NATIONAL QUALITY FORUM

Measure Submission and Evaluation Worksheet 5.0

This form contains the information submitted by measure developers/stewards, organized according to NQF's measure evaluation criteria and process. The evaluation criteria, evaluation guidance documents, and a blank online submission form are available on the submitting standards web page.

NQF #: 1822 NQF Project: Cancer Project
(for Endorsement Maintenance Review) Original Endorsement Date: Most Recent Endorsement Date:
BRIEF MEASURE INFORMATION
De.1 Measure Title: External Beam Radiotherapy for Bone Metastases
Co.1.1 Measure Steward: American Society for Radiation Oncology (ASTRO)
De.2 Brief Description of Measure: This measure reports the percentage of patients, regardless of age, with a diagnosis of painful bone metastases and no history of previous radiation who receive external beam radiation therapy (EBRT) with an acceptable fractionation scheme as defined by the guideline.
2a1.1 Numerator Statement: All patients, regardless of age, with painful bone metastases, and no previous radiation to the same anatomic site who receive EBRT with any of the following recommended fractionation schemes: 30Gy/10fxns, 24Gy/6fxns, 20Gy/5fxns, 8Gy/1fxn.
2a1.4 Denominator Statement: All patients with painful bone metastases and no previous radiation to the same anatomic site who receive EBRT
2a1.8 Denominator Exclusions: The medical reasons for denominator exclusions are: 1) Previous radiation treatment to the same anatomic site; 2) Patients with femoral axis cortical involvement greater than 3 cm in length; 3) Patients who have undergone a surgical stabilization procedure; and 4) Patients with spinal cord compression, cauda equina compression or radicular pain The patient reasons for denominator exclusions are: 1) Patient declines treatment; 2) Economic, social or religious reasons; and 3) Other documented patient reasons
1.1 Measure Type: Process 2a1. 25-26 Data Source: Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Paper Records 2a1.33 Level of Analysis: Clinician : Group/Practice, Clinician : Individual, Clinician : Team, Facility, Health Plan 1.2-1.4 Is this measure paired with another measure? No De.3 If included in a composite, please identify the composite measure (*title and NQF number if endorsed*): This measure is not included in a composite

STAFF NOTES (*issues or questions regarding any criteria*)
Comments on Conditions for Consideration: New Process Measure
Is the measure untested? Yes☐ No☒ If untested, explain how it meets criteria for consideration for time-limited endorsement:

1a. Specific national health goal/priority identified by DHHS or NPP addressed by the measure (*check De.5*): Overuse, Palliative Care and End of Life Care, Safety
5. Similar/related endorsed or submitted measures (*check 5.1*): no
Other Criteria:
Importance to Measure and Report
1b.1 Benefits envisioned by measure use: benefit envisioned by use of the measure is reduction in treatment variation (also intended to ensure use of appropriate fractionation schedule and prevent radiation therapy overuse – from 1c.1 "Evidence" section)
1b.2 Performance gap: a nearly 20% performance gap noted
1b.4 Disparities data: no disparities data found; Steering Committee may advise if aware of data

Evidence
1c.14 Summary of Controversy/Contradictory Evidence: none stated, Steering Committee may advise if aware of such evidence

Reliability/Validity Testing
2a1.2 Numerator Time Window, and
2a1.6 Denominator Time Window
--both are once per reporting period. May need to clarify reporting period

Staff Reviewer Name(s): Angela J. Franklin

1. IMPACT, OPPORTUITY, EVIDENCE - IMPORTANCE TO MEASURE AND REPORT

Importance to Measure and Report is a threshold criterion that must be met in order to recommend a measure for endorsement. All three subcriteria must be met to pass this criterion. See guidance on evidence.
Measures must be judged to be important to measure and report in order to be evaluated against the remaining criteria. (evaluation criteria)

1a. High Impact: H☐ M☐ L☐ I ☐
(*The measure directly addresses a specific national health goal/priority identified by DHHS or NPP, or some other high impact aspect of healthcare.*)

De.4 Subject/Topic Areas *(Check all the areas that apply)*: Cancer
De.5 Cross Cutting Areas (*Check all the areas that apply)*: Overuse, Palliative Care and End of Life Care, Safety

1a.1 Demonstrated High Impact Aspect of Healthcare: Affects large numbers, Frequently performed procedure, High resource use, Other

1a.2 If "Other," please describe: Patient centric

1a.3 Summary of Evidence of High Impact *(Provide epidemiologic or resource use data)*:
Cancer Incidence and Epidemiology of Bone Metastases:
It is estimated that nearly 1.4 million new cancer cases were diagnosed in 2011 (1). Bone metastases are a common manifestation of malignancy. The incidence of bone metastases differs among the sites of cancer as follows(2):

Tumor type	Prevalence of bone metastases
Multiple myeloma	70% to 95%
Prostate cancer	65% to 75%
Breast cancer	65% to 75%
Thyroid tumors	60%
Bladder cancer	40%
Lung cancer	30% to 40%
Renal cell carcinoma	20% to 25%

Impact of bone metastases:
Bone metastases can significantly affect the quality of life for patients by causing debilitating effects including pain, spinal cord

compression, hypercalcemia and pathologic fracture(3).
The management of painful bone metastases requires multidisciplinary approaches to care. Evidence shows that radiotherapy (RT) provides successful palliation of painful bone metastases. EBRT can provide significant palliation of painful bone metastases in 50-80% of patients (3).

Resource Use Data:
Although, the role of radiation therapy in palliation of bone metastases has been well established, literature shows widespread variation in the practice patterns for using radiation therapy for palliation. Even though several meta-analysis have shown the efficiency of using lower fractionation schedules, there has been a reluctance to adopt them. A most-recent survey studied international practice variations and found doses commonly prescribed ranging from 3Gy/1 fraction to 60Gy/20 fractions. Single fraction treatment was recommended in only 2-20% of cases presented in United States (4),(5).

Measure Importance:
Bone metastases is a common manifestation of malignancy and the evidence review shows variation in treatment with EBRT and thus a potential gap. This measure will monitor the appropriate use of EBRT for qualified patients and impact the quality of care provided to end of life patients needing palliation.

Patient quality of life:
Pain is an important indicator of quality of life and can be used as one of the indicators to evaluate the quality of supportive and end-of-life care for patients with advanced cancer (6). Alleviation of pain is important to enhance the quality of life for the patient. It is also important to take into consideration the burden of treatment cost, time and convenience to the patient when delivering care. The use of lower fractionation schedules may be preferred for patient convenience without loss of palliative effect. This measure will address concerns of end of life and palliative patients; both groups are identified as priority areas.

1a.4 Citations for Evidence of High Impact cited in 1a.3: (1)American Cancer Society. Cancer Facts & Figures 2011. Atlanta: American Cancer Society; 2011
(2)Coleman RE. Metastatic bone disease: clinical features, pathophysiology and treatment strategies. Cancer Treat Rev. 2001;27:165-176.
(3)Lutz S, Berk L, Chang E, et al. Palliative radiotherapy for bone metastases: An ASTRO evidence-based guideline. Int J Radiat Oncol Biol Phys. 2011;79(4):965-976.
(4)Van der Linden Y, Roos D, Lutz S, et al. International variations in radiotherapy fractionation for bone metastases:geographic borders define practice patterns? Clin Oncol (R Coll Radiol) 2009;21:655-65
(5)Chow E, Zeng L, Salvo N, Dennis K, Tsao M, Lutz S. Update on the systematic review of palliative radiotherapy trials for bone metastases. Clin Oncol (R Coll Radiol). 2011.
(6)Dy SM, Lorenz KA, O´Neill SM, et al. Cancer quality-ASSIST supportive oncology quality indicator set: Feasibility, reliability, and validity testing. Cancer. 2010;116(13):3267-3275.

1b. Opportunity for Improvement: H☐ M☐ L☐ I ☐
(*There is a demonstrated performance gap - variability or overall less than optimal performance*)

1b.1 Briefly explain the benefits (improvements in quality) envisioned by use of this measure:
Treatment Variation:
Although the role of radiation therapy in palliation of bone metastases has been well established, literature shows widespread variation in the practice patterns for using radiation therapy for palliation. Even though several meta-analysis have shown the efficiency of using lower fractionation schedules, there has been a reluctance to adopt them. A most-recent survey studied international practice variations and found doses commonly prescribed ranging from 3Gy/1 fraction to 60Gy/20 fractions. Single fraction treatment was recommended in only 2-20% of cases presented in United States (4),(5).

Numerous prospective randomized and retrospective trials have shown similar pain relief outcomes with shorter EBRT schedules than with longer courses of palliative radiation therapy (RT).

The clinical practice guideline on "Palliative Radiotherapy for Bone Metastases" reviewed evidence from nine studies. The guideline states: "Although various fractionation schemes can provide good rates of palliation, numerous prospective randomized trials have shown that 30Gy in 10 fractions, 24Gy in 6 fractions, 20Gy in 5 fractions, or 8Gy in a single fraction can provide excellent pain control and minimal side effects. The longer course has the advantage of lower incidence of repeat treatment to the same site, and

the single fraction has proved more convenient for patients and care givers."

Patient preferences: Studies assessing patient preferences, demonstrated that patients preferred short course treatments for reasons of convenience and fewer intrinsic costs associated with clinical visits.

This is a process measure intended to close the gap in the demonstrated treatment variation and ensure the use of an appropriate fractionation schedule as well as to prevent the overuse of radiation therapy. The measure also takes into account the effective schedule for relieving pain from bone metastases, patient preferences and time and cost effectiveness.

1b.2 Summary of Data Demonstrating Performance Gap *(Variation or overall less than optimal performance across providers)*: [*For Maintenance – Descriptive statistics for performance results for this measure - distribution of scores for measured entities by quartile/decile, mean, median, SD, min, max, etc.*]
Treatment variation data- Cross-sectional data from a payor represented a sample of 245 physicians from 3 states. The data reported between April 2009 through October 2011 indicates that 1635 cases of patients with bone metastases were treated with EBRT, the range of treatment fractions was between 1-25. 34% of these patients were prescribed more than 10 fractions. The ASTRO guideline recommends fractions between 1-10 fractions for treating bone metastases with EBRT.

The measure was also tested for performance gaps. The information on the testing results for the performance gaps are noted below. The sample included four practices representing various types, locations, specialties, department sizes and patient load. Please see the described information below:

Practice type: One hospital, two academic and one physician-owned private practices specializing in medical oncology, radiation oncology and prostate cancer treatments.

Practice-setting: Two practices were located in a sub-urban setting, one in an urban setting, whereas as one hospital had multiple practice sites in urban, rural and suburban settings.

Number of physicians: The size of the departments ranged from 4- 21 physicians.

Average number of patients: The average number of patient ranged between 250-1000 patients per month.

Data Source: Two sites had EHR and paper records, one site had paper records only and one site had- EHR only.

Sample size: A total of 155 patient charts were abstracted for the measure.

Records review timeframe: Randomly selected patients who received care during the 2010 calendar year.

Period of data collection: August - October 2011

Results: Sample = 155 patients, Exception Rate (1.9%)

Performance Rate without exceptions was 121 of 155 (78.1%)
Performance Rate with exceptions was 121 of 152 (79.6%)

These data demonstrate a sizable performance gap in adherence to the guideline for the use of EBRT to treat bone metastases.

1b.3 Citations for Data on Performance Gap: [*For Maintenance – Description of the data or sample for measure results reported in 1b.2 including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included*]
1.Van der Linden Y, Roos D, Lutz S, et al. International variations in radiotherapy fractionation for bone metastases:geographic borders define practice patterns? Clin Oncol (R Coll Radiol) 2009;21:655-65
2.Lutz S, Berk L, Chang E, et al. Palliative radiotherapy for bone metastases: An ASTRO evidence-based guideline. Int J Radiat Oncol Biol Phys. 2011;79(4):965-976.
3.Chow E, Zeng L, Salvo N, Dennis K, Tsao M, Lutz S. Update on the systematic review of palliative radiotherapy trials for bone metastases. Clin Oncol (R Coll Radiol). 2011.

1b.4 Summary of Data on Disparities by Population Group: [*For Maintenance –Descriptive statistics for performance results for this measure by population group*]
Data on disparities by population group could not be found in the literature.

1b.5 Citations for Data on Disparities Cited in 1b.4: [*For Maintenance – Description of the data or sample for measure results reported in 1b.4 including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included*]
Data on disparities by population group could not be found in the literature.

1c. Evidence (*Measure focus is a health outcome OR meets the criteria for quantity, quality, consistency of the body of evidence.*)
Is the measure focus a health outcome? Yes☐ No☐ If not a health outcome, rate the body of evidence.

Quantity: H☐ M☐ L☐ I☐ Quality: H☐ M☐ L☐ I☐ Consistency: H☐ M☐ L☐ I☐

Quantity	Quality	Consistency	Does the measure pass subcriterion1c?
M-H	M-H	M-H	Yes☐
L	M-H	M	Yes☐ IF additional research unlikely to change conclusion that benefits to patients outweigh harms: otherwise No☐
M-H	L	M-H	Yes☐ IF potential benefits to patients clearly outweigh potential harms: otherwise No☐
L-M-H	L-M-H	L	No ☐

Health outcome – rationale supports relationship to at least one healthcare structure, process, intervention, or service	Does the measure pass subcriterion1c? Yes☐ IF rationale supports relationship

1c.1 Structure-Process-Outcome Relationship *(Briefly state the measure focus, e.g., health outcome, intermediate clinical outcome, process, structure; then identify the appropriate links, e.g., structure-process-health outcome; process- health outcome; intermediate clinical outcome-health outcome)*:
This is a process measure intended to close the gap in the demonstrated treatment variation and ensure the use of an appropriate fractionation schedule as well as prevent the overuse of radiation therapy. The measure also takes into account the effective schedule for relieving pain from bone metastases, patient preferences and the time and cost effectiveness.

1c.2-3 Type of Evidence *(Check all that apply)*:
Clinical Practice Guideline, Systematic review of body of evidence (other than within guideline development)

1c.4 Directness of Evidence to the Specified Measure *(State the central topic, population, and outcomes addressed in the body of evidence and identify any differences from the measure focus and measure target population)*:
The measure is developed from the recommendations by the clinical-practice guideline. This measure is intended to close the gap in the demonstrated treatment variation and ensure the use of an appropriate fractionation schedule. The measure also takes into account the effective schedule for relieving pain from bone metastases, patient preferences and the time and cost effectiveness.

Population: The measure is applicable to all patients, regardless of age with a diagnosis of painful bone metastases who are prescribed EBRT unless there is a documented exclusion as specified.

There were no identified differences in the central topic/ focus and target population between the body of evidence and the measure.

1c.5 Quantity of Studies in the Body of Evidence *(Total number of studies, not articles)*: Nine randomized studies were included in the body of evidence in the guideline. These studies compared single fraction (8Gy/1) with multiple fractionation schemes.

References:
1. Jeremic B, Shibamoto Y, Acimovic L, et al. A randomized trial of three single-dose radiation therapy regimens in the treatment of metastatic bone pain. Int J Radiat Oncol Biol Phys 1998;42:161–167.

2. Bone Pain Trial Working Party. 8 Gy single fraction radiotherapy for the treatment of metastatic skeletal pain: Randomized comparison with a multifraction schedule over 12 months of patient follow-up. Radiother Oncol 1999;52:111–121.
3. Roos D, Turner S, O'Brien P, et al. Randomized trial of 8 Gy in 1 versus 20 Gy in 5 fractions of radiotherapy for neuropathic pain due to bone metastases (Trans-Tasman Radiation Oncology Group, TROG 96.05). Radiother Oncol 2005;75:
54–63.
4. Hartsell W, Konski A, Scott C, et al. Randomized trial of short versus long-course radiotherapy for palliation of painful bone metastases. J Natl Cancer Inst 2005;97:798–804.
5. Kaasa S, Brenne E, Lund J-A, et al. Prospective randomized multicentre trial on single fraction radiotherapy (8Gy/1) versus multiple fractions (3Gy/10) in the treatment of painful bone metastases. Radiother Oncol 2006;79:278–284.
6. Foro A, Fontanals A, Galceran J, et al. Randomized clinical trial with two palliative radiotherapy regimens in painful bone metastases: 30 Gy in 10 fractions compared with 8 Gy in single fraction. Radiother Oncol2008;89:150–155.
7. Sande T, Ruenes R, Lund J, et al. Long-term follow-up of cancer patients receiving radiotherapy for bone metastases: Results from a randomised multicentre trial. Radiother Oncol 2009;91:261–266.
8. Nielsen O, Bentzen S, Sandberg E, et al. Randomized trial of single dose versus fractionated palliative radiotherapy of bone metastases. Radiother Oncol 1998;47:233–240.
9. Steenland E, Leer J, van Houwelingen, et al. The effect of a single fraction compared to multiple fractions on painful bone metastases: A global analysis of the Dutch Bone Metastasis Study. Radiother Oncol 1999;52:101–109.

1c.6 Quality of Body of Evidence (*Summarize the certainty or confidence in the estimates of benefits and harms to patients across studies in the body of evidence resulting from study factors. Please address: a) study design/flaws; b) directness/indirectness of the evidence to this measure (e.g., interventions, comparisons, outcomes assessed, population included in the evidence); and c) imprecision/wide confidence intervals due to few patients or events*): A. Study Design/Flaws
1. Sample size: The sample sizes ranged from 160-171 patients.
2. Randomization Methods: Although randomization was described as a blinded process in two of the nine studies (2, 3), seven studies did not provide a description of whether a blinded process was used (1,4,5,6,8,9).
3. Power Calculation: Power Calculations were done a priori in seven of the nine studies (2,3,4.5,6,8,9) and two studies did not report power calculations (1,7).

Flaws: Four studies reported flaws as noted below:
1. Difficulty isolating the effect of radiation therapy on bone pain when co-interventions were used (8);
2. Lack of valid data on opioid consumption in the medical record and a failure to conduct baseline pain assessments (7);
3. The operational definition of "complete pain response" was less strigent than was used in previous studies, which may have resulted in better outcomes (2);
4. Study results may not be generalizable to patients with bone metastases from "all" primary cancer sites (2,4); and
5.The study was unable to establish dose-response in terms of complete response (9).

B. Directness/indirectness of the evidence to this measure (e.g., interventions, comparisons, outcomes assessed, population included in the evidence)
1. Interventions: All nine studies compared 8Gy single fraction to multiple fraction regimes using EBRT for painful bone metastases (1,2,3,4,5,6,7,8,9).
2. Comparisons: The studies compared the effectiveness of the use of EBRT 8Gy single fraction to multiple fraction regimes for (a) relieving pain (b) the extent of toxicity; (c) the use of analgesics; and (d) re-treatment rates(1,2,3,4,5,6,7,8,9).
3. Outcomes Assessed: The outcomes assessed included study participants self-assessment of pain relief using a quantitative scale (1,2,3,4,5,6,7,8,9).
4. Population Included in the Evidence: The studies used the following inclusion criteria:
a) Confirmed diagnosis of bone metastases due to a pathologically confirmed malignancy;
b)Ability to complete a consent form and independently score a pain scale;
c)Patients who scored a "2" on a scale of "10" on baseline;
d) Life expectancy of at least one month; and
e) Painful skeletal metastases
The studies used the following exclusion criteria:
a) Patients with pathological fractures or impending fractures;
b) Complicated bone metastases, for example spinal cord compression, metastases to more than one site; and
c) History of previous radiation treatment to the same anatomic site.

C. Imprecision and Confidence Intervals:
Only two of the nine studies reported confidence intervals(2,4,8).

a)78% patients with single fraction had overall pain relief at some time during the follow-up compared to 78% with multifraction: difference in absolute proportions = 0% with 95% CI (-6% to 6%). Fifty-seven percent experienced a complete response: 57% single fraction, 58% multifraction; difference in proportions = -1%, 95%CI (-9% to 6%)(2).

b)There were statistically significant differences in treatment to failure (TTF) by index site and by primary cancer for each of the three populations. For all randomized patients, the estimated median (TTF) (95%CI) for patients with spine index sites was 3.5 mo (2.4-6 mo) and with non-spine index sites 2.2 mo (1.4-3.0 mo); the estimated percentage without failure at 1 year (95%CI) was 23% (16-23%) vs 0%, respectively (P= 0.006)(4).

c)The study results demonstrated that there was no statistically significant difference between 8Gy single fraction and 20Gy in 4 daily fractions. At 4 weeks, the difference in pain relief was 6% (CI 7-20%); and at 8 weeks the difference was 13% (CI 3, 28%)(8).

1c.7 Consistency of Results across Studies *(Summarize the consistency of the magnitude and direction of the effect):*
Consistency of Results across Studies: All nine studies documented no statistically significant difference between 8Gy single fraction and multiple fraction regimens using EBRT for pain relief from bone metastases. The studies also showed comparatively higher re-treatment rates for 8Gy/single fraction.

1c.8 Net Benefit *(Provide estimates of effect for benefit/outcome; identify harms addressed and estimates of effect; and net benefit - benefit over harms)*:
A. Estimates of effect for benefits/outcomes are evidenced by relief of bone metastases pain (1,2,3,4,5,6,7); and no significant toxicity/ treatment complications (6,7,9).

B. Estimates of effect for harms are evidenced by:
I) Re treatment Rate: i) 2.5 fold greater risk of irradiation in the single fraction arm (7); ii) 23% single vs. 10%, diff in prop= 13% (8-19%), p<0.001(9); iii) 28% (single), 2% 30Gy/10, p<0.0001 (6); iv) 18% (single) vs. 9% (30Gy); p <.001 (4).
2)Toxicity: 17% (30Gy) vs. 10% (single), difference = 7% (3-12%), p=0.002) (4)

C. Net Benefit: Multiple fraction regimens have shown some dosing variance between studies, but the single fraction arm has been typically given as a dose of 8Gy. The control arms have included 30Gy in 10 fractions, 24 Gy in 6 fractions, 20Gy in 5 fractions and 20Gy in 4 fractions. The endpoints for these studies evaluated pain relief, narcotic relief, quality of life measures, and rates of pathological fractures and re-treatment.

1c.9 Grading of Strength/Quality of the Body of Evidence. Has the body of evidence been graded? Yes

1c.10 If body of evidence graded, identify the entity that graded the evidence including balance of representation and any disclosures regarding bias: ASTRO has graded the evidence using the USPSTF grading system.

1c.11 System Used for Grading the Body of Evidence: USPSTF

1c.12 If other, identify and describe the grading scale with definitions:

1c.13 Grade Assigned to the Body of Evidence: Good: Evidence includes consistent results from well-designed, well-conducted studies in representative populations that directly assess effects on health outcomes.

1c.14 Summary of Controversy/Contradictory Evidence:

1c.15 Citations for Evidence other than Guidelines*(Guidelines addressed below)*:
References:
1. Jeremic B, Shibamoto Y, Acimovic L, et al. A randomized trial of three single-dose radiation therapy regimens in the treatment of metastatic bone pain. Int J Radiat Oncol Biol Phys 1998;42:161–167.

2. Bone Pain Trial Working Party. 8 Gy single fraction radiotherapy for the treatment of metastatic skeletal pain: Randomized comparison with a multifraction schedule over 12 months of patient follow-up. Radiother Oncol 1999;52:111–121.
3. Roos D, Turner S, O'Brien P, et al. Randomized trial of 8 Gy in 1 versus 20 Gy in 5 fractions of radiotherapy for neuropathic pain due to bone metastases (Trans-Tasman Radiation Oncology Group, TROG 96.05). Radiother Oncol 2005;75:
54–63.
4. Hartsell W, Konski A, Scott C, et al. Randomized trial of short versus long-course radiotherapy for palliation of painful bone metastases. J Natl Cancer Inst 2005;97:798–804.
5. Kaasa S, Brenne E, Lund J-A, et al. Prospective randomized multicentre trial on single fraction radiotherapy (8Gy _ 1) versus multiple fractions (3Gy _ 10) in the treatment of painful bone metastases. Radiother Oncol 2006;79:278–284.
6. Foro A, Fontanals A, Galceran J, et al. Randomized clinical trial with two palliative radiotherapy regimens in painful bone metastases: 30 Gy in 10 fractions compared with 8 Gy in single fraction. Radiother Oncol2008;89:150–155.
7. Sande T, Ruenes R, Lund J, et al. Long-term follow-up of cancer patients receiving radiotherapy for bone metastases: Results from a randomised multicentre trial. Radiother Oncol 2009;91:261–266.
8. Nielsen O, Bentzen S, Sandberg E, et al. Randomized trial of single dose versus fractionated palliative radiotherapy of bone metastases. Radiother Oncol 1998;47:233–240.
9. Steenland E, Leer J, van Houwelingen, et al. The effect of a single fraction compared to multiple fractions on painful bone metastases: A global analysis of the Dutch Bone Metastasis Study. Radiother Oncol 1999;52:101–109.

1c.16 Quote verbatim, the specific guideline recommendation *(Including guideline # and/or page #)*:
Guideline Question: What fractionation schemes have been shown to be effective for the treatment of painful and/or prevention of morbidity from peripheral bone metastases?

Guideline Statement: Multiple prospective randomized trials have shown pain
relief equivalency for dosing schema, including 30 Gy in 10 fractions, 24 Gy in 6 fractions, 20 Gy in 5 fractions, and a single 8-Gy fraction for patients with previously unirradiated painful bone metastases. Fractionated RT courses have been associated with an 8% repeat treatment rate to the same anatomic site because of recurrent pain vs. 20% after a single fraction; however, the single fraction treatment approach optimizes patient and caregiver convenience.
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1c.17 Clinical Practice Guideline Citation: Lutz S, Berk L, Chang E, et al. Palliative radiotherapy for bone metastases: An ASTRO evidence-based guideline. Int J Radiat Oncol Biol Phys. 2011;79(4):965-976.

1c.18 National Guideline Clearinghouse or other URL: The guideline has been accepted by the National Guidelines Clearninghouse (NGC-8836) and is pending online publication on the NGC website. ASTRO URL for guideline: https://www.astro.org/Clinical-Practice/Guidelines/Bone-Metastases.aspx

1c.19 Grading of Strength of Guideline Recommendation. Has the recommendation been graded? No

1c.20 If guideline recommendation graded, identify the entity that graded the evidence including balance of representation and any disclosures regarding bias:

1c.21 System Used for Grading the Strength of Guideline Recommendation: Other

1c.22 If other, identify and describe the grading scale with definitions: The guideline recommendation was not graded

1c.23 Grade Assigned to the Recommendation: Guideline recommendation is not assigned a grade.

1c.24 Rationale for Using this Guideline Over Others: Concerns from private payers over EBRT treatment variations for bone metastases and the evidence review suggesting the same, led to the development of the guideline to provide recommendations to close the gap in variation for treating bone metastases with EBRT.

This is the only clinical practice guideline available for EBRT for bone metastases.

Based on the NQF descriptions for rating the evidence, what was the developer's assessment of the quantity, quality, and consistency of the body of evidence?

1c.25 Quantity: High 1c.26 Quality: High1c.27 Consistency: Moderate

Was the threshold criterion, *Importance to Measure and Report*, met?
(*1a & 1b must be rated moderate or high and 1c yes*) Yes☐ No☐
Provide rationale based on specific subcriteria:

For a new measure if the Committee votes NO, then STOP.
For a measure undergoing endorsement maintenance, if the Committee votes NO because of 1b. (no opportunity for improvement), it may be considered for continued endorsement and all criteria need to be evaluated.

2. RELIABILITY & VALIDITY - SCIENTIFIC ACCEPTABILITY OF MEASURE PROPERTIES

Extent to which the measure, as specified, produces consistent (reliable) and credible (valid) results about the quality of care when implemented. (evaluation criteria)
Measure testing must demonstrate adequate reliability and validity in order to be recommended for endorsement. Testing may be conducted for data elements and/or the computed measure score. Testing information and results should be entered in the appropriate field. Supplemental materials may be referenced or attached in item 2.1. See guidance on measure testing.

S.1 Measure Web Page *(In the future, NQF will require measure stewards to provide a URL link to a web page where current detailed specifications can be obtained*). Do you have a web page where current detailed specifications for this measure can be obtained? No

S.2 If yes, provide web page URL:

2a. RELIABILITY. Precise Specifications and Reliability Testing: H☐ M☐ L☐ I ☐

2a1. Precise Measure Specifications. (*The measure specifications precise and unambiguous.*)

2a1.1 Numerator Statement *(Brief, narrative description of the measure focus or what is being measured about the target population, e.g., cases from the target population with the target process, condition, event, or outcome)*:
All patients, regardless of age, with painful bone metastases, and no previous radiation to the same anatomic site who receive EBRT with any of the following recommended fractionation schemes: 30Gy/10fxns, 24Gy/6fxns, 20Gy/5fxns, 8Gy/1fxn.

2a1.2 Numerator Time Window *(The time period in which the target process, condition, event, or outcome is eligible for inclusion)*:
Once per reporting period

2a1.3 Numerator Details *(All information required to identify and calculate the cases from the target population with the target process, condition, event, or outcome such as definitions, codes with descriptors, and/or specific data collection items/responses*:
Bone metastases diagnosis (198.5- Secondary malignant neoplasm of bone and bone marrow)

Use of EBRT (Therapeutic radiology treatment planning:
CPT 77261; simple,
CPT 77262; Intermediate,
CPT 77263; complex)

2a1.4 Denominator Statement *(Brief, narrative description of the target population being measured)*:
All patients with painful bone metastases and no previous radiation to the same anatomic site who receive EBRT

2a1.5 Target Population Category *(Check all the populations for which the measure is specified and tested if any)*: Adult/Elderly Care, Children's Health

2a1.6 Denominator Time Window *(The time period in which cases are eligible for inclusion)*:
Once per reporting period

2a1.7 Denominator Details (*All information required to identify and calculate the target population/denominator such as definitions, codes with descriptors, and/or specific data collection items/responses)*:
Bone metastases diagnosis (198.5- Secondary malignant neoplasm of bone and bone marrow)

Use of EBRT (Therapeutic radiology treatment planning:
CPT 77261; simple,
CPT 77262; Intermediate,
CPT 77263; complex)

2a1.8 Denominator Exclusions *(Brief narrative description of exclusions from the target population)*:
The medical reasons for denominator exclusions are:
1) Previous radiation treatment to the same anatomic site;
2) Patients with femoral axis cortical involvement greater than 3 cm in length;
3) Patients who have undergone a surgical stabilization procedure; and
4) Patients with spinal cord compression, cauda equina compression or radicular pain

The patient reasons for denominator exclusions are:
1) Patient declines treatment;
2) Economic, social or religious reasons; and
3) Other documented patient reasons

2a1.9 Denominator Exclusion Details *(All information required to identify and calculate exclusions from the denominator such as definitions, codes with descriptors, and/or specific data collection items/responses)*:
A. Medical Reasons (Data Source)
1) Previous radiation treatment to the same anatomic site (Medical Record)
2) Patients with femoral axis cortical involvement greater than 3 cm in length(Imaging Studies)
3) Patients who have undergone a surgical stabilization procedure (Operative Report)
4) Patients with spinal cord compression, cauda equina compression or radicular pain (Diagnosis/Problem list)

B. Patient Reasons (Data Source)
1) Patient declines treatment (Medical Record)
2) Economic, social or religious reasons (Medical Record)
3) Other documented patient reasons (Medical Record)

2a1.10 Stratification Details/Variables *(All information required to stratify the measure results including the stratification variables, codes with descriptors, definitions, and/or specific data collection items/responses)*:
Stratification of the measure is not required.

2a1.11 Risk Adjustment Type *(Select type. Provide specifications for risk stratification in 2a1.10 and for statistical model in 2a1.13)*: No risk adjustment or risk stratification 2a1.12 If "Other," please describe:

2a1.13 Statistical Risk Model and Variables *(Name the statistical method - e.g., logistic regression and list all the risk factor variables. Note - risk model development should be addressed in 2b4.)*:
Not applicable

2a1.14-16 Detailed Risk Model Available at Web page URL (or attachment). Include coefficients, equations, codes with descriptors, definitions, and/or specific data collection items/responses. Attach documents only if they are not available on a webpage and keep attached file to 5 MB or less. NQF strongly prefers you make documents available at a Web page URL. Please supply login/password if needed:

2a1.17-18. Type of Score: Rate/proportion

2a1.19 Interpretation of Score *(Classifies interpretation of score according to whether better quality is associated with a higher score, a lower score, a score falling within a defined interval, or a passing score)*: Better quality = Higher score

2a1.20 Calculation Algorithm/Measure Logic*(Describe the calculation of the measure score as an ordered sequence of steps including identifying the target population; exclusions; cases meeting the target process, condition, event, or outcome; aggregating data; risk adjustment; etc.)*:
Denominator Calculation
Step 1: Identify patients with: (a) diagnosis of bone metastases and (b) a prescription for EBRT
Step 2: Identify patients with no history of previous radiation therapy to the same anatomic site
Step 3: Identify patients with specified exceptions and exclude from denominator calculation

Numerator Calculation:
Step 1: Identify patients with: (a) diagnosis of bone metastases and (b) a prescription for EBRT
Step 2: Identify patients prescribed with one of the recommended fractionation schemes: 30Gy/10fxns or 24Gy/6fxns or 20Gy/5fxns or 8Gy/1fxn

2a1.21-23 Calculation Algorithm/Measure Logic Diagram URL or attachment:

2a1.24 Sampling (Survey) Methodology. If measure is based on a sample (or survey), provide instructions for obtaining the sample, conducting the survey and guidance on minimum sample size (response rate):
The measure is based on a clinical practice guideline

2a1.25 Data Source *(Check all the sources for which the measure is specified and tested*). If other, please describe:
Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Paper Records

2a1.26 Data Source/Data Collection Instrument (*Identify the specific data source/data collection instrument, e.g. name of database, clinical registry, collection instrument, etc.*): The data sources for this measure include: Radiation oncologist consultation note, physician office progress note, radiation flow sheet, radiology report

2a1.27-29 Data Source/data Collection Instrument Reference Web Page URL or Attachment: Attachment
bone metastases DATA COLLECTION INSTRUMENT.docx

2a1.30-32 Data Dictionary/Code Table Web Page URL or Attachment:
Attachment
DATA ELEMENTS.docx

2a1.33 Level of Analysis (*Check the levels of analysis for which the measure is specified and tested)*: Clinician : Group/Practice, Clinician : Individual, Clinician : Team, Facility, Health Plan

2a1.34-35 Care Setting *(Check all the settings for which the measure is specified and tested)*: Ambulatory Care : Clinician Office, Hospital/Acute Care Facility

2a2. Reliability Testing. (*Reliability testing was conducted with appropriate method, scope, and adequate demonstration of reliability*.)

2a2.1 Data/Sample *(Description of the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included)*:
The measure was tested for reliability. The details of the testing are described below:
The sample included four practices representing various types, locations, specialties, department sizes and patient load. Please see the described information below:

Practice type: One hospital, two academic and one physician-owned private practices specializing in medical oncology, radiation oncology and prostate cancer treatments.

Practice-setting: Two practices were located in a sub-urban setting, one in an urban setting, whereas as one hospital had multiple practice sites in urban, rural and suburban settings.

Number of physicians: The size of the departments ranged from 4- 21 physicians.

Average number of patients: The average number of patient ranged between 250-1000 patients per month.

Data Source: Two sites had EHR and paper records, one site had paper records only and one site had- EHR only.

Sample size: A total of 155 patient charts were abstracted for the measure.

Records review time-frame: Randomly selected patients who received care during the 2010 calendar year.

Period of data collection: August - October 2011

2a2.2 Analytic Method *(Describe method of reliability testing & rationale)*:
The project was statistically powered to identify significant differences between levels of measure´s reliability using the kappa statistic. Inter-rater reliability was tested for the critical data elements. Each abstractor collected data from every randomly selected patient record. A comparison report was generated from the abstraction tool which created a side by side comparison of the two medical records. The abstractors adjudicated any mismatches and after a consensus process the appropriate answer was selected. A reason code for the mismatch was assigned for that data element.

Data analysis included percent (%) agreement and a kappa statistic was calculated to adjust for chance agreement at the level of the measure numerator, denominator, exception and overall measure calculation.

2a2.3 Testing Results *(Reliability statistics, assessment of adequacy in the context of norms for the test conducted)*:
The testing results are presented below:
Data Element (N, %Agreement, Kappa, 95% CI,)
Denominator (155, 100%)
Numerator (155, 98.7%, 0.96, 0-91-1.00)
Exception (155, 100%, 1)
Overall measure: % Agreement Rate = 98.7%, kappa = 0.964 (0.914 – 1.00)

These data speak to the reliability of this measure.

2b. VALIDITY. Validity, Testing, <u>including all Threats to Validity</u>: H☐ M☐ L☐ I ☐

2b1.1 Describe how the measure specifications *(measure focus, target population, and exclusions)* are consistent with the evidence cited in support of the measure focus (*criterion 1c)* and identify any differences from the evidence:
The evidence demonstrated variation in the fractionation schemes used for EBRT in patients with painful bone metastases. The clinical practice guideline recommends the use of the following fractions: 30Gy/10fxns, 24Gy/6fxns, 20Gy/5fxns, 8Gy/1fxn in all patients regardless of age with a diagnosis of painful bone metastases and those who are prescribed EBRT (exceptions excluded).

The measure numerator is counting the number of patients with painful bone metastases and receiving EBRT with one of the following fractions- 30Gy/10fxns, 24Gy/6fxns, 20Gy/5fxns, 8Gy/1fxn.

The measure specifications are consistent with the evidence cited and provide a foundation for validity of the measure as an indicator of quality.

2b2. Validity Testing. (*Validity testing was conducted with appropriate method, scope, and adequate demonstration of validity.)*

2b2.1 Data/Sample *(Description of the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included)*:
The face validity of the measure was tested using an online survey data collection instrument. The sample size included 20 radiation oncologists primarily involved in quality improvement and guideline development. Please see below for the details of the

members who responded to the survey:

Name, Organization, (City,State)
1.Alan Hartford, Dartmouth-Hitchcock Medical Center, (Lebanon, New Hampshire)
2.Andre Konski, Wayne State University, (Detroit, Michigan)
3.Andrew Vassil, Cleveland Clinic, (Strongsville, Ohio)
4.Arjun Sahgal, University of Toronto, (Toronto, New York)
5.B. Ashleigh Guadagnolo, MD Anderson, (Houston, Texas)
6.Benjamin Smith, MD Anderson, (Houston, Texas)
7.Carol Hahn, Duke University, (Durham, North Carolina)
8.Charles von Gunten, (Institute for Palliative Medicine, (San Diego, California)
9.David Beyer, Arizona Oncology Services, (Phoenix, Arizona)
10.David Sher, Rush University Medical Center, (Chicago, Illinois)
11.Deborah Watkins-Bruner, Emory University, (Atlanta, Georgia)
12.Edward Chow, Sunnybrook Odette Cancer Centre, (Toronto, Ohio)
13.Eric Chang, USC Keck School of Medicine, (Los Angeles, California)
14.Gregory Videtic, Cleveland Clinic, (Cleveland, Ohio)
15.James Hayman, University of Michigan, (Ann Arbor, Michigan)
16.Jeff Michalski, Washington University, (St. Louis, Missouri)
17.Lisa Kachnic, Boston Medical Center, (Boston, Massachusetts)
18.Ronald Chen, University of North Carolina, (Chapel Hill, NC)
19.Seth Rosenthal, Radiation Oncology Center, (Sacramento, California)
20.William Noyes, Cancer Center of North Dakota, (Grand Forks, North Dakota)

2b2.2 Analytic Method *(Describe method of validity testing and rationale; if face validity, describe systematic assessment)*:
Face Validity of the measure score as an indicator of quality was systematically assessed as follows:
After the measure was fully specified, the expert panel (membership) was asked to rate their agreement with the following statement:
The scores obtained from the measure as specified will accurately differentiate quality across providers. The panel used a rating scale of: 1= Strongly Disagree, 2= Disagree, 3= Neither Agree nor Disagree, 4= Agree, 5 = Strongly Agree

2b2.3 Testing Results *(Statistical results, assessment of adequacy in the context of norms for the test conducted; if face validity, describe results of systematic assessment)*:
The following provides the validity testing results obtained from the panel survey. (The scores obtained from the measure as specified will accurately differentiate quality across providers).
N = 20; Mean Rating 4.05
Frequency Distribution of Ratings:
(Strongly Disagree) = 0
(Disagree) = 3
(Neither Agree Nor Disagree) = 1
(Agree) = 8
(Strongly Agree) = 8

POTENTIAL THREATS TO VALIDITY. (*All potential threats to validity were appropriately tested with adequate results.*)

2b3. Measure Exclusions. (*Exclusions were supported by the clinical evidence in 1c or appropriately tested with results demonstrating the need to specify them.*)

2b3.1 Data/Sample for analysis of exclusions *(Description of the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included)*:
The measure exclusions are provided below:
Medical Reasons-(Data Source)
1) Previous radiation treatment to the same anatomic site - (Patient Record)
2) Patients with femoral axis cortical involvement greater than 3 cm in length-(Imaging studies)
3) Patients who have undergone a surgical stabilization procedure- (Operative report)

4) Patients with spinal cord compression, cauda equina compression or radicular pain - (Diagnosis/ Problem list)
Patient reasons- (Data Source)
1) Patient declines treatment - (Patient record)
2) Economic, social or religious reasons- (Patient record)
3) Other documented patient reasons- (Patient record)

The following provides the requested information:
The sample included four practices representing various types, locations, specialties, department sizes and patient load. Please see the described information below:

Practice type: One hospital, two academic and one physician-owned private practices specializing in medical oncology, radiation oncology and prostate cancer treatments.

Practice-setting: Two practices were located in a sub-urban setting, one in an urban setting, whereas as one hospital had multiple practice sites in urban, rural and suburban settings.

Number of physicians: The size of the departments ranged from 4- 21 physicians.

Average number of patients: The average number of patient ranged between 250-1000 patients per month.

Data Source: Two sites had EHR and paper records, one site had paper records only and one site had- EHR only.

Sample size: A total of 155 patient charts were abstracted for the measure.

Records review time-frame: Randomly selected patients who received care during the 2010 calendar year.

Period of data collection: August - October 2011

2b3.2 Analytic Method (*Describe type of analysis and rationale for examining exclusions, including exclusion related to patient preference)*:
The measure exclusions include:
Medical Reasons
1) Previous radiation treatment to the same anatomic site
2) Patients with femoral axis cortical involvement greater than 3 cm in length
3) Patients who have undergone a surgical stabilization procedure
4) Patients with spinal cord compression, cauda equina compression or radicular pain
Patient reasons
1) Patient declines treatment
2) Economic, social or religious reasons
3) Other documented patient reasons

The patient preference exclusions will be excluded from the denominator calculation.

The measure exclusions were tested for reliability using kappa statistic.

2b3.3 Results *(Provide statistical results for analysis of exclusions, e.g., frequency, variability, sensitivity analyses):*
Testing: The measure exclusions were tested for reliability using kappa statistic (kappa = 1). The following exclusions were documented: Patient has spinal cord compression and anterior spinal fusion.

2b4. Risk Adjustment Strategy. (*For outcome measures, adjustment for differences in case mix (severity) across measured entities was appropriately tested with adequate results.*)

2b4.1 Data/Sample *(Description of the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included)*:
No risk adjustment strategy identified.

2b4.2 Analytic Method (*Describe methods and rationale for development and testing of risk model or risk stratification including selection of factors/variables)*:
No risk adjustment strategy identified.

2b4.3 Testing Results *(Statistical risk model: Provide quantitative assessment of relative contribution of model risk factors; risk model performance metrics including cross-validation discrimination and calibration statistics, calibration curve and risk decile plot, and assessment of adequacy in the context of norms for risk models. Risk stratification: Provide quantitative assessment of relationship of risk factors to the outcome and differences in outcomes among the strata)*:
No risk adjustment strategy identified.

2b4.4 If outcome or resource use measure is not risk adjusted, provide rationale and analyses to justify lack of adjustment: No risk adjustment strategy identified.

2b5. Identification of Meaningful Differences in Performance. (*The performance measure scores were appropriately analyzed and discriminated meaningful differences in quality.*)

2b5.1 Data/Sample *(Describe the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included)*:
The sample for testing meaningful differences in performance included four practices representing various types, locations, specialties, department sizes and patient load. Please see the described information below.

Practice type: One hospital, two academic and one physician-owned private practices specializing in medical oncology, radiation oncology and prostate cancer treatments.

Practice-setting: Two practices were located in a sub-urban setting, one in an urban setting, whereas as one hospital had multiple practice sites in urban, rural and suburban settings.

Number of physicians: The size of the departments ranged from 4- 21 physicians.

Average number of patients: The average number of patient ranged between 250-1000 patients per month.

Data Source: Two sites had EHR and paper records, one site had paper records only and one site had- EHR only.

Sample size: A total of 155 patient charts were abstracted for the measure.

Records review time-frame: Randomly selected patients who received care during the 2010 calendar year.

Period of data collection: August - October 2011

2b5.2 Analytic Method *(Describe methods and rationale to identify statistically significant and practically/meaningfully differences in performance)*:
Performance results were calculated for the measure. Performance rates were calculated with and without exceptions applied. In addition, the exception documented in the medical record was captured by the abstractors as a part of their review.

2b5.3 Results *(Provide measure performance results/scores, e.g., distribution by quartile, mean, median, SD, etc.; identification of statistically significant and meaningfully differences in performance)*:

	N	(% Rate)
Measure Rate without exceptions	121 of 155	(78.1%)
Measure Rate with Exceptions	121 of 152	(79.6%)
Exception Rate		(1.9%)

2b6. Comparability of Multiple Data Sources/Methods. (*If specified for more than one data source, the various approaches result in comparable scores.*)

2b6.1 Data/Sample *(Describe the data or sample including number of measured entities; number of patients; dates of data; if a*

sample, characteristics of the entities included):
The measure is not currently included in PQRS or any other data source. Comparable data source/ method is not available currently.

2b6.2 Analytic Method *(Describe methods and rationale for testing comparability of scores produced by the different data sources specified in the measure)*:
The measure is not currently included in PQRS or any other data source. Comparable data source/ method is not available currently.

2b6.3 Testing Results *(Provide statistical results, e.g., correlation statistics, comparison of rankings; assessment of adequacy in the context of norms for the test conducted)*:
The measure is not currently included in PQRS or any other data source. Comparable data source/ method is not available currently.

2c. Disparities in Care: H☐ M☐ L☐ I ☐ NA☐ (*If applicable, the measure specifications allow identification of disparities.*)

2c.1 If measure is stratified for disparities, provide stratified results *(Scores by stratified categories/cohorts)*: The measure is not stratified for disparities. No disparities were identified in the literature.

2c.2 If disparities have been reported/identified (e.g., in 1b), but measure is not specified to detect disparities, please explain:
No disparities were identified in the literature.

2.1-2.3 Supplemental Testing Methodology Information:

Steering Committee: Overall, was the criterion, *Scientific Acceptability of Measure Properties*, met?
(*Reliability and Validity must be rated moderate or high*) Yes☐ No☐
Provide rationale based on specific subcriteria:

If the Committee votes No, STOP

3. USABILITY

Extent to which intended audiences (e.g., consumers, purchasers, providers, policy makers) can understand the results of the measure and are likely to find them useful for decision making. (evaluation criteria)

C.1 Intended Purpose/ Use *(Check all the purposes and/or uses for which the measure is intended)*: Payment Program, Public Reporting, Quality Improvement (Internal to the specific organization), Quality Improvement with Benchmarking (external benchmarking to multiple organizations)

3.1 Current Use *(Check all that apply; for any that are checked, provide the specific program information in the following questions)*: Not in use

3a. Usefulness for Public Reporting: H☐ M☐ L☐ I ☐
(*The measure is meaningful, understandable and useful for public reporting.*)

3a.1. Use in Public Reporting - disclosure of performance results to the public at large *(If used in a public reporting program, provide name of program(s), locations, Web page URL(s)).* If not publicly reported in a national or community program, state the reason AND plans to achieve public reporting, potential reporting programs or commitments, and timeline, e.g., within 3 years of endorsement: [*For Maintenance – If not publicly reported, describe progress made toward achieving disclosure of performance results to the public at large and expected date for public reporting; provide rationale why continued endorsement should be considered.*]
This measure is not currently known to be used in a public reporting program. Rationale for public reporting is grounded in the potential to improve practice variation patterns relative to the proposed measure. Additionally, public reporting of the proposed

measure has dual benefits to patients and providers. For instance, patients and providers can use these data to make more informed treatment decisions for management approaches for painful bone metastases. ASTRO memership is comprised of approximately 4500 radiation oncologists practicing in the United States and plans are currently underway to build a PQRS registry which will likely include this measure to facilitate public reporting. We have also suggested this measure for the PPS-exempt hospital; it is under consideration.

3a.2.Provide a rationale for why the measure performance results are meaningful, understandable, and useful for public reporting. If usefulness was demonstrated (e.g., focus group, cognitive testing), describe the data, method, and results: This measure is not currently known to be used in a public reporting program. However, the use of this measure for public reporting and performance measurement will be useful to improve practice variation patterns in EBRT for bone metastases.

3.2 Use for other Accountability Functions (payment, certification, accreditation). If used in a public accountability program, provide name of program(s), locations, Web page URL(s): Currently, the measure is not in use for programs with accountability functions.

3b. Usefulness for Quality Improvement: H☐ M☐ L☐ I ☐
(*The measure is meaningful, understandable and useful for quality improvement.*)

3b.1. Use in QI. If used in quality improvement program, provide name of program(s), locations, Web page URL(s):
[*For Maintenance – If not used for QI, indicate the reasons and describe progress toward using performance results for improvement*].
The measure is currently not used in any quality improvement program which highlights the need for this measure given the incidence of cancer, subsequent bone metastses and the documented evidence of treatment variation.

The Performance Assessment for the Advancement of Radiation Oncology Treatment program (PAAROT) is ASTRO´s practice improvement program which is approved by the American Board of Radiology (ABR) as a Type 2 PQI project (in partial fulfillment of requirements of the ABR Maintenance of Certification Program). This measure will be included in PAAROT to assess the trend in the treating bone metastases as well as to identify areas for performance gap and treatment variation.

3b.2. Provide rationale for why the measure performance results are meaningful, understandable, and useful for quality improvement. If usefulness was demonstrated *(e.g., QI initiative),* describe the data, method and results:
The measure is currently not used in any quality improvement program. However, the use of this measure in quality improvement programs will be useful to improve practice variation patterns in EBRT for bone metastases.

Overall, to what extent was the criterion, *Usability*, met? H☐ M☐ L☐ I ☐
Provide rationale based on specific subcriteria:

4. FEASIBILITY

Extent to which the required data are readily available, retrievable without undue burden, and can be implemented for performance measurement. (evaluation criteria)

4a. Data Generated as a Byproduct of Care Processes: H☐ M☐ L☐ I ☐

4a.1-2 How are the data elements needed to compute measure scores generated? *(Check all that apply).*
Data used in the measure are:
generated by and used by healthcare personnel during the provision of care, e.g., blood pressure, lab value, medical condition,
Abstracted from a record by someone other than person obtaining original information (e.g., chart abstraction for quality measure or registry)

4b. Electronic Sources: H☐ M☐ L☐ I ☐

4b.1 Are the data elements needed for the measure as specified available electronically *(Elements that are needed to compute measure scores are in defined, computer-readable fields)*: ALL data elements are in a combination of electronic sources

4b.2 If ALL data elements are not from electronic sources, specify a credible, near-term path to electronic capture, OR

provide a rationale for using other than electronic sources:

4c. Susceptibility to Inaccuracies, Errors, or Unintended Consequences: H☐ M☐ L☐ I ☐

4c.1 Identify susceptibility to inaccuracies, errors, or unintended consequences of the measurement identified during testing and/or operational use and strategies to prevent, minimize, or detect. If audited, provide results:
There was no identified susceptibility to inaccuracies, errors, or unintended consequences of measurement identified during testing.

4d. Data Collection Strategy/Implementation: H☐ M☐ L☐ I ☐

A.2 Please check if either of the following apply (*regarding proprietary measures*): Proprietary measure
4d.1 Describe what you have learned/modified as a result of testing and/or operational use of the measure regarding data collection, availability of data, missing data, timing and frequency of data collection, sampling, patient confidentiality, time and cost of data collection, other feasibility/implementation issues *(e.g., fees for use of proprietary measures)*:
The denominator for the measure includes all patients with a diagnosis of painful bone metastases and no previous radiation to that anatomical site, who were prescribed EBRT. Much of the information was found in consultation, office visit note, outpatient treatment center and other-treatment summaries. This was abstracted without difficulty.

The numerator for this measure includes all patients, regardless of age, with painful bone metastases and no previous radiation to that anatomical site, who were prescribed EBRT with any of the following fractionation schemes: 30Gy/10fxns, 24Gy/6fxns, 20Gy/5fxns or 8Gy/1fxn. The data for the numerator was contained in consultation, office visit notes, outpatient treatment center and problem/ diagnosis list. This was also abstracted without any difficulty.

The measure was abstracted without difficulty at four testing sites.

Overall, to what extent was the criterion, *Feasibility*, met? H☐ M☐ L☐ I ☐
Provide rationale based on specific subcriteria:

OVERALL SUITABILITY FOR ENDORSEMENT

Does the measure meet all the NQF criteria for endorsement? Yes☐ No☐
Rationale:

If the Committee votes No, STOP.
If the Committee votes Yes, the final recommendation is contingent on comparison to related and competing measures.

5. COMPARISON TO RELATED AND COMPETING MEASURES

If a measure meets the above criteria and there are endorsed or new related measures (either the same measure focus or the same target population) or competing measures (both the same measure focus and the same target population), the measures are compared to address harmonization and/or selection of the best measure before a final recommendation is made.

5.1 If there are related measures *(either same measure focus or target population)* or competing measures *(both the same measure focus and same target population*), list the NQF # and title of all related and/or competing measures:

5a. Harmonization

5a.1 If this measure has EITHER the same measure focus OR the same target population as NQF-endorsed measure(s): Are the measure specifications completely harmonized?

5a.2 If the measure specifications are not completely harmonized, identify the differences, rationale, and impact on interpretability and data collection burden:

5b. Competing Measure(s)

5b.1 If this measure has both the same measure focus and the same target population as NQF-endorsed measure(s): Describe why this measure is superior to competing measures *(e.g., a more valid or efficient way to measure quality);* OR

provide a rationale for the additive value of endorsing an additional measure. *(Provide analyses when possible)*:
No competing or related measures identified

CONTACT INFORMATION

Co.1 Measure Steward (Intellectual Property Owner): American Society for Radiation Oncology (ASTRO), 8280 Willow Oaks Corporate Drive, Suite 500, Fairfax, Virginia, 22031

Co.2 Point of Contact: Anushree, Vichare, MBBS, MPH, anushreev@astro.org, 703-839-7396-

Co.3 Measure Developer if different from Measure Steward: Suite 500, Fairfax, Virginia, 22031

Co.4 Point of Contact: Anushree, Vichare, MBBS, MPH, anushreev@astro.org, 703-839-7396-

Co.5 Submitter: Anushree, Vichare, MBBS, MPH, anushreev@astro.org, 703-839-7396-

Co.6 Additional organizations that sponsored/participated in measure development:
None

Co.7 Public Contact: Anushree, Vichare, MBBS, MPH, anushreev@astro.org, 703-839-7396-

ADDITIONAL INFORMATION

Workgroup/Expert Panel involved in measure development
Ad.1 Provide a list of sponsoring organizations and workgroup/panel members' names and organizations. Describe the members' role in measure development.
Anushree Vichare, MBBS MPH, Measures Development Manager, ASTRO: Measure Developer
Emily Wilson, Vice-President, Advocacy & Clinical Affairs Division, ASTRO: Measure Developer

Ad.2 If adapted, provide title of original measure, NQF # if endorsed, and measure steward. Briefly describe the reasons for adapting the original measure and any work with the original measure steward: Not applicable

Measure Developer/Steward Updates and Ongoing Maintenance
Ad.3 Year the measure was first released:
Ad.4 Month and Year of most recent revision:
Ad.5 What is your frequency for review/update of this measure?
Ad.6 When is the next scheduled review/update for this measure?

Ad.7 Copyright statement:

Ad.8 Disclaimers:

Ad.9 Additional Information/Comments:

Date of Submission (*MM/DD/YY*): 01/01/0001

BONE METASTASES DATA COLLECTION INSTRUMENT

Confirm Bone Metastases Diagnosis

Determine if the patient had a documented diagnosis of painful bone metastases and no previous radiation to that anatomic site and was prescribed external beam radiation therapy (EBRT).

___ Yes
___ No/not documented

Bone Metastases

Determine if patient, with painful bone metastases, was prescribed EBRT with any of the following fractionation schemes: 30 Gy/10 fxns, 24 Gy/6 fxns, 20 Gy/5 fxns or 8 Gy/1 fxn.

___ Yes
___ No/not documented
___ No/medical reason(s)
record medical reason(s)
_____(verbatim text)
___ No/patient reason(s)
record patient
reason(s)_____(verbatim
text)

DATA ELEMENTS/ VARIABLE NAMES	INSTRUCTIONS (DEFINITIONS, VALID VALUES)	INCLUSIONS/SYNONYMS	EXCEPTIONS
Clinic Name **[CLNAME]**	**Instruction**: Enter the name of the clinic.	Clinic - 1 Clinic - 2 Clinic - 3 Clinic - 4 Clinic - 5	None
Confirm Bone Metastases Diagnosis **[BONMETCONFIRM]**	**Instruction**: Determine if the patient had a documented diagnosis of painful bone metastases and was prescribed external beam radiation therapy (EBRT). **Yes (1)**: Select this option if the patient had a documented diagnosis of painful bone metastases and was prescribed EBRT. **No (0)**: Select this option if the patient did not have a diagnosis of painful bone metastases and was not prescribed EBRT.	Secondary malignant neoplasm of bone and bone marrow	None
Bone Metastases-Fractionation Schemes [**BONFRACTION]**	Instruction: Determine if patient, with painful bone metastases, was prescribed EBRT with any of the following fractionation schemes: 30 Gy/10 fxns, 24 Gy/6 fxns, 20 Gy/5 fxns or 8 Gy/1 fxn. **Yes (1)**: Select this option if the patient, with painful bone metastases, was prescribed EBRT with any of the following fractionation schemes: 30 Gy/10 fxns, 24 Gy/6 fxns, 20 Gy/5 fxns or 8 Gy/1 fxn. **No (0)**: Select this option if the patient, with painful bone metastases, was not prescribed EBRT with any of the following fractionation	See Table One for eligible population criteria	**No/medical reason(s) (2) may include:** previous treatment to the same anatomic site, patients with femoral axial cortical involvement greater than 3 cm in length, patients who have undergone a surgical stabilization procedure,

	schemes: 30 Gy/10 fxns, 24 Gy/6 fxns, 20 Gy/5 fxns or 8 Gy/1 fxn. **No/medical reason(s) (2)**: Select this option if the patient, with painful bone metastases, was not prescribed EBRT with any of the following fractionation schemes: 30 Gy/10 fxns, 24 Gy/6 fxns, 20 Gy/5 fxns or 8 Gy/1 fxn due to medical reason(s). **No/patient reason(s) (3)**: Select this option if the patient, with painful bone metastases, was not prescribed EBRT with any of the following fractionation schemes: 30 Gy/10 fxns, 24 Gy/6 fxns, 20 Gy/5 fxns or 8 Gy/1 fxn due to patient reason(s).		patients with spinal cord compression, cauda equine compression or radicular nerve pain, documented other medical reason(s) (not indicated/contraindicated) **No/patient reason(s) (3) may include:** patient declined treatment, economic, social or religious reasons, other patient reason(s)