-C30 EORTC QLQ-CR38 Dukes generic instrument	Selected mean scores for C30. Discussion (no data) for CR38 scores
Allal et al.[27]	Prospective	53	Local/locoregional	R	Radiotherapy and AR or APR	EORTC QLQ-C30 EORTC QLQ-CR38	All functional and symptom scales and items, women did not answer items on sexual dysfunction
Gosselink et al.[19]	Cross-sectional	167	No active disease	R	Colo-anal j-pouch or APR	EORTC QLQ-C30 EORTC QLQ-CR38 Rockwood faecal incontinence severity index system Euroqol EQ-5D	All functional and symptom scales and items
Sideris et al.[28]	Cross-sectional	132	No active disease	R	AR, APR, colo-anal anastomosis or pseudocontinent perineal colostomy	EORTC QLQ-C30 EORTC QLQ-CR38 Beck's depression inventory State Trait Anxiety Inventory	All functional and symptom scales and items
Hendren et al.[20]	Cross-sectional	180	No active disease	R	AR, APR and *trans*-anal excision	EORTC QLQ-C30 EORTC QLQ-CR38 FSFI IIEF	Sexual scales and items reported
Guren et al.[16]	Cross-sectional	319	No active disease	R	AR or APR	EORTC QLQ-C30 EORTC QLQ-CR38 Rectal function questionnaire	Selected scales and items from C30 and CR38. Female sexual problems and enjoyment scales not included
Jayne[8]	Prospective randomised	247	Local/locoregional	C, R	Laparoscopic and open resection	EORTC QLQ-CR38: (sexual and bladder function items) IPSS/FSFI/IIEF	Scores commented on in text
Schiedek[9]	Prospective	22	Local/locoregional	R	Laparoscopic and open resection	EORTC QLQ-CR38 only	Scores for micturition problems and sexual function scales only
King[29]	Randomised controlled trial	60	Local/locoregional	C, R	Laparoscopic or open resection	EORTC QLQ-C30 EORTC QLQ-CR38	Scores commented on in text

AR, anterior resection; APR, abdominoperineal resection; R, rectal cancer; C, colon cancer; EORTC, European Organisation for Research and Treatment of Cancer; QLQ-C30, Quality of life questionnaire-Core 30; QLQ-CR38, Quality of Life Questionnaire-Colorectal 38; SF-36, Short Form-36; BLM30, muscle-invasive bladder cancer module; GIQLI, Gastrointestinal quality of life index; PGI, Patient Generated Index; FSFI, Female Sexual Function Index; IIEF International Index of Erectile Function; IPSS, International Prostatic Symptom Score.

EORTC Quality of Life Group (Chair J.M.B.) made the final decisions about the module content. Written informed consent and ethical committee approval were obtained in participating centres and clinical and sociodemographic data recorded.

3. Results

Medline, Embase and Pubmed databases were searched from 1999 to April 2006. Twenty original articles reported data from the QLQ-CR38, of which 18 (90%) included patients with rectal

Table 3 – Clinical and socio-demographic patient details

	Interviews in Phase II (n = 79)	Interviews in Phase III (n = 120)
Gender		
Male (%)	48 (61)	71 (59)
Age in years (%)		
<70	24 (30)	21 (18)
60–69	30 (38)	50 (42)
50–59	17 (22)	34 (28)
<49	8 (11)	15 (13)
Nationality (%)		
UK	25 (32)	–
Germany	24 (30)	82 (68)
France	30 (38)	38 (32)
Cohabitants (%)		
Living alone	9 (11)	12(10)
With family or other adults	70 (89)	46(38)
Missing data	–	62(52)
Marital status (%)		
Single	1 (1)	4 (3)
Married/living with partner	68 (86)	41 (34)
Separated/divorced/widowed	10 (13)	13 (11)
Missing data	–	62 (52)
Education (%)		
Less than compulsory school education	1 (1)	0 (0)
Compulsory school education	43 (54)	31 (26)
Post school education	35 (44)	27 (23)
Missing data	–	62 (52)
Employment (%)		
Employed full time/part time (or sick leave)	19 (24)	45 (38)
Retired	50 (63)	63 (53)
Other	10 (13)	12 (10)
Karnofsky performance score (%)		
81–100	35 (44)	72 (60)
61–80	39 (50)	36 (30)
<60	3 (4)	12 (10)
Missing data	2 (2)	–
Timing of interview (%)		
Pre treatment	–	4 (3)
During treatment	43 (55)	35 (29)
Post treatment	36 (46)	67 (56)
Missing data	–	14 (12)
Treatment (%)		
Hemicolectomy (right, transverse, left, sigmoid) alone	0 (0)	18 (15)
Hemicolectomy (right, transverse, left, sigmoid) with radiotherapy and/or chemotherapy	23 (29)	43 (36)
Anterior or abdominal-perineal (AP) resection alone	11 (14)	7 (6)
Anterior or AP resection with radiotherapy and/or chemotherapy	40 (51)	36 (30)
Chemotherapy and radiotherapy or radiotherapy alone	5 (6)	12 (10)
Not started treatment yet	0 (0)	4 (3)
Current stoma (%)		
Yes	34 (44)	31 (26)
Known metastatic disease (%)		
Yes	28 (35)	28 (23)

cancer alone (Table 2). Most articles focussed on QOL and not clinical outcomes. The QLQ-CR38 was used with the QLQ-C30 in all but two studies[8,9] and papers generally reported mean QOL scores for scales in the CR38. Notable exceptions were CR38 data missing from the sexual functioning and problem scales, and the item assessing sexual enjoyment.[10–17] Reasons for not reporting these data were generally not given. In addition, the QLQ-C30 and CR38 were supplemented by more de-

Table 4 – Interviews with patients and health care professionals with the QLQ-CR38

Items in QLQ-CR38	Patients $n = 79$			HCPs $n = 11$
	Missing data (%)	Mean item score (SD)	Retain item (%)	Retain item (%)
Micturition scale				
1. Did you urinate frequently during the day?	1 (1)	48 (30)	61 (77)	11 (100)
2. Did you urinate frequently during the night?	1 (1)	35 (28)	62 (79)	10 (91)
3. Did you have pain when you urinated?	2 (3)	6 (16)	60 (76)	10 (91)
Gastro intestinal scale				
4. Did you have a bloated feeling in your abdomen?	2 (3)	23 (30)	61 (77)	7 (64)
5. Did you have abdominal pain?	2 (3)	16 (28)	67 (85)	10 (91)
6. Did you have pain in your buttocks?	2 (3)	23 (28)	63 (80)	8 (73)
7. Were you bothered by gas (flatulence)?	2 (3)	33 (32)	69 (88)	9 (82)
8. Did you belch?	3 (4)	22 (32)	36 (46)	2 (18)
Single item				
9. Have you lost weight?	3 (4)	15 (27)	69 (88)	8 (73)
Chemotherapy scale				
10. Did you have a dry mouth?	3 (4)	28 (32)	62 (79)	5 (46)
11. Have you had thin or lifeless hair as a result of your disease or treatment?	3 (4)	22 (31)	55 (70)	5 (46)
12. Did food and drink taste different from usual?	2 (3)	14 (24)	63 (80)	10 (91)
Body image scale				
13. Have you felt physically less attractive as a result of your disease or treatment?	6 (8)	29 (36)	56 (71)	10 (91)
14. Have you been feeling less feminine/ masculine as a result of your disease or treatment?	6 (8)	31 (36)	60 (76)	9 (82)
15. Have you been dissatisfied with your body?	3 (4)	36 (36)	55 (70)	11 (100)
Single item				
16. Were you worried about your health in the future?	1 (1)	52 (33)	70 (89)	9 (82)
Sexual function scale				
17. To what extent were you interested in sex?	15 (19)*	29 (29)	59 (75)	8 (73)
18. To what extent were you sexually active (with or without intercourse)?	18 (23)*	14 (23)	40 (51)	9 (82)
Sexual enjoyment single item				
19. Answer this question only if you have been sexually active: To what extent was sex enjoyable for you?	54 (68)*	41 (32)	39 (49)	8 (73)
Male sexual problems (men n = 48)				
20. For men only: Did you have difficulty getting or maintaining an erection?	16 (33)	61 (38)	37 (47)	10 (91)
21. Did you have problems with ejaculation (e.g. so-called "dry ejaculation")?	17 (35)	43 (46)	33 (42)	11 (100)
Female sexual problems (women n = 31)				
22. For women only: Did you have a dry vagina during intercourse?	21 (67)	43 (41)	25 (32)	10 (91)
23. Did you have pain during intercourse?	22 (70)	22 (44)	27 (34)	11 (100)
24. Do you have a stoma bag?	N/A	N/A	79 (100)	11 (100)
Response of no stoma (n = 45)				
25. Did you have frequent bowel movements during the day?	1 (1)	54 (31)	45 (100)	11 (100)
26. Did you have frequent bowel movements during the night?	1 (1)	26 (30)	45 (100)	11 (100)
27. Did you feel the urge to move your bowels without actually producing any stools?	1 (1)	32 (36)	45 (100)	11 (100)
28. Have you had any unintentional release of stools?	1 (1)	21 (29)	45 (100)	11 (100)

(*continued on next page*)

Table 4 – *continued*

Items in QLQ-CR38	Patients $n = 79$			HCPs $n = 11$
	Missing data (%)	Mean item score (SD)	Retain item (%)	Retain item (%)
29. Have you had any blood with your stools?	1 (1)	6 (16)	45 (100)	7 (64)
30. Have you had difficulty in moving your bowels?	1 (1)	26 (32)	45 (100)	11 (100)
31. Have your bowel movements been painful?	1 (1)	16 (27)	45 (100)	10 (91)
Response of yes stoma (n = 34)				
32. Were you afraid that other people would be able to hear your stoma?	1 (1)	47 (42)	29 (85)	11 (100)
33. Were you afraid that other people would be able to smell your stools	1 (1)	52 (41)	33 (97)	11 (100)
34. Were you worried about possible leakage from the stoma bag?	1 (1)	65 (36)	34 (100)	11 (100)
35. Did you have problems with caring for your stoma	2 (3)	22 (33)	34 (100)	11 (100)
36. Was your skin around the stoma irritated?	1 (1)	37 (36)	34 (100)	11 (100)
37. Did you feel embarrassed because of your stoma?	2 (3)	40 (42)	33 (97)	11 (100)
38. Did you feel less complete because of your stoma?	2 (3)	50 (39)	29 (85)	11 (100)
Potential new QOL issues (quite or very relevant)				
Incontinence of flatus	1 (1)	34 (27)		11 (100)
Incontinence of mucus	2 (3)	34 (36)		10 (91)
Incontinence of urine (need pads)	5 (7)	32 (33)		10 (91)
Anal skin irritation	5 (7)	31 (38)		8 (68)
Suggested additional issues	None			No

HCP, healthcare professional; QOL, quality of life.

tailed questionnaires addressing ano-rectal function in 8 of the studies.[8,15,16,18–21] Four disease-specific QOL instruments were identified.[1,22–24] After this review four additional QOL issues were identified. These were, incontinence of gas and mucus, anal irritation, social problems related to incontinence and wearing of pads. These were examined in the subsequent patient and professional interviews.

Interviews with 79 patients with CRC from France, Germany and the UK and 11 healthcare professionals (specialist and stoma nurses, surgeons and oncologists) were performed (clinical and socio-demographic details, Table 3). Sixteen items were removed, either because they had low scores ($n = 9$) or because patients and/or professionals felt they were less important than other items or because they overlapped and this allowed two items to be merged to form one (e.g. pain in your buttocks was merged with painful bowel movements) to form a new item 'Did you have pain in your buttocks/anal area or rectum?'. The item addressing hair loss was retained despite low mean scores because of health professionals' views. Three items were reworded to synchronise with items from other gastrointestinal modules (e.g. weight loss, taste change and hair loss). Two items of the potential four new issues were added (unintentional release of urine and mucus in the stools). Gastrointestinal items in the stoma and non-stoma scales were streamlined so that all patients answered similar items (Table 4). The scales addressing sexual problems were reorganised for men and women separately with two items. The EORTC Quality of Life Group Module Development Committee reviewed and approved the provisional new module, the QLQ-CR29.

3.1. *Pre-testing of acceptability and content validity of new module*

The provisional new module, the QLQ-CR29, was pre-tested in patients with CRC from France and Germany ($n = 120$, Table 3). Patients reported that the questionnaire was well understood and acceptable. Some translational issues required modification in the French language version. Response rates were high for three of the four sexual items (>80%), but only 26 women (53%) responded to the item about dyspareunia (Table 5). Ten women (43%) of those electing not to respond to this item reported being upset by it. Some men found questions related to sexual function and impotence upsetting, but not to the same extent. The layout of the QLQ-CR29 was considered in detail. Based upon patient suggestions it was decided to separate items for patients with and without a stoma, but to ensure that the items were similar for both groups of patients. The final QLQ-CR29 questionnaire module is hypothesised to contain 6 scales and 11 single items. A summary of the development process is shown in Fig. 1.

4. Discussion

The EORTC QLQ-CR29 has been updated and modified based on evidence from the literature, expert opinion and interviews with patients undergoing a variety of treatments from

Table 5 – Response rates and reasons for non-response to items addressing sexual interest and function in the EORTC QLQ-CR29 (*n* = 120)

Items in EORTC CR29	Response rate (%)	Responded reported being upset (%)	Non response rate (%)	Non response and reported being upset (%)
Men n = 71				
To what extent were you interested in sex?	68 (96)	2 (3)	3 (4)	0 (0)
Did you have difficulty getting or maintaining an erection?	61 (86)	2 (3)	10 (14)	3 (30)
Women n = 49				
To what extent were you interested in sex?	40 (82)	4 (10)	9 (18)	7 (78)
Did you have pain or discomfort during intercourse?	26 (53)	1 (4)	23 (47)	10 (43)

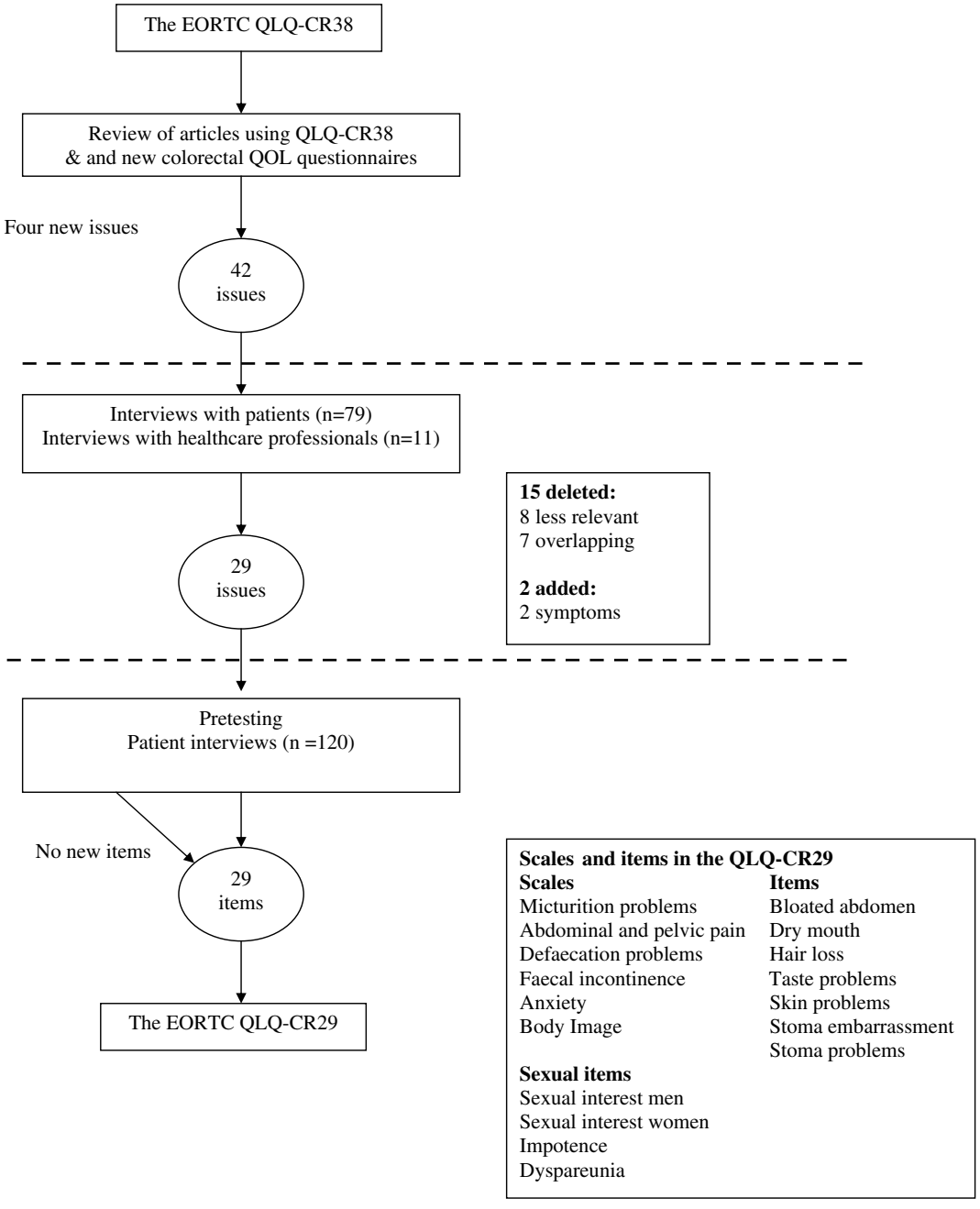

Fig. 1 – Update of the EORTC QLQ-CR38 to the QLQ-CR29.

three European countries. It has been formatted according to standard EORTC Quality of Life Group guidelines and further examined to ensure that it is comprehensive and clearly understood by patients undergoing treatment for CRC. The new module, the EORTC QLQ-CR29, therefore, is expected to be able to assess all major dimensions of QOL in patients with CRC undergoing a wide range of treatments and an international validation study will further evaluate its clinical and psychometric properties. It is currently available from the Quality of Life Unit at the EORTC data centre, www.eortc.be/home/qol.

There are several measurement systems for assessing QOL in patients with CRC, but only the EORTC and FACT systems are developed for use in international clinical trials. Despite careful design, both questionnaire modules have some deficiencies that may result in measurement error.[4,25] Indeed, it has recently been suggested that separate questionnaires for colon and rectal cancer are required.[4] In this study, the EORTC colorectal module has been updated to refine scales for assessing gastrointestinal symptoms including problems with defaecation and faecal incontinence. In the planned international validation study, including currently five European countries, the QLQ-CR29 will be examined in patients with colon and rectal cancer separately to ensure that it is sensitive to clinically important differences between the two groups of patients. It will also be tested to examine whether patients with and without a stoma report expected differences in QOL. Having one module for CRC is useful for comparing outcomes between patients with colon and rectal cancer and it is useful for patients with cancer of the rectosigmoid, where choosing between separate colon or rectum modules may be problematic.

Updating and improving QOL measures to remain relevant to new treatments for cancer is essential. Methods for this process are developing within the EORTC QOL group and have not yet been formalised. Performing a literature review of clinical studies that have used and reported data from the original module will identify some problems with scales and items in the questionnaire as well as highlight possible deficits. The review of papers using the QLQ-CR38 found missing data from items addressing sexual functioning and the need for additional scales addressing ano-rectal function in more detail. Although data are commonly missing from other questionnaires about sexual functioning, the updated QLQ-CR29 has revised these scales to improve response rates. During the update process, interviews with patients undergoing new treatments are necessary to modify the original module to capture additional treatment side effects and interviews with health professionals using new treatments are also recommended. The EORTC methods for questionnaire development can therefore be adapted to guide methods for updating QOL modules to assess new oncological treatments.

The rigorous development and updating process of the EORTC QOL group will therefore ensure that the EORTC QLQ-CR29 is solidly based in the issues that are important to patients with CRC, at every stage of treatment. External peer review and use of tried and tested questionnaire formats should eliminate difficulties with wording of questions and ensure that the questionnaire is comprehensible to patients and that the responses are easy to evaluate. The EORTC QLQ-CR29 is currently available in six European languages. It will undergo psychometric examination in an international field study to ensure that it is an appropriate and psychometrically tested instrument to be used in international clinical trials in patients with cancer of the colon and rectum.

Conflict of interest statement

None declared.

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