



Development of an international bone metastases module to accompany the European Organization for Research and Treatment of Cancer Quality of Life Group core questionnaire (EORTC QLQ-C30) for future clinical trials in patients with bone metastases.

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when it matters
MOST



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On behalf of the EORTC Quality of Life
Bone Metastases Module Development Group

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Background

- Bone metastases are a frequent complication in the oncologic population
- Pain is the most common symptom requiring treatment
- Skeletal related events:
 - 10-20% fractures of weight bearing bones
 - 10-15% hypercalcaemia
 - 5% spinal cord or nerve root progression
- Successful management of bone metastases
 - Reduce skeletal complications
 - Maximize patient quality of life (QOL)



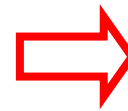
Background

- Treatment options have expanded
 - Newer generation of bisphosphonates
 - Increased use of orthopaedic surgery
- Advances have increased life expectancy
 - Breast and prostate patients with metastases (average 2-5 years)
- Great need to monitor not only benefits, but also side effects of these treatments



Background

- Previous clinical trials on bone metastases have largely focused on objective endpoints:
 - Analgesic consumption
 - Hypercalcemia
 - Pathological fracture
 - Spinal cord compression
 - Use of surgery and radiation
- WHO describes health as “not merely the absence of disease or infirmity, but a state of physical, mental and social well-being”



Skeletal Related Events (SRE)



Background

- In palliative trials QOL is a major endpoint
- QOL is subjective:
 - Reflects functional status, psychosocial well-being, health and disease perceptions, disease and treatment related symptoms
 - Incorporates expectation, satisfaction, value system and many aspects of a patient's life
 - Important consideration when making treatment related decisions
- Important to understand the impact of disease and treatment through patient's experiences
- QOL instruments for patients with bone metastases are lacking



Objective

- *To develop a set of robust items and scales for assessing quality of life issues not sufficiently covered by the EORTC QLQ-C30 core questionnaire and considered to be relevant for cancer patients with bone metastases in clinical trials.*
- Specific aims - to develop the QOL items addressing:
 - Disease symptoms related to bone metastases or its diagnosis;
 - Side effects, complications and other issues related to treatment of bone metastases and;
 - Additional quality of life dimensions that are relevant across diagnosis and treatment modalities in the management of bone metastases



Methods

Module development – 4 Phases

Phase 1 - Generation of relevant QOL issues

Phase 2 - Operationalization of the QOL issues
into a set of items

Phase 3 - Pre-testing the module questionnaire

Phase 4 - Large-scale international field testing



Phase I

Generation of relevant QOL Issues

1) Literature search

- Medline (1966-2005) and Psychinfo (1966-2005)
- Keywords: Bone Neoplasms/Bone Metastases combined with Quality of Life; Quality of Life with Terminal Cancer
- 377 records (246 and 131 respectively)
- 42 articles evaluated QOL in patients with bone metastases
- EORTC QLQ C30; Brief Pain Inventory; Functional Living Index-Cancer (FLIC), FACT, Health Related Quality of Life (HRQOL), SF-36 health survey, social support list, global quality of life measure and/or performance status scores such as KPS, ECOG or WHO
- No questionnaires specific to bone metastases reported



Phase I

1) Literature search

- Previously developed EORTC disease-specific modules
 - QLQ-MY20 was especially helpful
- Barton *et al* article
 - “Palliative radiotherapy of bone metastases: an evaluation of outcome measures”
 - Offered patient’s perspective on the impact of metastases and radiotherapy treatment on daily life and psychological, emotional and social functioning, treatment expectations and outcome evaluations, priorities in daily living and concern regarding symptoms and side effects of treatment bone metastases



Phase I

2) Interviews

- Qualitative
- Toronto Sunnybrook Regional Cancer Centre
- **Patients:** bisphosphonates and/or systemic therapy; radiation therapy; orthopaedic intervention; palliative symptom control
- **Health care professionals (HCPs):** radiation oncology; medical oncology; palliative care services; orthopaedic surgery; nursing; radiation therapy; pharmacy; psychosocial-spiritual care
- Between May – July 2005, 20 patients and 52 HCPs were interviewed
- Patients and HCPs generated 100 and 134 quality of life issues respectively



Phase I

- Issues were pooled and grouped into similar themes
- Final list: 61 QOL issues
 - Symptoms (13)
 - Functions (15)
 - Side effects of treatment of bone metastases (3)
 - Psychosocial issues (27)
 - Treatment expectations (2)
 - Other (1)



QOL Questionnaire

QUALITY OF LIFE ISSUES		i) Please indicate for each experience separately, the extent to which you have had it during your illness, on a scale of (1) "not at all" to (4) "very much."				ii) Include this issue on the final questionnaire? (circle Yes or No for each item)	
		Not At All (1)	A Little (2)	Quite a Bit (3)	Very Much (4)		
SYMPTOMS							
1	Long-term (or chronic) pain	1	2	3	4	Yes	No
2	Short-term (or acute), severe pain	1	2	3	4	Yes	No
3	Pain at rest (i.e. when sitting)	1	2	3	4	Yes	No
4	Pain with activity (i.e. when walking)	1	2	3	4	Yes	No
5	Pain aggravation with movement or weight-bearing	1	2	3	4	Yes	No
6	Uncontrolled, unmanageable pain not relieved by pain killers	1	2	3	4	Yes	No
7	Pain at night preventing sleep	1	2	3	4	Yes	No
8	Aches and stiffness	1	2	3	4	Yes	No
9	Lack of energy	1	2	3	4	Yes	No
10	Numbness	1	2	3	4	Yes	No
11	Tingling	1	2	3	4	Yes	No
12	Burning Sensation	1	2	3	4	Yes	No
13	Postural problems	1	2	3	4	Yes	No
FUNCTION							
14	Limited movement due to pain	1	2	3	4	Yes	No
15	Difficulty planning activities outside the home	1	2	3	4	Yes	No
16	Difficulty traveling outside the home (i.e. using public transportation, driving, sitting in car)	1	2	3	4	Yes	No

QUALITY OF LIFE ISSUES		i) Please indicate for each experience separately, the extent to which you have had it during your illness, on a scale of (1) "not at all" to (4) "very much."				ii) Include this issue on the final questionnaire? (circle Yes or No for each item)	
		Not At All (1)	A Little (2)	Quite a Bit (3)	Very Much (4)		
FUNCTION (continued)							
17	Difficulty in carrying out meaningful activity (including employment)	1	2	3	4	Yes	No
18	Able to perform self-care	1	2	3	4	Yes	No
19	Able to return to work promptly	1	2	3	4	Yes	No
20	Difficulty carrying out usual daily tasks (i.e. grocery shopping, work outside the home, housework)	1	2	3	4	Yes	No
21	Difficulty bending	1	2	3	4	Yes	No
22	Difficulty lifting	1	2	3	4	Yes	No
23	Difficulty standing up	1	2	3	4	Yes	No
24	Difficulty climbing stairs	1	2	3	4	Yes	No
25	Difficulty sitting	1	2	3	4	Yes	No
26	Difficulty lying in bed	1	2	3	4	Yes	No
27	Difficulty lying flat	1	2	3	4	Yes	No
28	Ability to have sex	1	2	3	4	Yes	No
SIDE EFFECTS FROM TREATMENT OF BONE METASTASES							
29	Drowsiness	1	2	3	4	Yes	No
30	Confusion	1	2	3	4	Yes	No
31	Dizziness	1	2	3	4	Yes	No
PSYCHOSOCIAL							
32	Able to perform role functioning (including domestic and family roles)	1	2	3	4	Yes	No
33	Feeling socially isolated	1	2	3	4	Yes	No



QOL Questionnaire

QUALITY OF LIFE ISSUES		i) Please indicate for each experience separately, the extent to which you have had it during your illness, on a scale of (1) "not at all" to (4) "very much."				ii) Include this issue on the final questionnaire? (circle Yes or No for each item)	
		Not At All (1)	A Little (2)	Quite a Bit (3)	Very Much (4)		
PSYCHOSOCIAL (continued)							
34	Strengthened relationships with family and friends	1	2	3	4	Yes	No
35	Have a clear, alert mind	1	2	3	4	Yes	No
36	Feel in control, positive, and confident	1	2	3	4	Yes	No
37	Hope to live as long as possible	1	2	3	4	Yes	No
38	Reluctance to use pain medication	1	2	3	4	Yes	No
39	Fear of addiction to pain medication	1	2	3	4	Yes	No
40	Anxiety	1	2	3	4	Yes	No
41	Frustration	1	2	3	4	Yes	No
42	Mood changes	1	2	3	4	Yes	No
43	Emotional stress of diagnosis of advanced, incurable cancer	1	2	3	4	Yes	No
44	Increased focus on spiritual issues	1	2	3	4	Yes	No
45	Loss of interest in activities you normally enjoy	1	2	3	4	Yes	No
46	Loss of interest in sex	1	2	3	4	Yes	No
47	Worry about pain	1	2	3	4	Yes	No
48	Worry about suffering	1	2	3	4	Yes	No
49	Worry about loss of mobility compromising independence	1	2	3	4	Yes	No
50	Worry about becoming dependent on others	1	2	3	4	Yes	No
51	Worry about current health status	1	2	3	4	Yes	No

QUALITY OF LIFE ISSUES		i) Please indicate for each experience separately, the extent to which you have had it during your illness, on a scale of (1) "not at all" to (4) "very much."				ii) Include this issue on the final questionnaire? (circle Yes or No for each item)	
		Not At All (1)	A Little (2)	Quite a Bit (3)	Very Much (4)		
PSYCHOSOCIAL (continued)							
52	Worry about the future	1	2	3	4	Yes	No
53	Worry about becoming bed-bound	1	2	3	4	Yes	No
54	Worry about disease progression, deterioration in condition, and future complications	1	2	3	4	Yes	No
55	Worry about running out of medical treatments	1	2	3	4	Yes	No
56	Worry about hospitalization	1	2	3	4	Yes	No
57	Worry about ending days in a hospital or nursing home	1	2	3	4	Yes	No
58	Worry about death	1	2	3	4	Yes	No
TREATMENT EXPECTATIONS							
59	Hope for sustained pain relief (reduce pain for as long as possible)	1	2	3	4	Yes	No
60	Hope treatment will reduce pain as much as possible	1	2	3	4	Yes	No
OTHER ISSUES							
61	Financial burden due to the illness	1	2	3	4	Yes	No



QOL Questionnaire

- iv. If you circled “yes” for more than 10 issues (in part ii), please indicate which **5 to 10 issues** (from the above list, issues #1 to #61) affect the QOL of patients with bone metastases most profoundly, that we should definitely include in the final questionnaire.

(Items do not need to be ranked)

f) # _____ f) # _____

g) # _____ g) # _____

h) # _____ h) # _____

i) # _____ i) # _____

j) # _____ j) # _____

PART B:

The following 3 pages contain an existing questionnaire that asks you about you and your health. These questions may be of value for all those patients who have cancer. Could you please **read** these questions?

(NOTE: Please do not answer these questions. We would just like you to read the questions).

You may have had some **other experiences** that are not included in this questionnaire or in the previous questionnaire (that is the list of issues you just rated).

1. Can you think of anything else that you have experienced or had to cope with during your illness with bone metastases that is not included in these questionnaires?
2. If yes, please name each of these experiences.



Phase I

- Sites:

- Canada
 - Toronto Sunnybrook Regional Cancer Centre (TSRCC)
 - Princess Margaret Hospital (PMH)
 - Tom Baker Cancer Centre (TBCC)
- Liverpool Hospital (Australia)
- Charité Hospital (Universitätsmedizin Berlin, Germany)



Phase I

- Eligibility:
 - Patients with radiographic evidence of bone metastases regardless of their primary cancer site, age or gender
 - HCPs involved with the care of bone metastases patients
 - Informed consent
 - Only English speaking in Canada and Australia



Canada



Canada

Demographics – Patients

N=330

Site:

Toronto Sunnybrook Regional Cancer Centre	131 (40%)
Princess Margaret Hospital	132 (40%)
Tom Baker Cancer Centre	67 (20%)

Age (years):

Median 63 (30-92)

Gender:

Female 186 (57%)
Male 144 (43%)

Primary Cancer Site:

Breast 132 (40%)
Lung 66 (20%)
Prostate 33 (10%)



Top 10 QOL Issues – Patients

Rank	QOL Issue	Freq.	N	%
1	Long-term (chronic) pain	124	303	41
1	Worry about becoming dependent on others	124	303	41
3	Difficulty carrying out usual daily tasks	121	304	40
4	Worry about loss of mobility compromising independence	112	304	37
5	Difficulty in carrying out meaningful activity	102	303	34
6	Able to perform self-care	96	303	32
6	Able to perform role functioning	96	304	32
8	Worry about disease progression, deterioration in condition and future complications	94	303	31
9	Financial burden due to the illness	80	304	26
10	Lack of energy	71	303	23



Canada

Demographics - HCPs

N=115

Site:

Toronto Sunnybrook Regional Cancer Centre	45 (39%)
Princess Margaret Hospital	47 (41%)
Tom Baker Cancer Centre	23 (20%)

Specialty:

Radiation Oncologist	39 (34%)
Nurse	30 (26%)
Medical Oncologist	22 (19%)
Palliative Care Physician	12 (10%)
Social Worker	5 (4%)
Others	7 (6%)

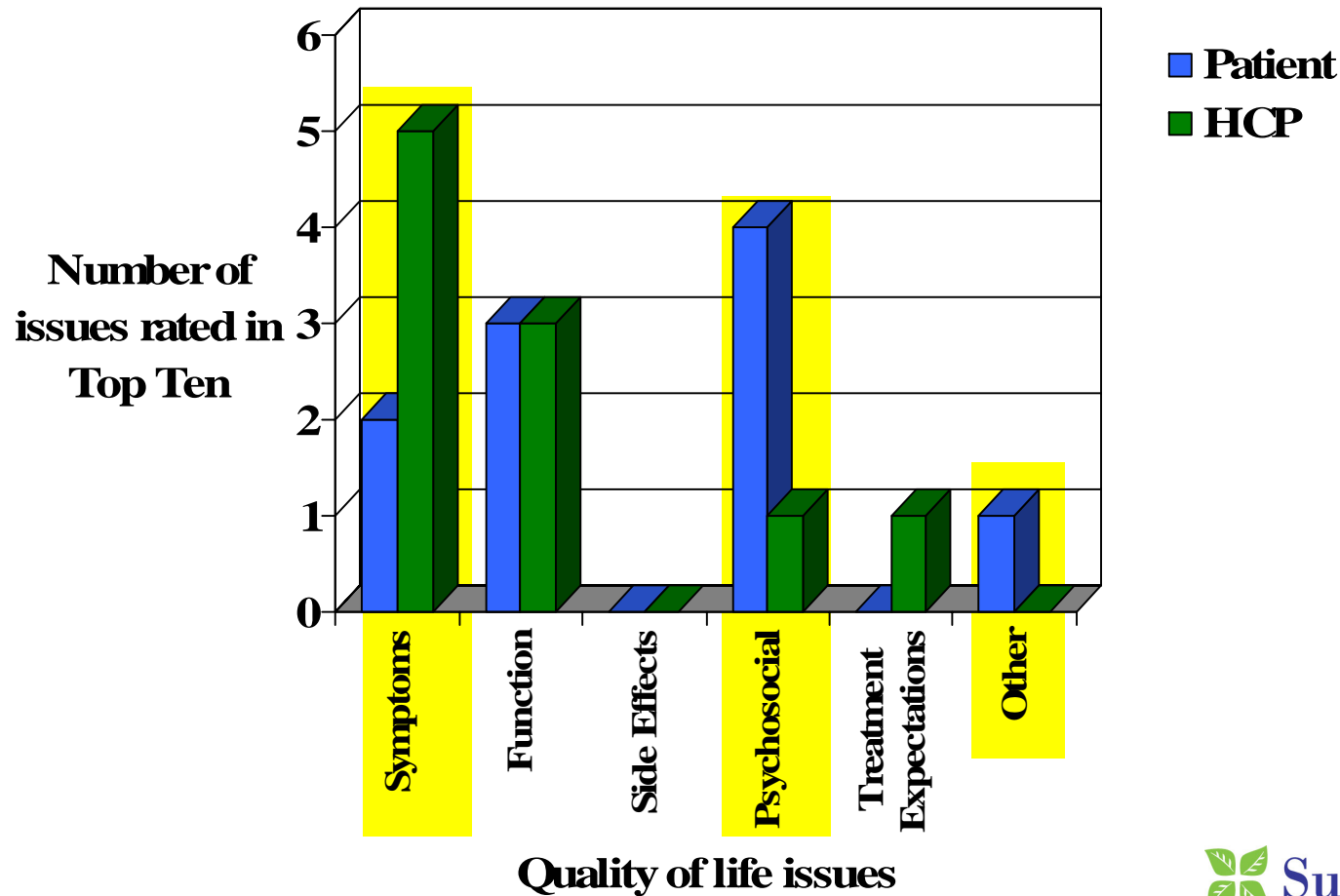


Top 10 QOL Issues - HCPs

Rank	QOL Issues	Freq.	N	%
1	Able to perform self-care	66	108	61%
2	Short-term (acute) pain relief	64	108	59%
3	Long-term (chronic) pain relief	61	107	57%
3	Uncontrolled, unmanageable pain relieved by pain killers	62	109	57%
5	Pain at night preventing sleep	56	107	52%
6	Limited movement due to pain	48	108	44%
7	Pain at rest	46	107	43%
8	Hope for sustained pain relief	45	109	41%
8	Able to perform role functioning	44	108	41%
10	Difficulty carrying out usual daily tasks	43	108	40%



Difference in Perspectives





Australia



Demographics - Patients

N=42

Age (years):

Median 62 (85-34)

Gender:

Female 29 (69%)

Male 13 (31%)

Primary Cancer Site:

Breast 24 (57%)

Lung 8 (19%)

Prostate 3 (13%)



Top Ten QOL Issues - Patients

Rank	QOL Issues	Freq.	N	%
1	Long-term (or chronic) pain	18	40	45%
2	Difficulty carrying out usual daily tasks	17	40	43%
2	Hope treatment will reduce pain as much as possible	17	40	43%
4	Able to perform self-care	16	40	40%
4	Emotional stress of diagnosis of advanced incurable cancer	16	40	40%
4	Worry about loss of mobility compromising independence	16	40	40%
7	Worry about becoming dependent on others	14	40	35%
8	Difficulty in carrying out meaningful activity	13	40	33%
8	Hope for sustained pain relief	13	40	33%
10	Uncontrolled, unmanageable pain not relieved by pain killers	12	40	30%
10	Hope to live as long as possible	12	40	30%
10	Worry about becoming bed-bound	12	40	30%
10	Worry about disease progression, deterioration in condition and future complications	12	40	30%



Demographics - HCPs

N=26

Specialty:

Medical Oncologist	24% (n=7)
Radiation Oncologist	24% (n=7)
Palliative Care Physician	21% (n=6)
Orthopedic Surgeon	21% (n=6)
Nurse	10% (n=3)

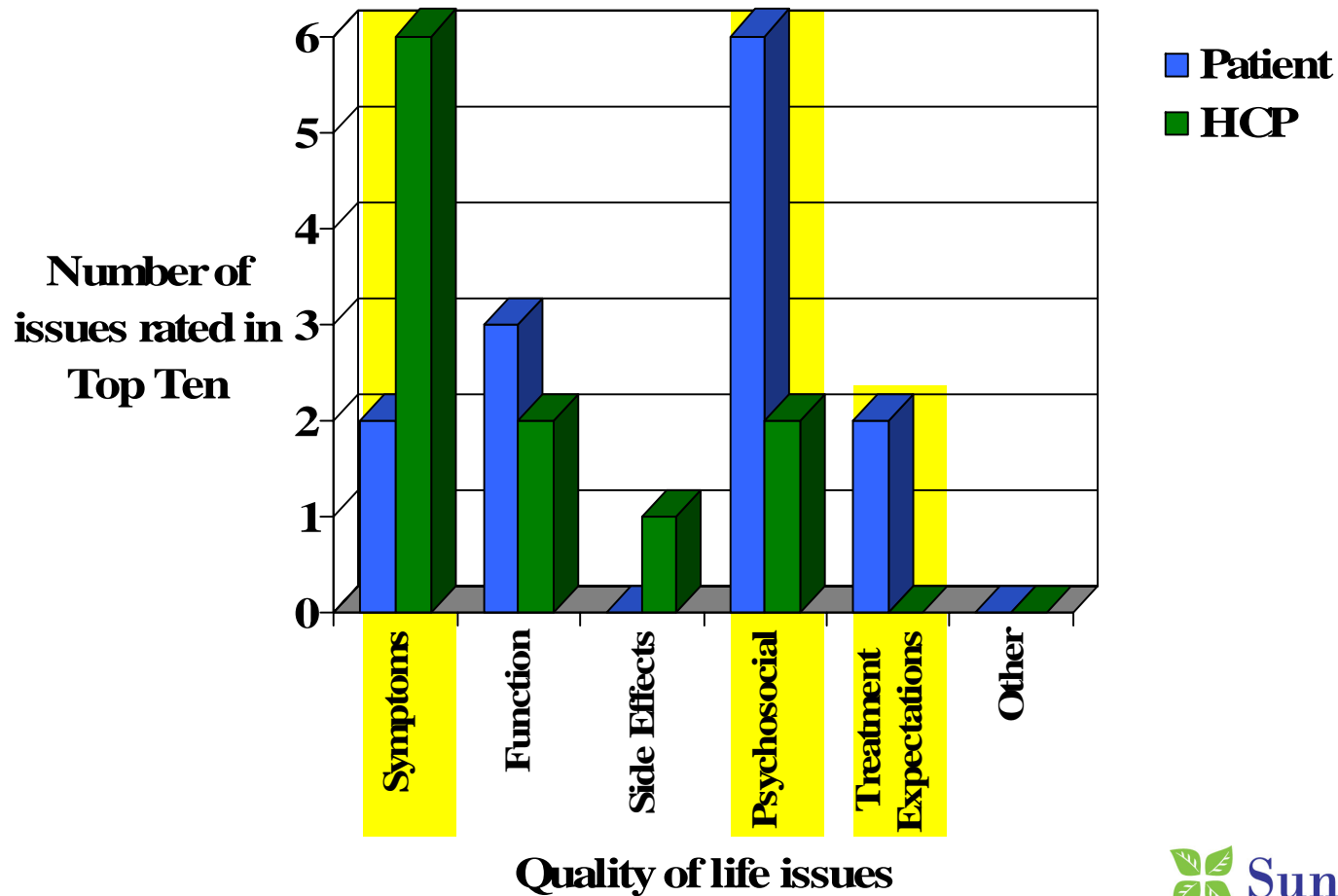


Top Ten QOL Issues - HCPs

Rank	QOL Issues	Freq.	N	%
1	Uncontrolled, unmanageable pain not relieved by pain killers	20	26	77%
2	Able to perform self-care	16	26	62%
3	Limited movement due to pain	14	26	54%
4	Pain at rest	13	26	50%
4	Pain with activity	13	26	50%
6	Long-term pain	12	26	46%
7	Short-term pain	11	26	42%
7	Pain at night preventing sleep	11	26	42%
7	Drowsiness	11	26	42%
10	Able to perform role functioning	9	26	35%
10	Reluctance to use pain medication	9	26	35%



Difference in perspectives





Germany



Demographics - Patient

N = 41

Age (years):

Median 66 (53-84)

Gender:

Female 24 (59%)

Male 17 (41%)

Primary Cancer Site:

Multiple Myeloma 37 (90%)

Breast 4 (10%)



Top Ten QOL Issues - Patients

Rank	QOL Issue	Freq.	N	%
1	Worry about disease progression, deterioration in condition and future complications	17	27	63%
2	Hope to live as long as possible	16	27	59%
3	Able to perform role functioning	15	27	56%
4	Long-term (chronic) pain	14	27	52%
4	Hope treatment will reduce pain as much as possible	14	27	52%
6	Worry about loss of mobility compromising independence	13	27	48%
6	Worry about ending days in a hospital or nursing home	13	27	48%
8	Limited movement due to pain	12	27	44%
8	Difficulty traveling outside the home	12	27	44%
8	Difficulty carrying out usual daily tasks	12	27	44%
8	Hope for sustained pain relief	12	27	44%



Demographics - HCPs

N=11

Specialty:

Medical Oncologist 3 (27%)

Hematologist 8 (73%)

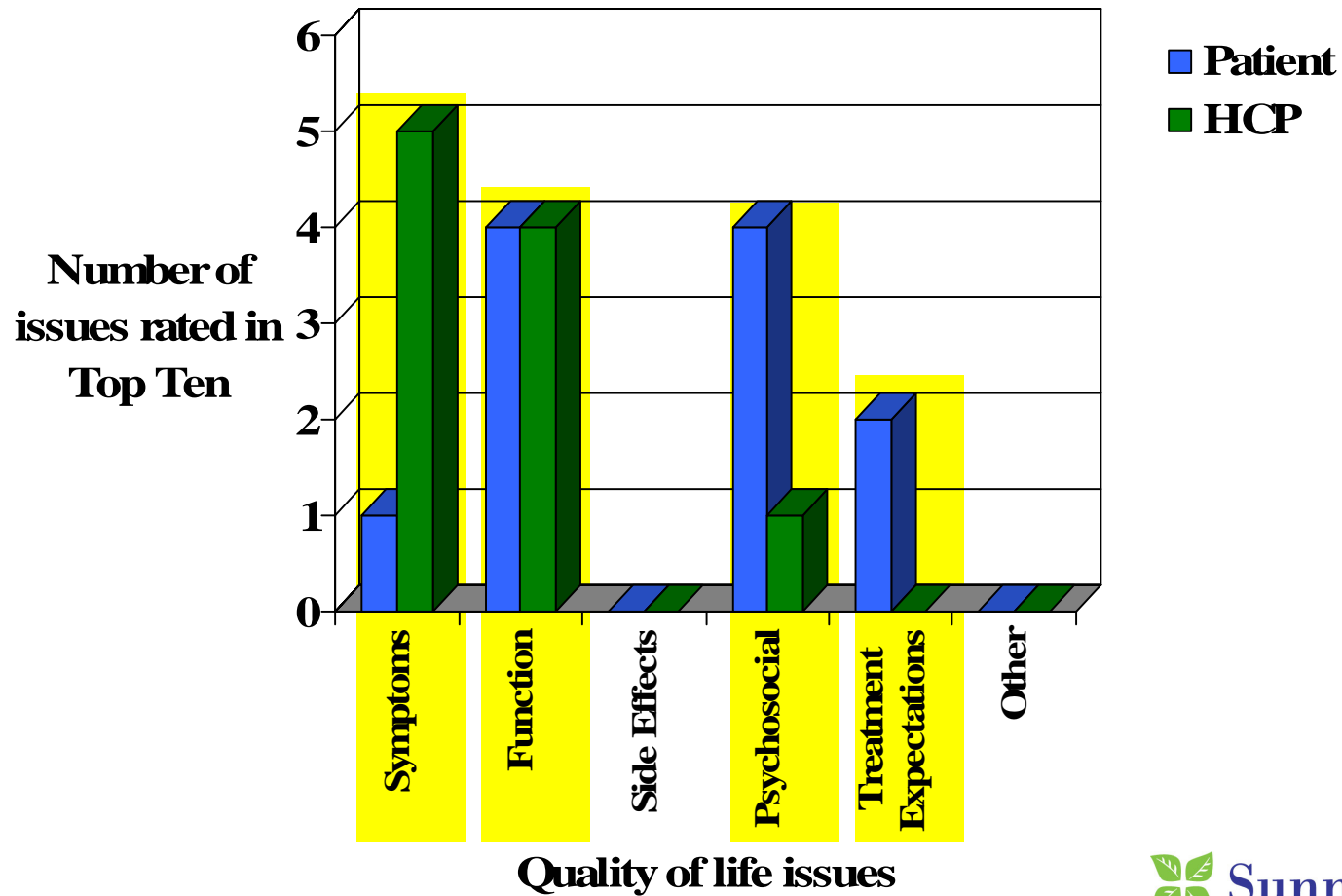


Top Ten QOL Issues - HCPs

Rank	QOL Issue	Freq.	N	%
1	Able to perform self-care	8	11	73%
2	Uncontrollable, unmanageable pain not relieved by pain killers	7	11	64%
3	Pain at rest	6	11	55%
4	Long-term (chronic) pain	5	11	45%
4	Pain with activity	5	11	45%
4	Pain at night preventing sleep	5	11	45%
4	Limited movement due to pain	5	11	45%
4	Difficulty carrying out meaningful activity	5	11	45%
4	Difficulty carrying out usual daily tasks	5	11	45%
4	Feeling socially isolated	5	11	45%



Difference in perspectives





Overall



Overall

Top Ten QOL Issues - Patients

Rank	QOL Issue	Freq.	N	%
1	Long-term (chronic) pain	156	370	41%
2	Difficulty carrying out usual daily tasks	150	371	40%
3	Worry about becoming dependent on others	146	370	39%
4	Worry about loss of mobility compromising independence	141	371	37%
5	Worry about disease progression, deterioration in condition and future complications	124	370	33%
5	Able to perform self-care	123	370	33%
7	Difficulty in carrying out meaningful activity	121	370	32%
8	Able to perform role functioning	121	371	32%
9	Financial burden due to the illness	92	371	24%
10	Hope treatment will reduce pain as much as possible	89	371	24%



Overall

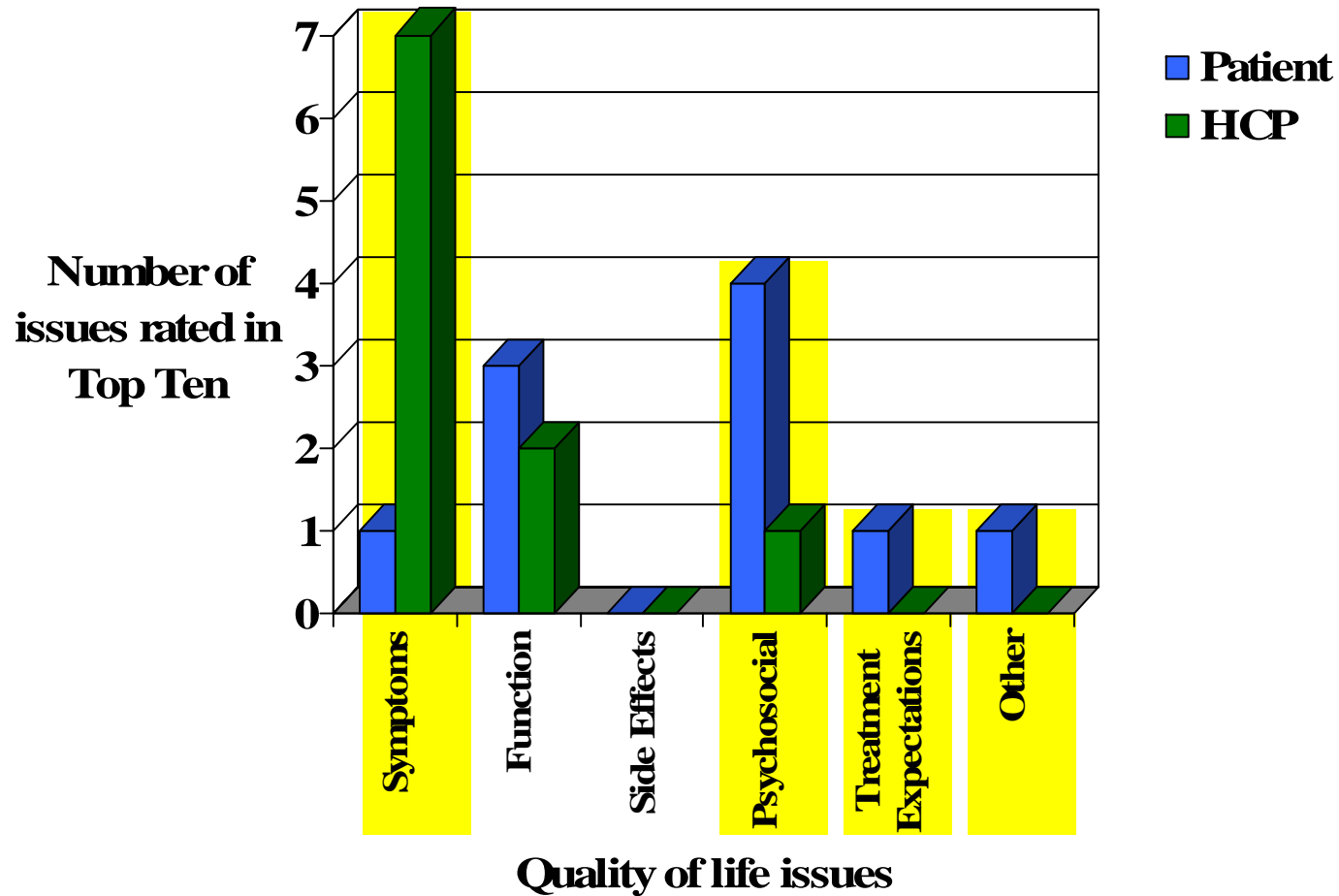
Top Ten QOL Issues - HCPs

Rank	QOL Issue	Freq.	N	%
1	Able to perform self-care	90	145	62%
2	Uncontrolled, unmanageable pain not relieved by pain killers	89	146	61%
3	Long-term (chronic) pain	78	144	54%
4	Short-term (acute) pain	76	145	52%
5	Pain at night preventing sleep	72	144	50%
6	Limited movement due to pain	68	145	47%
7	Pain at rest	65	144	45%
8	Pain with activity	59	144	41%
9	Able to perform role functioning	57	145	39%
10	Difficulty carrying out usual daily tasks	52	145	36%



Overall

Difference in Perspectives





Difference in Perspectives

Patient Rank	QOL Issue	HCP Rank
1	Long-term (chronic) pain	3
2	Difficulty carrying out usual daily tasks	10
3	Worry about becoming dependent on others	20
4	Worry about loss of mobility compromising independence	22
5	Worry about disease progression, deterioration in condition and future complications	16
6	Able to perform self-care	1
7	Difficulty in carrying out meaningful activity	12
8	Able to perform role functioning	9
9	Financial burden due to the illness	18
10	Hope treatment will reduce pain as much as possible	17



Difference in Perspectives

HCP Rank	QOL Issue	Patient Rank
1	Able to perform self-care	6
2	Uncontrolled, unmanageable pain not relieved by pain killers	14
3	Long-term (chronic) pain	1
4	Short-term (acute) pain	24
5	Pain at night preventing sleep	29
6	Limited movement due to pain	20
7	Pain at rest	38
8	Pain with activity	26
9	Able to perform role functioning	8
10	Difficulty carrying out usual daily tasks	2



Summary

- Top tens were very similar between the countries
- Issues in Common
 - Long term (or chronic) pain
 - Able to perform self-care
 - Difficulty carrying out usual daily tasks
 - Able to perform role-functioning
- Issues related to pain
 - HCPs 7 of 10
 - Patients 2 of 10
- 55/61 items did not have statistically significant differences between HCP specialties



Analysis



Decision Rules

- 1) mean score of patients' quality of life (1-4):
< 2.5 vs. ≥ 2.5 ;
- 2) prevalence ratio of patients' quality of life (1, 2 vs. 3, 4): < 30% vs. $\geq 30\%$;
- 3) range of patients' quality of life (1-4):
< 2 vs. ≥ 2 ;
- 4) priority patients (say 'yes' in final questionnaire):
< 1/3 vs. $\geq 1/3$; and
- 5) priority HCPs (say 'yes' in final questionnaire):
< 1/3 vs. $\geq 1/3$



Decision Rules

Inclusion:

1) Decision rank (1-5) ≥ 3

- 23 items

- 9 issues with **low** decision rankings were included because:

- (1) they were ranked within the HCPs' top ten (items 3, 6 and 7)

- (2) examples in other issues (items 21, 23, 24, 25 and 26)

- (3) item 33 was included because investigators felt there should be some mention of social/family life, however “able to perform role functioning” was already included in the QLQ-C30

2) Additional issues selected **more than twice** by HCPs and patients in Part B of questionnaire

- Uncertainty about the future & treatment



Decision Rules

Exclusion:

- Decision rank (1-5) < 3
 - 38 items (-9)
- Too similar to QLQ-C30
 - 5 items



Decision Rules

61-Item #	Issue	EORTC QLQ-C30 question #	Question
9	Lack of energy	18	Were you tired?
18	Able to perform self-care	5	Do you need help with eating, dressing, washing yourself or using the toilet?
20	Difficulty carrying out usual daily tasks (i.e. grocery shopping, work outside the home, housework)	6	Were you limited in doing either your work or other daily activities?
32	Able to perform role functioning (including domestic and family roles)	26	Has your physical condition or medical treatment interfered with your <u>family</u> life?
35	Have a clear, alert mind	20	Have you had difficulty in concentrating on things, like reading a newspaper or watching television?



Decision Rules

Exclusion:

- Decision rank (1-5) < 3
 - 38 items (-9)
- Too similar to QLQ-C30
 - 5 items
- Not specific to bone metastases
 - 3 items



Decision Rules

Category	Included	Excluded	Total
Symptom	7	6	13
Function	8	8	16
Side Effects of Treatment of Bone Metastases	0	2	2
Psychosocial	7	20	27
Treatment Expectations	2	0	2
Other	0	1	1
Total	24	37	61

+ Uncertainty about the future & treatment



Phase II

Operationalization

- Formatted in accordance with EORTC templates:
 - 1) questions arranged for “during the past week;”
 - 2) phrased in the “have you had” format
 - 3) measured on a 4-point scale from (1) “not at all” to (4) “very much”
- EORTC Quality of Life Item Bank
 - 450 validated items



Item	Derived from:	Module Ques. #	Decision	Rephrased/Reason removed or added
Have you had pain in your back?	Item Bank	MY32	Add	
Have you had pain in your leg(s) or hip(s)?	Item Bank	MY33	Add	
Have you had pain in your arm(s) or shoulder(s)?	Item Bank	MY34	Add	
Have you had pain in your buttock(s)?	Item Bank	CR36	Add	
Have you had pain in your chest?	Item Bank	MY35	Add but rephrase	Have you had pain in your chest or ribs? Rib pain is a significant problem for bone metastases patients.
Have you had uncontrollable, unmanageable pain that was not relieved by painkillers?	Similar to Item Bank	H&N61	Rephrase	Have you had pain that was not relieved by painkillers? Wordy
Have you had difficulty in carrying out meaningful activity?	Similar to Item Bank	CLL46	Rephrase	Have you had difficulty performing your desired tasks? Similar
Have you felt isolated?	Similar to Item Bank	HDC56	Rephrase	Have you felt isolated from those close to you (i.e. family, friends)? Similar, more specific
Have you been worried about your current health?	Similar to Item Bank	MY52	Rephrase	Have you been thinking about your illness? Similar
Have you worried about your cancer getting worse and causing more health problems in the future?	Similar to Item Bank	MY54	Rephrase	Have you worried about your health in the future? Similar



Pilot Testing

- QLQ-BM22 (September 8, 2006 version)

N=31

Site:	TSRCC	15 (48%)
	PMH	16 (52%)

Age (years):		
Median		61 (38-82)

Gender:		
Female		16 (52%)
Male		15 (48%)

Primary Cancer Site:		
Breast		10 (33%)
Multiple Myeloma		8 (26%)
Prostate		6 (19%)



Pilot Testing

- Overall, patients felt the BM22 was worded appropriately and addressed the most important issues relating to bone metastases



EORTC QLQ – BM22

Patients sometimes report that they have the following symptoms or problems. Please indicate the extent to which you have experienced these symptoms or problems **during the past week**. Please answer by circling the number that best applies to you.

During the past week have you had pain in any of the following parts of your body?

- 1. **Much** in your back?
- 2. in your leg(s) or hip(s)?
- 3. in your arm(s) or shoulder(s)?
- 4. in your chest or rib(s)?
- 5. in your buttock(s)?

Not at All A Quite Very
1 2 3 4
4 3 2 1

During the past week:

- 6. Have you had constant pain?
- 7. Have you have intermittent pain?
- 8. Have you had pain not relieved by pain medications?
- 9. Have pain while sitting or lying down?
- 10. Have you had pain while walking or climbing stairs?

1 2 3 4
1 2 3 4
1 2 3 4
1 2 3 4
1 2 3 4



During the past week:

	Not at All	A Little	Quite a Bit	Very Much
12. Have you had pain with activities such as bending 4 or climbing stairs?		1	2	3
13. Have you had pain with strenuous activity (e.g. exercise, lifting)?	1	2	3	4
14. Has pain interfere with your sleeping at night?	1	2	3	4
15. Have you had to modify your daily activities? 4		1	2	3
16. Have you felt isolated from those close to you (e.g. family, friends)?	1	2	3	4
17. Have you been thinking about your illness?	1	2	3	4
18. Have you felt hopeful your pain can get better?	1	2	3	4
19. Have you felt positive about your health?	1	2	3	4
20. Have you worried about loss of mobility because of your illness?	1	2	3	4
21. Have you worried about becoming dependent on others because of your illness?	1	2	3	4
22. Have you worried about your health in the future?	1	2	3	4



Scoring

Issues:

- Q1-5 form a pain scale and therefore the scores can be added to reflect patient's condition
- Reverse scoring of positively phrased questions (18, 19)
 - QLQ-BR23, QLQ-MY24, QLQ-OES18 and QLQ-OV28 have positively phrased questions



Next steps



Phase III

Pre-testing

- Identify and solve potential problems in the administration of the questionnaire (e.g. the phrasing and sequence of the questions)
- Determine the need for additional questions or the elimination of others
- Determine the overall degree of eliciting attention and interest



Phase III Questionnaire

Phase III- Pre-testing Questions-BM 22 – Patient Demographics

Patient Study ID: _____ Date of interview: ___/___/___
dd/mm/yyyy

Patient Initials: _____ B#: _____ DOB: ___/___/___ M/F
dd/mm/yyyy

Clinic (circle): RAD ONC MED ONC PAL RAD OUTPT INPT OTHER: _____

Primary: _____ Date of diagnosis: ___/___
mm/yyyy

Sites of Metastases: Bone Soft Tissue Brain Lungs Liver Other(s): _____ Date of diagnosis: ___/___
(date of bone mets diag) mm/ yyyy

Skeletal Related Events: Pathological fracture (Current/Past) Spinal Cord Compression (Current/Past)
(if yes, circle past/present) Hyper Ca+ (Current/Past)

TREATMENT:

Chemotherapy:	NO	YES	<input type="checkbox"/> currently	<input type="checkbox"/> <3 months	<input type="checkbox"/> 3-6 months	<input type="checkbox"/> >6 months ago	Type: _____
Surgery:	NO	YES	<input type="checkbox"/> currently	<input type="checkbox"/> <3 months	<input type="checkbox"/> 3-6 months	<input type="checkbox"/> >6 months ago	
Radiation:	NO	YES	<input type="checkbox"/> currently	<input type="checkbox"/> <3 months	<input type="checkbox"/> 3-6 months	<input type="checkbox"/> >6 months ago	
Bisphosphonate:	NO	YES	<input type="checkbox"/> currently	<input type="checkbox"/> <3 months	<input type="checkbox"/> 3-6 months	<input type="checkbox"/> >6 months ago	Type: _____
Hormone:	NO	YES	<input type="checkbox"/> currently	<input type="checkbox"/> <3 months	<input type="checkbox"/> 3-6 months	<input type="checkbox"/> >6 months ago	Type: _____

Is further Chemotherapy planned?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unknown
Is further Surgery planned?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unknown
Is further Radiation planned?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unknown
Is further Bisphosphonate planned?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unknown
Is further Hormone planned?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unknown



Phase III Questionnaire

Phase III- Pre-testing Questions-BM 22 – Interviewer guide

1. I see that you **had** pain in your back during the past week. (2-4)

Is this correct?	<input type="checkbox"/>
Can you tell me about this problem?	
Do you think that this problem is related to bone metastases?	
Did you have difficulty in replying to this question?	
Did you find this question annoying/confusing/upsetting?	
How would you have asked this question?	

I see that you **did not have** pain in your back during the past week. (1)

Is this correct?
Have you ever experienced this problem before last week?
If yes, do you have any idea if that had something to do with bone metastases or its treatment?
If yes, can you tell me about this problem?
Did you have difficulty in replying to this question?
Did you find this question annoying/confusing/upsetting?
How would you have asked this question?

2. I see that you **had** pain in your leg(s) or hip(s) during the past week. (2-4)

Is this correct?	<input type="checkbox"/>
Can you tell me about this problem?	
Do you think that this problem is related to bone metastases?	
Did you have difficulty in replying to this question?	
Did you find this question annoying/confusing/upsetting?	
How would you have asked this question?	

I see that you **did not have** pain in your leg(s) or hip(s) during the past week. (1)

Is this correct?
Have you ever experienced this problem before last week?
If yes, do you have any idea if that had something to do with bone metastases or its treatment?
If yes, can you tell me about this problem?
Did you have difficulty in replying to this question?
Did you find this question annoying/confusing/upsetting?
How would you have asked this question?

9. I see that pain **limited** your ability to rest during the past week. (2-4)

Is this correct?	<input type="checkbox"/>
Can you tell me about this (ability)?	
Do you think that bone metastases or its treatment has affected in any sense your ability to rest?	
Did you have any difficulty in replying to this question?	
Did you find this question annoying/confusing/upsetting?	
How would you have asked this question?	

I see that pain **did not limit** your ability to rest during the past week. (1)

Is this correct?
Can you tell me about this (ability)?
Were you ever limited in your capacity to rest before last week?
If yes, do you have any ideas if that had something to do with your cancer spread to the bone or its treatment?
Did you have difficulty in replying to this question?
Did you find this question annoying/confusing/upsetting?
How would you have asked this question?

10. I see that pain **limited** your ability to stand up during the past week. (2-4)

Is this correct?	<input type="checkbox"/>
Can you tell me about this (ability)?	
Do you think that bone metastases or its treatment has affected in any sense your ability to stand up?	
Did you have any difficulty in replying to this question?	
Did you find this question annoying/confusing/upsetting?	
How would you have asked this question?	

I see that pain **did not limit** your ability to stand up during the past week. (1)

Is this correct?
Can you tell me about this (ability)?
Were you ever limited in your capacity to stand up before last week?
If yes, do you have any ideas if that had something to do with your cancer spread to the bone or its treatment?
Did you have difficulty in replying to this question?
Did you find this question annoying/confusing/upsetting?
How would you have asked this question?



Phase III Questionnaire

21. I see that during the past week you **have been** worried about dependence on others. (2-4)

Is this correct?	<input type="checkbox"/>
Can you tell me about this feeling?	
Do you think that this feeling is related to bone metastases?	
Did you have difficulty in replying to this question?	
Did you find this question annoying/confusing/upsetting?	
How would you have asked this question?	

I see that during the past week you **did not** worry about dependence on others. (1)

Is this correct?	<input type="checkbox"/>
Have you ever experienced this feeling before last week?	
If yes, do you have any idea if that had something to do with bone metastases or its treatment?	
If yes, can you tell me about this feeling?	
Did you have difficulty in replying to this question?	
Did you find this question annoying/confusing/upsetting?	
How would you have asked this question?	

22. I see that during the past week you **have been** worried about your future health. (2-4)

Is this correct?	<input type="checkbox"/>
Can you tell me about this feeling?	
Do you think that this feeling is related to bone metastases?	
Did you have difficulty in replying to this question?	
Did you find this question annoying/confusing/upsetting?	
How would you have asked this question?	

I see that during the past week you **did not** worry about your future health. (1)

Is this correct?	<input type="checkbox"/>
Have you ever experienced this feeling before last week?	
If yes, do you have any idea if that had something to do with bone metastases or its treatment?	
If yes, can you tell me about this feeling?	
Did you have difficulty in replying to this question?	
Did you find this question annoying/confusing/upsetting?	
How would you have asked this question?	

Completion of the interview with: Questions directed EORTC QLQ-C30 and BM23

Were there questions that you found irrelevant?
Can you think of additional issues that are relevant for you but not included in this questionnaire?
Were there questions that you found confusing?
Were there questions that you found upsetting?
Were there questions that you found intrusive?
Do you have other comments about these questions?

Overall module questions if patient is **too tired to answer** for each individual item

Were there question that you found difficult to answer?
Were there questions that you found annoying?
Were there questions that you found confusing?
Were there questions that you found upsetting?
Were there questions that you found intrusive?
Do you have other comments about these questions?



International Collaboration

Translation

- 8 languages:
 - Danish, Dutch, French, German, Italian (mixed), Norwegian, Spanish (mixed) and Swedish
- 2 forward and 2 backward translations
- Pilot testing of translations is appropriate for each country

Ethics

- Performed at each site



International Collaboration

Name	Affiliation	City, Country	Status
Sam Ahmedzai	Royal Hallamshire Hospital	Sheffield, UK	Confirmed
Peter Hoskin	Mount Vernon Hospital	Northwood, Middlesex, UK	Confirmed
Robert Coleman	Weston Park Hospital, Cancer Research Centre University of Sheffield	Sheffield, UK	Confirmed
Yvette van der Linden	Leiden University Medical Centre	Leiden, The Netherlands	Confirmed
Brigette Ma	Prince of Wales Hospital Chinese University of Hong Kong	Shatin, Hong Kong	Confirmed
Mónica Castro	Instituto de Oncología Angel H. Roffo, Universidad de Buenos Aires	Buenos Aires, Argentina	Confirmed
Orhan Sezer	Universitätsklinikum Charité	Berlin, Germany	Confirmed
Jesmin Shafiq	CCORE, Liverpool Hospital	Liverpool, NSW, Australia	Confirmed
Anita Zahlten-Hinguranage	University of Heidelberg	Heidelberg, Austria	Awaiting confirmation
Bhaksar Somani	University of Aberdeen	Aberdeen, UK	Awaiting confirmation
Bernhard Holzner	University Hospital of Innsbruck	Innsbruck, Austria	Awaiting confirmation



Thank you!

We need more countries to join Phase III

If interested, please contact Dr. Edward Chow at

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