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 #: 0209 NQF Project: Palliative Care and End-of-Life Care

(for Endorsement Maintenance Review)
Original Endorsement Date: Aug 10, 2009 Most Recent Endorsement Date: Aug 10, 2009

BRIEF MEASURE INFORMATION

De.1 Measure Title: Comfortable Dying: Pain Brought to a Comfortable Level Within 48 Hours of Initial Assessment

Co.1.1 Measure Steward: National Hospice and Palliative Care Organization

De.2 Brief Description of Measure: Number of patients who report being uncomfortable because of pain at the initial assessment (after admission to hospice services) who report pain was brought to a comfortable level within 48 hours.

2a1.1 Numerator Statement: Patients whose pain was brought to a comfortable level (as defined by patient) within 48 hours of initial assessment (after admission to hospice services).

2a1.4 Denominator Statement: Patients who replied "yes" when asked if they were uncomfortable because of pain at the initial assessment (after admission to hospice services).

2a1.8 Denominator Exclusions: Inclusions: Patients are eligible if they:
Report they are uncomfortable because of pain at the initial assessment (after admission to hospice services);
Are able to communicate and understand the language of the person asking the question;
Are able to self-report; and
Are at least 18 years of age or older.

1.1 Measure Type: Outcome
2a1. 25-26 Data Source: Patient Reported Data/Survey
2a1.33 Level of Analysis: Facility, Population : National

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*):

STAFF NOTES (*issues or questions regarding any criteria*)

Comments on Conditions for Consideration:

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*):
5. Similar/related endorsed or submitted measures (*check 5.1*):
Other Criteria:

Staff Reviewer Name(s):

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, Cardiovascular, GI, Infectious Diseases, Musculoskeletal, Neurology, Pulmonary/Critical Care : Chronic Obstructive Pulmonary Disease (COPD), Renal
De.5 Cross Cutting Areas (*Check all the areas that apply)*: Palliative Care and End of Life Care

1a.1 Demonstrated High Impact Aspect of Healthcare: Patient/societal consequences of poor quality, Other

1a.2 If "Other," please describe: Pain management is essential component of care at end-of-life

1a.3 Summary of Evidence of High Impact *(Provide epidemiologic or resource use data)*:
Inadequacies and need for improvement of pain managment for the dying have been pointed out by studies showing that 40 - 70% of Americans have substantial pai in the last days of life. Four our of 10 dying painte are in sever pain most of the time.
Poorly controlled pain diminishes patient quality of life and functional status, and causes suffering for patients and family caregivers. Pain is highly prevalent during the last week of life, so the timely evaluation and treatment of pain at the time of admission, before the patient is either unable to respond or detailed assessment becomes an additional burden is a priority.

1a.4 Citations for Evidence of High Impact cited in 1a.3: The Study to Understand Prognoses and Preferences for Outcomes and Risks of Treatments (SUPPORT). The
SUPPORT principle investigators. JAMA. 1995 274: 1591-98.

Hall CT, In Search of a Good Death, San Francisco Chronicle Tuesday, April 6, 1999

Fine PG. The ethical imperative to relieve pain at life´s end. J Pain Symptom Manage. 2002;23:273-277.

Conill C, Verger E, Henriquez I, Saiz N, Espier M, Lugo F, Garrigos A. Symptom prevalence in the last week of life. J Pain Symptom Manage. 1997; 14:328-331.

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:
The Comfortable Dying Measure reflects patient goals for pain management.
The use of a dichotomous rating, incorporating the patient's perception of
his/her own degree of comfort, is a more useful determinant for addressing achievement of comfort/pain managment for the following reasons:
1. While it is recognized that pain scales have intra-individual validity and that mean values have importance for population studies, the utility of numerical pain scores for a concurrently evaluated outcome measure and for program/system accountability is problematic.
the onset of "discomfort" and functionality is impaired at 5-6, agreement on the value of numerical rating has not been demonstrated.
2. Not all patients mean the same thing when they give a rating – one person's 3 may be someone else's 6. The value of a numerical rating scale lies in comparison within subjects(comparing ratings over time) – and the fact that change is accomplished, or not, is more relevant than the absolute number achieved.
3. Using a set numeric rating as goal loses, or at least undermines, the concept of self-determination. If pain is an individual experience with an individual response, then the decision of what is acceptable/comfortable
should be left up to the individual, not determined arbitrarily. It's more consistent with patient-centered care to care to ask the patient to decide how comfortable he/she wants to be,rather than use a rating, even if that rating can be linked to functionality. The Comfortable Dying measure also allows for a broader conceptualization of pain than use of a measure that relies solely on a numeric intensity rating.

4. Not all patients who are capable of describing their pain are able to do so using a numerical rating scale. The Comfortable Dying measure identifies those patients who require intervention and at the same time allows the clinician to use the most appropriate means of pain assessment for each individual patient.

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.*]
Descriptive Statistics for calendar year 2010:
Quarter 1: Agency mean: 69.6; 25th percentile: 50.0; 50th percentile: 75.3; 75th percentil: 72.5
Quarter 2: Agency mean:73.6; 25th percentile: 61.5; 50th percentile: 75.3; 75th percentile: 98.0
Quarter 3: Agency mean:74.8; 25th percentile: 62.5; 50th percentile: 81.8; 75th percentil 100.0
Quarter 4: Agency mean: 73.5; 25th percentile: 55.6; 50th percentile: 78.6; 75th percentile: 96.2.
Quarter 3:
Quarter 4:

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*]
NHPCO collects and analyzes data from hospice providers that choose to participate in the Comfortable Dying measure and produces a national level report for hospices to use for comparison to their own scores on a quarterly basis. Results for the measure include national agency mean and quartiles. In addition, results are provided detailing agency means and quartiles for the patients assessed for the measure and the patients included in the denominator.
For 2010 calendar year quarters:
Quarter 1: Patients Assessed: 12,096; Patients uncomfortable: 2,381
Quarter 2: Patients Assessed: 11,031; Patients uncomfortable: 2,146
Quarter 3 Patients Assessed: 9,706; Patients uncomfortable: 1,897
Quarter 4: Patients Assessed: 9,814; Patients uncomfortable: 1,940

1b.4 Summary of Data on Disparities by Population Group: [*For Maintenance –Descriptive statistics for performance results for this measure by population group*]
Original testing of the measure showed that patients whose pain was not brought to a comfortable level make up 19% of those patients with a cancer diagnosis vs. 15.2%(p=0.59) of patients with a non-cancer diagnosis. There was no statistically significant difference (p=.52) in the ethnic distribution of patients whose pain was not brought to a comfortable level compared to those who had their pain relieved. More recent patient level data are not available.

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*]
The initial testing included a total of 1409 patients, 463 (32.86%0 of whom responded that they were uncomfortable because of pain. On follow up, 60 (13%)indicated their pain was not brought to a comfortable level, 87 (18.8%) were unable to self report, and 44 (9.5%) had missing data. Data were collected over a 6 month period from all patients on initial assessment enrolled in the hospices participating in the testing of the measure.

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)*:
Measure focus is a health outcome that reflects patient goals for pain management and whether those goals were met.
The underlying structures, processes and intermediate outcomes that support the outcome are not part of the measure.

1c.2-3 Type of Evidence *(Check all that apply)*:
Other
A National Framework and Preferred Practices for Palliative and Hospice Quality

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)*:
Measure is consistent with Domains and Preferred Practices delineated in the NQF consensus report titled A National Framework and Preferred Practices for Palliative and Hospice Care Quality endorsed by NQF in 2006.
Specifically:
Domain 2. Physical Aspects of Care
*Symptoms and side effects are managed in a timely, safe, and effective manner.
*Symptom and side effect management is done in a manner that is patient and family centered.
Preferred Practice #13. Assess and manage symptoms and side effects in a timely, safe, and effective manner to a level that is acceptable to the patient and family.

1c.5 Quantity of Studies in the Body of Evidence *(Total number of studies, not articles)*: N/A

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*): N/A

1c.7 Consistency of Results across Studies *(Summarize the consistency of the magnitude and direction of the effect):*

1c.8 Net Benefit *(Provide estimates of effect for benefit/outcome; identify harms addressed and estimates of effect; and net benefit - benefit over harms)*:
N/A

1c.9 Grading of Strength/Quality of the Body of Evidence. Has the body of evidence been graded? No

1c.10 If body of evidence graded, identify the entity that graded the evidence including balance of representation and any disclosures regarding bias: N/A

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

1c.12 If other, identify and describe the grading scale with definitions: Outcome measure - No grading scale used - body of evidence not graded

1c.13 Grade Assigned to the Body of Evidence: Outcome measure - No grade assigned - body of evidence not graded

1c.14 Summary of Controversy/Contradictory Evidence: N/A

1c.15 Citations for Evidence other than Guidelines*(Guidelines addressed below)*:
N/A

1c.16 Quote verbatim, the specific guideline recommendation *(Including guideline # and/or page #)*:

N/A

1c.17 Clinical Practice Guideline Citation: N/A

1c.18 National Guideline Clearinghouse or other URL: N/A

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: No grading scale used - strength of guideline recommendation not graded

1c.23 Grade Assigned to the Recommendation: No grading scale used; grade assigned -

1c.24 Rationale for Using this Guideline Over Others: N/A

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: High

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? Yes

S.2 If yes, provide web page URL: www.nhpco.org/outcomemeasures

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)*:
Patients whose pain was brought to a comfortable level (as defined by patient) within 48 hours of initial assessment (after admission to hospice services).

2a1.2 Numerator Time Window *(The time period in which the target process, condition, event, or outcome is eligible for inclusion)*:
Up to 48 hours after initial assessment (after admission to hospice services).

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*:
Number of patients who replied "yes" when asked if their pain was brought to a comfortable level within 48 hours of initial assessment (after admission to hospice services).

2a1.4 Denominator Statement *(Brief, narrative description of the target population being measured)*:
Patients who replied "yes" when asked if they were uncomfortable because of pain at the initial assessment (after admission to hospice services).

2a1.5 Target Population Category *(Check all the populations for which the measure is specified and tested if any)*: Adult/Elderly Care, Populations at Risk, Special Healthcare Needs

2a1.6 Denominator Time Window *(The time period in which cases are eligible for inclusion)*:
At time of initial assessment (after admission to hospice services).

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)*:
Adult patients who are able to self report pain information and replied "yes" when asked if they were uncomfortable because of pain at the initial assessment (after admission to hospice services).

2a1.8 Denominator Exclusions *(Brief narrative description of exclusions from the target population)*:
Inclusions: Patients are eligible if they:
Report they are uncomfortable because of pain at the initial assessment (after admission to hospice services);
Are able to communicate and understand the language of the person asking the question;
Are able to self-report; and
Are at least 18 years of age or older.

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)*:
Exclusion: Patients are excluded if they are:
lAre less than 18 years of age;
Cannot understand language of hospice nurse performing the assessment;
Cannot self report pain information;
Deny being uncomfortable because of pain

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)*:
None

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.)*:
N/A

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.)*:
Measure scores are calculated on a calendar year quarterly basis.
Calculation of measure score (Attainment Score):
1. Identify number of patients admitted to hospice services during quarter.
2. Identify number of admitted patients who were able to respond to the question "Are you uncomfortable because of pain?" during the initial assessment and were not excluded because they met the exclusion criteria.
3. Identify the number of patients who responded "yes" to the question "Are you uncomfortable because of pain?" during the initial assessment.
4. Identify the number of patients who were contacted within 72 hours of the initial assessment and responded "yes" to the question: "Was your pain brought to a comfortable level within 48 hours of the start of hospice services?" This number is the numerator.
4. Divide the number of patients whose pain was brought to a comfortable level within 48 hours after initial assessment by the number of patients who reported they were uncomfortable because of pain at the initial assessment.
2. Multiply this number by 100 to get the hospice's score as a percent. This is the proportion of patients who reported being uncomfortable because of pain at initial assessment whose pain was brought to a comfortable level within 48 hours of the start of hospice services.
NOTE: A Problem Score is also calculated as a complement to the Attainment Score. The Problem Score is calculated by dividing the number of patients whose pain was NOT brought to a comfortable level within 48 hours after the initial assessment by the number of patients who were uncomfortable on admission. Multiply this number by 100 to get the hospice's score as a percent. A lower score/percentile = better performance. The Problem Score offsets negative bias introduced by additional context and insight for setting performance improvement goals.

2a1.21-23 Calculation Algorithm/Measure Logic Diagram URL or attachment:
Attachment
Comf Dying Meaure Logic Diagram FINAL.docx

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):
No sampling methodology used. All patients are assessed for eligibility for inclusion in the measure at the initial assessment after admission to hospice services.

2a1.25 Data Source *(Check all the sources for which the measure is specified and tested*). If other, please describe:
Patient Reported Data/Survey

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.*): Data specific to measure (initial question on admission and follow-up question asked within 72 hours of admission) recorded by hospice on Patient Core Measure Sheet provided by NHPCO (www.nhpco.org/outcomemeasures) or on comparable tracking form devised by hospice. Data can be part of patient record or recorded and tracked separately.
Data are aggregated and submitted quarterly by hospices to NHPCO which maintains a national repository. NHPCO analyzes the data and produces a quarterly national level report for hospices as a source of comparative data for use in performance improvement initiatives.

2a1.27-29 Data Source/data Collection Instrument Reference Web Page URL or Attachment: URL
www.nhpco.org/outcomemeasures

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

2a1.33 Level of Analysis (*Check the levels of analysis for which the measure is specified and tested)*: Facility, Population : National

2a1.34-35 Care Setting *(Check all the settings for which the measure is specified and tested)*: Hospice

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)*:
A sample of quarterly data submissions was taken covering two years (2009 and 2010) worth of submissions. The sample consisted of only those agencies that submitted multiple (=2) quarters worth of data during that period. There were 79 hospices agencies that submitted usable data for the Comfortable Dying measure covering 285 quarters (in total) worth of data and nearly 50,000 patients. Of those 79 hospice agencies, 58 (73.4%) provided multiple quarters worth of data during that period, covering data on over 38,000 patients. The two-year quarterly average percent of patients reporting being uncomfortable due to pain on admission was 20.8% (95% CI 19.5% - 22.1%). The two-year quarterly average percent of patients reporting having their pain brought to a comfortable level within 48 hours of admission was 69.3% (95% CI 66.3% - 72.3%).

2a2.2 Analytic Method *(Describe method of reliability testing & rationale)*:
Intraclass correlation was used for reliablity testing for the measure. To provide evidence of measure reliability we must show that, all things being equal, hospices will reliably submit the same data over multiple quarters. Put another way, given that the proportion of patients who's pain is brought to a comfortable level within 48 hours of admission does not significantly change between quarter, the reported proportion will also remain the same.
To test this hypothesis, agency-level results were calculated from the sample hospice for the percent of hospice patients reporting being uncomfortable due to pain on admission, and the percent of patients who report having their pain brought to a comfortable level within 48 hours after admission. Univariate analysis was performed to provide the overall distribution of results for both variables results. To examine the similarity of data submitted in each quarter, an analysis of variance was performed to determine if significant differences existed in between the quarterly means for both agency level results. Next, an analysis of variance was performed to examine the differences in mean scores between and among hospices over the two years. Finally, intra-class correlations coefficients (ICC) were calculated to examine the measurements reliability over the sample years. Statistical significance was set at $P < 0.05$. All analysis completed utilizing SAS version 9.2.
NOTE: Test-retest is a frequently used method for reliability testing with single item measures and has been used with pain measures. However, the Comfortable Dying Measure assesses a characteristic that can inherhently be expected to change rapidly (interventions to achieve better pain control can be and often are institituted at the time of assessment) making test-retest an inappropriate choice for reliability testing for this measure.

2a2.3 Testing Results *(Reliability statistics, assessment of adequacy in the context of norms for the test conducted)*:
The analysis of variance of quarterly mean percents of patients who reported being uncomfortable due to pain on admission showed no significant difference of mean scores between quarters (F-value = 1.11; P = 0.355). Variance of this measure demonstrated the expected significant difference between submitting hospices agencies (F-value = 7.48; P<0.0001). The intra-class correlation coefficient for the difference of the between and within hospice variation was 0.76 (95% CI 0.70 – 0.81).
The analysis of variance of quarterly mean percents of patients who reported having their pain brought to a comfortable level within 48 hours of admission also showed no significant difference of mean scores between quarter (F-value = 1.7; P=0.991). The Hospice level variance analysis of this measure showed significant differences between hospice agencies (F-value = 5.87; P<0.001). The intra-class correlation coefficient for the between and within hospice 0.71 (95% CI 0.63 – 0.77).
The analysis of the data showed that indeed, over two-years of quarterly data submissions, the percent of patients reporting being uncomfortable due to pain remained relatively constant. Since the assumption of similarity between quarters was met it was then safe to examine the relative between and among variation in results for the same measure. As expected, there were significant differences in the percent of hospice patients uncomfortable due to pain on admission reported by each hospice. However, the ICC demonstrated good (over 75%) consistency of results within hospices from quarter to quarter.

Similarly, these results show that the percent of patients who's pain was brought to a comfortable level within 48 hours of admission, remained non-significantly differently. In fact, the results show that there was nearly no difference from quarter to quarter the results for this measure. The ICC for this measure also demonstrated good consistency (approximately 71%) of results within hospices from quarter to quarter. This slightly smaller ICC for measure (when compared to the percent uncomfortable due to pain on admission ICC) is not necessarily an indication of reduced reliability. Increased within hospice variation would be expected as hospices make process changes to increase their score for this measure. Indeed this expectation is observed in the variance of hospice scores for percent of patients uncomfortable due to pain on admission compared to those whose pain was brought to a comfortable level within 48 hours (F-values = 7.48 and 5.87 respectively).
It is likely that both ICC scores are conservative estimates of the true reliability of the measure. Even though there was little quarterly change in the percent of patients uncomfortable due to pain on admission (and likewise having their pain brought to a comfortable level), common sense dictates that real differences actually occurred at the hospice level. Since we know that the assumption of consistency of the base data can't be exactly true, we know that the true ICC's for these measures must be higher than what was observed.
In conclusion, this analysis provides statistical evidence that the NHPCO Comfortable Dying measure has good reliability.

2b. VALIDITY. Validity, Testing, including all Threats to Validity: 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:
A high incidence of pain has been demonstsrted in patients at the end of life. This means that patients may have uncontrolled pain (i.e., be uncomfortable due to pain) when first enrolled in hospice services. Getting a patient´s pain to a comfortable level as quickly as safe and effective clinical practice allows will enhance patient quality of life and functional status, and minimize suffering for patients and family caregivers.

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)*:
Initial testing of measure performed with 686 patients in 9 hospices. Of those, 212 (31%) indicated that they were uncomfortable because of pain at the initial assessment on admission to hospice services.

2b2.2 Analytic Method *(Describe method of validity testing and rationale; if face validity, describe systematic assessment)*:
Criterion (concurrent) validity was tested by using two different wordings for the follow up question related to whether pain was managed. Patients first were asked if their pain was brought to a comfortable level within 48 hours and then they were asked if their pain was brought to an acceptable level within 48 hours. These two forms of the follow-up question were judged by the expert panel for the Comfortable Dying Measure to be equivalent in that they equally reflected patient preference and level of effectiveness achived for pain management.

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)*:
Sixty percent (N = 127)of the patients who initially responded that they were uncomfortable because of pain responded that their pain was brought to a comfortable level within 48 hours. Of those same patients, 64% (N = 136) responded that their pain was brought to an acceptable level within 48 hours. The two questions elicited very little difference in the proportion of patients replying that their pain was brought under control, indicating acceptable concurrent criterion validity of the measure.

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)*:
For 2010 calendar year quarters, the numbers for patients excluded for the measure can be imputed from the following totals:
Quarter 1: Total Admissions:13,633(mean=156.7); Patients Assessed: 12,096
Quarter 2: Total Admisisons:13,200(mean=159.0); Patients Assessed: 11,031
Quarter 3 Total Admissions:10,905(mean=145.4); Patients Assessed: 9,706
Quarter 4: Total Admissions:13,488(mean=179.8) Patients Assessed: 9,814

2b3.2 Analytic Method (*Describe type of analysis and rationale for examining exclusions, including exclusion related to patient preference)*:
N/A. Exclusions not examined; no patient level data available.

2b3.3 Results *(Provide statistical results for analysis of exclusions, e.g., frequency, variability, sensitivity analyses):*
N/A

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)*:
N/A

2b4.2 Analytic Method (*Describe methods and rationale for development and testing of risk model or risk stratification including selection of factors/variables)*:
N/A

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)*:
N/A

2b4.4 If outcome or resource use measure is not risk adjusted, provide rationale and analyses to justify lack of adjustment: The standard of care for hospices is to provide timely and effective pain management based on patient preferences for all patients regardless of primary diagnosis, underlying mechanism for pain, or other patient characteristics, including pain intensity rating. Because the measure is based on the patient´s statement of comfort/discomfort no adjustment is necessary (e.g., for patient´s who report a high pain intensity but refuse intervention aimed at lowering pain intensity levels).

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)*:
From 2004 through 2010 the National Hospice and Palliative Care Organization has collected aggregate data from hospices for the Comfortable Dying Measure. Data collected during that time provide evidence for an overall less-than-optimal performance by participant providers. Deviation from the national mean and the presence of providers with substantially higher (better) scores indicate that performance of individual hospices and the industry as a whole can be significantly improved.
The data were obtained through an ongoing collection effort by the NHCPO and submitted by hospices voluntarily providing their aggregated data. From 2004 through 2007, hospices submitted data annually through the NHPCO Data Analysis and Reporting Tools (DART) system and by manual submission of raw data files (e.g., CSV files). From 2008 to the present, participating hospices voluntarily submit data on a quarterly basis only through the DART system.
After collecting data for the specified period of time (one year / one quarter), hospices reported to NHPCO their aggregated numerator and denominator totals. The numerator represents the total number of hospice patients who reported being uncomfortable due to pain on admission and were made comfortable with regards to pain within 48 hours after admission. The denominator value represents the total number of patients admitted to the hospice during the time period who self-report being uncomfortable due to pain on admission. Hospices also reported time-period totals for admissions, patients self-reported comfort level due to pain (uncomfortable, not uncomfortable, not able to participate), and patient's comfort level due to pain after admissions (limited to patients reporting being uncomfortable due to pain on admission).

2b5.2 Analytic Method *(Describe methods and rationale to identify statistically significant and practically/meaningfully differences in performance)*:
After the submission period ends, agency-level data are aggregated to the national-level to produce the national mean percent of; admissions participating in the pain measure protocol, patients uncomfortable due to pain on admission, and patients who's pain

was brought to a comfortable level within 48 hours after admission to hospice. National means as well as agency quartile scores are reported in a National Summary Report for hospices use to compare to their own results.
Hospices evaluate their individual results for subpar performance by comparing their percent of patients whos pain was brought to a comfortable level within 48 hours of admission with the national mean and quartile scores. A score below the national average, or even below the 75th percentile, generally indicates significant room for improved pain management care.

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)*:
The seven year Comfortable Dying Measure data collection by NHPCO represents a sample of more than 625 hospice providers, reporting on over 470,000 hospice patients. Data were collected annually from 2004 through 2007 and then quarterly from 2008 through the present. The seven-year national mean score of 72.2% (SD = 4.2% 95% CI = 68.4% to 76.1%) indicates that more than a quarter of hospice patients do not receive sufficient interventions to bring their pain to a comfortable level within 48 hours after admission to hospice. The yearly national averages have stayed within a relatively narrow range of scores (minimum = 65.3%, maximum 77.4%) indicating a consistent measure performance over time.
More recent results obtained from the quarterly submissions of hospices during 2010, show a wide range of individual hospice performance within the quarter. The 2010 mean national percent of patients whose pain was brought to a comfortable level within 48 hours of admission was 72.6% (95% CI 69.1% - 76.2%). The 75th percentile of hospice's performance each quarter for 2010 was 94.7%, 98%, 100%, and 96.2% while the 25th percentile was 50%, 61.5%, 62.5%, and 55.6% respectively.

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)*:
N/A

2b6.2 Analytic Method *(Describe methods and rationale for testing comparability of scores produced by the different data sources specified in the measure)*:
N/A

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)*:
N/A

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)*: N/A

2c.2 If disparities have been reported/identified (e.g., in 1b), but measure is not specified to detect disparities, please explain:
N/A

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)*: 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)*: Quality Improvement with Benchmarking (external benchmarking to multiple organizations), Quality Improvement (Internal to the specific organization)

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.*]
Measure results are not currently reported, but the Comfortable Dying measure one of the measures selected for quality reporting by the federal government. amends the Social Security Act to authorize a quality reporting program for hospices, beginning in FY2014. The Secretary (CMS)is required to reduce the market basket update of the hospice by 2 percentage points for any hospice that does not submit comply with the quality data submission requirements. In addition, while no timeline is specified, CMS is also expected to begin planning for public reporting of results for the Comfortable Dying measure.

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: Pain is typcially considered an adverse experience and the desire for avoidance and/or management of pain can be expected to universally resonate with the public. Results from the Comfortable Dying measure can be readily understood by the public, even though those who are not clinically knowledgeable or familiar with hospice care. The concept of comfort, specifically whether (yes/no)pain was brought to a comfortable level quickly is straighforward and expressed in language that is easily comprehended. Consequently, for public reporting the Comfortable Dying measure is more advantageous than pain measures that rely on numeric or scored results that require additional interpretation.

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): As stated in 3a.1, CMS has included the Comfortable Dying measure in the proposed rule that delineates measures for hospice quality reporting as required in the Section 3004 of the Affordable Care Act.

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 Comfortable Dying measure provides information that hospices use in their Quality Assessment and Performance Improvement (QAPI) programs. Implememtation of QAPI programs is required in the Medicare Conditions of Participation for hospices.

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:
Hospices can use the qualtertly measure results provided by NHPCO to set performance improvment goals related to pain management and to monitor progress toward those those goals. Informal feedback from hospices that have implemented the Comfortable Dying measure has indicated that efforts to improve scores on the Comfortable Dying measure can have broad effects throughout a hospice´s entire pain management practice. Use of the measure has generated improvements ranging from modifications in communication and follow up of patient´s reports of pain to revision of nurse competencies for pain management.

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

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)*: Some data elements are in 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:
Potential errors in data collection and reporting have been identified during seven years of data collection. Most errors in data collection are now prevented through additional explanatory language in the Guidelines documents that are part of the measure implementation instructions. There are also several data checks built into the analysis of quarterly data, which allow for identification and correction of unlikely results.
Identified data collection errors occur usually during the follow-up when providers attempt to obtain the patient's comfort level due to pain within the 48 to 72 hours post admission period. Sometimes patients are not available (e.g., they are sleeping) verses unable (e.g., cognitively impaired) to respond at the time of follow-up. The measure protocol directs providers to attempt multiple follow-ups until the patient is available to report, however, organization can experience difficulty complying with the increased burden on staff from multiple follow-up attempts.
There are two common data reporting errors with this measure. Both errors are easily identifiable and correctable. The first common error is reporting admissions assessments on more patients than were admitted during the reporting period. A data quality check built into the analysis automatically flags this type of error which allows for reach-back to the offending organization for correction or removal of those data from inclusion in the analysis. The other common reporting error occurs when all patients are assed for comfort level due to pain after 48 hours, regardless of reported comfort level on admission. This error is also easily detectable during analysis because the total number of patients assessed on admission will equal the total number assessed at 48 hours. Again, these data errors are flagged for reach back and correction or removal from further analysis.
Finally, other types of reporting errors occur occasionally but are usually detected and flagged during analysis. The most common of the other errors is reporting more patients at follow-up than were uncomfortable due to pain on admission. This type of error usually indicates a misunderstanding of the measure protocol and is correctable with reach back to the offending hospice.
There have been no identified unintended consequences from resulting from the implementation of this measure. There are however examples of organizations revamping their processes soon after implementation of the measure. The resultant improved procedures has near-universally resulted is substantial improvement in the comfort-level of patients within the first 48 hours after admission to hospice.

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

A.2 Please check if either of the following apply (*regarding proprietary measures*):
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)*:
NHPCO maintains ongoing support(in the form of written materials and one-on-one guidance)for hospice providers who use the measure for all aspects of the FEHC survey process, ranging from survey administration to results interpretation. Monitoring of support requests has not shown any trends in problems or issues that indicated the need for modifications in the approach to data

collection. Hospices vary in size and resources, and data collection strategies employed tend to vary with the individual characteristics of the hospices. We regularly plan and implement modifications to support materials to improve clarity and assist hospice with implementation of the measure.

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)*:

CONTACT INFORMATION

Co.1 Measure Steward (Intellectual Property Owner): National Hospice and Palliative Care Organization, 1731 King Street, Suite 100, Alexandria, Virginia, 22314

Co.2 Point of Contact: Carol, Spence, PhD, cspence@nhpco.org, 703-837-3137-

Co.3 Measure Developer if different from Measure Steward: National Hospice and Palliative Care Organization, 1731 King Street, Suite 100, Alexandria, Virginia, 22314

Co.4 Point of Contact: Carol, Spence, PhD, cspence@nhpco.org, 703-837-3137-

Co.5 Submitter: Carol, Spence, PhD, cspence@nhpco.org, 703-837-3137-, National Hospice and Palliative Care Organization

Co.6 Additional organizations that sponsored/participated in measure development:
National Hospice Work Group

Co.7 Public Contact: Carol, Spence, PhD, cspence@nhpco.org, 703-837-3137-, National Hospice and Palliative Care Organization

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.

Members of Outcomes Forum - a group of experts that was convened and worked together over a three year period (1998 through 2000) to develop and test measures dervived from a commone conceptual framework as delineated in the NHPCO publication: A Pathway for Patients and Families Facing Terminal Illness. Members included:

Carla Alexander,Ina Boyd, Deborah Childs, Stephen Clauser, Chis Cody, Stephen Connor, Gail Cooney, Jeanne Dennis, Kathy Egan, Perry Fine, Melinda Garverick, Barbara Head, Marcia Lattanzi-Licht, Judi Lund-Person, Dale Lupu, Susan Mann, Melanie Merriman, Naomi Naierman, Betty Oldanie, Peggy Parks, True Ryndes, Shareefa Sabur, Sherri Solomon, Janet Snapp, Sharon Sprenger, Carol Spence, Joan Teno, Patti Thielmann.

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: N/A

Measure Developer/Steward Updates and Ongoing Maintenance

Ad.3 Year the measure was first released: 2000

Ad.4 Month and Year of most recent revision: 06, 2011

Ad.5 What is your frequency for review/update of this measure? Quarterly

Ad.6 When is the next scheduled review/update for this measure? 09, 2011

Ad.7 Copyright statement: Copyright holder of the Comfortable Dying Measure is NHPCO which makes the measure available for use free of charge with the provision it is not modified or sold.

Ad.8 Disclaimers:

Ad.9 Additional Information/Comments:

Date of Submission (*MM/DD/YY*): 06/13/2011

PATIENT OUTCOME MEASURES

Comfortable Dying Measure: Comfort Within 48 Hours of Initial Assessment after Admission

Measure Specifications

Description: Percentage of patients who reported being uncomfortable because of pain at the initial assessment after admission to hospice services whose pain was brought to a comfortable level, as defined/reported by the patient, within 48 hours of the initial assessment.

Numerator: Number of patients who reported being uncomfortable because of pain who report pain was brought to a comfortable level within 48 hours of initial assessment after admission to hospice services.
****** in data path diagram

Denominator: Number of patients who reported being uncomfortable because of pain at initial assessment after admission to hospice services.
***** in data path diagram

Steps for Measure Administration:

1. At initial assessment after admission to hospice services, prior to beginning a clinical pain assessment, the nurse will ask the question: "Are you uncomfortable because of pain?"
2. If the patient responds "yes" and does not meet the other exclusion criteria for the measure, the patient's response is documented and the patient is included in the measure.
3. If the patient responds "no" the patient's response is documented, and the patient is excluded from the measure.

4. The nurse proceeds with the clinical pain assessment, initiating intervention as clinically appropriate to improve management of patient's pain, according to the policies and procedures for pain management established by the hospice.
5. From 48 to 72 hours after the initial assessment, a hospice staff member or volunteer will contact the patient and ask the question: "Was your pain brought to a comfortable level within 48 hours of the start of hospice care?" The patient's response is documented.
6. If no patient response is obtained within 72 hours after the initial assessment, document the reason: a) patient no longer enrolled in hospice due to death; b) patient no longer enrolled in hospice due to discharge or revocation; c) patient unable to communicate due to deterioration in condition; d) follow-up not done within 72 hours; e) other reason with explanation.

Comfortable Dying Measure
Data Collection and Reporting Path