



The EORTC Quality of Life Modules for Bone Metastases and Brain Metastases

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Development of the EORTC Quality of Life Module for Bone Metastases: The EORTC QLQ-BM22



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- EORTC Quality of Life Group
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Objectives

- To present the development of the EORTC Bone Metastases Module (EORTC QLQ-BM22)
- To highlight the important quality of life issues from the perspectives of patients and health care professionals



Background

- Bone Metastases- frequent complication of cancer
- 50% of patients diagnosed with cancer will eventually metastasize
- Over 50% of metastases will be to bone
- Most frequent in breast and prostate (60-75%)
- Lung, thyroid, renal (30-40%)



What are Bone Metastases?

- Bone homeostasis is maintained by a balance:
 - Osteoclast- removes bone tissue (resorption)
 - Osteoblast- bone formation
 - Sclerotic
 - Lytic





Morbidities

- Pain (most common – well localized or diffuse)
- Hypercalcemia
- Pathologic fractures – breast, lung, renal, thyroid
- Spinal cord compression



Survival

- 6 months to many years
- Varies depending on tumour type and sites of involvement
- Advances in treatment-increase survival
 - (breast and prostate with bone mets. 2-5 yrs)
- Successful management essential
 - Reduce skeletal related complications
 - Q of L becomes an issue



Treatment Options

- Expanded treatment options:
 - Chemotherapy, Hormone Therapy
 - Newer generation of Bisphosphonates
 - Surgery (more options and minimally invasive)
 - Radiation therapy
- Depends on extent of disease, life expectancy, biology of disease



Background

- Great need to monitor not only benefits & side effects of these treatments, along with disease itself
 - Health care professionals (HCPs) and clinical trials: traditionally monitor tumor control, survival, analgesic use, and skeletal-related events (hypercalcemia, pathological fracture, spinal cord compression, use of surgery and radiation)
 - Additional patient concern: impact of disease and treatments on daily life



Importance of Quality of Life

- QOL is subjective and multidimensional
 - Reflects functional status, psychosocial well-being, health perceptions, disease perceptions, disease and treatment related symptoms from the patient's perspective
 - WHO describes health as “ a statement of complete physical, mental and social well being and not merely the absence of disease infirmity”
 - Important consideration when decision making
 - In palliative trials, QOL is a major endpoint
- A well-developed bone metastases-specific instrument is lacking



Objective

- To develop a set of robust items and scales for assessing QOL 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
- To compare health-care professional (HCP) and patient perspectives on QOL for bone metastases



Specific Aims

- To develop the quality of life items and scales addressing:
 - **Disease** symptoms related to bone metastases
 - **Treatment** side effects, complications and other issues
 - Additional quality of life dimensions that are relevant across diagnosis and treatment modalities in management of bone metastases



Methods

- The module development process consists of 4 phases, following the EORTC Module Development Guidelines

Phase I - Generation of relevant QOL issues

Phase II - Construction of a provisional questionnaire

Phase III - Pre-testing the module questionnaire

Phase IV - Large-scale international field testing



Phase I: Generation of relevant QOL issues

- 1) Literature search (Medline & Psycho info databases, 1966-2005)
- 2) Interviews with 58 health care professionals
- 3) Interviews with 61 patients
 - Bisphosphonates and/or systemic therapy
 - Radiation therapy
 - Orthopedic intervention
 - Palliative symptom control



Phase I: Generation of relevant QOL issues

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

- Items formatted into a questionnaire, and administered to patients and health care professionals



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 Cont'd

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 Cont'd

Generation of Relevant Quality of Life Issues Health Care Professional Perspective

1. 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.



Phase I: HCP Interview

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) # _____ |



Phase I: Patient Interview

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



Phase I: Patient Interview

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



Data Collection

- Basic demographics
 - Age, gender, KPS
- Cancer and treatment history
- Skeletal related events
 - Hypercalcemia, pathologic fracture, spinal cord compression, radiotherapy and surgery



Phase I: Patient Results

Patient Demographics (N=413)	Number (%)
Centre/Country	
PMH/Canada	132 (32.0%)
OCC/Canada	131 (31.7%)
TBCC/Canada	67 (16.2%)
Liverpool/Australia	42 (10.2%)
Charité/Germany	41 (9.9%)
Sex	
Female	239 (57.9%)
Male	174 (42.1%)
Age (years) (n=409)	
Median (range)	64 (30 – 93)
Mean	63



Phase I: Patient Results

Primary Cancer Site	
Breast	160 (38.8%)
Prostate	71 (17.2%)
Multiple myeloma	61 (14.8%)
Lung	57 (13.8%)
Others	22 (5.3%)
Renal	20 (4.9%)
Gastrointestinal	16 (3.4%)
Unknown	5 (1.2%)
Treatment (Current/Past)	
Radiation (n=348)	242 (69.5%)
Chemotherapy (n=329)	231 (70.2%)
Bisphosphonates (n=322)	177 (55.0%)
Hormonal therapy (n=314)	175 (55.7%)
Surgery (n=372)	20 (5.4%)
Skeletal Related Event	
Pathological fracture (n=371)	29 (7.8%)
Spinal cord compression (n=372)	21 (5.6%)
Hypercalcaemia (n=372)	16 (4.3%)



Phase I: HCP Results

Health Care Professional Demographics (N=152)	Number (%)
Centre/Country	
PMH/Canada	47 (30.9%)
OCC/Canada	45 (29.6%)
Liverpool/Australia	26 (17.1%)
TBCC/Canada	23 (15.1%)
Charité/Germany	11 (7.2%)
Speciality	
Radiation Oncologists	46 (30.3%)
Medical Oncologists	40 (26.3%)
Nurses	33 (21.7%)
Palliative Care Physicians	18 (11.8 %)
Surgeons	7 (4.6%)
Social Workers	5 (3.3%)
Others	3 (2.0%)



Phase I: Patient vs HCP Results

Top 10 QOL issues for patients and health care professionals

	Patients	%	HCP	%
1	Long-term (or chronic) <i>pain</i>	41.4	Able to perform self-care	62.1
2	Difficulty carrying out usual daily tasks (grocery shopping work outside the home housework)	39.7	Uncontrolled unmanageable <i>pain</i> not relieved by pain killers	61.0
3	<i>Worry</i> about becoming dependent on others	38.7	Long-term (or chronic) <i>pain</i>	54.2
7	<i>Worry</i> about loss of mobility compromising independence	37.3	Short-term (or acute) severe <i>pain</i>	52.4
5	<i>Worry</i> about disease progression deterioration in condition and future complications	32.9	<i>Pain</i> at night preventing sleep	50.0
6	Able to perform self-care	32.6	Limited movement due to <i>pain</i>	46.9
7	Difficulty in carrying out meaningful activity (including employment)	32.1	<i>Pain</i> at rest (when sitting)	45.1
8	Able to perform role functioning (including domestic and family roles)	32.0	<i>Pain</i> with activity (when walking)	41.0
9	Financial burden due to the illness	24.3	Able to perform role functioning (including domestic and family roles)	39.3
10	Hope treatment will reduce <i>pain</i> as much as possible	23.6	Difficulty carrying out usual daily tasks (grocery shopping work outside the home housework)	35.9



Phase I: Patient vs HCP Results

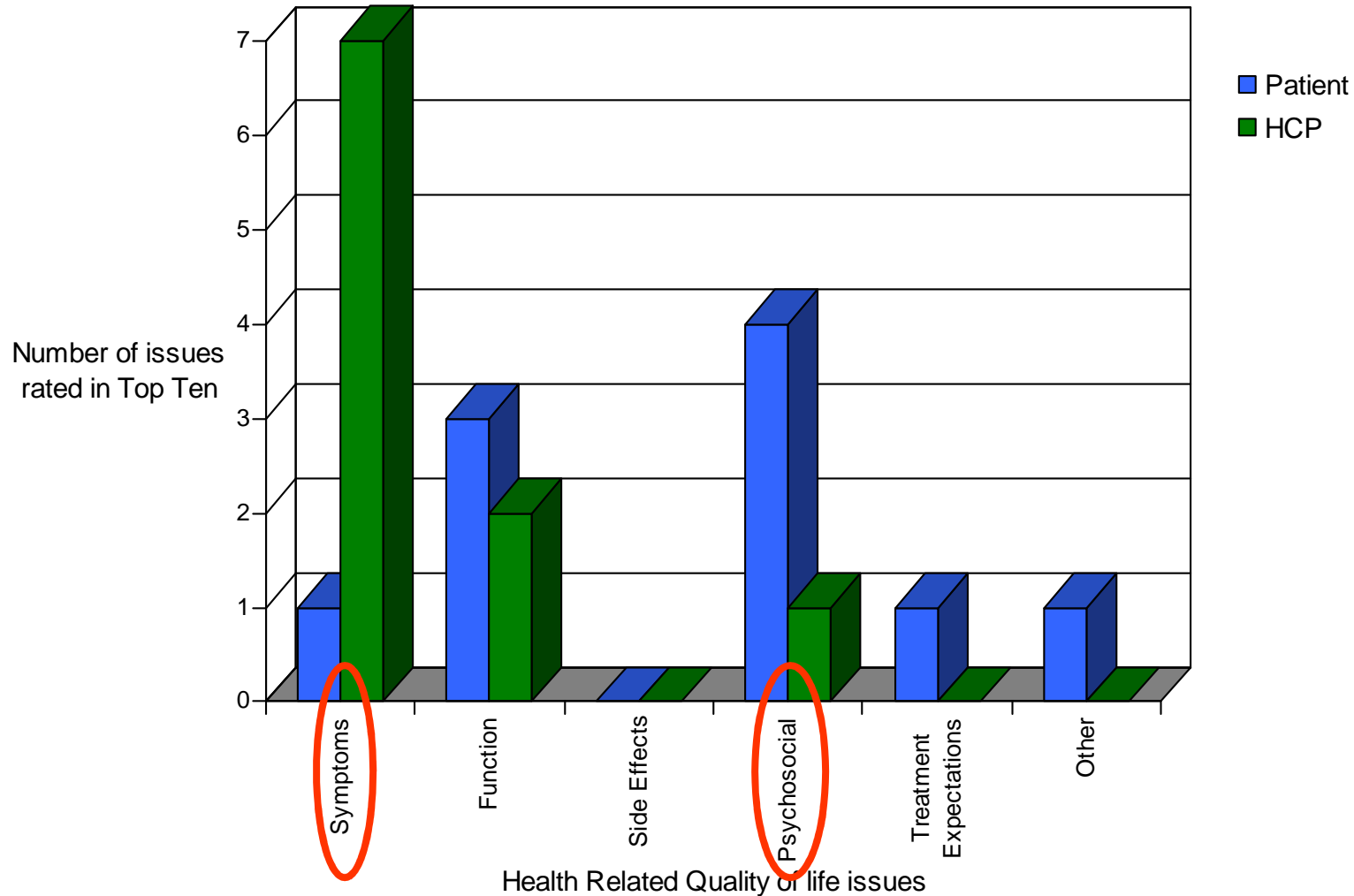
Top 10 QOL issues for patients and health care professionals

	Patients	%	HCP	%
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2	Difficulty carrying out usual daily tasks (grocery shopping work outside the home housework)	39.7	Uncontrolled unmanageable <i>pain</i> not relieved by pain killers	61.0
3	Worry about becoming dependent on others	38.7	Long-term (or chronic) pain	54.2
7	Worry about loss of mobility compromising independence	37.3	Short-term (or acute) severe <i>pain</i>	52.4
5	Worry about disease progression deterioration in condition and future complications	32.9	<i>Pain</i> at night preventing sleep	50.0
6	Able to perform self-care	32.6	Limited movement due to <i>pain</i>	46.9
7	Difficulty in carrying out meaningful activity (including employment)	32.1	<i>Pain</i> at rest (when sitting)	45.1
8	Able to perform role functioning (including domestic and family roles)	32.0	<i>Pain</i> with activity (when walking)	41.0
9	Financial burden due to the illness	24.3	Able to perform role functioning (including domestic and family roles)	39.3
10	Hope treatment will reduce <i>pain</i> as much as possible	23.6	Difficulty carrying out usual daily tasks (grocery shopping, work outside the home)	35.9



Phase I: Patient vs HCP Results

Top 10 QOL issues for patients and HCP, with items grouped in themes:





Canadian Comparison of Perspectives

Issues in Common

- Long term (or chronic) pain
- Difficulty carrying out usual daily tasks
- Able to perform self-care
- Able to perform role-functioning

Issues related to pain

- HCPs 7 of 10
- Patients 1 of 10



Australian Results - Patients

N= 42

Gender

- Female 29 (69%)
- Male 13 (31%)

Age (Years)

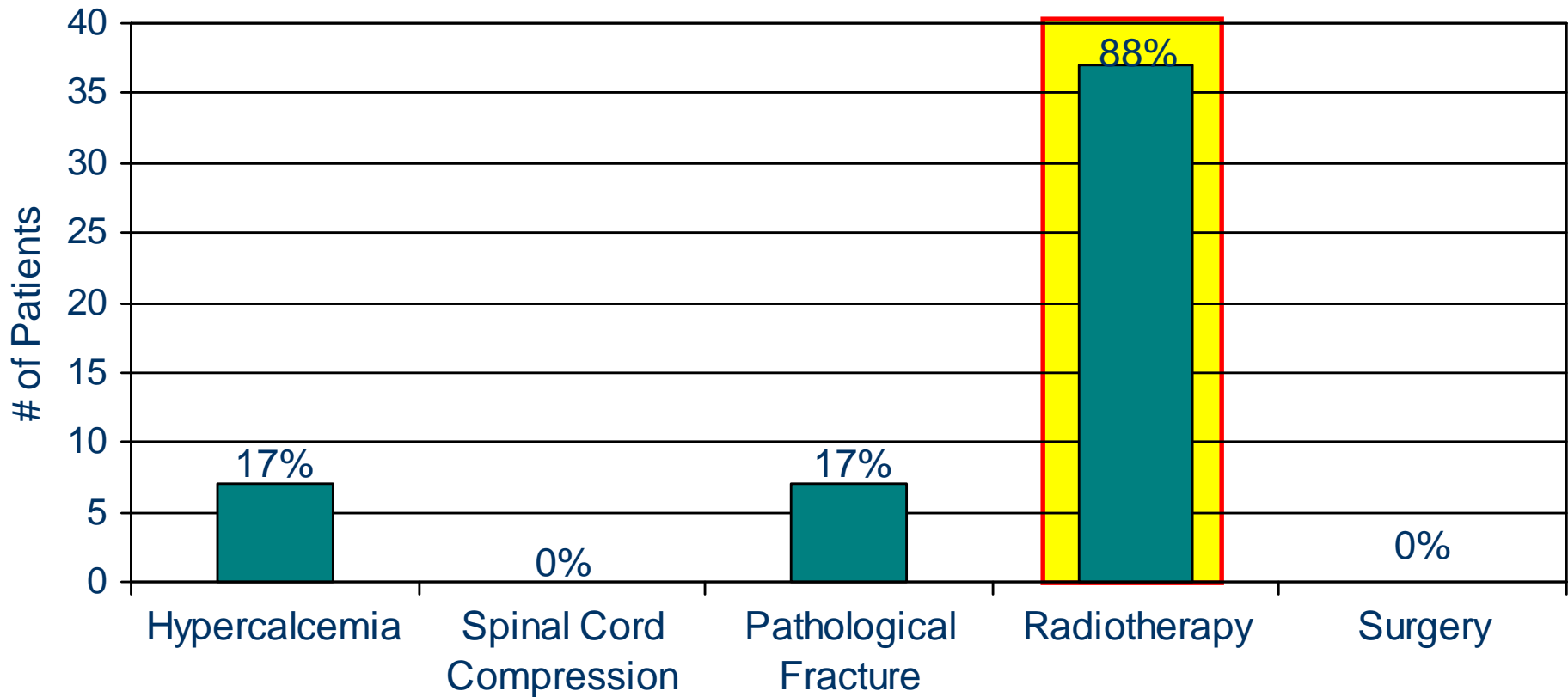
- Median 62
- Range 34-85

Primary Cancer Sites		
Breast	(n=24)	57%
Lung	(n=8)	19%
Prostate	(n=3)	7%
Others	(n=7)	17%



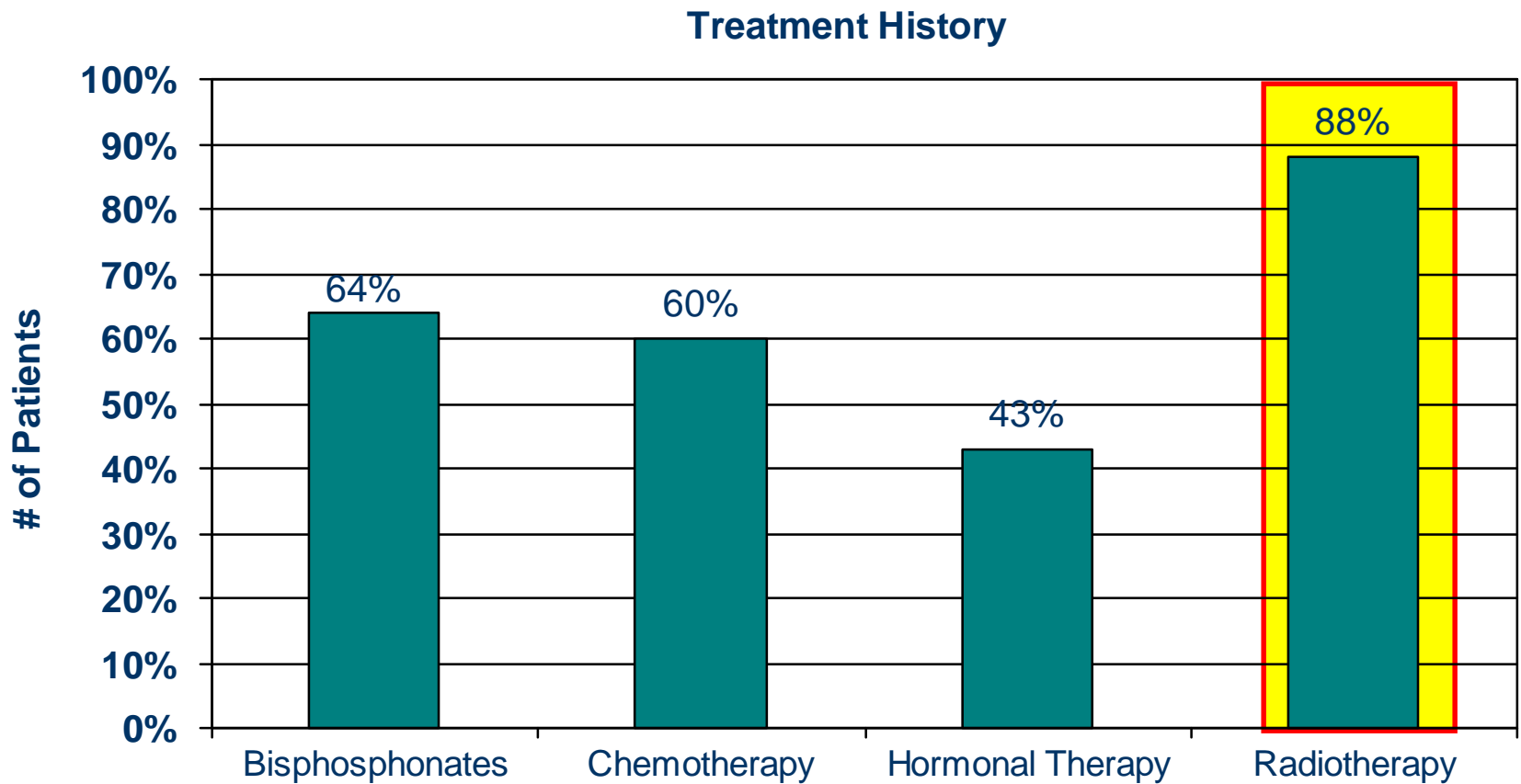
Australian Results - Patients

Skeletal Related Events (SRE)





Australian Results - Patients





Australian Patients –Top 10 QOL Issues

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



Australian Results - HCPs

N= 26

Occupational Distribution of HCPs		
Radiation Oncologists	(n=7)	27%
Medical Oncologists	(n=7)	27%
Palliative Care Physicians	(n=6)	23%
Orthopaedic Surgeons	(n=3)	12%
Nurses	(n=3)	12%



Australian HCPs –Top 10 QOL Issues

Rank	QOL Issue	Freq	%
1	Uncontrolled, unmanageable pain not relieved by pain killers	20	77
2	Able to perform self-care	16	62
3	Limited movement due to pain	14	54
4	Pain at rest	13	50
4	Pain with activity	13	50
6	Long-term pain	12	46
7	Short-term pain	11	42
7	Pain at night preventing sleep	11	42
7	Drowsiness	11	42
10	Able to perform role functioning (including domestic and family roles)		



Australian Difference in Perspectives

Patients' Rank	QOL Issue	HCPs Rank
1	Long-term (or chronic) pain	6
2	Difficulty carrying out usual daily tasks	20
2	Hope treatment will reduce pain as much as possible	15
4	Able to perform self-care	2
4	Emotional stress of diagnosis of advanced incurable cancer	16
4	Worry about loss of mobility compromising independence	18
7	Worry about becoming dependent on others	24
8	Difficulty in carrying out meaningful activity	23
8	Hope for sustained pain relief	19
10	Uncontrolled, unmanageable pain not relieved by pain killers	1
10	Hope to live as long as possible	53
10	Worry about becoming bed-bound	60
10	Worry about disease progression, deterioration in condition, and future complications	17





Australian Difference in Perspectives

HCPs' Rank	QOL Issue	Patients' Rank
1	Uncontrolled unmanageable pain not relieved by pain killers	10
2	Able to perform self-care	4
3	Limited movement due to pain	29
4	Pain at rest (when sitting)	48
4	Pain with activity (when walking)	35
6	Long-term pain	1
7	Short-term pain	18
7	Pain at night preventing sleep	19
7	Drowsiness	31
10	Able to perform role functioning (including domestic and family roles)	15



Australian Comparison of Perspectives

Issues in Common

- Long term (or chronic) pain
- Able to perform self care
- Uncontrolled unmanageable pain not relieved by pain killers

Issues related to pain

- HCPs 7 of 10
- Patients 4 of 13



Results from Germany - Patients

N= 41

Gender

- Female 24 (59%)
- Male 17 (41%)

Age (Years)

- Median 66
- Range 53-84

Primary Cancer Sites	
Multiple Myeloma (n=37)	90%
Breast (n=4)	10%



German Patients –Top 10 QOL Issues

Rank	QOL Issue	Freq.	%
1	Worry about disease progression, deterioration in condition, and future complications	17	50
2	Hope to live as long as possible	16	47
3	Able to perform role functioning	15	44
4	Long-term (or chronic) pain	14	41
4	Hope treatment will reduce pain as much as possible	14	41
6	Worry about loss of mobility compromising independence	13	38
6	Worry about ending days in a hospital or nursing home	13	38
8	Limited movement due to pain	12	35
8	Difficulty traveling outside the home	12	35
8	Difficulty carrying out usual daily tasks	12	35
8	Hope for sustained pain relief	12	35



German Results - HCPs

N= 11

Occupational Distribution of HCPs		
Medical Oncologists	(n=11)	100%



German HCPs – Top 10 QOL Issues

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



German Difference in Perspectives

Patients' Rank	QOL Issue	HCPs' Rank
1	Worry about disease progression deterioration in condition and future complications	41
2	Hope to live as long as possible	56
3	Able to perform role functioning	11
4	Long-term (chronic) pain	4
4	Hope treatment will reduce pain as much as possible	29
6	Worry about loss of mobility compromising independence	16
6	Worry about ending days in a hospital or nursing home	27
8	Limited movement due to pain	4
8	Difficulty travelling outside the home	50
8	Difficulty carrying out usual daily tasks	4
8	Hope for sustained pain relief	28

HEALTH S

when it matters
MOST



German Difference in Perspectives

HCPs' Rank	QOL Issue	Patients' Rank
1	Able to perform self-care	12
2	Uncontrollable, unmanageable pain not relieved by pain killers	13
3	Pain at rest (when sitting)	14
4	Long-term (chronic) pain	4
4	Pain with activity	19
4	Pain at night preventing sleep	23
4	Limited movement due to pain	8
4	Difficulty carrying out meaningful activity	24
4	Difficulty carrying out usual daily tasks	8
4	Feeling socially isolated	30





German Comparison of Perspectives

Issues in Common

- Long-term (chronic) pain
- Limited movement due to pain
- Difficulty carrying out usual daily tasks

Issues related to pain

- HCPs 6 of 10
- Patients 4 of 11



Phase II:

Construction of a provisional questionnaire

EORTC Decision rules for module adaptation

Items were retained if they met at least 3 of the following criteria:

- Mean score for each item (≥ 2.5)
 - response categories ranging from 1 “not at all” (no problems) to 4 “very much” (many problems)
- Prevalence ratio ($\geq 30\%$)
 - the number of patients who have the particular complaint divided by the total number who have completed the item
- Range of responses (≥ 2 points, ie: 1-3 or 2-4)
- Priority ratings by patients and HCPs (say ‘yes’ to inclusion in final questionnaire) ($\geq 1/3$)

Rules are a guideline: we also take patient comments into consideration



Phase II:

Construction of a provisional questionnaire

<i>Symptom Scales</i>
Painful Sites
1) back
2) leg(s) or hip(s)
3) arm(s) or shoulder(s)
4) chest or ribs
5) buttocks
Pain Characteristics
6) constant pain
7) intermittent pain
8) pain not relieved by medications

5 items localizing pain
3 items characterizing pain

7 items of pain triggers

7 psychosocial items

<i>Functional Scales</i>
Functional Interference
9) pain while sitting or lying down
10) pain when trying to stand up
11) pain while walking
12) pain with activities such as bending or climbing stairs
13) pain with strenuous activity
14) pain interfered with your sleeping
15) modify your daily activities
Psychosocial Aspects
16) felt isolated from those close to you
17) worried about loss of mobility
18) worried about becoming dependent on others
19) worried about your health in the future
20) been thinking about your illness
21) felt hopeful your pain will get better
22) felt positive about your health

- After quantitative analysis, 39 issues were deleted.
- Items were constructed for the 22 retained issues



Phase III: Pre-testing the questionnaire

Goal: to identify problems with wording or clarity of items, and the need to add or delete items

- Patients were asked to complete the bone metastases module (**QLQ-BM22**) with the EORTC core QOL questionnaire (**QLQ-C30**)
- Structured interview:
 - Any items that were annoying, confusing, upsetting, intrusive?
 - Any questions that were irrelevant?
 - Any additional issues not included in the module?



Phase III: Results

Country	
Canada	35 (21%)
Greece	29 (17%)
The Netherlands	22 (13%)
China (Hong Kong)	20 (12%)
Germany	20 (12%)
Australia	16 (9%)
Argentina	14 (8%)
Spain	10 (6%)
The United Kingdom	4 (2%)
Gender (n=170)	
Female	87 (51%)
Male	83 (49%)

■ 170 patients
from 9 countries



Phase III: Results

Age in years	
Median (Range)	60 (29-92)
Primary Cancer Site	
Breast	52 (31%)
Multiple Myeloma	33 (19%)
Lung	22 (13%)
Prostate	20 (12%)
Colorectal	19 (11%)
Others	16 (9%)
Renal Cell	8 (5%)
Time from Bone Metastases Diagnosis to Interview (years)	
Median (Range)	1 (0-21)



Phase III: Results

- Changes made to final questionnaire based on analysis of results and patient comments:
 - “Have you had pain while lying down or sitting?” was split into 2 questions at the request of patients in several countries
 - “Have you been thinking about your illness” was deleted, as it was felt to be self-evident, upsetting, and depressing



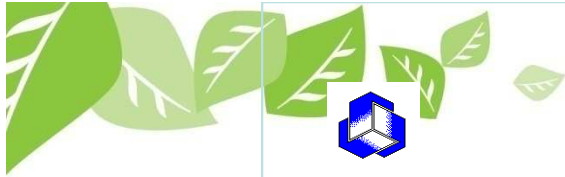
EORTC QLQ – BM22

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 <u>past week</u> have you had <u>pain</u> in any of the following parts of your body?	Not at All	A Little	Quite a Bit	Very Much
1. in your back?	1	2	3	4
2. in your leg(s) or hip(s)?	1	2	3	4
3. in your arm(s) or shoulder(s)?	1	2	3	4
4. in your chest or rib(s)?	1	2	3	4
5. in your buttock(s)?	1	2	3	4
During the <u>past week</u>:				
6. Have you had constant pain?	1	2	3	4
7. Have you had intermittent pain?	1	2	3	4
8. Have you had pain not relieved by pain medications?	1	2	3	4
9. Have you had pain while lying down?	1	2	3	4
10. Have you had pain while sitting?	1	2	3	4
11. Have you had pain when trying to stand up?	1	2	3	4
12. Have you had pain while walking?	1	2	3	4



13. Have you had pain with activities such as bending or climbing stairs?	1	2	3	4
14. Have you had pain with strenuous activity (e.g. exercise, lifting)?	1	2	3	4
15. Has pain interfered with your sleeping at night?	1	2	3	4
16. Have you had to modify your daily activities because of your illness?	1	2	3	4
17. Have you felt isolated from those close to you (e.g. family, friends)?	1	2	3	4
18. Have you worried about loss of mobility because of your illness?	1	2	3	4
19. Have you worried about becoming dependent on others because of your illness?	1	2	3	4
20. Have you worried about your health in the future?	1	2	3	4
21. Have you felt hopeful your pain will get better?	1	2	3	4
22. Have you felt positive about your health?	1	2	3	4



Final EORTC QLQ-BM22 Questionnaire

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.

5 items: Pain
Localization

During the <u>past week</u> have you had <u>pain</u> in any of the following parts of your body?		Not at All	A Little	Quite a Bit	Very Much
1.	in your back?	1	2	3	4
2.	in your leg(s) or hip(s)?	1	2	3	4
3.	in your arm(s) or shoulder(s)?	1	2	3	4
4.	in your chest or rib(s)?	1	2	3	4
5.	in your buttock(s)?	1	2	3	4
During the past week:					
6.	Have you had constant pain?	1	2	3	4
7.	Have you had intermittent pain?	1	2	3	4
8.	Have you had pain not relieved by pain medications?	1	2	3	4
9.	Have you had pain while lying down?	1	2	3	4
10.	Have you had pain while sitting?	1	2	3	4
11.	Have you had pain when trying to stand up?	1	2	3	4
12.	Have you had pain while walking?	1	2	3	4

3 items: Pain
Characteristics

8 items:
Pain Triggers



13) Have you had pain with activities such as bending or climbing stairs?		1	2	3	4
14) Have you had pain with strenuous activity (e.g. exercise, lifting)?		1	2	3	4
15) Has pain interfered with your sleeping at night?		1	2	3	4
16) Have you had to modify your daily activities because of your illness?		1	2	3	4
17) Have you felt isolated from those close to you (e.g. family, friends)?		1	2	3	4
18) Have you worried about loss of mobility because of your illness?		1	2	3	4
19) Have you worried about becoming dependent on others because of your illness?		1	2	3	4
20) Have you worried about your health in the future?		1	2	3	4
21) Have you felt hopeful your pain will get better?		1	2	3	4
22) Have you felt positive about your health?		1	2	3	4

6 items:
Psychosocial



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The European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire for patients with Bone Metastases: The EORTC QLQ-BM22

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 Yvette van der Linden^j, Brigette Ma^k, Monica Castro^l, Palmira Foro Arnalot^m,
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Patients' and health care professionals' evaluation of health-related quality of life issues in bone metastases

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Next Steps

- Phase IV Large – scale international field-testing
 - Reliability and validity of the module development phase I-III will be tested



Phase IV:

Large-scale International Field-testing

- Patients are asked to complete the bone metastases module QLQ-BM22 with the QLQ C15-PAL
- Debriefing questionnaire:
 - How long did it take you to complete the questionnaires?
 - Did anyone help you?
 - Any questions which were upsetting, confusing, or difficult to answer?
 - Other comments



Phase IV:

Large-scale International Field-testing

- Patients treated with the following modalities are approached:
 - A) Palliative radiotherapy or radiosurgery
 - B) Receiving a new bisphosphonate within the previous 2 wks
 - C) Receiving a new systemic therapy within the previous 2 wks
 - D) Undergoing orthopedic stabilization
 - E) Undergoing minimally invasive procedures
 - F) Undergoing analgesic adjustments for pain and symptom management
 - G) Stable bone metastases patients (not undergoing new treatment for at least 2 wks)



Phase IV:

Large-scale International Field-testing

Follow-Up Assessment:

- EORTC QLQ-C15-PAL or EORTC QLQ-C30 and QLQ-BM22 completed by telephone or in person (if patient has a clinic visit)
- KPS, current systemic therapy, and current/recent hospitalization will be documented

Timing of Follow-up Assessment:

- **Patient groups A-F:** 1 month after intervention/change in treatment
- **Patient group G (group not undergoing treatment):** 1 week (test-retest group)



Phase IV:

Preliminary Results with QLQ-C15-PAL

- Data from January 2009 - present (PMH and OCC, Toronto, ON; CCI, Edmonton AB; TBCC, Calgary AB; Cypress Greece)
- **N= 223** (106 males, 117 females)
- Primary Cancer Sites:
 - Breast: 85 (38%)
 - Prostate: 62 (28%)
 - Lung: 33 (15%)
 - Others: 43 (19%)
- Age:
 - Median: 61 yrs (28-87 yrs)
- KPS:
 - Median: 80 (40-100)
- Previous SRE(s): 126 (57%)
 - Radiation: 115 (58%)
 - Pathological fracture: 34 (18%)
 - Orthopedic surgery: 25 (13%)
 - Spinal cord compression: 11 (6%)
 - Hypercalcemia: 8 (4%)
- Previous/current systemic therapy: 182 (82%)
 - Chemotherapy: 132 (40%)
 - Hormone therapy: 112 (34%)
 - Bisphosphonate: 83 (46%)



BM22 Patient Groups

Group	Patients receiving/undergoing:	# Patients
A	Radiotherapy/radiosurgery	111 (50%)
B	New bisphosphonate within next 2 weeks	25 (11%)
C	New systemic therapy within next 2 weeks	12 (6%)
D	Orthopedic stabilization	5 (2%)
E	Minimally invasive procedures	1 (1%)
F	Analgesic adjustments in pain and symptom management	18 (8%)
G	Not undergoing any new treatment within next 2 weeks - stable bone metastases	48 (22%)



Baseline BM22 (n=223)

BM22 ITEMS - During the past week	Not at all (%)	A little (%)	Quite a bit (%)	Very much (%)
1. Pain in your back?	32	33	20	15
2. Pain in your leg(s) or hip(s)?	29	23	27	21
3. Pain in your arm(s) or shoulder(s)?	61	24	10	6
4. Pain in your chest or rib(s)?	59	21	12	7
5. Pain in your buttock(s)?	56	26	11	7
6. Have you had constant pain?	38	24	27	12
7. Have you had intermittent pain?	19	44	30	8
8. Have you had pain not relieved by pain medications?	40	33	20	7
9. Have you had pain while lying down?	35	40	16	9
10. Have you had pain while sitting?	28	46	18	8
11. Have you had pain when trying to stand up?	27	30	25	18
12. Have you had pain while walking?	24	33	27	16
13. Have you had pain with activities such as bending or climbing stairs?	21	26	32	21
14. Have you had pain with strenuous activity?	22	23	29	25
15. Has pain interfered with your sleeping at night?	45	24	21	10
16. Have you had to modify your daily activities because of your illness?	18	21	35	26
17. Have you felt isolated from those close to you?	64	17	11	8
18. Have you worried about loss of mobility because of your illness?	33	28	20	19
19. Have you worried about becoming dependent on others?	32	27	20	22
20. Have you worried about your health in the future?	17	26	31	26
21. Have you felt hopeful your pain will get better?	9	19	39	33
22. Have you felt positive about your health?	13	29	34	25



Follow-up BM22 (n=171)

BM22 ITEMS - During the past week	Not at all (%)	A little (%)	Quite a bit (%)	Very much (%)
1. Pain in your back?	44	32	21	4
2. Pain in your leg(s) or hip(s)?	42	29	21	8
3. Pain in your arm(s) or shoulder(s)?	71	18	8	4
4. Pain in your chest or rib(s)?	74	18	8	1
5. Pain in your buttock(s)?	74	15	7	4
6. Have you had constant pain?	58	22	15	5
7. Have you had intermittent pain?	30	46	21	3
8. Have you had pain not relieved by pain medications?	53	36	9	2
9. Have you had pain while lying down?	57	28	12	3
10. Have you had pain while sitting?	40	44	14	2
11. Have you had pain when trying to stand up?	41	28	23	9
12. Have you had pain while walking?	40	31	22	8
13. Have you had pain with activities such as bending or climbing stairs?	34	29	29	8
14. Have you had pain with strenuous activity?	36	25	24	14
15. Has pain interfered with your sleeping at night?	60	25	12	2
16. Have you had to modify your daily activities because of your illness?	32	23	30	15
17. Have you felt isolated from those close to you?	72	14	12	1
18. Have you worried about loss of mobility because of your illness?	47	25	20	8
19. Have you worried about becoming dependent on others?	44	29	19	8
20. Have you worried about your health in the future?	28	35	24	14
21. Have you felt hopeful your pain will get better?	11	27	36	27
22. Have you felt positive about your health?	15	24	38	23



Phase IV: Preliminary Results with QLQ-C15-PAL

- Overall Symptom severity appears to have improved at 1 month

	Not at all	A little	Quite a bit	Very Much
Baseline	33%	28%	23%	15%
FU	46%	27%	19%	7%

- 5 (2.2%) patients passed away before 1 month FU
- 6 (2.7%) patients withdrew from study
- 27 (12%) patients could not be contacted



Phase IV: Preliminary Results with QLQ-C15-PAL

- Questionnaires took between 2 – 30 minutes to complete (9 minutes on average)
- 41/223 (18%) patients needed assistance to complete BM22
- Patients found some items upsetting:
 - Q19 (“Worried about becoming dependent?”) (4 patients)
 - Q20 (“Worried about health in the future?”) (4 patients)
- Vast majority of the patients did not find any questions difficult or confusing to answer



Phase IV:

Large-scale International Field-testing

Goal: to test the reliability, validity, and cross-cultural applicability of the module

- Currently ongoing
- Participating countries: Canada (4 centres), USA, Spain, Greece, Japan, Hong Kong, Egypt, Turkey, Australia
- Other countries have been invited and expressed interest: UK, Germany, Norway, Italy, China



Next Steps

- Begun accrual for Phase IV International Large-scale field testing using QLQ-C30 questionnaire (as of March 15th, 2010)
- Translation of BM22 Module ongoing
 - Arabic – translation is finished and waiting to be approved
 - Turkish – translation is finished and currently being pilot tested before it is validated
 - Hindi – currently being translated
 - Portuguese – underway
- Analysis of data for Phase IV from all participating centres





Validation of the EORTC Brain Cancer Module (QLQ-BN20) in Brain Metastases Patients



Background

- 20-40% of cancer patients will develop brain metastases during their illness
- Most common treatment is whole brain radiotherapy (WBRT): median survival 3-6 months
- Goals of WBRT:
 - Improve neurological symptoms
 - Allow tapering of steroids
 - Possibly improve survival
 - ? Maintain/Improve Quality of Life (QOL)



Background

- Because of the short survival of brain metastases patients, consideration of **QOL** is very important
- However, there is no standard, validated QOL instrument for use in this patient population



QOL Instruments used in Brain Metastases Clinical Trials

QOL Instrument	Frequency (# of studies)
Spitzer Quality of Life Index (SQLI)	4
Study-designed QOL assessment	2
Edmonton Symptom Assessment Scale (ESAS)	1
EORTC QLQ C30 (alone)	1
With Brain Cancer Module (BN20)	4
With Lung Cancer Module (LC13)	1
Functional Assessment of Cancer Therapy – General scale (FACT-G) (alone)	1
With Brain Subscale (FACT-Br)	5
Profile of Mood States- Short Form (POMS-SF)	1

Literature Search from 1950-2010



QOL Instruments used in Brain Metastases Clinical Trials

QOL Instrument	# of Questions
Spitzer Quality of Life Index (SQLI)	5
Edmonton Symptom Assessment Scale (ESAS)	9
EORTC QLQ C30 (alone)	30
With Brain Cancer Module (BN20)	$30 + 20 = 50$
With Lung Cancer Module (LC13)	$30 + 13 = 43$
Functional Assessment of Cancer Therapy – General scale (FACT-G) (alone)	27
With Brain Subscale (FACT-Br)	$27 + 23 = 50$
Profile of Mood States- Short Form (POMS-SF)	30



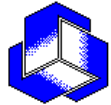
EORTC QLQ-BN20

- Used with the EORTC QLQ-C30
- QOL assessment tool validated in patients with primary brain tumors
- Has not been **validated** in brain metastases pts



Validation of the **BN20 + C15-PAL**

- There is a need to **validate** an instrument in patients with brain metastases before application as QOL tool
- We chose to validate the EORTC QLQ-BN20
- EORTC QLQ-C30 + EORTC QLQ-BN20 = 50 items
- However,
 - The C30 has been shortened to produce the EORTC **QLQ-C15-PAL**
 - 15 questions validated among 41 patients and 66 health care professionals in 6 countries



EORTC QLQ-C15-PAL (Version 1)

We are interested in some things about you and your health.

Please answer all of the questions yourself by circling the number that best applies to you.

There are no "right" or "wrong" answers. The information that you provide will remain strictly confidential.

	Not at All	A Little	Quite a Bit	Very Much
1. Do you have any trouble taking a <u>short</u> walk outside of the house?	1	2	3	4
2. Do you need to stay in bed or a chair during the day?	1	2	3	4
3. Do you need help with eating, dressing, washing yourself or using the toilet?	1	2	3	4

During the past week:

	Not at All	A Little	Quite a Bit	Very Much
4. Were you short of breath?	1	2	3	4
5. Have you had pain?	1	2	3	4
6. Have you had trouble sleeping?	1	2	3	4
7. Have you felt weak?	1	2	3	4
8. Have you lacked appetite?	1	2	3	4
9. Have you felt nauseated?	1	2	3	4



EORTC QLQ-C15-PAL (Version 1) (*continued*)

During the past week:

	All	Not at Little	A a Bit	Quite Much	Very
10. Have you been constipated?		1	2	3	4
11. Were you tired?		1	2	3	4
12. Did pain interfere with your daily activities?		1	2	3	4
13. Did you feel tense?		1	2	3	4
14. Did you feel depressed?		1	2	3	4

For the following questions please circle the number between 1 and 7 that best applies to you

15. How would you rate your overall quality of life during the past week?

1 2 3 4 5 6 7

Very poor

Excellent



BN20+2

- However, 2 cognitive items were removed from the C30 when creating the C15-PAL:

During the past week:

	Not at All	A Little	Quite a Bit	Very Much
20. Have you had difficulty in concentrating on things, like reading a newspaper or watching television?	1	2	3	4
25. Have you had difficulty remembering things?	1	2	3	4

- These were added to the BN20, making it **BN20+2**
- Therefore, a total of **37** items (vs. 50 items) assess QOL in patients with brain metastases in future trials



EORTC QLQ–BN20 + 2 Cognitive Items



Patients sometimes report that they have the following symptoms. Please indicate the extent to which you have experienced these symptoms or problems during the past week.

During the past week:	Not at all	A little	Quite a bit	Very much
1. Did you feel uncertain about the future?	1	2	3	4
2. Did you feel you had setbacks in your condition?	1	2	3	4
3. Were you concerned about disruption of family life?	1	2	3	4
4. Did you have headaches?	1	2	3	4
5. Did your outlook on the future worsen?	1	2	3	4
6. Did you have double vision?	1	2	3	4
7. Was your vision blurred?	1	2	3	4
8. Did you have difficulty reading because of your vision?	1	2	3	4
9. Did you have seizures?	1	2	3	4
10. Did you have weakness on one side of your body?	1	2	3	4
11. Did you have trouble finding the right words to express yourself?	1	2	3	4
12. Did you have difficulty speaking?	1	2	3	4



EORTC QLQ–BN20 + 2 Cognitive Items *(continued)*

Patients sometimes report that they have the following symptoms. Please indicate the extent to which you have experienced these symptoms or problems during the past week.

During the past week:	Not at all	A little	Quite a bit	Very much
13. Did you have trouble communicating your thoughts?	1	2	3	4
14. Have you had difficulty in concentrating on things, like reading a newspaper or watching television?	1	2	3	4
15. Have you had difficulty remembering things?	1	2	3	4
16. Did you feel drowsy during the daytime?	1	2	3	4
17. Did you have trouble with your coordination?	1	2	3	4
18. Did hair loss bother you?	1	2	3	4
19. Did itching of your skin bother you?	1	2	3	4
20. Did you have weakness of both legs?	1	2	3	4
21. Did you feel unsteady on your feet?	1	2	3	4
22. Did you have trouble controlling your bladder?	1	2	3	4



Methods

Methods of questionnaire validation follow the EORTC Module Development Guidelines

- 1) **Content validation** of the EORTC QLQ-BN20+2 and EORTC QLQ-C15-PAL in patients with brain metastases
 - Patient Interviews
 - Health Care Professional Interviews
 - Modification of BN20+2 if necessary prior to field testing

- 2) **Large scale field testing**
 - Assess the reliability, validity, inter- and intra-subject variability, and test-retest reproducibility



Step 1: Content Validation

Patient Interviews

Goal: to identify problems with wording or clarity of items, and the need to add or delete items

- Patients were asked to complete the brain metastases module (**QLQ-BN20+2**) with the EORTC **QLQ-C15-PAL**
- Structured interview:
 - Any items that were annoying, confusing, upsetting, intrusive?
 - Any questions that were irrelevant?
 - Any additional issues not included in module?



Content Validation

Healthcare Professional (HCP) Interviews

Asked to rank each item of the BN20+2

QUALITY OF LIFE ISSUES	i) Please indicate for each item the relevancy of it during patient illness, on a scale of (1) “not at all” to (4) “very much”. RELEVANT				ii) Include this item in the final questionnaire? (circle Yes or No for each item)	
During the <u>past week</u>:	Not at All	A Little	Quite a Bit	Very Much		
1. Did you feel uncertain about the future?	1	2	3	4	Yes	No



Content Validation

Healthcare Professional (HCP) Interviews

- After ranking each item, asked 3 more questions:
- Please indicate which 5 to 10 issues affect the quality of life of patients with brain metastases **most profoundly**, that we should **definitely include** in the final questionnaire
- For each issue that you circled a 1 (“not at all relevant”) or 2 (“a little relevant”) **why** you consider it not or only a little relevant?
- Please let us know if you think any of the questions are **inappropriate, irrelevant, or upsetting** to patients.



Content Validation

After patient and HCP interviews....

- **Modification** of the BN20+2 *if necessary*
 - deletion, addition, and/or modification of items according to EORTC Module Development Guidelines
- Proceed to Step 2: **Large-Scale Field-Testing:**
 - patients treated with the following modalities who were not approached in the first step



Step 1 (Content Validation): Preliminary Results

Patient Results

- Data from Feb 2008 to present (PMH, and OCC, Toronto, ON; CCI, Edmonton AB)
- **N= 37** (10 males, 27 females)
- Primary Cancer Sites:
 - Lung: 21 (57%)
 - Breast: 9 (24%)
 - Others: 7 (19%)
- Age:
 - Mean: 61.9 years
 - Median: 61 years
 - Range: 40-86 years
- KPS:
 - Median: 60 (30-90)
- Treatment:
 - Radiation: 25 (57%)
 - Chemotherapy: 15 (34%)
 - Surgery 4 (9%)



Step 1: Patient Results

BN20+2 Items	Not at all/A little (%)	Quite a bit/Very much (%)	Related to brain metastases?	
			Yes (%)	No (%)
1. Feel uncertain about the future	60	40	86	14
2. Feel had setbacks in condition	50	50	83	17
3. Concerned about disruption in family life	52	48	81	19
4. Headaches	81	19	86	14
5. Outlook on the future worsened	69	31	93	7
6. Double Vision	91	9	55	45
7. Blurred vision	83	17	65	35
8. Difficulty reading because of vision	88	12	63	37
9. Seizures	95	5	51	49
10. Weakness on one side of the body	53	47	86	14
11. Trouble finding the right words to express themselves	90	10	91	9
12. Difficulty speaking	96	4	82	18
13. Trouble communicating thoughts	96	4	82	18
14. Drowsy during the daytime	79	21	91	9
15. Difficulty remembering things	89	11	81	19
16. Feel drowsy during the daytime	75	25	64	36
17. Trouble with coordination	78	22	84	16
18. Bothered by hair loss	85	15	40	60
19. Bothered by itching of skin	84	16	68	32
20. Weakness in both legs	65	34	58	42
21. Feel unsteady on feet	44	56	77	23
22. Trouble controlling bladder	92	8	20	80

“Already lost hair from chemo”

“Not sure if related to brain mets”



Step 1: Patient Results

- **General Comments**
 - Questionnaire was well received by most patients
- **Specific Comments**
 - Q1: Did you feel uncertain about the future?
 - Not related to brain metastases (n=6)
 - Uncertain about health in general (n=3)
 - Q3: Were you concerned about disruption of family life?
 - Not related to brain metastases (n=4)
 - Upsetting (n=6)
 - Q5: Did your outlook on the future worsen?
 - Upsetting (n=7)
 - Related to health and disease in general (n=4)



Step 1 : HCP Results

n=69

CENTRES/COUNTRY	n (%)
PMH/Canada	31 (44.9%)
OCC/Canada	30 (43.5%)
CCI/ Canada	8 (11.6%)
SEX	
Female	37 (60.7%)
Male	15 (24.6%)
SPECIALTY	
Radiation Therapists	26 (37.7%)
Registered Nurses	15 (21.7%)
Radiation Oncologists	15 (21.7%)
Medical Oncologists	6 (8.7%)
Social Workers	4 (5.8%)
Palliative Care Physicians	3 (4.3%)



Step 1 : HCP Results

Specific Comments

- Q1: Did you feel uncertain about the future?
 - Not specific to brain metastases pts (n=4)
 - Overlaps with Q5 (n=2)
- Q22: Did you have trouble controlling your bladder?
 - Uncommon manifestation in brain metastases patients (n=5)



Step 1 : HCP Results

BN20+2 Items	Not at all/A little relevant (%)	Quite a bit/Very much relevant (%)	Include in BN20+2?	
			Yes	No
1. Feel uncertain about the future	25	75	63	37
2. Feel had setbacks in condition	40	60	48	52
3. Concerned about disruption in family life	18	82	74	26
4. Headaches	3	97	90	10
5. Outlook on the future worsened	33	67	36	64
6. Double Vision	13	87	69	31
7. Blurred vision	13	87	72	28
8. Difficulty reading because of vision	15	85	58	42
9. Seizures	3	97	90	10
10. Weakness on one side of the body	4	96	85	15
11. Trouble finding the right words to express themselves	11	89	69	31
12. Difficulty speaking	8	92	82	18
13. Trouble communicating thoughts	6	94	85	15
14. Difficulty concentrating	8	92	88	12
15. Difficulty remembering things	3	97	93	7
16. Feel drowsy during the daytime	20	80	66	34
17. Trouble with coordination	9	91	85	16
18. Bothered by hair loss	34	66	57	43
19. Bothered by itching of skin	50	50	33	67
20. Weakness in both legs	14	86	59	41
21. Feel unsteady on feet	6	94	84	16
22. Trouble controlling bladder	24	76	69	31

→ “Overlaps with ‘Feel uncertain about future’ ”

→ “Not a major issue for most patients, easy to treat”



Step 2: Large-Scale Field Testing

Goal: to test the reliability, validity, and cross-cultural applicability of the module

- To take place following completion/analysis of Step 1
- Upon completion, patients will be asked to complete original brain metastases module (**QLQ-BN20** with EORTC **QLQ-C30**)
- Debriefing questionnaire:
 - How long did it take you to complete the questionnaires?
 - Did anyone help you?
 - Any questions which were upsetting, confusing, or difficult to answer?
 - Other comments



Step 2: Large-Scale Field Testing

Group	BN20
A	Patients undergoing neurosurgery
B	Patients undergoing radiosurgery/gamma knife +/- whole brain radiotherapy
C	Patients undergoing whole brain radiotherapy alone
D	Patients undergoing symptomatic management (e.g. Steroid therapy)



Large-Scale Field Testing

Follow-Up Assessment:

- EORTC QLQ-C30 and QLQ-BN20 completed by telephone or in person (if patient has a clinic visit)
- KPS, current systemic therapy, and current/recent hospitalization will be documented

Timing of Follow-up Assessment:

- **WBRT** and **radiosurgery/gamma knife** patients: 4-6 weeks after initial assessment
- **Symptom control** patients: 2-4 weeks after initial assessment
- **Neurosurgery** patients: 1 week after initial assessment (test-retest), and then again 4 weeks later



Next Steps

- Analysis of data for Step 1 (Content Validation) from all participating centres
 - Current participating countries: Canada, Spain, Greece, Hong Kong, Turkey, Argentina
 - Centres which have expressed interest in joining: Netherlands, Germany, USA
- Modification of BN20 (if necessary)
- Accrual for Step 2 (Large-scale field testing) using both the QLQ-C30 with the QLQ-BN20



Thank-you!

Questions? Comments?

Please contact us if you are interested in participating

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