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EORTC radiation proctitis-specific quality of life module – Pretesting in four European countries

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ABSTRACT

Background and purpose: Radiation proctitis is a side effect which can occur after pelvic radiation therapy. Currently available questionnaires do not comprehensively assess the range of problems, nor impact on quality of life associated with proctitis. This article reports on the cultural testing phase of an EORTC module (QLQ-PRT21) developed to assess radiation proctitis specific issues and designed to be used in conjunction with the EORTC core quality of life questionnaire (QLQ-C30).

Methods: The previously developed 21-item module, pre-tested in Australia, was translated into Norwegian, German, French and Italian. Patients completed the EORTC QLQ-C30 and module questionnaires towards the end of their radical pelvic radiation treatment to target acute side effects. Patients experiencing chronic proctitis were also surveyed. Patients also participated in structured interviews to determine issues of comprehensibility, coverage and relevance. Results were compared with Australian data.

Results: Questionnaires were completed by 64 European patients. The module was found to be relevant and culturally acceptable to participants. Feedback has led to minor translation modifications and the inclusion of two additional questions.

Conclusion: This module is ready for Phase IV testing which will consist of large scale field testing with the aim to perform psychometric analysis and finalise a module that will be suitable in the assessment of radiation induced proctitis.

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Radiation proctitis is an unfortunate complication that can follow radical radiation treatment for cancers in the pelvic region [1–4]. It is characterized by symptoms of abdominal pain, diarrhoea, faecal and/or mucous incontinence, tenesmus, rectal bleeding and blood clots as well as extreme bowel urgency [1–3,5,6]. The term acute proctitis refers to early inflammation in the pelvis after radiation treatment [2]. Chronic radiation proctitis generally refers to radiation induced injury to the rectum occurring from three months after treatment. This has been reported to affect 5–20% of patients and may only present months or years after the radiation exposure [1,7]. However, the absence of specific criteria for diagnosis of radiation proctitis has meant that the true incidence of proctitis is underestimated because current toxicity scales focus on rectal bleeding and do not include assessment of other symptoms such as bowel urgency and incontinence [4]. There is also evidence to suggest that there are only a small

proportion of patients who actually seek help for symptoms of proctitis [4].

More recently, the indications for pelvic radiation have increased to include post operative adjuvant radiation for prostate cancer, neoadjuvant pre-operative chemoradiotherapy for rectal cancer [8], as well as, the increasing use of concurrent chemotherapy programs, and dose escalation strategies, such as those employed with prostate cancer, all of which are likely to increase the prevalence of this condition. Hence, there is an urgent need for instruments that can reliably characterise this condition to ensure timely diagnosis, to accurately establish its prevalence, and provide robust endpoints for clinical trials [4,5,9].

Quality of life methodology offers a robust process for the development of patient self-reported instruments that could comprehensively assess the range of problems, and their impact on the patient of this condition [4,10,11]. The widely employed physician completed radiation therapy oncology group (RTOG) scoring system for lower gastrointestinal and genitourinary acute toxicity and small/large intestine late morbidity is significantly limited because it does not include all symptoms related to proctitis (including urgency, fecal incontinence and pain) [12]. A recent

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modification, the radiotherapy-induced lower intestinal toxicity scale is another option that has been explored for measuring the symptoms of proctitis [13]. While this scale collects data on proctitis symptoms such as diarrhoea, rectal blood loss (RBL), mucus loss, incontinence, abdominal cramps, urgency, frequency and anal pain, it is completed by clinicians rather than patients and does not include other quality of life scores. In a recent study conducted by Olopade et al. [11] the modified inflammatory bowel disease questionnaire (IBDQ) and the Vaizey incontinence questionnaire were assessed in order to determine whether they accurately depicted the degree of gastrointestinal chronic toxicity and the disability experienced after pelvic radiotherapy. While dealing with the side effects of pelvic irradiation, the severity of radiation proctitis and impact on the patient's quality of life were not covered. Similarly, the self-completed rectal bleeding quality of life scale [14], another instrument used to measure the perceived QoL of patients with chronic radiation proctitis, focuses on rectal bleeding and does not cover all issues related to proctitis. As a stand alone instrument, it does not enable easy comparison with other measures of QoL [14]. The prostate cancer module (EORTC QLQ-PR25) and cervical cancer module (EORTC QLQ-CX24) developed by the European Organization for Research and Treatment of Cancer (EORTC) to be used in conjunction with the self-reported EORTC QLQ-C30 cover some aspects of bowel function [15–17]. In summary, there are currently no instruments that measure radiation proctitis and adequately address the quality of life problems associated with radiation proctitis.

To address this need, our research team has developed and tested a specific module for proctitis in Australia (PRT21) and preliminary results have been reported [18]. The aim of this study was to pretest the rigorous translations of EORTC QLQ-PRT21 into 4 European languages to confirm the appropriateness, relevance and cross-cultural acceptability to patients who have received high-dose radiation therapy to their pelvis. It was particularly important to confirm cross-cultural equivalence of this module because it asks patients to self-report what may be considered embarrassing and/or sensitive symptoms (such as bowel problems).

If items were proven difficult to translate they could be considered for re-wording or even deletion from the original English version. The finalised module will be employed in the forthcoming EORTC International Phase IV field validation study.

Methods and materials

The four stages for the development of EORTC modules include:

- Phase I: Generation of quality of life issues.
- Phase II: Construction of issues into a provisional questionnaire.
- Phase III: Testing of the questionnaire for acceptability and relevance.
- Phase IV Field testing in an international group of patients [19].

We have already reported the development of the module up to the point of International pretesting [18]. However, the module was developed only in English and tested in the Australian population. It was therefore necessary to test the cross-cultural equivalence of the module.

Prior to the translation process, all questions were compared with those in the EORTC item bank. This is a new procedure that employs a comprehensive resource of EORTC QOL questions that have already been validated in other areas for comprehensibility and clarity, and in many cases, have translations in many other languages [20]. Where appropriate, our questions were adjusted to adopt the existing item bank phrasing.

Rigorous translation procedures as described in the EORTC Translation manual [21] were then undertaken to ensure that the module was translated as appropriate for each country. This translation procedure involves two forward translations, two backward translations, comparison of backward translations with the original English version and finally pilot testing in 5–10 patients to identify any problems with wording and understanding.

Pretesting of translated modules procedure

Administration procedure

The 21-item module (EORTC QLQ-PRT21) was translated by the EORTC translation unit, into Norwegian, German, French and Italian, and collaborators were identified for each participating country. Eligible subjects were (1) those undergoing high dose pelvic radiation where administration of the module was timed to coincide at the time of likely peak acute side effects (end of treatment course) and (2) patients with chronic proctitis (patients who were experiencing proctitis symptoms post treatment completion). Ethics approval was gained in each of the countries, and all participants were provided with an information sheet describing the study, and were required to provide written informed consent.

Participants completed the EORTC QLQ-C30 followed by the 21-item proctitis module, and then subsequently participated in The EORTC QLG structured interview program with either their clinician or a research assistant to determine issues of comprehensibility, coverage and relevance. The interview protocol consisted of 6 specific questions and 2 general questions: Were there questions that you found difficult to answer? (2) Were there questions that you found annoying? (3) Were there questions that you found confusing? (4) Were there questions that you found upsetting? (5) Were there questions that you found intrusive? (6) Were there questions that you found irrelevant? (7) Do you have other comments about these questions? (8) Can you think of additional issues that are relevant for you but are not included in this questionnaire? [22] Patients were also asked whether the module needed to be reworded to make sense in their own language.

Analysis

Quantitative analysis

Individual items for the proctitis module responses were scored from 1 = not at all to 4 = very much. Data were entered into SPSS version 17 and analysed using descriptive statistics. Demographic data and mean scores for each item of the proctitis module were compared numerically with the Australian data previously collected. Participants' responses to the interview questions were compiled into a table to determine what changes needed to be made to the translated questionnaires and whether all items of the questionnaire should be included in the module.

Criteria for inclusion and exclusion of items

The EORTC criteria for consideration for deletion are as follows: mean score of ≥ 1.5 (patient scored items were 1 = not at all to 4 = very much); prevalence ratio for patients experiencing the symptoms $>30\%$ (number of patients with particular complaint divided by total number completing item); range for patient responses of ≥ 2 points; priority given to item by patients if $>1/3$ (15%) and the priority identified by consultants if $>1/3$ (15%). The EORTC guidelines (20) suggest that items meeting at least 3 of these 5 criteria may be retained in the list and that items that meet 2 or less of the criteria could be deleted. These criteria were previously used to assess the Australian data and were again used to

assess data obtained from the European sample. We report here on the European Data.

Interview analysis

Each participant was interviewed following completion of the proctitis module.

Participants' responses were recorded for each question on a data sheet. These responses were then entered into Microsoft Excel. Each question was analysed separately and results were compiled into a table to facilitate assessment of whether items needed changing.

Results

Sample

Questionnaires and interviews were completed by 64 European patients. Their characteristics are recorded in Table 1. Nearly eighty percent ($n = 50$) of participants were male and 70% ($n = 44$) of the patients had prostate cancer. Patients recruited in Europe were significantly younger (mean age 67 years vs. 72 years, independent t -test $p = 0.017$), and more commonly undergoing treatment (64% vs. 46%, Chi Square test $p > 0.05$) than the assessed Australian cohort. Patients over the age of 80 were recruited in Australia; however, this was not the case in Europe.

Quantitative analysis

Table 2 provides an analysis of the scores provided for each item in the proctitis module when it was administered to patients in Europe and Australia.

There were some differences in the patterns of response to the proctitis items between Australian and European subjects. For nine of the questions there were differences in the prevalence ratios of greater than 10%. These questions included:

- Have you had a bloated feeling in your abdomen?
- Were you troubled by passing wind/gas/flatulence?
- Have you had excessive gurgling noise from your abdomen?
- Have you had pain/discomfort related to your anal opening (back passage)?
- Have you had to wear a pad because of your bowel problems?
- Have you had difficulty going out of the house, because you needed to be close to a toilet, because of bowel problems?

- Have your daily activities been limited by your bowel problems?
- Did your treatment restrict the types of food you can eat due to your bowel problem?
- How unhappy would you feel if you lived the rest of your life with your bowel habit as it is now?

The prevalence for all of these questions was higher in Europe except for the question: "Have you had to wear a pad because of your bowel problems?"

The four questions under consideration for deletion after 64 interviews with patients in Europe were:

37. Have you had abdominal pain or cramping not related to a bowel movement?
40. Have you had bright blood in your stools?
41. Have you had dark blood clots in your motions?
43. Have you had to wear a pad because of your bowel problems?

Questions 37 and 41 were also identified as meeting some of the criteria for deletion in the Australian data. However, these questions were not deleted because responses to these questions depend on the severity of proctitis that is experienced by patients. Testing with a larger sample may enable us to determine when these symptoms are more likely to be experienced by patients and during what time frame after treatment completion.

The team also considered whether questions 40 and 41 could be combined. However, it is proposed that these two questions may measure different symptoms, and could have a discriminative function later. This issue will be reconsidered following the Phase IV study.

The module also includes three optional questions that are not included in the above analysis because they use different scales and do not meet the current EORTC criteria for QOL inclusion. The first question records whether medication is being taken for bowel disturbance. This information would be useful when interpreting symptom prevalence. The second question assessed the number of bowel actions in a 24-h period, as an independent anchor for severity, and the third is used to identify need for more assistance 'Would you like more assistance to manage your bowel problem?' This question is only of use if the treating medical practitioner reviews the completed survey inspects the results. These questions were not included in the analysis.

Table 1

Patient demographics in Europe and Australia.

Patient characteristics	Norway	Germany	France	Italy	Total in Europe	Australia
Number of patients	15	15	11	23	64	28
Mean age in years (SD)	66.71 (8.96)	69.67 (6.89)	64.00 (8.25)	67.17 (9.86)	67.11 (8.74)	72.03 (8.85)
Range in years	48–79	56–79	49–79	39–80	39–80	58–87
Male (%)	69	100	91	65	78	79
<i>Diagnosis</i>						
Prostate	8	14	8	14	44	18
Bladder					0	3
Cervical cancer				1	1	
Rectal cancer			2	1	8	2
Anal canal	1	1		1	3	3
Endometrial cancer			1	3	4	0
Squamous carcinoma of vulva				1	1	0
Uterine cancer				2	2	0
Hodgkin's lymphoma					0	1
Non-Hodgkin's lymphoma	1				1	1
Total	15	15	11	23	64	28
Currently receiving treatment	15	15	2	9	41	13

Table 2
Scoring parameters reported by European ($n = 64$) and Australian ($n = 28$) participants for 21 item scale (1 = not at all, 2 = a little, 3 = quite a bit, 4 = very much).

Question	Europe			Australia		
	Mean (SD)	Range	Prev ratio (%)	Mean (SD)	Range	Prev ratio (%)
31. Have you had a bloated feeling in your abdomen?	1.73 (0.72)	3	61	1.44 (0.62)	2	39
32. Were you troubled by passing wind/gas/flatulence?	2.00 (0.82)	3	69	1.83 (1.04)	3	50
33. Have you had excessive gurgling noise from your abdomen?	1.73 (0.73)	3	56	1.56 (0.86)	3	39
34. Have you had unintentional release (leakage) of wind or mucous?	1.58 (0.69)	3	48	1.61 (0.85)	3	44
35. Have you had unintentional release (leakage) of liquid stools?	1.53 (0.76)	3	41	1.56 (0.92)	3	33
36. Have you needed to get up at night to open your bowels?	1.44 (0.77)	3	31	1.67 (1.03)	3	39
37. Have you had abdominal pain or cramping not related to bowel movement?	1.34 (0.67)	3	25	1.39 (0.85)	3	22
38. Have you had pain/discomfort related to your anal opening (back passage)?	1.81 (0.91)	3	53	1.67 (0.97)	3	44
39. Have you had pain in your rectum (deep inside your back passage)?	1.46 (0.78)	3	31	1.5 (0.99)	3	28
40. Have you had bright blood in your motions?	1.30 (0.59)	2	23	1.5 (0.92)	3	28
41. Have you had dark blood clots in your motions?	1.09 (0.34)	2	8	1.0 (0)	0	0
42. Does passing water cause your bowels to act immediately?	1.50 (0.74)	3	37.5	1.5 (0.62)	2	44
43. Have you had to wear a pad because of your bowel problems?	1.41 (0.83)	3	25	1.78 (1.06)	3	44
44. Have you had difficulty going out of the house, because you needed to be close to a toilet, because of bowel problems?	1.64 (0.80)	3	47	1.61 (0.98)	3	33
45. Have your daily activities been limited by your bowel problems?	1.56 (0.73)	3	44	1.61 (1.09)	3	28
46. Did your treatment restrict the types of food you can eat due to your bowel problem?	1.66 (0.88)	3	44	1.83 (1.25)	3	33
47. Did you worry about your bowel problem?	1.76 (0.80)	3	55	1.89 (1.13)	3	50
48. Did you feel embarrassed by your bowel problem?	1.53 (0.86)	3	33	1.61 (0.98)	3	33
49. How unhappy would you feel if you lived the rest of your life with your bowel habit as it is now?	2.30 (1.21)	3	61	1.94 (1.16)	3	44

*Criteria for deletion: mean < 1.5; range < 2; prevalence ratio < 30%. If criteria met, box is italics.

Interview analysis

Table 3 lists the specific comments made by patients regarding a number of questions and the rationale for keeping or changing these questions.

Following this feedback it was necessary to revise the questionnaire. Table 4 provides a list of the items and describes the changes that were made. The following two questions were added to the module in response to patient feedback: "Have you been unable to wait 15 min to open your bowels?" and "Have you had the feeling of being unable to completely empty your bowels". The first question was added because it was identified that the module did not include a question on urgency, and the second question was added because patients identified that they were having issues with being unable to empty their bowels.

Discussion

The international Phase III pretesting of the provisional proctitis module (EORTC QLQ-PRT21) has been successfully completed according to EORTC guidelines [19]. Minor modifications to the translated items were not considered sufficient to require further pretesting. The module is now identified as EORTC QLQ-PRT23 because two additional items have been identified for inclusion. The questionnaire will now proceed to phase IV testing.

In total, 92 patients participated in five countries (including Australia, Germany, France, Norway and Italy) and using five different languages. The feedback from patients and clinicians in the five countries has been incorporated to finalise the proctitis module for proceeding to Phase IV. With this culturally acceptable version, the module will be administered to a larger number of patients ($n > 350$). The primary objective of this last phase is to test the scale structure, reliability and validity and cross-cultural applicability of the proctitis module to be used alone or together with the EORTC quality of life questionnaire (EORTC QLQ-C30) in patients who are currently receiving radiation therapy to their pelvic region and likely to be experiencing acute radiation proctitis, and at the same time also explore its use in patients experiencing chronic proctitis.

In both Australia and Europe nearly 80% of participants were males. This occurred because a large proportion of patients were

receiving treatment for prostate cancer (64% in Australia and 69% in Europe). The incidence of prostate cancer is much higher internationally than other cancers located in the pelvic region. We could have expected that more women with cervical cancer would be recruited for Phase III of the study. However, while the incidence of proctitis has been high in patients receiving treatment for cervical cancer in the past, the number of patients being diagnosed with advanced cervical cancer has decreased significantly with increased cervical cancer screening. Early stage cervical cancer requires the use of smaller radiation therapy treatment field and therefore reduces the risk of patients experiencing proctitis. During Phase IV we aim to recruit men and women to this study; however, we anticipate that the percentages of men will again be higher.

There were differences between the Australian and European samples that should be noted. First, patients who participated in the study in Europe were significantly younger in comparison with Australian participants (mean age 67 years vs. 72 years, independent t -test $p = 0.017$). In Australia we recruited participants up to the age of 87 whereas in Europe the oldest patient was 80. It is important to recognise that patients above the age of 80 are uncommonly referred for high-dose radiation therapy, but we had specifically targeted patients in this age group in Australia, to ensure some coverage of this uncommon, but, given the aging of the population, likely increasing presence. In Phase IV, we anticipate that there will be a small number of patients above the age of 80.

Second, in Australia more patients who had completed treatment were recruited than in each of the European countries. However, a chi square analysis demonstrated that this difference was not statistically significant. Recruitment in each country was by opportunity and it was easier for clinicians to recruit patients who were on treatment, than to recruit patients during treatment follow-up. During Phase IV of the study we aim to recruit adequate number to assess both chronic and acute proctitis because it is likely that patients experience different symptoms.

There were some differences in the patterns of response to the proctitis items between Australian and European subjects. For nine of the questions there were differences in the prevalence ratios of greater than 10% (see Section "Results"). We suggest that these differences are explained by the higher proportion of European subjects with acute symptom issues assessed during active treatment.

Table 3

Summary of patients' comments (F = French, N = Norwegian, G = German, I = Italian).

Questions	Patient number	Comments made	Decision made regarding changes to questions
32. Avez-vous ete gene par le besoin d'expulser des vents/gaz/flatulences?	F007	French translation of question 32 is not appropriate	Change to the following: "Avez-vous ete gene par la survenue de gaz ou de flatulences?"
34. Have you had any unintentional release (leakage) of wind or mucous?	N007 N001 G004	Two comments related to what is leakage and if it is diarrhoea and whether the release has to be unintentional as the question states	Questions not altered
35. Have you had any unintentional release (leakage) of liquid stools?			The issue of intentional vs. non intentional needs to be addressed. The inclusion of a question on urgency will address this. This new question is added below (in the section on general comments)
37. Have you had abdominal pain or cramping not related to a bowel movement	N013 G009	This question can be easily misunderstood	Accepted as a negative phrasing problem, however question not altered
38. Have you had pain/discomfort related to your anal opening (back passage)?	G001 G006 G007 N012	It was noted respondents seek further clarification regarding the difference between rectal and anal pain i.e. "how deep"	Re-wording of question 38 and 39 as follows:
39. Have you had pain in your rectum (deep inside the back passage)?			38. Have you had pain/discomfort around your anal canal? This will also address the issue that skin irritation/soreness has not been addressed in the questionnaire 39. Have you had pain or cramping in your rectum? Questions will be reordered to follow the anatomical order i.e. abdomen, rectum and anus. To do this question 38 and 39 will swap positions
42 Le fait d'uriner a-t-il declenche une reaction immediate au niveau de vos intestins?	F007	French translation of question inappropriate	Question changed to: "le fait d'uriner declenche t-il l'envie d'aller a la selle?"
51. What was the highest number of times you had to open your bowels in the last 24 h? Please indicate number in box	N008 G003	Confusing Respondent thought it might be interesting to not only ask for "how often" but to specifically ask for "when" and "what was the defecation provoked by"	Continual debate about this question is occurring because patients have found it difficult to understand The question is to be changed to: "During the past week – What was the highest number of times you had to open your bowels in any 24 h period?" As mentioned above, questions 50–52 are designed for review with oncologist and the patient, not for patient to answer alone
52. Would you like more assistance to manage your bowel problem? (optional question)	N002 G013 G014	Respondent thought it could help to specify who can help them with their problem (doctor? radiation therapist? nurse?) Patient said the question seemed paradox to him because he was filling in the questionnaire and this suggested that these problems would therefore hopefully be addressed Patient was not sure if he understood the intention of the question	This change was not made because it would be difficult to ensure that it was monitored and extends beyond the purpose of this questionnaire This question has been kept in the questionnaire because some patients have identified that they would like more assistance in managing their bowel problems This question will be monitored and if necessary health professionals can explain this question to patients
Added questions as suggested by patients and their treating clinicians	F011 I010 G008 F008 F010 F007 F010 N001 N004 I013	Having the feeling of not completely emptying the bowel urgency (inability to defer defecation) Skin issues such as soreness and irritation	An additional question has now been added: "Have you had the feeling of being unable to completely empty your bowels?" An additional question has now been added: "Have you been unable to wait 15 min to open your bowels?" Comment valid. Question required to address skin issues and it is incorporated within question 38. "Have you had pain/discomfort around your anal canal?"
Timing issues relating to the questionnaire	F005 G006 G008 F001 F009 F011	Comments related to the questionnaire timeframe as respondents felt experience of symptoms in the 'past week' was not reflective of their experience. I.e. G008 response "for example some days were bad/severe symptoms and others were ok"	Noted as an issue; however, the EORTC define the time frame for use in the questionnaire. Patients to be given clear guidance (verbally and in information sheet) relating to the time frame the survey is referring to (i.e. in regard to the 'past week')

(continued on next page)

Table 3 (continued)

Questions	Patient number	Comments made	Decision made regarding changes to questions
General comments regarding questions not addressed by module	F004 N005 F006 G007 N009 I010 F011	Questions regarding: Patient experience prior to treatment What provoked the onset of the symptoms Lifestyle factors and nutrition, type of food consumed Psychological stress General state of tiredness, fatigue, nausea, bad appetite, thirst Sexual life	These questions were not included as they were deemed not relevant to this particular study and will not impact on whether the patient is diagnosed with proctitis or not
Irrelevant questions to some patients' situations	N004	One respondent found some questions irrelevant due to having a colostomy bag	These questions will not be removed because many patients do not have colostomy bags It would be useful to collect further details about the patient's medical history to reduce irrelevance of questions to their situations. This may be implemented in the next Phase of the study

Table 4

Changes that were made to the proctitis module.

Item	Changes made and reason
Have you had a bloated feeling in your abdomen?	Nil
Were you troubled by passing wind/gas/flatulence?	Nil
Have you had excessive gurgling noise from your abdomen?	Nil
Have you had any unintentional release (leakage) of wind or mucous?	Nil
Have you had any unintentional release (leakage) of liquid stools?	Nil
Have you needed to get up at night to open your bowels?	Nil
Have you had abdominal pain or cramping not related to a bowel movement.	Nil
Have you had pain or cramping in your rectum (deep inside the back passage)?	Item altered to provide clearer understanding of the location of the pain
Have you had pain/discomfort around your anal opening (back passage)?	Item altered to provide clearer understanding of the location of the pain
Have you had bright blood in your stools?	Nil
Have you had dark blood clots in your stools?	Nil
Have you been unable to wait 15 min to open your bowels?	Item added to module because previously questions did not address urgency
Have you had the feeling of being unable to completely empty your bowels?	Item added to module because previously questions did not address whether patient's felt able to completely empty their bowels
Does passing water cause your bowels to act immediately?	Nil
Have you had to wear a pad because of your bowel problems?	Nil
Have you had difficulty going out of the house, because you needed to be close to a toilet, because of bowel problems?	Nil
Have your daily activities been limited by your bowel problems?	Nil
Did your treatment restrict the types of food you can eat due to your bowel problems?	Nil
Did you worry about your bowel problem?	Nil
Did you feel embarrassed by your bowel problem?	Nil
How unhappy would you feel if you lived the rest of your life with your bowel habit as it is now?	Nil
Have you needed to take medication to control diarrhoea?	Nil
What was the highest number of times you had to open your bowels in any 24 h period?	Item wording altered because patients and clinicians found the question unclear
Would you like more assistance to manage your bowel problem? (optional question)	Nil

Patients assessed with chronic problems represent a somewhat different cohort and much less common cohort. They were selected on the basis of ongoing significant bowel problems. It is likely adaptation and response shift issues would apply in this situation. Further testing of this questionnaire during Phase IV of the study will help establish possible differences in the symptom profiles that characterise the acute phase, and much less common chronic phases.

A limitation of this module was that it was not initially developed simultaneously in several languages (which is the standard EORTC approach). However, the current study presented in this manuscript ensures appropriate cultural adaptation of this module. Difficulties in the translated languages led to changes in the original items of this module, thus leading to better cultural adaptation.

We can recommend that translations are completed early in the questionnaire developments, so that changes can be made to the original module before further testing is conducted. The EORTC is confident that this module is now suitable for Phase IV testing.

Conclusion

We have developed and pre-tested a proctitis module (EORTC QLQ-PRT23) that can be used in conjunction with the EORTC quality of life questionnaire. Following large scale field testing of this module, it is planned that this module will be suitable to be employed for the assessment of the endpoint of radiation induced proctitis.

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References

- [1] Leiper K, Morris A. Treatment of radiation proctitis. *Clin Oncol* 2007;19:724–9.
- [2] Hayne D, Vaizey C, Boulos P. Anorectal injury following Pelvic radiotherapy. *Br J Surg* 2001;88:1037–48.
- [3] Jones K, Evans A, Bistrow R, Levin W. Treatment of radiation proctitis with hyperbaric oxygen. *Radiother Oncol* 2006;78:91–4.
- [4] Denton A, Forbes A, Andreyev J. Non surgical interventions for late radiation proctitis in patients who have received radical radiotherapy to the pelvis. *Cochrane Database System* 2002.
- [5] Capp A, Inostroza-Ponta M, Bill D, et al. Is there more than one proctitis syndrome? A revisitiation using data from the TROG 96.01 trial. *Radiother Oncol* 2009;90:400–7.
- [6] Agrawal P, Bansal N, et al. Management of chronic hemorrhagic radiation proctitis. *J Clin Oncol* 2007;3:19–29.
- [7] Aaltomaa S, Kataja V, Lahtinen T, Palmgren J, Forsell T. Eight years experience of local prostate cancer treatment with permanent I125 seed brachytherapy – morbidity and outcome results. *Radiother Oncol* 2009;91:213–6.
- [8] Giralt J, Tabernero J, Navalpotro B, et al. Pre-operative chemoradiotherapy with UFT and Leucovorin in patients with advanced rectal cancer: a phase II study. *Radiother Oncol* 2008;89(3):263–9.
- [9] Chapuis P. Challenge of chronic radiation-induced rectal bleeding. *Aust N Z J Surg* 2001;71:200–1.
- [10] Colwell J, Goldberg M. A review of radiation proctitis in the treatment of prostate cancer. *J Wound Ostomy Continence Nurs* 2000;27:179–87.
- [11] Olopade F, Norman A, Blake P, et al. A modified inflammatory bowel disease questionnaire and the Vaizey incontinence questionnaire are simple ways to identify patients with significant gastrointestinal symptoms after pelvic radiotherapy. *Br J Cancer* 2005;92:1663–70.
- [12] Cox J, Dtetz J, Pajak T. Toxicity criteria of the radiation therapy oncology group (RTOG) and the European Organization for Research and Treatment of Cancer (EORTC). *Int J Radiat Oncol Biol Phys* 1995;31:1341–6.
- [13] Fonteyne V, De Neve W, Villeirs G, De Wagter C, De Meerleer G. Late radiotherapy-induced lower intestinal toxicity (RILIT) of intensity-modulated radiotherapy for prostate cancer: The need for adapting toxicity scales and the appearance of the sigmoid colon as co-responsible organ for lower intestinal toxicity. *Radiother Oncol* 2007;84:156–63.
- [14] Dent O, Galt E, Chapuis P, et al. Quality of life in patients undergoing treatment for chronic radiation induced rectal bleeding. *Br J Surg* 1998;85:1251–4.
- [15] Aaronson N, Ahmedzai S, Bergman B, et al. The European Organization for Research and Treatment of Cancer QLQ-C30: A Quality-of-Life Instrument for Use in International Clinical Trials in Oncology. *J Natl Cancer Inst* 1993;85:365–76.
- [16] Geinitz H, Zimmermann F, Thamm R, et al. Late rectal symptoms and quality of life after conformal radiation therapy for prostate cancer. *Radiother Oncol* 2006;79:341–7.
- [17] Vordermark D, Wulf J, Markert K, et al. 3-D conformal treatment of prostate cancer to 74 Gy vs. High-dose-rate brachytherapy boost: a cross-sectional quality-of-life survey. *Acta Oncol* 2006;45:708–16.
- [18] Spry N, Halkett G, Aoun S, Spry J, Yeoh E. Development of an EORTC module to assess the quality of life of patients with proctitis following pelvic radiotherapy for malignancy. *International Journal of Radiation Oncology, Biology and Physics* 2008;72(2):522–8.
- [19] Blazeby J, Sprangers M, Cull A, Mogens G, Bottomley A. EORTC Quality of Life Group: Guidelines for Developing Questionnaire Modules. EORTC Quality of Life Group 2002.
- [20] Vachalec S, Bjordal K, Bottomley A, et al. EORTC Item Bank Guidelines. Brussels: EORTC Publications; 2001.
- [21] Cull A, Sprangers M, Bjordal K, et al. EORTC Quality of Life Group Translation Procedure. Brussels: EORTC; 2002.
- [22] von Euler-Chelpin M, Olsen A, Njor S, et al. Socio-demographic determinants of participation in mammography screening. *Int J Cancer* 2008;122:418–23.