

**Development of a bone metastases
module to accompany the EORTC QLQ-
C30 for future clinical trials in patients
with bone metastases**

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Objectives

- To update the results of the interviews with the patients and health care professionals
- To highlight the important quality of life issues from the perspectives of patients and health care professionals
- To compare the results from the 3 Canadian centers and one center from Australia
- To outline the next steps

Background

- Bone metastases → a frequent complication of cancer
- Advances in treatment → increased survival of patients with bone metastases
 - Breast and prostate cancer (2-5 years)
- Successful management essential
 - Reduce skeletal complications
 - Maximize patient quality of life (QOL)



Background

- Treatment options for bone metastases expanded
 - Newer generation of bisphosphonates
 - Increased use of orthopedic surgery
- Great need to monitor
 - Not only benefits
 - Also side effects of these treatments

Background

- Health care professionals (HCPs) and clinical trials traditionally monitor:
 - Tumor control
 - Survival
- Additional patient concern:
 - Impact of disease and treatments on daily life

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

⇒ **Skeletal Related Events (SRE)**

Background

- World Health Organization describes health as “not merely the absence of disease or infirmity but as a stated of physical, mental and social well-being”
- In palliative trials QOL is a major endpoint

Background

- QOL is subjective:
 - Multidimensional reflecting functional status, psychosocial well-being, health perceptions, disease perceptions, disease and treatment related symptoms from the patient's perspective
 - Incorporates expectations, satisfaction, value system and many aspects of a patient's life
 - Important consideration when decision making

Background

- Well-developed bone metastases specific quality of life instruments 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 quality of life items and scales 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 management of bone metastases

Methods

- The actual module development process consists of four phases
 - Phase 1 - Generation of relevant QOL issues
 - Phase 2 - Operationalization of the QOL issue into a set of items
 - Phase 3 - Pre-testing the module questionnaire
 - Phase 4 - Large-scale international field testing

Methods

■ Phase I - Generation of relevant QOL Issues

- 1) Literature searches
- 2) Interviews with health care providers
- 3) Patients' interviews
 - Bisphosphonates and/or systemic therapy
 - Radiation therapy
 - Orthopedic intervention
 - Palliative symptom control



- From May 2005- July 2005, 61 patients and 58 HCPs were interviewed to generate a final list of 61 items

Methods

GENERATION OF RELEVANT QUALITY-OF-LIFE ISSUES PATIENT PERSPECTIVE

- 1) 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”
- 2) Please indicate for **each issue separately** whether it should be included in the final questionnaire or not by circling either yes or no.
- 3) Please indicate the 5 to 10 issues that, in your opinion, affect your quality of life most profoundly, caused you the most trouble, nuisance or distress, and that we should definitely include in the final questionnaire.

Methods

The core instrument (EORTC QLQ-C30)

- 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.

Methods

GENERATION OF RELEVANT QUALITY-OF-LIFE ISSUES HEALTH CARE PROFESSIONAL PERSPECTIVE

- 1) Please indicate for each experience separately, the extent to which you find it relevant for patients with bone metastases on a scale of (1) “not at all” to (4) “very much”

“Relevance” refers to the frequency with which a specific complaint occurs and , when it occurs, the trouble it may cause. Thus, the more frequently a complaint occurs and the more trouble it causes, the more relevant it will be for this patient group.

Methods

GENERATION OF RELEVANT QUALITY-OF-LIFE ISSUES HEALTH CARE PROFESSIONAL PERSPECTIVE

The list of issues is too long to be administered to patients. Therefore, a subset of items must be chosen

- 2) Please indicate for each issue separately whether it should be included in the final questionnaire or not by circling either yes or no.
- 3) Please indicate the 5 to 10 issues that, in your opinion, affect patients quality of life most profoundly, and that we should definitely include in the final questionnaire.

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

iii. 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)

- | | |
|------------|------------|
| a) # _____ | f) # _____ |
| b) # _____ | g) # _____ |
| c) # _____ | h) # _____ |
| d) # _____ | i) # _____ |
| e) # _____ | j) # _____ |

QOL Questionnaire

- 61 items
 - Symptoms (13)
 - Functions (15)
 - Side effects of treatment of bone metastases (3)
 - Psychosocial issues (27)
 - Treatment expectations (2)
 - Financial issue (1)

Data Collection

- Patient Demographics
 - Age, Gender, Clinical setting
- Karnofsky Performance Status (KPS)
- Cancer history
- Treatment history
- Skeletal related events history
 - Hypercalcemia, Pathological fracture, Spinal cord compression, Radiotherapy and Surgery

Canadian Results - Patients

- N= 328 (July 2005- March 2006)
 - Toronto Sunnybrook Regional Cancer Centre = 131 (40%)
 - Princess Margaret Hospital = 130 (40%)
 - Tom Baker Cancer Centre = 67 (20%)
- Gender
 - Female 186 (57 %)
 - Male 142 (43%)
- Age (Years)
 - Median 63
 - Range 30-92

Results - Patients

Clinical Settings	
Medical Oncology Outpatient Clinics	61%
Palliative Radiotherapy Outpatient Clinics	18%
Radiation Oncology Outpatient Clinics	14%
In Patients	5%
Pain Clinics	2%

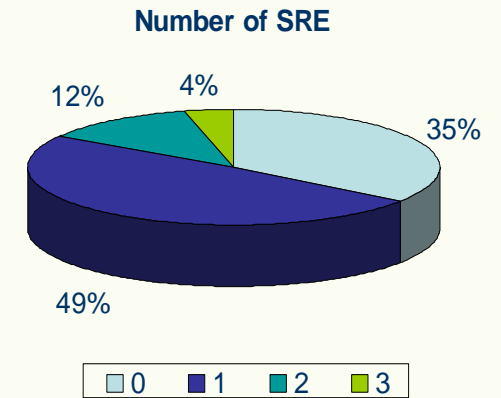
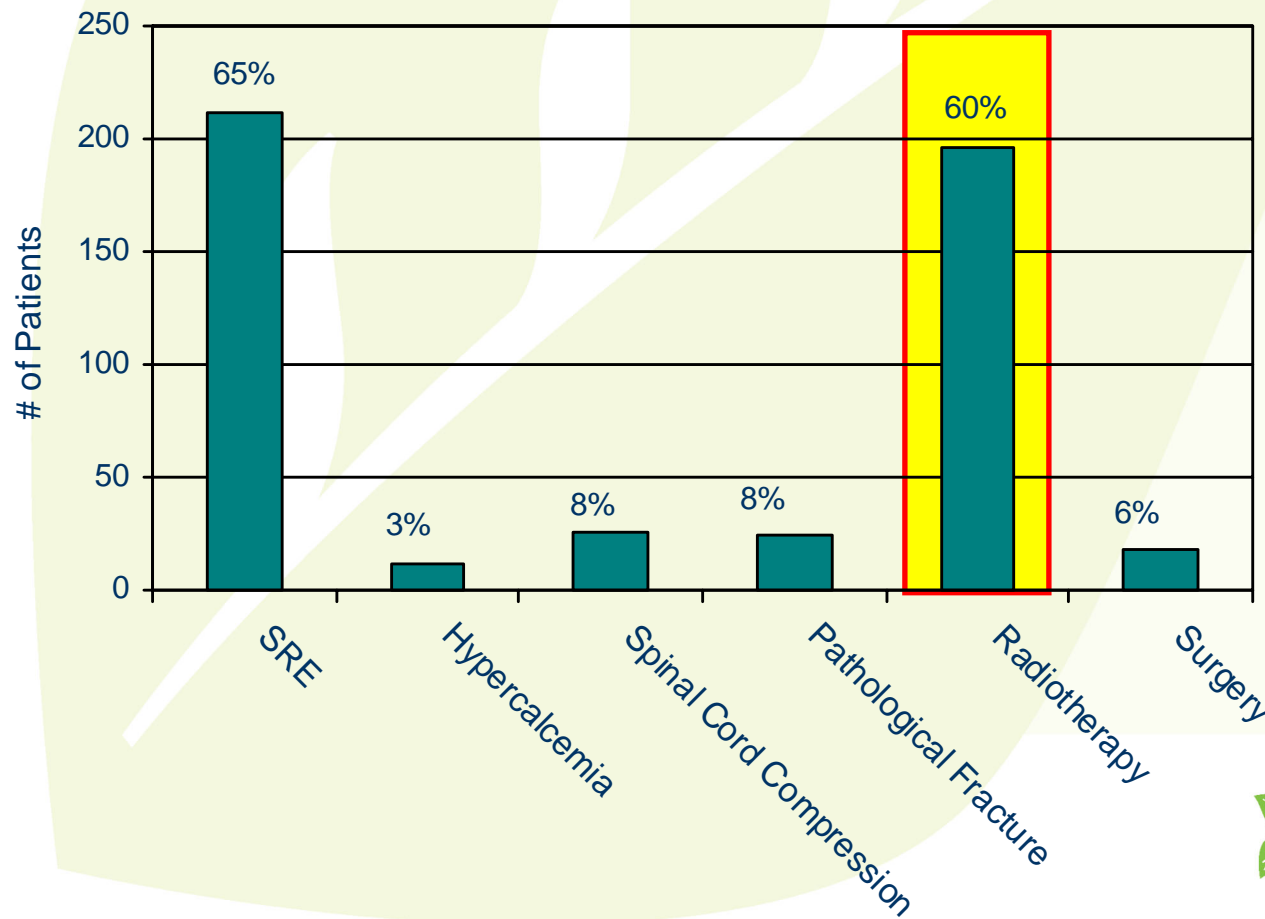
Primary Cancer Sites	
Breast	40%
Prostate	20%
Lung	15%
Others	24%
Unknown	1%

Results - Patients

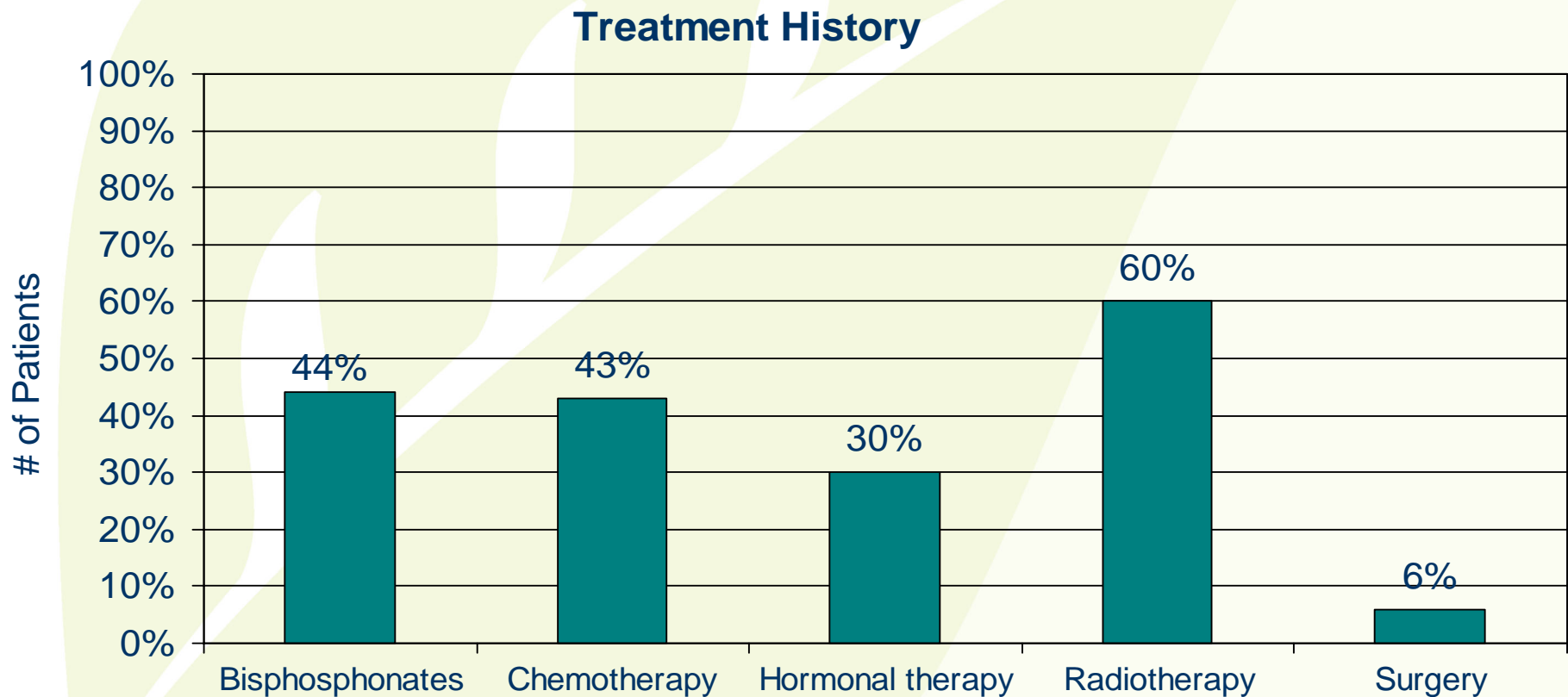
	Mean (SD)
Duration of bone metastases (Yrs)	1.93 (\pm 2.99)
Duration of primary cancer (Yrs)	5.67 (\pm 5.90)
KPS (0-100)	73.1 (\pm 16.4)

Results - Patients

Skeletal Related Events(SRE)



Results - Patients



- 85 % of patients have previous treatment history (bisphosphonates, chemotherapy, hormonal therapy, radiotherapy or surgery)

Patients – Top 10 QOL Issues

Rank	QOL Issue	Freq.	%
1	Worry about becoming dependent on others	124	41
2	Long-term (or chronic pain)	123	41
3	Difficulty carrying out usual daily tasks	121	40
4	Worry about loss of mobility compromising independence	112	37
5	Difficulty in carrying out meaningful activity	102	34
6	Able to perform self-care	96	32
7	Worry about disease progression, deterioration in condition and future complications	95	32
8	Able to perform role functioning	95	32
9	Financial burden due to the illness	79	26
10	Lack of energy	71	24

Canadian Results - HCPs

- **N= 106:**
 - Toronto Sunnybrook Regional Cancer Centre- 44 (41%)
 - Princess Margaret Hospital- 39 (37%)
 - Tom Baker Cancer Centre- 23 (22%)

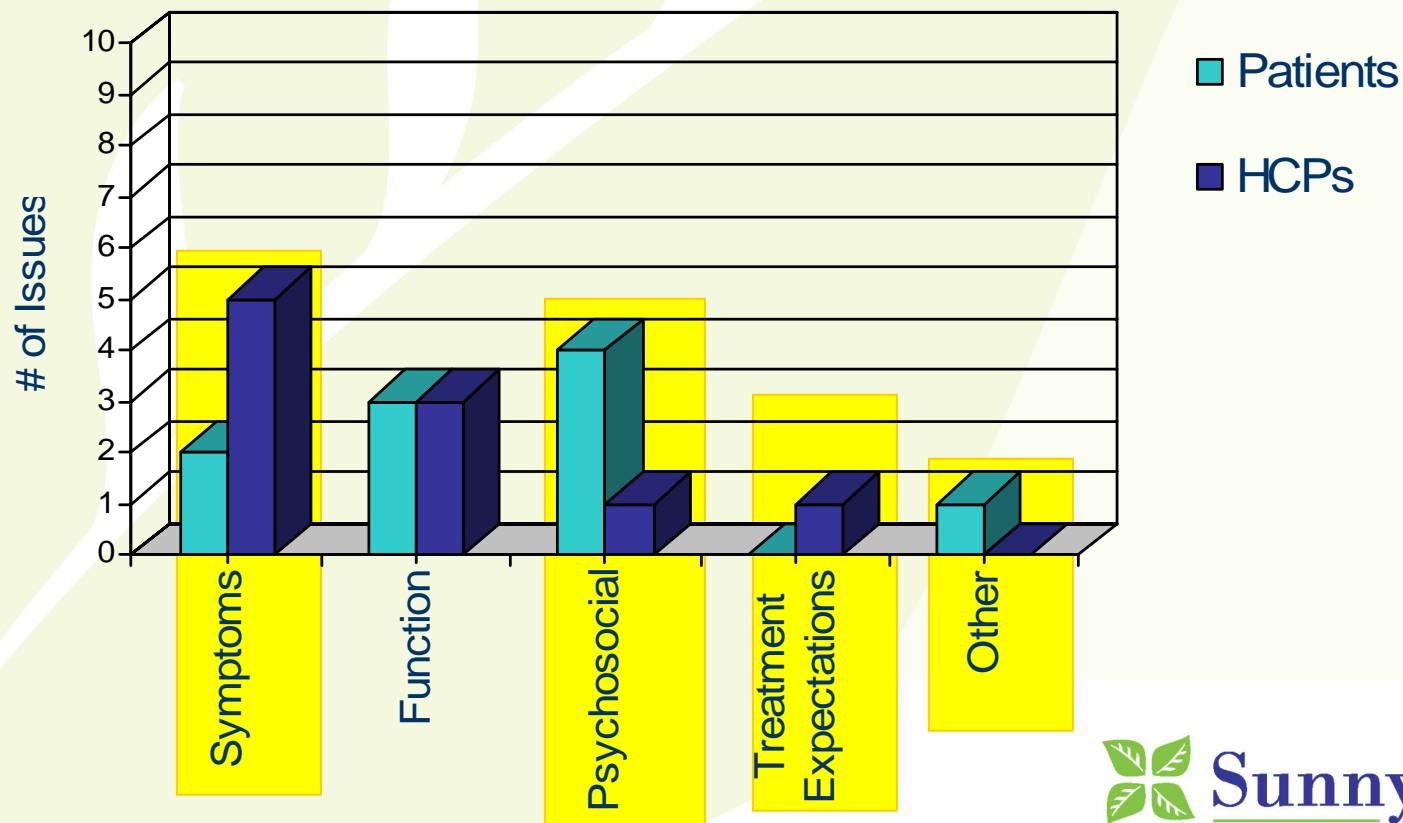
Occupational Distribution of HCPs		
Radiation Oncologists	36	33%
Nurses	26	25%
Medical Oncologists	22	21%
Palliative Care Physicians	11	10%
Social Workers	5	5%
Orthopaedic Surgeons	4	4%
Radiation Therapists	2	2%

HCPs – Top 10 QOL issues

Rank	QOL Issue	Freq	%
1	Short-term (or acute) severe pain	63	64
2	Able to perform self-care	61	62
3	Long-term (or chronic) pain	56	57
4	Uncontrolled, unmanageable pain not relieved by pain killers	56	56
5	Pain at night preventing sleep	52	53
6	Limited movement due to pain	46	47
7	Pain at rest (when sitting)	43	44
8	Difficulty carrying out usual daily tasks	41	41
9	Able to perform role functioning	41	41
10	Hope for sustained pain relief	40	40

Difference in Perspectives

Comparison of issue categories



Difference in Perspectives

Patients Rank	QOL Issues	HCPs Rank
1	Worry about becoming dependent on others	19
2	Long-term (or chronic) pain	1
3	Difficulty carrying out usual daily tasks	8
4	Worry about loss of mobility compromising independence	23
5	Difficulty in carrying out meaningful activity	13
6	Able to perform self-care	2
7	Worry about disease progression deterioration in condition and future complications	15
8	Able to perform role functioning	9
9	Financial burden due to the illness	16
10	Lack of energy	26

Difference in Perspectives

HCPs Rank	QOL Issues	Patients Rank
1	Short-term (or acute) severe pain	25
2	Able to perform self-care	6
3	Long-term (or chronic) pain	2
4	Uncontrolled unmanageable pain not relieved by pain killers	14
5	Pain at night preventing sleep	31
6	Limited movement due to pain	15
7	Pain at rest (when sitting)	38
8	Difficulty carrying out usual daily tasks	3
9	Able to perform role functioning	8
10	Hope for sustained pain relief	12

Comparison of Perspectives

- 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 1 of 10

Summary from Canada

- Difference in patients' and HCPs' perspectives on the most important quality of life issues in bone metastases

- Top 10 QOL issue from patients' perspective

– Psychosocial	4
– Function	3
– Symptoms	2
– Other	1

- Top 10 QOL issues from HCPs perspective

– Symptoms	5
– Function	3
– Psychosocial	1
– Treatment Expectations	1

Comparisons

- Patients from different settings do not show a difference in their choice of top QOL issues
- Severity of symptoms (i.e. extent of experience of issue) not affecting what patients view as top QOL issues
- Top QOL issues from patients' perspectives not influenced by KPS
- HCPs from different occupational backgrounds agree on the top QOL issues

Comparison between Canadian Centres

Issue	P-value	TSRCC		PMH		TBCC	
		n	%	n	%	n	%
Lack of Energy	<0.0001	38	30.4	7	6.1	26	41.9
Able to perform self-care	<0.0001	60	48	27	23.7	9	14.5
Difficulty carrying out daily tasks	0.006	63	50.4	35	30.4	23	37.1
Feeling socially isolated	<0.0001	39	31.2	12	10.5	5	8.1
Increased focus on spiritual issues	0.0028	2	1.6	14	12.2	8	12.9
Hope for sustained pain relief (reduce pain for as long as possible)	0.0003	19	15.2	37	32.2	6	9.7
Hope treatment will reduce pain as much as possible	0.001	21	16.8	33	28.9	4	6.5

Preliminary Results from Australia- Patients

- N= 20
- Gender
 - Female 16 (80%)
 - Male 4 (20%)
- Age (Years)
 - Median 63
 - Range 34-85

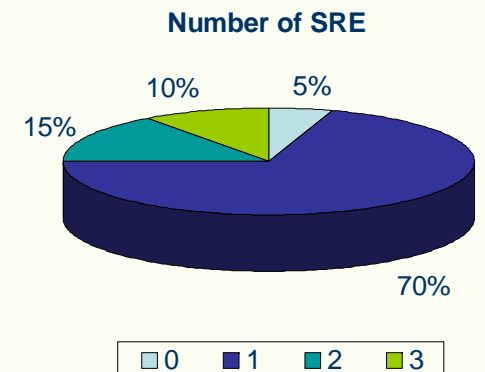
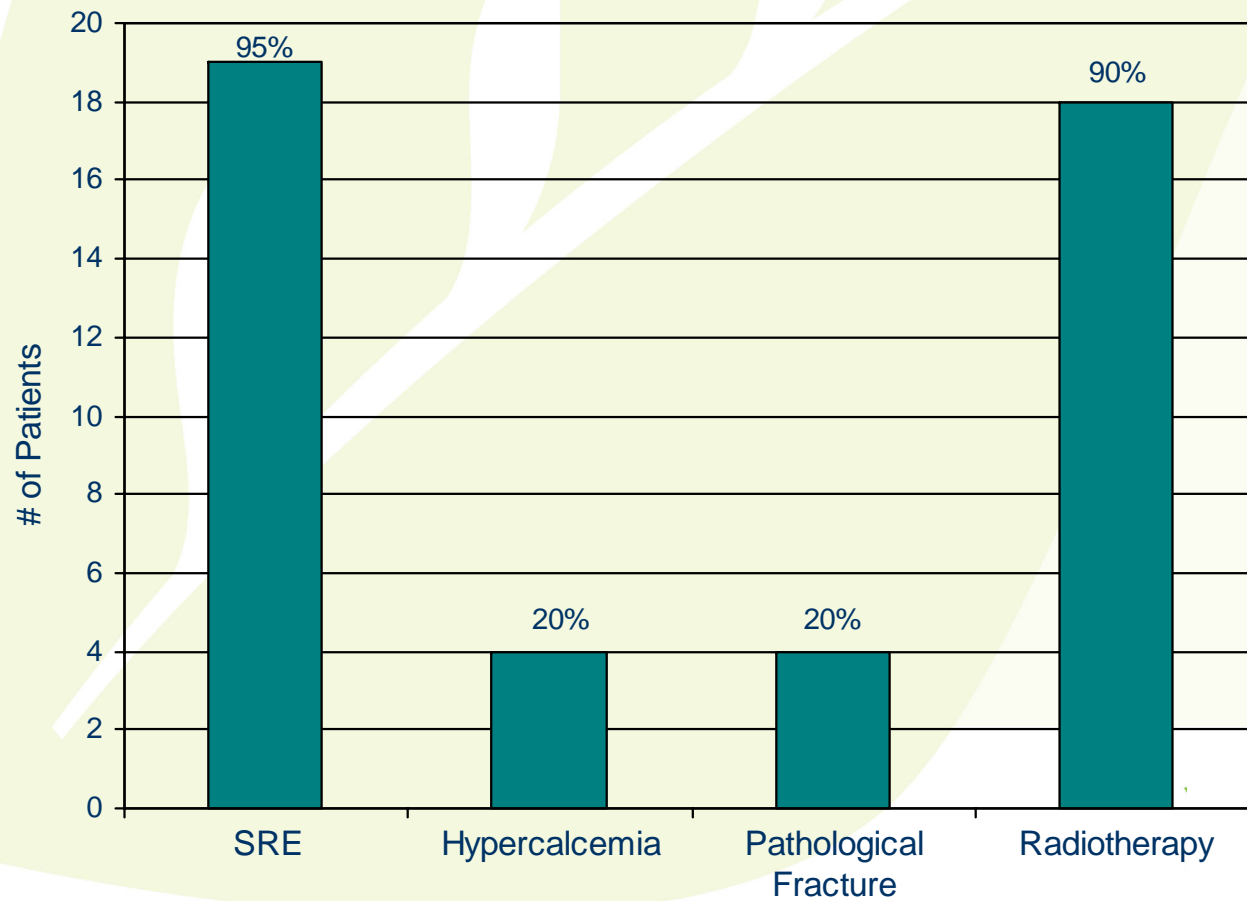
Primary Cancer Sites	
Breast (n=15)	75%
Lung (n=2)	10%
Prostate (n=1)	5%
Others (n=2)	10%

Preliminary Results from Australia- Patients

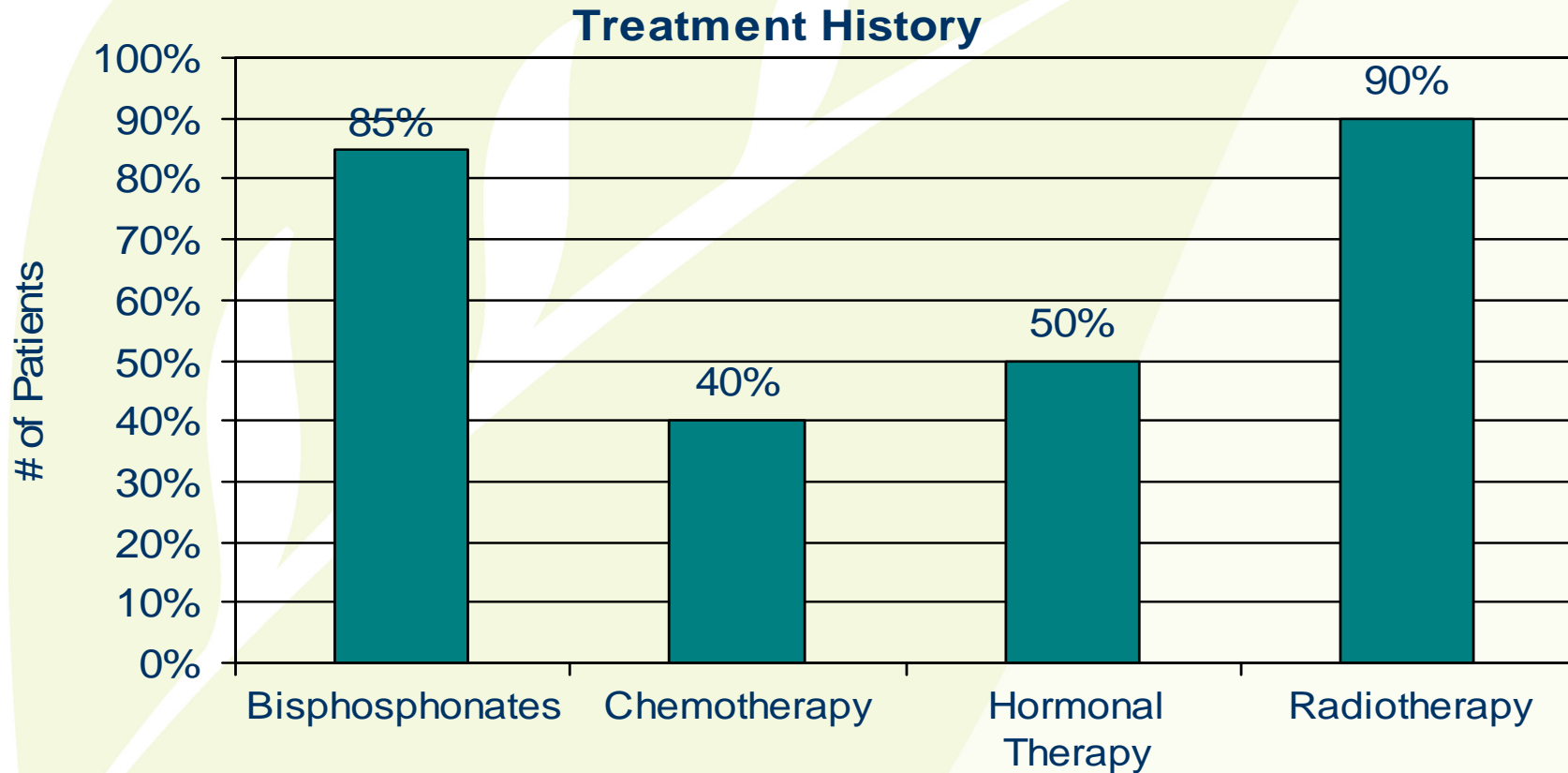
	Mean (SD)
Duration of bone metastases (Yrs)	1.78 ± 1.39
Duration of primary cancer (Yrs)	4.71 ± 3.84

Preliminary Results from Australia- Patients

Skeletal Related Events(SRE)



Preliminary Results from Australia- Patients



- 100 % of patients have previous treatment history (bisphosphonates, chemotherapy, hormonal therapy or radiotherapy)

Patients – Top 10 QOL Issues

Rank	QOL Issue	Freq.	%
1	Long-term (or chronic) pain	12	60
2	Emotional stress of diagnosis of advanced, incurable cancer	11	55
3	Hope treatment will reduce pain as much as possible	9	45
4	Difficulty carrying out usual daily tasks	8	40
5	Worry about becoming dependent on others	8	40
6	Worry about the future	8	40
7	Hope for sustained pain relief	8	40
8	Lack of energy	7	35
9	Worry about becoming bed-bound	7	35
10	Worry about disease progression deterioration in condition and future complications	7	35

Results – Australian HCPs

▪ N= 22

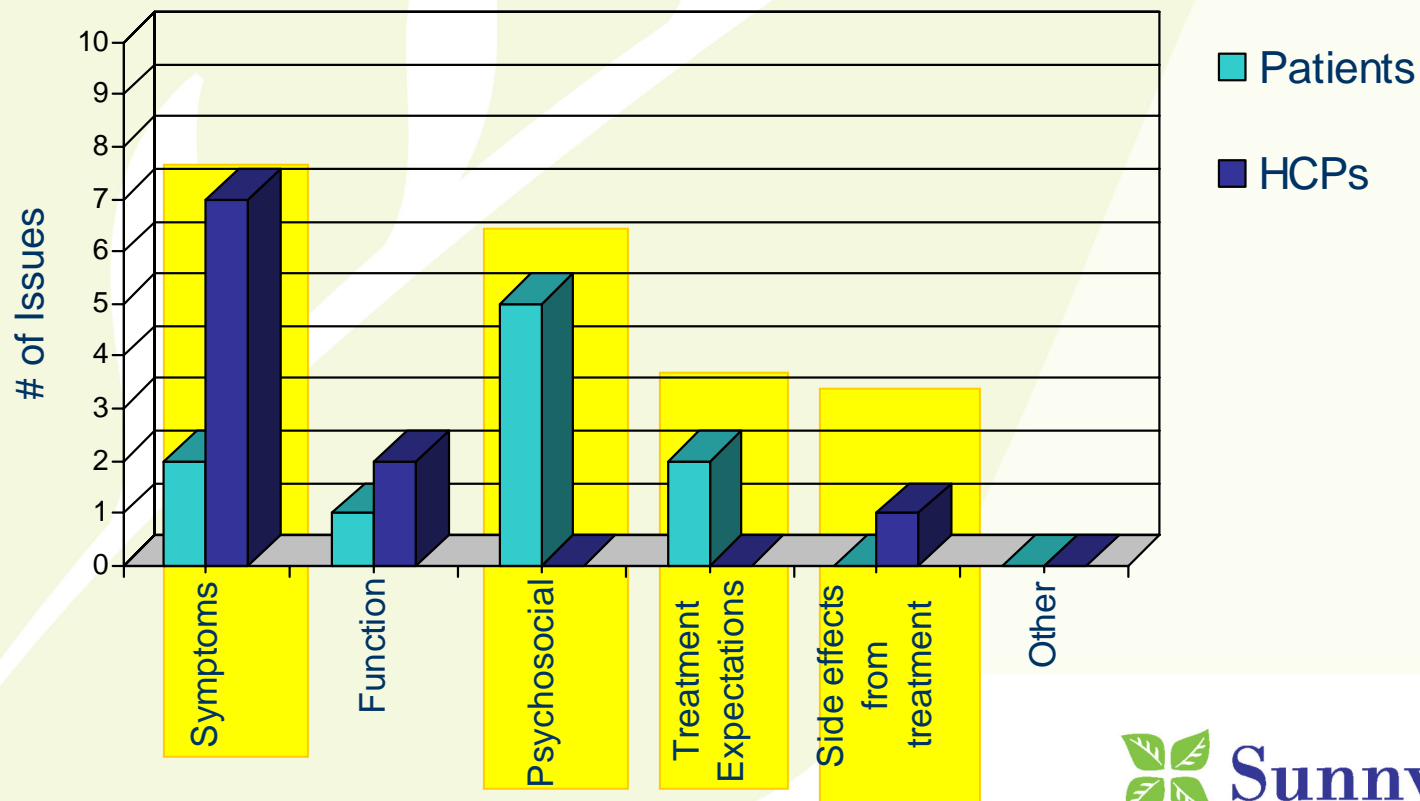
Occupational Distribution of HCPs		
Radiation Oncologists	(n=7)	32%
Medical Oncologists	(n=6)	27%
Palliative Care Physicians	(n=6)	27%
Orthopaedic Surgeons	(n=3)	14%

HCPs – Top 10 QOL issues

Rank	QOL Issue	Freq	%
1	Uncontrolled, unmanageable pain not relieved by pain killers	63	64
2	Able to perform self-care	61	62
3	Pain at rest (when sitting)	56	57
4	Pain with activity (when walking)	56	56
5	Limited movement due to pain	52	53
6	Short-term (or acute) severe pain	46	47
7	Long-term (or chronic) pain	43	44
8	Drowsiness	41	41
9	Pain aggravation with movement or weight bearing	41	41
10	Pain at night preventing sleep	40	40

Difference in Perspectives

Comparison of issue categories



Difference in Perspectives

Patients' Rank	QOL Issue	HCPs Rank
1	Long-term (or chronic) pain	7
2	Emotional stress of diagnosis of advanced incurable cancer	16
3	Hope treatment will reduce pain as much as possible	15
4	Difficulty carrying out usual daily tasks	22
5	Worry about becoming dependent on others	32
6	Worry about the future	58
7	Hope for sustained pain relief	18
8	Lack of energy	45
9	Worry about becoming bed-bound	59
10	Worry about disease progression deterioration in condition and future complications	17

Difference in Perspectives

HCPs Rank	QOL Issue	Patients' Rank
1	Uncontrolled unmanageable pain not relieved by pain killers	14
2	Able to perform self-care	12
3	Pain at rest (when sitting)	52
4	Pain with activity (when walking)	31
5	Limited movement due to pain	18
6	Short-term (or acute) severe pain	11
7	Long-term (or chronic) pain	1
8	Drowsiness	22
9	Pain aggravation with movement or weight bearing	20
10	Pain at night preventing sleep	32

Comparison of Perspectives

- Issues in Common
 - Long term (or chronic) pain
- Issues related to pain
 - HCPs 8 of 10
 - Patients 3 of 10

Summary from Australia

- Difference in patients' and HCPs' perspectives on the most important quality of life issues in bone metastases

- Top 10 QOL issue from patients' perspective

– Psychosocial	5
– Function	1
– Symptoms	2
– Treatment expectations	2

- Top 10 QOL issues from HCPs perspective

– Symptoms	7
– Function	2
– Side effects from treatment	1

Next steps

Phase 1 - Generation of relevant QOL issues

- Literature searches
- Interviews with health care providers
- Patients' interviews
- **Adaptation of the list**

EORTC Decision rules for module adaptation

Parameters to be considered are:

- Mean score
 - response categories ranging from 1 “not at all” (no problems) to 4 “very much” (many problems)
- Prevalence ratio
 - the number of patients who have the particular complaint divided by the total number who have completed the item)
- Range of responses
- Priority ratings by patients
- Priority ratings by HCPs

EORTC Quality of Life Group Recommendations

The following cut-off points may be chosen

- Mean score: < 1.5 versus ≥ 1.5
- Prevalence ratio: $< 30\%$ versus $\geq 30\%$
- Range: < 2 points versus ≥ 2 points
- Priority patients: $< \text{a third}$ versus $\geq \text{a third}$; and
- Priority consultants: $< \text{a third}$ versus $\geq \text{a third}$

Recommendations—Canadian data

Five decision rules for module adaptation used

- Mean score of patients' response in quality of life (1-4):
<2.5 vs. ≥ 2.5
- Prevalence ratio of patients' response in quality of life (1,2 vs. 3,4):
<30% vs. $\geq 30\%$
- Range of patients' response in quality of life (1-4):
<2 vs. ≥ 2
- Priority patients (say 'yes' in final questionnaire):
<1/3 vs. $\geq 1/3$
- Priority HCP (say 'yes' in final questionnaire):
<1/3 vs. $\geq 1/3$

Top 15 items from decision rules

1. Difficulty carrying out meaningful activity
2. Difficulty carrying out usual daily tasks
3. Worry about loss of mobility compromising independence
4. Worry about becoming dependent on others
5. Long-term (or chronic) pain
6. Pain aggravation with movement or weight-bearing
7. Lack of energy
8. Able to perform self-care
9. Able to perform role-functioning
10. Have a clear, alert mind
11. Feel in control, positive, and confident
12. Emotional stress of diagnosis of advanced, incurable cancer
13. Worry about disease progression, deterioration in condition, and future complications
14. Hope for sustained pain relief
15. Hope treatment will reduce pain as much as possible

Top 16-31 items from decision rules

16. Short-term (or acute), severe pain
17. Pain with activity (i.e. when walking)
18. Limited movement due to pain
19. Difficulty planning activities outside the home
20. Difficulty traveling outside the home (i.e. using public transportation, driving, sitting in car)
21. Difficulty climbing stairs
22. Drowsiness
23. Reluctance to use pain medication
24. Anxiety
25. Worry about pain
26. Worry about suffering
27. Worry about the future
28. Difficulty lifting
29. Strengthened relationships with family and friends
30. Hope to live as long as possible
31. Dizziness

Decision rules vs. patients' ranking

- Top 15 issues from decision rules, also found in patients' top 10 issues (9 out of 10)
 - Difficulty carrying out meaningful activity
 - Difficulty carrying out usual daily tasks
 - Worry about loss of mobility compromising independence
 - Worry about becoming dependent on others
 - Long-term (or chronic) pain
 - Lack of energy
 - Able to perform self-care
 - Able to perform role-functioning
 - Worry about disease progression, deterioration in condition, and future complications

Decision rules vs. HCPs ranking

- Top 15 issues from decision rules, also found in HCPs' top 10 issues (5 out of 10)
 - Difficulty carrying out usual daily tasks
 - Long-term (or chronic) pain
 - Able to perform self-care
 - Able to perform role-functioning
 - Hope for sustained pain relief

Next steps

Phase 1 - Generation of relevant QOL issues

- Literature searches
- Interviews with health care providers
- Patients' interviews
- **Adaptation of the list**

Next steps

Adaptation of the list

- Employ decision rules on the list QOL issues
- Issues reviewed for overlap
- Issues in common with EORTC QLQ-C30 reviewed for redundancy and eliminated

Next Steps

Phase 2- Operationalization

- QOL issues will be operationalized into questions with the format and time frame being compatible with QLQ-C30
- ***The EORTC Quality of Life Group Item Bank***
 - Has over 450 validated items translated into 5000 items
 - Issues from phase 1 will be searched for in the Item Bank facilitated by a web-based application
 - Most appropriate items will be chosen to include in module
 - In cases of several items addressing similar issues, may be tested on patients

Next Steps

Phase 3 - Pre-testing

- To identify and solve potential problems, need for additional questions or eliminations and to determine overall degree of eliciting attention and interest
- Administer module and core questionnaire to patients with bone metastases who were not involved in phase 1

Next Steps

Phase 3 - Pre-testing

- **Structured interview** - Interview directed to each item in the module separately
 - 1) The particular experience to which the item refers
 - Is this experience related to your disease or treatment?
 - 2) The wording of the item itself
 - Was the item difficult to respond to?
 - Was the item annoying, confusing or upsetting?
 - How would you have asked this question?



Next Steps

Phase 3 - Pre-testing

- **Structured interview** - Two questions directed to entire questionnaire (core questionnaire + bone metastases module)
 - 1) Were there questions that you found relevant?
 - 2) Can you think of additional issues that are relevant for you but are not included in this questionnaire?
- On the basis of this pre-testing phase, the module may require adaptation

Next Steps

- International investigators have agreed to join and will conduct phase 1-3 concurrently with same methodology
 - Canada
 - Australia
 - United Kingdom
 - Netherlands
- Results will be discussed and analyzed at the end of each phase
- The EORTC Quality of Life Group will actively follow this module development and approve the results and analysis at each phase as a quality control

Next Steps

Phase 4 – Large-scale international field-testing

- The reliability and validity of the module development phase 1-3 will be tested
- International validation project once phase 1-3 are completed in Canada, Australia, UK and Netherlands

Thank you

- If you are interested in participating, please kindly contact

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