

NATIONAL QUALITY FORUM

Measure Evaluation 4.1 December 2009

This form contains the measure information submitted by stewards. Blank fields indicate no information was provided. Attachments also may have been submitted and are provided to reviewers. The subcriteria and most of the footnotes from the evaluation criteria are provided in Word comments within the form and will appear if your cursor is over the highlighted area. Hyperlinks to the evaluation criteria and ratings are provided in each section.

TAP/Workgroup (if utilized): Complete all **yellow highlighted** areas of the form. Evaluate the extent to which each subcriterion is met. Based on your evaluation, summarize the strengths and weaknesses in each section.

Note: *If there is no TAP or workgroup, the SC also evaluates the subcriteria (yellow highlighted areas).*

Steering Committee: Complete all **pink** highlighted areas of the form. Review the workgroup/TAP assessment of the subcriteria, noting any areas of disagreement; then evaluate the extent to which each major criterion is met; and finally, indicate your recommendation for the endorsement. Provide the rationale for your ratings.

Evaluation ratings of the extent to which the criteria are met

- C = Completely (unquestionably demonstrated to meet the criterion)
- P = Partially (demonstrated to partially meet the criterion)
- M = Minimally (addressed BUT demonstrated to only minimally meet the criterion)
- N = Not at all (NOT addressed; OR incorrectly addressed; OR demonstrated to NOT meet the criterion)
- NA = Not applicable (only an option for a few subcriteria as indicated)

(for NQF staff use) NQF Review #: NH-009-10	NQF Project: Nursing Homes 2010
MEASURE DESCRIPTIVE INFORMATION	
De.1 Measure Title: The Percentage of Residents on a Scheduled Pain Medication Regimen on Admission Who Self-Report a Decrease in Pain Intensity or Frequency (Short-stay)	
De.2 Brief description of measure: This measure is based on data from the MDS 3.0 assessment of short-stay nursing facility residents and reports the percentage of those short-stay residents who can self-report and who are on a scheduled pain medication regimen at admission (5-day PPS MDS assessment) and who report lower levels of pain on their discharge MDS 3.0 assessment or their 14-day PPS MDS assessment (whichever comes first) when compared with the 5-day PPS MDS assessment.	
1.1-2 Type of Measure: Outcome	
De.3 If included in a composite or paired with another measure, please identify composite or paired measure	
De.4 National Priority Partners Priority Area: Care coordination	
De.5 IOM Quality Domain: Patient-centered	
De.6 Consumer Care Need:	

CONDITIONS FOR CONSIDERATION BY NQF	
Four conditions must be met before proposed measures may be considered and evaluated for suitability as voluntary consensus standards:	NQF Staff
A. The measure is in the public domain or an intellectual property (measure steward agreement) is signed. <i>Public domain only applies to governmental organizations. All non-government organizations must sign a measure steward agreement even if measures are made publicly and freely available.</i>	A Y <input type="checkbox"/> N <input type="checkbox"/>
A.1 Do you attest that the measure steward holds intellectual property rights to the measure and the right to use aspects of the measure owned by another entity (e.g., risk model, code set)? Yes	
A.2 Indicate if Proprietary Measure (as defined in measure steward agreement):	
A.3 Measure Steward Agreement: Government entity and in the public domain - no agreement necessary	
A.4 Measure Steward Agreement attached:	

Rating: C=Completely; P=Partially; M=Minimally; N=Not at all; NA=Not applicable

B. The measure owner/steward verifies there is an identified responsible entity and process to maintain and update the measure on a schedule that is commensurate with the rate of clinical innovation, but at least every 3 years. Yes, information provided in contact section	B Y <input type="checkbox"/> N <input type="checkbox"/>
C. The intended use of the measure includes <u>both</u> public reporting <u>and</u> quality improvement. ► Purpose: Public reporting , Internal quality improvement	C Y <input type="checkbox"/> N <input type="checkbox"/>
D. The requested measure submission information is complete. Generally, measures should be fully developed and tested so that all the evaluation criteria have been addressed and information needed to evaluate the measure is provided. Measures that have not been tested are only potentially eligible for a time-limited endorsement and in that case, measure owners must verify that testing will be completed within 12 months of endorsement. D.1 Testing: No, testing will be completed within 12 months D.2 Have NQF-endorsd measures been reviewed to identify if there are similar or related measures? Yes (for NQF staff use) Have all conditions for consideration been met? Staff Notes to Steward (<i>if submission returned</i>): Staff Notes to Reviewers (<i>issues or questions regarding any criteria</i>): Staff Reviewer Name(s):	D Y <input type="checkbox"/> N <input type="checkbox"/> Met Y <input type="checkbox"/> N <input type="checkbox"/>

TAP/Workgroup Reviewer Name:	
Steering Committee Reviewer Name:	
1. IMPORTANCE TO MEASURE AND REPORT	
Extent to which the specific measure focus is important to making significant gains in health care quality (safety, timeliness, effectiveness, efficiency, equity, patient-centeredness) and improving health outcomes for a specific high impact aspect of healthcare where there is variation in or overall poor performance. <i>Measures must be judged to be important to measure and report in order to be evaluated against the remaining criteria.</i> (evaluation criteria) 1a. High Impact _____	Eval Rating
(for NQF staff use) Specific NPP goal:	
1a.1 Demonstrated High Impact Aspect of Healthcare: Patient/societal consequences of poor quality 1a.2 1a.3 Summary of Evidence of High Impact: Research indicates that at least 40-85% of nursing facility residents have persistent pain. The percentage may be even higher; research suggests that pain is often not fully documented. (1, 2, 3, 4, 5, 6, 7) Failure to identify the presence of pain or to assess its severity and functional impact is an important indicator of poor quality of care. Not identifying pain can leave a potentially treatable symptom unrecognized and therefore unlikely to be addressed. Indeed, evidence suggests that pain is consistently under-treated, particularly among individuals with cognitive impairment.(8, 9, 10) A standard measure of resident pain is needed because of gaps in nursing staff's knowledge of "best practice" pain management in hospitals and nursing facilities.(4, 11, 12, 13, 14) A standard measure also provides a benchmark for pain management practices that vary widely across nursing facilities.(14, 15, 16, 17, 18) Among the potential adverse physiological and psychological effects of unrelieved pain are impaired gastrointestinal and pulmonary function; nausea and dyspnea; increased metabolic rate, including increased tumor growth and metastasis in cancer; impaired immune response; insomnia, delayed healing, increased blood clotting, loss of appetite, and the inability to walk or move about; impairment of joint	1a C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/>

Comment [KP1]: 1a. The measure focus addresses:
 • a specific national health goal/priority identified by NQF's National Priorities Partners; OR
 • a demonstrated high impact aspect of healthcare (e.g., affects large numbers, leading cause of morbidity/mortality, high resource use (current and/or future), severity of illness, and patient/societal consequences of poor quality).

function with functional decline and increased dependency; and anxiety and depression. (17, 18, 19, 20) In the general population, unrelieved pain costs millions of dollars annually as a result of longer hospital stays, rehospitalizations, outpatient care, and emergency room visits. (21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32)

Resident pain in nursing facilities is a subject of great interest to the public. Pain management in nursing facilities is central to the Omnibus Budget Reconciliation Act of 1987 (OBRA 87) mandate to promote "maximum practicable functioning" among residents, and failure to identify and address pain denies a resident the right granted in OBRA 87 to freedom from neglect. (33) Advancing Excellence in America's Nursing Homes has made the management of resident pain one of its major goals. (34)

- 1a.4 Citations for Evidence of High Impact:**
1. Ferrell BA, Ferrell BR, Osterweil D. Pain in the nursing home. *Journal of the American Geriatrics Society*. 1990;38(4):409-14.
 2. Parmelee P, Smith B, Katz I. Pain complaints and cognitive status among elderly institution residents. *Journal of the American Geriatrics Society*. 1993;41(5):517-22.
 3. Sengstaken E, King S. The problems of pain and its detection among geriatric nursing home residents. *Journal of the American Geriatrics Society*. 1993;41(5):541-44.
 4. Weiner D, Rudy T. Attitudinal barriers to effective treatment of persistent pain in nursing home residents. *Journal of the American Geriatrics Society*. 2002;50(12):2035-40.
 5. CMS. CMS MDS Quality Measure/Indicator Report. Available from http://www.cms.hhs.gov/MDSPubOlandResRep/02_qmreport.asp?isSubmitted=qm3&group=08&qtr=14.
 6. Mor V, Zinn J, Angelelli J, Teno J, Miller S. Driven to tiers: socioeconomic and racial disparities in the quality of nursing home care. *The Milbank Quarterly*. 2004;82(2):227-56.
 7. Wu N, Miller S, Lapane K, Gozalo P. The problem of assessment bias when measuring the hospice effect on nursing home residents' pain. *Journal of Pain and Symptom Management*. 2003;26(5):998-1009.
 8. Sengstaken E, King S. The problems of pain and its detection among geriatric nursing home residents. *Journal of the American Geriatrics Society*. 1993;41(5):541-44.
 9. Cook A, Niven C, Downs M. Assessing the pain of people with cognitive impairment. *International Journal of Geriatric Psychiatry*. 1999;14(6):421-25.
 10. Won A, Lapane K, Gambassi G, Bernabei R, Mor V, Lipsitz LA. Correlates and management of nonmalignant pain in the nursing home. SAGE study group. Systematic assessment of geriatric drug use via epidemiology. *Journal of the American Geriatrics Society*. 1999;47(8):936-42.
 11. McMillan S, Tittle M, Hagan S, Laughlin J, Tabler RE. Knowledge and attitudes of nurses in veterans hospitals about pain management in patients with cancer. *Oncology Nursing Forum*. 2000;27(9):1415-23.
 12. Mrozek J, Werner J. Nurses' attitudes toward pain, pain assessment, and pain management practices in long-term care facilities. *Pain Management Nursing: Official Journal of the American Society of Pain Management Nurses*. 2001;2(4):154-62.
 13. Sloman R, Ahern M, Wright A, Brown L. Nurses' knowledge of pain in the elderly. *Journal of Pain and Symptom Management*. 2001;21(4):317-22.
 14. Cramer G, Galer B, Mendelson M, Thompson GD. A drug use evaluation of selected opioid and nonopioid analgesics in the nursing facility setting. *Journal of the American Geriatrics Society*. 2000;48(4):398-404.
 15. Allcock N, McGarry J, Elkan R. Management of pain in older people within the nursing home: a preliminary study. *Health & Social Care in the Community*. 2002;10(6):464-71.

16. Saliba D, Buchanan J. Development and validation of a revised nursing home assessment tool: MDS 3.0. Contract No. 500-00-0027/Task Order #2. Santa Monica, CA: Rand Corporation, Apr 2008. Available from <http://www.cms.hhs.gov/NursingHomeQualityInits/Downloads/MDS30FinalReport.pdf>.

17. Scherder E, Bouma A. Visual analogue scales for pain assessment in Alzheimer's disease. *Gerontology*. 2000;46(1):47-53.

18. Wrede-Seaman L. Treatment options to manage pain at the end of life. *American Journal of Hospice and Palliative Care*. 2001;18(2):89-101.

19. Sachs G, Shega J, Cox-Hayley D. Barriers to excellent end-of-life care for patients with dementia. *Journal of General Internal Medicine*. 2004;19(10):1057-63.

20. Hanson L, Tulsy J, Danis M. Can clinical interventions change care at the end of life? *Annals of Internal Medicine*. 1997;126(5):381-88. See also the statement of the American Pain Society at <http://www.ampainsoc.org/advocacy/treatment.htm>.

21. Berry P, Dahl J. The new JCAHO pain standards: implications for pain management nurses. *Pain Management Nursing*. 2001;1(1):3-12.

22. Cousins M. Acute post-operative pain (3rd ed.) Pp. 357-385 in *Textbook of Pain*. Wall PD, Melzak R (Ed.). Churchill Livingstone: New York.

23. Sydow F. The influence of anesthesia and postoperative analgesic management on lung function. *Acta Chirurgica Scandinavica*. 1988;550(suppl.):159-65.

24. Wattine M. Postoperative pain relief and gastrointestinal motility. *Acta Chirurgica Scandinavica*. 1988;550(suppl.):140-45.

25. Desbiens N, Mueller-Rizner N, Connors A, Hamel MB, Wenger NS. Pain in the oldest-old during hospitalization and up to one year later. *Journal of the American Geriatrics Society*. 1997;45:1167-72.

26. Bendebba M, Torgerson W, Long D. Personality traits, pain duration and severity, functional impairment, and psychological distress in patients with persistent low back pain. *Pain*. 1997;72:115-25.

27. Liu S, Carpenter R, Neal J. Epidural anesthesia and analgesia. *Anesthesia*. 1995;82:1474-1506.

28. McCaffery M, Pasero C. *Pain: clinical manual*. 1999. Mosby, St. Louis.

29. Hughes S, Gibbs J, Dunlop D, Edelman P, Singer R, Chang RW. Predictors of decline in manual performance in older adults. *Journal of the American Geriatrics Society*. 1997;45:905-10.

30. Casten R, Parmalee P, Kleban M, Lawton MP, Katz IR. The relationships among anxiety, depression, and pain in a geriatric institutionalized sample. *Pain*. 1995;61:271-76.

31. Grant M, Ferrell B, Rivera L, Lee J. Unscheduled readmissions for uncontrolled symptoms: a health care challenge for nurses. *Nursing Clinics of North America*. 1995;30:673-82.

32. Sheehan J, McKay J, Ryan M. What cost chronic pain? *Irish Medical Journal*. 1996;89:218-19.

33. Wiener J, Freiman M, Brown D. *Nursing home care quality twenty years after the Omnibus Budget Reconciliation Act of 1987*. 2007. RTI International.

34. *Advancing Excellence in America's Nursing Homes* Web site. Accessed January 21, 2010. Available from http://www.nhqualitycampaign.org/star_index.aspx?controls=eightgoals.

1b. Opportunity for Improvement

1b.1 Benefits (improvements in quality) envisioned by use of this measure: Use of this measure should

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Comment [KP2]: 1b. Demonstration of quality problems and opportunity for improvement, i.e., data demonstrating considerable variation, or overall poor performance, in the quality of care across providers and/or population groups (disparities in care).

prompt nursing facilities to examine their attention to pain severity in recently admitted residents and lead to an increase in pain management efforts and reduction in pain severity.

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1b.2 Summary of data demonstrating performance gap (variation or overall poor performance) across providers:

This proposed measure is a new quality measure but a quality measure examining the incidence of frequent or severe pain has been in use by CMS since 2002, drawing on data from MDS 2.0 items based on staff assessment, but otherwise similar to those items supporting this measure. Although further testing of this proposed measure will be needed, the performance of the MDS 2.0 pain items has been studied as it related to the current frequent and severe pain measure, and the results of that testing suggest that this measure is likely to exhibit an acceptable degree of variability. As conducted by the University of Colorado, the study showed an acceptable degree of variability across facilities for the current post-acute care measure in the first quarter (Q1) of 2006.(1)

See attached Table 1: Measure Variability Across Facilities.

Although the number of high-quality studies of pain management in nursing facilities is limited, the existing studies agree that resident pain is under-recognized and under-treated, with room for significant improvement.(2) For example, a recent record audit of 291 residents in 14 long-term care facilities found a significant gap between evidence-based pain management recommendations and facility practices. Assessment was particularly weak; only 32% of the cases reported pain once or twice a week, and only 3% of the cases reviewed had reported that pain impacted functioning and quality of life two or more times in the previous 30 days.(3) One study focusing on pain in cancer patients reported inadequate pain treatment for this population, with underuse of analgesics and hospice, along with nursing home staffing patterns as key issues.(4) Many studies and literature maintain that almost all pain, including pain at the end of life, can be managed with appropriate assessment and treatment, and research in pain management has identified the adoption of systematic implementation models, clinical decision-making algorithms, interdisciplinary approaches, and ongoing outcome evaluations as effective means to deliver effective pain relief in nursing facilities.(5, 6, 7, 8, 9)

1b.3 Citations for data on performance gap:

1. Brega A, Goodrich G, Nuccio E, Hittle D. Transition of publicly reported nursing home quality measures to MDS 3.0—draft. Denver: Division of Health Care Policy and Research University of Colorado at Denver, 2008.
2. Herman A, Johnson T, Ritchie C, Parmelee P. Pain management interventions in the nursing home: a structured review of the literature. *Journal of the American Geriatrics Society*. 2009;57(7):1258-67.
3. Jablonski A, Ersek M. Nursing home staff adherence to evidence-based pain management practices. *Journal of Gerontological Nursing*. 2009;35(7):28-34.
4. Duncan J, Forbes-Thompson S, Bott M. Unmet symptom management needs of nursing home residents with cancer. *Cancer Nursing*. 2008;31(4):265-73.
5. Scherder E, Bouma A. Visual analogue scales for pain assessment in Alzheimer’s disease. *Gerontology*. 2000;46(1):47-53.
6. Wrede-Seaman L. Treatment options to manage pain at the end of life. *American Journal of Hospice and Palliative Care*. 2001;18(2):89-101.
7. Sachs G, Shega J, Cox-Hayley D. Barriers to excellent end-of-life care for patients with dementia. *Journal of General Internal Medicine*. 2004;19(10):1057-63.
8. Hanson L, Tulsy J, Danis M. Can clinical interventions change care at the end of life? *Annals of Internal Medicine*. 1997;126(5):381-88. See also the statement of the American Pain Society at <http://www.ampainsoc.org/advocacy/treatment.htm>.
9. Swafford K, Miller L, Tsai P, Herr K, Ersek M. Improving the process of pain care in nursing homes: a

Comment [k3]: 1 Examples of data on opportunity for improvement include, but are not limited to: prior studies, epidemiologic data, measure data from pilot testing or implementation. If data are not available, the measure focus is systematically assessed (e.g., expert panel rating) and judged to be a quality problem.

literature synthesis. Journal of the American Geriatrics Society. 2009;57(6):1080-87.

1b.4 Summary of Data on disparities by population group:

Although there is evidence of racial segregation between nursing facilities, with African-Americans tending to be concentrated in facilities with higher deficiency ratings, there has been little study of resulting potential disparities in reported pain.(1, 2, 3) The research conducted on racial disparities in pain treatment has shown a greater incidence of untreated pain for black residents with cancer as compared to white residents with cancer.(4, 5)

Research has also identified disparities in pain management between cognitively intact residents and those who are cognitively impaired. In the current MDS pain item, staff recording of cognitive status was inversely proportional to pain report; the most cognitively impaired residents were recording as suffering the least pain and received the least pain therapy.(6)

1b.5 Citations for data on Disparities:

1. Smith D, Feng Z, Fennell M, Zinn J, Mor V. Separate and unequal: racial segregation and disparities in quality across U.S. nursing homes. Health Affairs (Millwood). 2007;26(5):1448-1558.
2. Howard D, Sloane P, Zimmerman S, Eckert J, Walsh J, Buie V, Taylor P, Koch G. Distribution of African Americans in residential care/assisted living and nursing homes: more evidence of racial disparity? American Journal of Public Health. 2002;92(8):1272-77.
3. Grabowski D. The admission of blacks to high-deficiency nursing homes. Med Care. 2004;42(5):456-64.
4. Bernabei R, Gambassi G, Lapane K, Landi F, Garsonis C, Dunlop R, Lipsitz L, Steel K, Mov V. Management of pain in elderly patients with cancer. SAGE study group. Systematic assessment of geriatric drug use via epidemiology. Journal of the American Medical Association. 1998;279(23):1877-82.
5. Hanlon J, Wang X, Good C, Rossi M, Stone R, Selma T, Handler S. Racial differences in medication use among older, long-stay Veterans Affairs nursing home care unit patients. The Consultant Pharmacist. 2009;24(6):439-46.
6. Reynolds K, Hanson L, DeVellis R, Henderson M, Steinhauser K. Disparities in pain management between cognitively intact and cognitively impaired nursing home residents. Journal of Pain and Symptom Management. 2008;35(4):388-96.

1c. Outcome or Evidence to Support Measure Focus

1c.1 Relationship to Outcomes (For non-outcome measures, briefly describe the relationship to desired outcome. For outcomes, describe why it is relevant to the target population): Pain relief is associated with increased quality of life. In addition to the discomfort associated with pain, pain leads to declines in autonomy and sense of well-being and increases in anxiety and depression.

1c.2-3. Type of Evidence: Randomized controlled trial, Observational study

1c.4 Summary of Evidence (as described in the criteria; for outcomes, summarize any evidence that healthcare services/care processes influence the outcome):

Pain has been shown to have a negative effect on quality of life. Studies have found that pain is associated with declines in autonomy, security, and spiritual well-being and increases in anxiety and depression.(1) Existing research studies reviewing the impact of pain relief interventions at the actor, decision-support, treatment, and system levels agree that pain relief leads to increased quality of life.(2, 3, 4)

1c.5 Rating of strength/quality of evidence (also provide narrative description of the rating and by whom):

The evidence has not been rated. However, there are numerous longitudinal and cross-sectional studies addressing this issue, including reviews of interventions, resident surveys and descriptive reports. The studies show that pain has a negative effect on quality of life, is associated with a decline in well-being and an increase in depression and anxiety, and that pain management can reduce pain.

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Comment [k4]: 1c. The measure focus is:
 •an outcome (e.g., morbidity, mortality, function, health-related quality of life) that is relevant to, or associated with, a national health goal/priority, the condition, population, and/or care being addressed;
 OR
 •if an intermediate outcome, process, structure, etc., there is evidence that supports the specific measure focus as follows:
 oIntermediate outcome - evidence that the measured intermediate outcome (e.g., blood pressure, Hba1c) leads to improved health/avoidance of harm or cost/benefit
 oProcess - evidence that the measured clinical or administrative process leads to improved health/avoidance of harm and if the measure focus is on one step in a multi-step care process, it measures the step that has the greatest effect on improving the specified desired outcome(s).
 oStructure - evidence that the measured structure supports the consistent delivery of effective processes or access that lead to improved health/avoidance of harm or cost/benefit.
 oPatient experience - evidence that an association exists between the measure of patient experience of health care and the outcomes, values and preferences of individuals/ the public.
 oAccess - evidence that an association exists between access to a health service and the outcomes of, or experience with, care. ... [1]

Comment [k5]: 4 Clinical care processes typically include multiple steps: assess → identify problem/potential problem → choose/plan intervention (with patient input) → provide intervention → evaluate impact on health status. If the measure focus is one step in such a multi-step process, the step with the greatest effect on the desired outcome should be selected as the focus of measurement. For example, although assessment of immunization status and recommending immunization are necessary steps, they are not sufficient to achieve the desired impact on health status - patients must be vaccinated to achieve immunity. This does not preclude consideration of measures of preventive screening interventions where there is a strong link with desired outcomes (e.g., mammography) or measures for multiple care processes that affect a single outcome.

Comment [k6]: 3 The strength of the body of evidence for the specific measure focus should be systematically assessed and rated (e.g., USPSTF grading system <http://www.ahrq.gov/clinic/uspstf07/methods/benefit.htm>). If the USPSTF grading system was not used, the grading system is explained including how it relates to the USPSTF grades or why it does not. However, evidence is not limited to quantitative studies and the best type of evidence depends upon the question being studied (e.g., randomized controlled trials appropriate for studying drug efficacy are not well suited for complex system changes). When qualitative studies are used, appropriate qualitative research criteria are used to judge the strength of the evidence.

1c.6 Method for rating evidence: The evidence has not been rated.

1c.7 Summary of Controversy/Contradictory Evidence: No contradictory evidence has been identified.

1c.8 Citations for Evidence (other than guidelines): 1. Herman AD, Johnson TM 2nd, Ritchie CS, Parmelee PA. Pain management interventions in the nursing home: a structured review of the literature. *J Am Geriatr Soc.* 2009 Jul;57(7):1258-67.

2. Degenholtz HB, Rosen J, Castle N, Mittal V, Liu D. The association between changes in health status and nursing home resident quality of life. *Gerontologist.* 2008 Oct;48(5):584-92.

3. Zanocchi M, Maero B, Nicola E, Martinelli E, Luppino A, Gonella M, Gariglio F, Fissore L, Bardelli B, Obialero R, Molaschi M. Chronic pain in a sample of nursing home residents: prevalence, characteristics, influence on quality of life (QoL). *Arch Gerontol Geriatr.* 2008 Jul-Aug;47(1):121-8.

4. Kenefick AL. Pain treatment and quality of life: reducing depression and improving cognitive impairment. *J Gerontol Nurs.* 2004 May;30(5):22-9.

1c.9 Quote the Specific guideline recommendation (including guideline number and/or page number): The specific recommendation is acute pain management in older adults.

1c.10 Clinical Practice Guideline Citation: University of Iowa Gerontological Nursing Interventions Research Center, Research Translation and Dissemination Core. 1997.

1c.11 National Guideline Clearinghouse or other URL:
http://www.guideline.gov/summary/summary.aspx?doc_id=10198&nbr=5382

1c.12 Rating of strength of recommendation (also provide narrative description of the rating and by whom):

The University of Iowa rated the relevant portions of the recommendations as follows: Pain Management Plan: 1. Develop and Document the pain management treatment plan as early in the course of acute pain episode as possible (e.g. preoperatively). 2. Set realistic comfort-function goals in collaboration with the older person. 3. Include multiple strategies in the comprehensive pain management plan. The guideline is based on research not specific to adults or disabled populations.

1c.13 Method for rating strength of recommendation (If different from USPSTF system, also describe rating and how it relates to USPSTF):

The rating system used by the recommendation employs a 5-point scale as follows:

- A. There is evidence of well-designed meta-analysis in older adults.
- B. There is evidence of well-designed controlled trials in the older adult population; randomized and nonrandomized, well-designed quasi-experimental and cohort studies in older adult populations with results that consistently support a specific action (e.g., assessment, intervention or treatment).
- C. There is evidence of observational studies (e.g., correlational, descriptive studies) or controlled trials in older adults with inconsistent results.
- D. There is evidence of integrative reviews, national clinical practice guidelines, or acute pain research in adults but not specific to older adults.
- E. There is evidence of expert opinion or multiple case reports regarding older adults.

The USPSTF grading system, described at <http://www.ahrq.gov/clinic/3rduspstf/ratings.htm>, grades the quality of the overall evidence for a service on a three-point scale (i.e., good, fair, or poor):

- Good: Evidence includes consistent results from well-designed, well-conducted studies in representative populations that directly assess the effects on health outcomes.
- Fair: Evidence is sufficient to determine the effects on health outcomes, but the strength of the evidence is limited by the number, quality, or consistency of the individual studies, generalizability to routine practice, or indirect nature of the evidence on health outcomes.
- Poor: Evidence is insufficient to assess the effects on health outcomes because of the limited number or power of studies, important flaws in their design or conduct, gaps in the chain of evidence, or the lack of information on important health outcomes.

Comment [k7]: USPSTF grading system <http://www.ahrq.gov/clinic/uspstf/grades.htm>: A - The USPSTF recommends the service. There is high certainty that the net benefit is substantial. B - The USPSTF recommends the service. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial. C - The USPSTF recommends against routinely providing the service. There may be considerations that support providing the service in an individual patient. There is at least moderate certainty that the net benefit is small. Offer or provide this service only if other considerations support the offering or providing the service in an individual patient. D - The USPSTF recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits. I - The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.

<p>1c.14 Rationale for using this guideline over others: This guideline, registered with the National Guideline Clearinghouse, addresses acute pain management for rehabilitation.</p>	
<p>TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for <i>Importance to Measure and Report</i>?</p>	1
<p>Steering Committee: Was the threshold criterion, <i>Importance to Measure and Report</i>, met? Rationale:</p>	1 Y <input type="checkbox"/> N <input type="checkbox"/>
<p>2. SCIENTIFIC ACCEPTABILITY OF MEASURE PROPERTIES</p>	
<p>Extent to which the measure, <u>as specified</u>, produces consistent (reliable) and credible (valid) results about the quality of care when implemented. (evaluation criteria)</p>	Eval Rating
<p>2a. MEASURE SPECIFICATIONS</p>	
<p>S.1 Do you have a web page where current detailed measure specifications can be obtained? S.2 If yes, provide web page URL:</p> <p>2a. Precisely Specified _____</p>	
<p>2a.1 Numerator Statement (<i>Brief, text description of the numerator - what is being measured about the target population, e.g. target condition, event, or outcome</i>): The numerator is the number of short-stay residents who have a 14-day PPS assessment or discharge assessment (whichever comes first), who can self-report, (MDS 3.0 item J200=1) and who are on a scheduled pain medication regimen (MDS 3.0 item J0100A = 1), reporting a defined reduction in pain when compared to their earlier assessment (a 5-day PPS assessment). Reduced pain is indicated, when compared to the prior assessment, there is a decrease in pain frequency (MDS 3.0 item J0400) or a decrease in pain intensity (as reported in MDS 3.0 item J0600A = 0-10, with 10 being the worst pain you can imagine, or a decrease in the verbal description of pain (MDS 3.0 item J0600B = 1-4, with 4 being very severe, horrible pain).</p> <p>2a.2 Numerator Time Window (<i>The time period in which cases are eligible for inclusion in the numerator</i>): The numerator data come from the target MDS 3.0 assessment (which may be the 14-day PPS assessment or the discharge assessment) and refers to pain reduction reported since the previous assessment (a 5-day PPS) in the selected quarter (3 month period). Change is based on the difference in pain between the admission assessment and the next assessment (either the 14 day or discharge, whichever comes first).</p> <p>2a.3 Numerator Details (<i>All information required to collect/calculate the numerator, including all codes, logic, and definitions</i>): Residents are counted if they are short-stay residents, defined as residents whose length of stay is less than or equal to 100 days. The numerator counts short-stay residents with both a 5-day PPS MDS 3.0 assessment and a 14-day PPS MDS 3.0 assessment or a discharge MDS 3.0 assessment (whichever comes first); who have been on a scheduled pain medication regimen (J0100A = 1), who self-report a reduction in pain. A reduction in pain is defined as one of the followings: 1) reduced frequency of pain between the two assessments (J0400) or reduced intensity of pain (J0600A) or reduced verbal descriptor of pain (J0600B). Higher scores of these items reflect more frequent or severe pain, and so a reduction in pain is calculated if the score on any of these items is lower compared to the score of the previous assessment.</p>	
<p>2a.4 Denominator Statement (<i>Brief, text description of the denominator - target population being measured</i>): The denominator is the total of all short-stay residents in the nursing facility who have a 5-day PPS MDS 3.0 assessment and either a 14-day PPS MDS 3.0 assessment or a discharge MDS 3.0 assessment (whichever comes first); who have been on a scheduled pain medication regimen (MDS 3.0 item J0100A = 1) and who do not meet the exclusion criteria.</p>	2a- specs C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/>
<p>2a.5 Target population gender: Female, Male</p>	

Comment [KP8]: 2a. The measure is well defined and precisely specified so that it can be implemented consistently within and across organizations and allow for comparability. The required data elements are of high quality as defined by NQF's Health Information Technology Expert Panel (HITEP) .

<p>2a.6 Target population age range: The target short-stay population includes all ages who are admitted to the nursing facility.</p>
<p>2a.7 Denominator Time Window (<i>The time period in which cases are eligible for inclusion in the denominator</i>): Denominator data come from admission (OBRA) or 5-day PPS assessments and discharge or 14-day MDS 3.0 assessments (whichever comes first) conducted during each quarter (3-month period).</p>
<p>2a.8 Denominator Details (<i>All information required to collect/calculate the denominator - the target population being measured - including all codes, logic, and definitions</i>): Residents are counted if they are short-stay residents, defined as residents whose length of stay is less than or equal to 100 days. The target population includes all short-stay residents who have had a 5-day MDS 3.0 PPS assessment (A0301.B = 1) and an MDS 3.0 discharge assessment (A0301.F = 10 or 11) or a 14-day MDS 3.0 PPS assessment (A0301.B = 2) (whichever comes first) during the selected quarter, except those who meet the exclusion criteria.</p>
<p>2a.9 Denominator Exclusions (<i>Brief text description of exclusions from the target population</i>): A resident is excluded from the denominator if there are missing data in the relevant MDS questions.</p> <p>If the short-stay facility has fewer than 20 residents in the sample, they are excluded from public reporting because of small sample size.</p>
<p>2a.10 Denominator Exclusion Details (<i>All information required to collect exclusions to the denominator, including all codes, logic, and definitions</i>): Assessments are excluded if there are missing or inconsistent data for pain in the following MDS 3.0 items: J0100A, J0400, and J0600A or J0600B. Item J0100A records whether the resident has been on a scheduled pain medication regimen. J0400 is the question about frequency of pain in the resident interview, with a 1 to 4 numeric rating response scale. J0600A is the numeric rating question about intensity of pain in the resident interview, with a 0 to 10 response scale. J0600B is the verbal descriptor scale question about the intensity of pain in the resident interview, with a 1-4 verbal descriptor response scale.</p>
<p>2a.11 Stratification Details/Variables (<i>All information required to stratify the measure including the stratification variables, all codes, logic, and definitions</i>): This is not applicable.</p>
<p>2a.12-13 Risk Adjustment Type: No risk adjustment necessary</p>
<p>2a.14 Risk Adjustment Methodology/Variables (<i>List risk adjustment variables and describe conceptual models, statistical models, or other aspects of model or method</i>): This is not applicable.</p>
<p>2a.15-17 Detailed risk model available Web page URL or attachment:</p>
<p>2a.18-19 Type of Score: Ratio</p>
<p>2a.20 Interpretation of Score:</p>
<p>2a.21 Calculation Algorithm (<i>Describe the calculation of the measure as a flowchart or series of steps</i>): For each facility, the number of short-stay residents meeting the numerator criteria and the number of (non-excluded) residents meeting the denominator criteria for this measure are counted. The facility-observed score for the measure is a prevalence score calculated as the number of residents in the facility in the numerator divided by all non-excluded residents in the denominator.</p>
<p>2a.22 Describe the method for discriminating performance (<i>e.g., significance testing</i>): Because the computed scores are not estimates, but include all residents who meet the measure criteria, in terms of discriminating performance, the computed scores can be used to make valid comparisons.</p>
<p>2a.23 Sampling (Survey) Methodology <i>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)</i>: This is not applicable.</p>

Comment [k9]: 11 Risk factors that influence outcomes should not be specified as exclusions.
12 Patient preference is not a clinical exception to eligibility and can be influenced by provider interventions.

2a.24 Data Source (Check the source(s) for which the measure is specified and tested)
 Electronic clinical data

2a.25 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 source or collection instrument is Nursing Home Minimum Data Set 3.0.

2a.26-28 Data source/data collection instrument reference web page URL or attachment: URL
http://www.cms.hhs.gov/NursingHomeQualityInits/25_NHQIMDS30.asp#TopOfPage

2a.29-31 Data dictionary/code table web page URL or attachment: URL
http://www.cms.hhs.gov/NursingHomeQualityInits/25_NHQIMDS30.asp#TopOfPage

2a.32-35 Level of Measurement/Analysis (Check the level(s) for which the measure is specified and tested)
 Facility/Agency

2a.36-37 Care Settings (Check the setting(s) for which the measure is specified and tested)
 Nursing home (NH) /Skilled Nursing Facility (SNF)

2a.38-41 Clinical Services (Healthcare services being measured, check all that apply)

TESTING/ANALYSIS

2b. Reliability testing

2b.1 Data/sample (description of data/sample and size): Yes, the testing is incomplete because the reliability testing is based on the MDS 2.0. This is a newly proposed measure.

The proposed measure is based on two pain items in MDS 3.0, Section J items J0400 and J0600, with the numerator including all those residents who have been assessed during the selected quarter and have almost constant or frequent pain (MDS 3.0 item J0400 = 1 or 2) AND at least one episode of moderate to severe pain (item J0600A = 5, 6, 7, 8, or 9 OR item J0600B = 2 or 3) OR very severe/horrible pain of any frequency (item J0600A = 10 OR item J0600B = 4) in the 5 days prior to the assessment.

Two major tests of the reliability of the current measures that evaluate pain severity have been conducted. First, the MDS 2.0 measure items and the current post-acute care pain quality measure were tested in the Data Assessment and Verification (DAVE 2) project conducted by Abt Associates. This project used a nationwide sample of randomly selected nursing homes using MDS assessments for the period from April 1 to December 31, 2006. During this project, 173 two-stage reviews were performed.(1)

Second, the University of Colorado used national facility-level quality measure data from third quarter (Q3) of 2003 through Q3 of 2006, which came from the Quality Improvement and Evaluation System (QIES) MDS Express Reports on the CMS Intranet; and Online Survey, Certification, and Reporting (OSCAR) data related to facility characteristics (e.g., state, resident census, number of beds, staffing) and certification survey results were downloaded from the QIES Workbench.(2) A 10% random sample of all Medicare-certified nursing facilities was also downloaded from MDS assessment records. Analyses were based on complete MDS data from January 2005 through March 2006, nearly complete data for April 2006, and partial data for May and June 2006.

1. Abt Associates, Inc.; Stepwise Systems, Inc.; Qualidigm. Data Assessment and Verification (DAVE 2) project—MDS two-stage discrepancy findings, April-December 2006. Cambridge, MA: Abt Associates, Inc, 2007.

2. Brega A, Hittle D, Goodrich G, Kramer A, Conway K, Levy C. Empirical review of publicly reported nursing home quality measures. Denver: Division of Health Care Policy and Research University of Colorado at Denver; Abt Associates, Inc, 2007.

Comment [KP10]: 2b. Reliability testing demonstrates the measure results are repeatable, producing the same results a high proportion of the time when assessed in the same population in the same time period.

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2b.2 Analytic Method (type of reliability & rationale, method for testing):

The DAVE 2 project used a two-stage cluster sample design to examine MDS reporting for the current measures that evaluate pain severity. A trained nurse reviewer selected a current resident with a recent assessment performed by the nursing facility within the past 14 days. In Stage 1 of this review, the nurse reviewer conducted a blind reassessment of the resident using standard MDS assessment and coding procedures (examination of the medical record; observation of the resident; interview of staff, resident, and family; and use of coding criteria). In Stage 2 of this assessment, the DAVE 2 nurse reviewer's assessment was compared to the corresponding nursing facility assessment and each discrepancy was reconciled, with the nursing facility assessor and the nurse reviewer agreeing on the appropriate response. In addition to data entering the facility MDS code, the DAVE 2 code, and the reconciled code into the MDS-QC data entry software, the DAVE 2 nurse reviewer entered a "reason code" to attribute the cause of the discrepancy, per MDS item reviewed, to an established list of reasons.

The national test of MDS 3.0 items by Saliba and Buchanan examined the agreement between assessors (reliability); the response rates for interview items; user satisfaction and feedback on changes; and the time to complete the assessment. The network of Quality Improvement Organizations was used to identify the gold-standard (research) nurses and recruit community nursing facilities to participate in the national evaluation, including a representative sample of for-profit and not-for-profit facilities and hospital-based and free-standing facilities. The gold-standard nurses were trained in the MDS 3.0 instrument, and they, in turn, trained a facility nurse from each participating nursing facility in their home states. Residents participating in the test were selected to capture a representative sample of short- and long-stay residents.

2b.3 Testing Results (reliability statistics, assessment of adequacy in the context of norms for the test conducted):

The DAVE 2 project found a two-stage discrepancy rate of 7.3% for the MDS 2.0 pain frequency item (J0400) and 9.1% for the MDS 2.0 pain intensity item (J0600). (1) These MDS 2.0 measure items correspond to J0400 and J0600 of MDS 3.0, which are essentially the same in scope, although they rely on a nurse assessment rather than a resident report.

The national pilot test of the MDS 3.0 items showed good reliability with little evidence of confusion. For the pain items, the average kappa for gold-standard nurse to gold-standard nurse agreement was .961, and the average kappa for gold-standard nurse to facility nurse agreement was .967. (2)

1. Abt Associates, Inc.; Stepwise Systems, Inc.; Qualidigm. Data Assessment and Verification (DAVE 2) project—MDS two-stage discrepancy findings, April-December 2006. Cambridge, MA: Abt Associates, Inc, 2007.
2. Saliba D, Buchanan J. Development and validation of a revised nursing home assessment tool: MDS 3.0. Contract No. 500-00-0027/Task Order #2. Santa Monica, CA: Rand Corporation, Apr 2008. Available from <http://www.cms.hhs.gov/NursingHomeQualityInits/Downloads/MDS30FinalReport.pdf>.

Comment [k11]: 8 Examples of reliability testing include, but are not limited to: inter-rater/abstractor or intra-rater/abstractor studies; internal consistency for multi-item scales; test-retest for survey items. Reliability testing may address the data items or final measure score.

2c. Validity testing

2c.1 Data/sample (description of data/sample and size): The data came from two sources: (1) national facility-level quality measure data from Q3 of 2003 through Q3 of 2006, which came from the QIES MDS Express Reports on the CMS Intranet; and (2) OSCAR data related to facility characteristics (e.g., state, resident census, number of beds, staffing) and certification survey results were downloaded from the QIES Workbench. A 10% random sample of all Medicare-certified nursing facilities was also downloaded from MDS assessment records. Analyses were based on complete MDS data from January 2005 through March 2006, nearly complete data for April 2006, and partial data for May and June 2006.

Information for this response and the other responses in regard to Validity Testing is from:

1. Brega A, Hittle D, Goodrich G, Kramer A, Conway K, Levy C. Empirical review of publicly reported nursing home quality measures. Denver: Division of Health Care Policy and Research University of Colorado at Denver; Abt Associates, Inc, 2007.

Comment [KP12]: 2c. Validity testing demonstrates that the measure reflects the quality of care provided, adequately distinguishing good and poor quality. If face validity is the only validity addressed, it is systematically assessed.

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2. Brega A, Goodrich G, Nuccio E, Hittle D. Transition of publicly reported nursing home quality measures to MDS 3.0—draft. Denver: Division of Health Care Policy and Research University of Colorado at Denver, 2008.

2c.2 Analytic Method (*type of validity & rationale, method for testing*):

The analysis evaluated measure validity in a number of ways to examine the expected positive influence of public reporting on quality of care, which is an assessment of the degree to which quality measure triggering rates have improved over time; evaluate convergent validity, which is an assessment of the correlation of the quality measure with all other measures; determine if the quality measure triggering rate was influenced by factors that are unrelated to facility quality, which is an evaluation of seasonal variations in triggering rates across the 13 quarters of data. The analysis also computed descriptive statistics and conducted a one-way analysis of variance (ANOVA) for the measure to examine the amount of variance in triggering rates explained by the state where a facility was located.

2c.3 Testing Results (*statistical results, assessment of adequacy in the context of norms for the test conducted*):

These results reflect the performance of the current post-acute and chronic care pain measures and the underlying MDS 2.0 items for those measures, which measure the same pain factors as the MDS 3.0 items for the proposed measure. In the proposed measure, data will be collected directly from the resident.

Only 8.0% of the variance in report rate for the current post acute care pain measure was explained by the state where a facility was located. The analysis found that public reporting may have had some influence on the decreased report of pain over time due to the decline in the triggering rate.

See attached Table 2: Measure Trends Over Time.

The current chronic care pain measure has also demonstrated a correlation of .55 with the current post-acute care pain measure, although correlations with other clinical measures are weak.

See attached Table 3: Correlations of Quality Measures.

There is little evidence of seasonal variations, as shown by the previously mentioned rates, and the analysis found that only 8% of the variance in report rate for this measure was explained by the state where a facility was located. The limited correlation to other clinical measures may reflect the multiplicity of causes and potential treatments for pain, and the limited variation in seasonal rate and rate among states makes this measure a reliable guide to the level of reported pain.

2d. Exclusions Justified

2d.1 Summary of Evidence supporting exclusion(s):

All short-stay residents for which complete data exists are included. Excluding missing data for existing quality measures is standard practice and was initially endorsed by NQF. Missing data is excluded from the calculation of the quality measures for several reasons. 1) There are legitimate reasons for facility staff not to select a 'dash' rather than a response; for example, if a resident is discharged or transferred abruptly, the staff may not be able to complete all items, however, an assessment is required for payment. The intent of the 'dash' is to allow the facility to submit an assessment when the staff are unable to complete the entire assessment. 2) Historically there has been very little missing data. For example, the current quality measure "Percent of residents who were physically restrained", is based on three fields on the MDS 3.0. For all of the non-admission target assessments for calendar year 2009, there were 5,242,022 such assessments and 629 assessments (0.012%) had a dash for one or more of the three fields for the physical restraint measure. 3) We remain concerned about a change in measure definition that may result in incentivizing the facility staff to fill in a response to avoid a missing item. We believe that the result will lead to decreased validity and usefulness of the measure.

2d.2 Citations for Evidence:

This is not applicable.

2d.3 Data/sample (*description of data/sample and size*): This is not applicable.

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Comment [k13]: 9 Examples of validity testing include, but are not limited to: determining if measure scores adequately distinguish between providers known to have good or poor quality assessed by another valid method; correlation of measure scores with another valid indicator of quality for the specific topic; ability of measure scores to predict scores on some other related valid measure; content validity for multi-item scales/tests. Face validity is a subjective assessment by experts of whether the measure reflects the quality of care (e.g., whether the proportion of patients with BP < 140/90 is a marker of quality). If face validity is the only validity addressed, it is systematically assessed (e.g., ratings by relevant stakeholders) and the measure is judged to represent quality care for the specific topic and that the measure focus is the most important aspect of quality for the specific topic.

Comment [KP14]: 2d. Clinically necessary measure exclusions are identified and must be:
 •supported by evidence of sufficient frequency of occurrence so that results are distorted without the exclusion;
 AND
 •a clinically appropriate exception (e.g., contraindication) to eligibility for the measure focus;
 AND
 •precisely defined and specified:
 –if there is substantial variability in exclusions across providers, the measure is specified so that exclusions are computable and the effect on the measure is transparent (i.e., impact clearly delineated, such as number of cases excluded, exclusion rates by type of exclusion);
 if patient preference (e.g., informed decision-making) is a basis for exclusion, there must be evidence that it strongly impacts performance on the measure and the measure must be specified so that the information about patient preference and the effect on the measure is transparent (e.g., numerator category computed separately, denominator exclusion category computed separately).

Comment [k15]: 10 Examples of evidence that an exclusion distorts measure results include, but are not limited to: frequency of occurrence, sensitivity analyses with and without the exclusion, and variability of exclusions across providers.

<p>2d.4 Analytic Method (<i>type analysis & rationale</i>): This is not applicable.</p> <p>2d.5 Testing Results (<i>e.g., frequency, variability, sensitivity analyses</i>): This is not applicable.</p>	
<p>2e. Risk Adjustment for Outcomes/ Resource Use Measures</p> <p>2e.1 Data/sample (<i>description of data/sample and size</i>): This is not applicable.</p> <p>2e.2 Analytic Method (<i>type of risk adjustment, analysis, & rationale</i>): This is not applicable.</p> <p>2e.3 Testing Results (<i>risk model performance metrics</i>): This is not applicable.</p> <p>2e.4 If outcome or resource use measure is not risk adjusted, provide rationale: No adequate risk adjustment has been developed.</p>	<p>2e C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/> NA <input type="checkbox"/></p>
<p>2f. Identification of Meaningful Differences in Performance</p> <p>2f.1 Data/sample from Testing or Current Use (<i>description of data/sample and size</i>): These results reflect the performance of the current post-acute care pain measure and the underlying MDS 2.0 items for that measure, which measures the same pain factors as the MDS 3.0 items for the proposed measure. In the proposed measure, data will be collected directly from the resident.</p> <p>The data came from two sources: (1) national facility-level quality measure data from Q3 of 2003 through Q3 of 2006, which came from the QIES MDS Express Reports on the CMS Intranet; and (2) OSCAR data related to facility characteristics (e.g., state, resident census, number of beds, staffing) and certification survey results were downloaded from QIES Workbench. A 10% random sample of all Medicare-certified nursing facilities was also downloaded from MDS assessment records. Analyses were based on complete MDS data from January 2005 through March 2006, nearly complete data for April 2006, and partial data for May and June 2006.</p> <p>2f.2 Methods to identify statistically significant and practically/meaningfully differences in performance (<i>type of analysis & rationale</i>): Because the computed scores are not estimates, but include all residents who meet the measure criteria, in terms of discriminating performance, the computed scores can be used to make valid comparisons.</p> <p>2f.3 Provide Measure Scores from Testing or Current Use (<i>description of scores, e.g., distribution by quartile, mean, median, SD, etc.; identification of statistically significant and meaningfully differences in performance</i>): An analytical team at the University of Colorado's Health Sciences Center examined the triggering rates for the measure at the facility level. Below are the measure scores from testing or current use (description of scores [e.g., distribution by quartile, mean, median, standard deviation], identification of statistically significant and meaningfully differences in performance). For 10,976 facilities, the mean triggering rate was 21.7% with a standard deviation of 14.2%. The following table reports the full results of the analysis: See attached Table 1: Measure Variability Across Facilities.</p>	<p>2f C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/></p>
<p>2g. Comparability of Multiple Data Sources/Methods</p> <p>2g.1 Data/sample (<i>description of data/sample and size</i>): This is not applicable.</p>	<p>2g C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/></p>

Comment [KP16]: 2e. For outcome measures and other measures (e.g., resource use) when indicated:

- an evidence-based risk-adjustment strategy (e.g., risk models, risk stratification) is specified and is based on patient clinical factors that influence the measured outcome (but not disparities in care) and are present at start of care. OR rationale/data support no risk adjustment.

Comment [k17]: 13 Risk models should not obscure disparities in care for populations by including factors that are associated with differences/inequalities in care such as race, socioeconomic status, gender (e.g., poorer treatment outcomes of African American men with prostate cancer, inequalities in treatment for CVD risk factors between men and women). It is preferable to stratify measures by race and socioeconomic status rather than adjusting out differences.

Comment [KP18]: 2f. Data analysis demonstrates that methods for scoring and analysis of the specified measure allow for identification of statistically significant and practically/clinically meaningful differences in performance.

Comment [k19]: 14 With large enough sample sizes, small differences that are statistically significant may or may not be practically or clinically meaningful. The substantive question may be, for example, whether a statistically significant difference of one percentage point in the percentage of patients who received smoking cessation counseling (e.g., 74% v. 75%) is clinically meaningful; or whether a statistically significant difference of \$25 in cost for an episode of care (e.g., \$5,000 v. \$5,025) is practically meaningful. Measures with overall poor performance may not demonstrate much variability across providers.

Comment [KP20]: 2g. If multiple data sources/methods are allowed, there is demonstration they produce comparable results.

<p>2g.2 Analytic Method (<i>type of analysis & rationale</i>): This is not applicable.</p> <p>2g.3 Testing Results (<i>e.g., correlation statistics, comparison of rankings</i>): This is not applicable.</p>	<p>N <input type="checkbox"/> NA <input type="checkbox"/></p>
<p>2h. Disparities in Care</p> <p>2h.1 If measure is stratified, provide stratified results (<i>scores by stratified categories/cohorts</i>): The measure is not stratified.</p> <p>2h.2 If disparities have been reported/identified, but measure is not specified to detect disparities, provide follow-up plans: Although MDS 3.0 collects data on the resident's race, there are no current plans to stratify the measure by race because facilities tend to be homogenous by race, making disparities generally evident in the rating of the facility. (1, 2, 3) In the MDS 3.0, new pain items were included that focus on patient interview and have been shown to be able to be answered by cognitively impaired residents. (4) However, the sample size at the facility level may not support stratification, but this will be evaluated in the future as MDS 3.0 data become available.</p> <p>1. Smith D, Feng Z, Zinn J, Mor V. 2008. Racial disparities in access to long-term care: the illusive pursuit of equity. <i>Journal of Health Politics, Policy, and Law</i>. 2008;33(5):861-81.</p> <p>2. Smith D, Feng Z, Fennell M, Zinn J, Mor V. Separate and unequal: racial segregation and disparities in quality across U.S. nursing homes. <i>Health Affairs (Millwood)</i>. 2007;26(5):1448-1558.</p> <p>3. Mor V, Berg K, Angelelli J, Gifford D, Morris J, Moore T. 2003. The quality of quality measurement in U.S. nursing homes. <i>The Gerontologist</i>. 2003;43(Special Issue II):37-46.</p> <p>4. Reynolds K, Hanson L, DeVellis R, Henderson M, Steinhauser K. Disparities in pain management between cognitively intact and cognitively impaired nursing home residents. <i>Journal of Pain and Symptom Management</i>. 2008;35(4):388-96.</p> <p>5. Saliba D, Buchanan J. Development and validation of a revised nursing home assessment tool: MDS 3.0. Contract No. 500-00-0027/Task Order #2. Santa Monica, CA: Rand Corporation, Apr 2008. Available from http://www.cms.hhs.gov/NursingHomeQualityInits/Downloads/MDS30FinalReport.pdf.</p>	<p>2h C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/> NA <input type="checkbox"/></p>
<p>TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for <i>Scientific Acceptability of Measure Properties</i>?</p>	<p>2</p>
<p>Steering Committee: Overall, to what extent was the criterion, <i>Scientific Acceptability of Measure Properties</i>, met? Rationale:</p>	<p>2 C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/></p>
<p>3. USABILITY</p>	
<p>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)</p>	<p>Eval Rating</p>
<p>3a. Meaningful, Understandable, and Useful Information</p> <p>3a.1 Current Use: Testing not yet completed</p> <p>3a.2 Use in a public reporting initiative (disclosure of performance results to the public at large) (<i>If used in a public reporting initiative, provide name of initiative(s), locations, Web page URL(s). If not publicly reported, state the plans to achieve public reporting within 3 years</i>): It is intended that the proposed measure will be publicly reported when the quality measures generated from MDS 3.0 data are added to the Nursing Home Compare website. Public reporting of the nursing home quality measures based on MDS 3.0 data is expected in early 2012.</p>	<p>3a C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/></p>

Comment [KP21]: 2h. If disparities in care have been identified, measure specifications, scoring, and analysis allow for identification of disparities through stratification of results (e.g., by race, ethnicity, socioeconomic status, gender); OR rationale/data justifies why stratification is not necessary or not feasible.

Comment [KP22]: 3a. Demonstration that information produced by the measure is meaningful, understandable, and useful to the intended audience(s) for both public reporting (e.g., focus group, cognitive testing) and informing quality improvement (e.g., quality improvement initiatives). An important outcome that may not have an identified improvement strategy still can be useful for informing quality improvement by identifying the need for and stimulating new approaches to improvement.

<p>3a.3 If used in other programs/initiatives <i>(If used in quality improvement or other programs/initiatives, name of initiative(s), locations, Web page URL(s). If not used for QI, state the plans to achieve use for QI within 3 years):</i> CMS expects that this quality measure will be used by nursing facilities as a tool to monitor the effectiveness of their pain management efforts.</p> <p>A pain management measure is also supported by the Mission of the Advancing Excellence in America's Nursing Homes Campaign, a cooperative quality program sponsored by long-term care providers; consumers and advocates; and nursing facility practitioners, including nurses, health care professionals, medical directors, nursing home administrators, government agencies, quality improvement organizations, and private organizations supporting nursing facility education. The campaign has proposed many goals for pain management in short-term care. First, the national average of moderate or severe pain experienced by post-acute residents will be at or below 16%. Second, 30% of nursing facilities will regularly report rates of moderate or severe pain for post-acute residents at or below 7%. Third, the average of the scores of the nursing facilities exceeding the 2009 Q1 90th percentile (n = 1,182) will be reduced from 48% to 34%. Fourth, by December 2011, there will be 5,000 fewer short-stay nursing facility residents experiencing moderate to severe pain per 100,000 residents. Applying this to the current post-acute care pain denominator of approximately 800,000 results in 40,000 fewer short-stay residents with moderate to severe pain. Fifth, each state will attain an average facility-level improvement of one decile. Lastly, each nursing facility will set a specific target to improve the prevalence of post-acute care pain by one decile rank over a 24-month period. (http://www.nhqualitycampaign.org/files/impguides/5_Pain_TAW_Guide_FINAL_Oct_15.pdf).</p> <p>Testing of Interpretability <i>(Testing that demonstrates the results are understood by the potential users for public reporting and quality improvement)</i> 3a.4 Data/sample <i>(description of data/sample and size):</i> A recent study examined found consumers could accurately interpret the quality information given for all the measures reported by Nursing Home Compare.(1)</p> <p>Data were collected from 4,754 family members of nursing home residents.</p> <p>1. Castle N. The Nursing Home Compare report card: consumers' use and understanding. <i>Journal of Aging and Social Policy</i>. 2009;21(2):187-208.</p> <p>3a.5 Methods <i>(e.g., focus group, survey, QI project):</i> A comprehension index was used to examine whether the information contained in Nursing Home Compare for each quality measure was understood by family members.</p> <p>3a.6 Results <i>(qualitative and/or quantitative results and conclusions):</i> The study found that 31% of the consumers used the Internet to help them choose a nursing facility, 12% recalled using Nursing Home Compare, and, in general, the consumers' comprehension index scores were high, indicating a good understanding. The comprehension index for the current post-acute care pain measure was among the highest, 5.62 on a scale of 1 to 8. Although the proposed measure is new, it is based on the same MDS items as the current pain measure.</p>	
<p>3b/3c. Relation to other NQF-endorsed measures</p> <p>3b.1 NQF # and Title of similar or related measures: The proposed new measure is related to NQF #0186—Recently hospitalized residents who experienced moderate to severe pain at any time during the 7-day assessment period. NQF #0192 Residents who experience moderate to severe pain during the 7-day assessment period (risk-adjusted). NQF #0177 Improvement in pain interfering with activity NQF#0523 Pain Assessment Conducted; NQF#0420 Pain Assessment Prior to Initiation of Patient Therapy NQF#0524 Pain Interventions Implemented.</p>	
<p>(for NQF staff use) Notes on similar/related endorsed or submitted measures:</p>	
<p>3b. Harmonization</p>	<p>3b <input type="checkbox"/></p>

Comment [KP23]: 3b. The measure specifications are harmonized with other measures, and are applicable to multiple levels and settings.

<p>If this measure is related to measure(s) already endorsed by NQF (e.g., same topic, but different target population/setting/data source <u>or</u> different topic but same target population):</p> <p>3b.2 Are the measure specifications harmonized? If not, why?</p> <p>No. All the above measures are based on other instruments except for NQF #0186 and NQF #0192, which are being replaced as the data source is changing; the MDS 2.0 is being replaced by the MDS 3.0.</p>	<p>P <input type="checkbox"/></p> <p>M <input type="checkbox"/></p> <p>N <input type="checkbox"/></p> <p>NA <input type="checkbox"/></p>
<p>3c. Distinctive or Additive Value</p> <p>3c.1 Describe the distinctive, improved, or additive value this measure provides to existing NQF-endorsed measures:</p> <p>This proposed short-stay measure reports the success of the nursing facility in addressing the pain upon admission for short-stay residents. The two existing MDS 2.0-based pain measures for the nursing facility population will be replaced with measures based on the MDS 3.0. The two proposed measures report the prevalence of pain among the short-stay and long-stay residents.</p> <p>5.1 If this measure is similar to measure(s) already endorsed by NQF (i.e., on the same topic and the same target population), Describe why it is a more valid or efficient way to measure quality:</p> <p>This measure is not being proposed to replace other nursing facility pain measures, but rather to supplement them.</p>	<p>3c</p> <p>C <input type="checkbox"/></p> <p>P <input type="checkbox"/></p> <p>M <input type="checkbox"/></p> <p>N <input type="checkbox"/></p> <p>NA <input type="checkbox"/></p>
<p>TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for Usability?</p>	<p>3</p>
<p>Steering Committee: Overall, to what extent was the criterion, Usability, met?</p> <p>Rationale:</p>	<p>3</p> <p>C <input type="checkbox"/></p> <p>P <input type="checkbox"/></p> <p>M <input type="checkbox"/></p> <p>N <input type="checkbox"/></p>
<p>4. FEASIBILITY</p>	
<p>Extent to which the required data are readily available, retrievable without undue burden, and can be implemented for performance measurement. (evaluation criteria)</p>	<p>Eval Rating</p>
<p>4a. Data Generated as a Byproduct of Care Processes</p> <p>4a.1-2 How are the data elements that are needed to compute measure scores generated?</p> <p>Data generated as byproduct of care processes during care delivery (Data are generated and used by healthcare personnel during the provision of care, e.g., blood pressure, lab value, medical condition), Coding/abstraction performed by someone other than person obtaining original information (E.g., DRG, ICD-9 codes on claims, chart abstraction for quality measure or registry)</p>	<p>4a</p> <p>C <input type="checkbox"/></p> <p>P <input type="checkbox"/></p> <p>M <input type="checkbox"/></p> <p>N <input type="checkbox"/></p>
<p>4b. Electronic Sources</p> <p>4b.1 Are all the data elements available electronically? (elements that are needed to compute measure scores are in defined, computer-readable fields, e.g., electronic health record, electronic claims)</p> <p>No</p> <p>4b.2 If not, specify the near-term path to achieve electronic capture by most providers.</p> <p>Not applicable.</p>	<p>4b</p> <p>C <input type="checkbox"/></p> <p>P <input type="checkbox"/></p> <p>M <input type="checkbox"/></p> <p>N <input type="checkbox"/></p>
<p>4c. Exclusions</p> <p>4c.1 Do the specified exclusions require additional data sources beyond what is required for the numerator and denominator specifications?</p> <p>No</p> <p>4c.2 If yes, provide justification.</p>	<p>4c</p> <p>C <input type="checkbox"/></p> <p>P <input type="checkbox"/></p> <p>M <input type="checkbox"/></p> <p>N <input type="checkbox"/></p> <p>NA <input type="checkbox"/></p>
<p>4d. Susceptibility to Inaccuracies, Errors, or Unintended Consequences</p> <p>4d.1 Identify susceptibility to inaccuracies, errors, or unintended consequences of the measure and describe how these potential problems could be audited. If audited, provide results.</p>	<p>4d</p> <p>C <input type="checkbox"/></p> <p>P <input type="checkbox"/></p> <p>M <input type="checkbox"/></p>

Comment [k24]: 16 Measure harmonization refers to the standardization of specifications for similar measures on the same topic (e.g., *influenza immunization* of patients in hospitals or nursing homes), or related measures for the same target population (e.g., eye exam and HbA1c for *patients with diabetes*), or definitions applicable to many measures (e.g., age designation for children) so that they are uniform or compatible, unless differences are dictated by the evidence. The dimensions of harmonization can include numerator, denominator, exclusions, and data source and collection instructions. The extent of harmonization depends on the relationship of the measures, the evidence for the specific measure focus, and differences in data sources.

Comment [KP25]: 3c. Review of existing endorsed measures and measure sets demonstrates that the measure provides a distinctive or additive value to existing NQF-endorsed measures (e.g., provides a more complete picture of quality for a particular condition or aspect of healthcare, is a more valid or efficient way to measure).

Comment [KP26]: 4a. For clinical measures, required data elements are routinely generated concurrent with and as a byproduct of care processes during care delivery. (e.g., BP recorded in the electronic record, not abstracted from the record later by other personnel; patient self-assessment tools, e.g., depression scale; lab values, meds, etc.)

Comment [KP27]: 4b. The required data elements are available in electronic sources. If the required data are not in existing electronic sources, a credible, near-term path to electronic collection by most providers is specified and clinical data elements are specified for transition to the electronic health record.

Comment [KP28]: 4c. Exclusions should not require additional data sources beyond what is required for scoring the measure (e.g., numerator and denominator) unless justified as supporting measure validity.

Comment [KP29]: 4d. Susceptibility to inaccuracies, errors, or unintended consequences and the ability to audit the data items to detect such problems are identified.

The proposed measure, which relies on resident self-report, is based on MDS 3.0 items, which may under-report pain for those nursing facility residents who are unable to report their pain, generally due to dementia. However, patient self-report of the presence and severity of pain, which is incorporated in the MDS 3.0 items supporting the proposed measure, is considered the most reliable and accurate approach to pain assessment. Both the American Geriatrics Society Panel on Persistent Pain in Older Persons and the Department of Veterans Affairs endorse this approach. (1, 2) A growing number of studies and other literature demonstrate that even nursing home residents with moderate to severe cognitive impairment can reliably respond to questions about pain.(3, 4, 5, 6, 7, 8) Several studies in elders with varying cognitive status suggest that some tools may be more reliable and "user friendly" than others for obtaining self-reports of pain from this population, and the new items in MDS 3.0 incorporate these more reliable and user-friendly approaches.(8, 9, 10, 11, 12, 13) A national test of the MDS 3.0 items supporting the proposed measure found that 87% of the test sample of residents and 89% of a validation sample of residents were able to successfully complete the pain interview portion of the MDS 3.0 upon which this measure is based.(9) The proposed measure also uses a standard scale for the resident interview, with a standardized scale of 1 (almost constantly) to 4 (rarely) for frequency of pain and a choice of standardized scales of 0 (no pain) to 10 (worst pain you can imagine) or 1 (mild) to 5 (very severe, horrible) for pain intensity.(9) Further testing may be needed to test whether the number of residents who cannot be interviewed will be higher when MDS 3.0 is placed into general use.(13)

N

An example of an unintended consequence of this measure may occur if residents report that pain frequency decreased, however, pain intensity increased; or the reverse occurs, if pain intensity decreased but pain frequency increased. As part of the validation testing for this measure, RTI will examine responses for change, lack of change, and direction of change as well as patterns of both the frequency and intensity to assess whether there is an effect on the face validity of the measure.

1. American Geriatrics Society Panel on Persistent Pain in Older Persons. The management of persistent pain in older persons. J Am Geriatr Soc. 2002;50:S205-44.
2. Department of Veterans Affairs. VHA directive 2003-021: pain management. 2003.
3. Parmelee PA, Smith B, Katz IR. Pain complaints and cognitive status among elderly institution residents. J Am Geriatr Soc. 1993;41(5):517-22.
4. Engle V, Graney M, Chan A. Accuracy and bias of licensed practical nurse and nursing assistant ratings of nursing home residents' pain. J Gerontol A Biol Sci Med Sci. 2001;56(7):M405-11.
5. Parmelee P. Pain in cognitively impaired older persons. Clin Geriatr Med. 1996;12(3):473-87.
6. Ferrell B, Ferrell B, Rivera L. Pain in cognitively impaired nursing home patients. J Pain Symptom Manage. 1995;10(8):591-8.
7. Weiner D, Peterson B, Ladd K, McConnell E, Keefe F. Pain in nursing home residents: an exploration of prevalence, staff perspectives, and practical aspects of measurement. Clin J Pain. 1999;15(2):92-101.
8. Wynne F, Ling S, Reimsburg R. Comparison of pain assessment instruments in cognitively intact and cognitively impaired nursing home residents. Geriatr Nurs. 2000;21(1):20-3.
9. Saliba D, Buchanan J. Development and validation of a revised nursing home assessment tool: MDS 3.0. Contract No. 500-00-0027/Task Order #2. Santa Monica, CA: Rand Corporation, Apr 2008. Available from <http://www.cms.hhs.gov/NursingHomeQualityInits/Downloads/MDS30FinalReport.pdf>.
10. Ferrell BA, Ferrell BR, Osterweil D. Pain in the nursing home. J Am Geriatr Soc. 1990;38(4):409-14
11. Scherder EJ, Bouma A. Visual analogue scales for pain assessment in Alzheimer's disease. Gerontol. 2000;46(1):47-53.
12. Krulewicz H, London M, Skakel V, Lundstedt GJ, Thomason H, Brummel-Smith K. Assessment of pain in cognitively impaired older adults: a comparison of pain assessment tools and their use by nonprofessional caregivers. J Am Geriatr Soc. 2000;48(12):1607-11.
13. Herr K, Mobily P. Comparison of selected pain assessment tools for use with the elderly. Appl Nurs Res. 1993;6(1):39-46.
14. Manz B, Mosier R, Nusser-Gerlach M, Bergstrom N, Agrawal S. Pain assessment in the cognitively impaired and unimpaired elderly. Pain Manag Nurs. 2000;1(4):106-115.
15. RTI International. Transition of Publicly Reported Nursing Home Measures to MDS 3.0 Draft Technical Expert Panel Report. 2009.

This was not audited.

4e. Data Collection Strategy/Implementation

4e

Comment [KP30]: 4e. Demonstration that the data collection strategy (e.g., source, timing, frequency, sampling, patient confidentiality, etc.) can be implemented (e.g., already in operational use, or testing demonstrates that it is ready to put into operational use).

<p>4e.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/frequency of data collection, patient confidentiality, time/cost of data collection, other feasibility/ implementation issues: The data collection method is already in operational use, and no issues are anticipated. However, the items used to collect information about pain are new and will require additional staff training, which CMS is developing.</p> <p>4e.2 Costs to implement the measure (<i>costs of data collection, fees associated with proprietary measures</i>): Data are collected as part of an existing process with no additional cost.</p> <p>4e.3 Evidence for costs: This is not applicable.</p> <p>4e.4 Business case documentation: The proposed measure relies on data from the MDS 3.0. As there is no change in the data collection method for the MDS 3.0 as compared with its predecessor, the MDS 2.0, we do not anticipate any additional burden to nursing facilities. MDS 2.0, and soon to be MDS 3.0, data are collected as part of an existing, federally mandated process used for payment and quality monitoring purposes.</p>	C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/>
<p>TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for <i>Feasibility</i>?</p>	4
<p>Steering Committee: Overall, to what extent was the criterion, <i>Feasibility</i>, met? Rationale:</p>	4 C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/>
RECOMMENDATION	
<p>(for NQF staff use) Check if measure is untested and only eligible for time-limited endorsement.</p>	Time-limited <input type="checkbox"/>
<p>Steering Committee: Do you recommend for endorsement? Comments:</p>	Y <input type="checkbox"/> N <input type="checkbox"/> A <input type="checkbox"/>
CONTACT INFORMATION	
<p>Co.1 Measure Steward (Intellectual Property Owner) Co.1 Organization Centers for Medicare & Medicaid Services, 7500 Security Boulevard , Mail Stop S3-02-01, Baltimore, Maryland, 21244-1850</p> <p>Co.2 Point of Contact Judith, Tobin, PT, MBA, Judith.Tobin@cms.hhs.gov, 410-786-6892-</p>	
<p>Measure Developer If different from Measure Steward Co.3 Organization RTI International, 1440 Main Street, Suite 310, Waltham, Massachusetts, 02451-1623</p> <p>Co.4 Point of Contact Roberta, Constantine, RN, MBA, PhD, rconstantine@rti.org, 781-434-1700-1711</p>	
<p>Co.5 Submitter If different from Measure Steward POC Roberta, Constantine, RN, MBA, PhD, rconstantine@rti.org, 781-434-1700-1711, RTI International</p>	
<p>Co.6 Additional organizations that sponsored/participated in measure development</p>	

ADDITIONAL INFORMATION
<p>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. See attached Table 4: Nursing Home Quality Measures Technical Expert Panel (January 2009).</p> <p>This technical expert panel met during 2 days in January 2009 to review an environmental scan of the current quality measures and make recommendations regarding their transition from MDS 2.0 to MDS 3.0.</p>
<p>Ad.2 If adapted, provide name of original measure: This is not applicable. Ad.3-5 If adapted, provide original specifications URL or attachment</p>
<p>Measure Developer/Steward Updates and Ongoing Maintenance Ad.6 Year the measure was first released: Ad.7 Month and Year of most recent revision: 02, 2010 Ad.8 What is your frequency for review/update of this measure? Every 3 years Ad.9 When is the next scheduled review/update for this measure? 02, 2013</p>
<p>Ad.10 Copyright statement/disclaimers:</p>
<p>Ad.11 -13 Additional Information web page URL or attachment: Attachment Pain Management Short Stay tables_FINAL.doc</p>
<p>Date of Submission (MM/DD/YY): 10/11/2010</p>

1c. The measure focus is:

- an outcome (e.g., morbidity, mortality, function, health-related quality of life) that is relevant to, or associated with, a national health goal/priority, the condition, population, and/or care being addressed;

OR

- if an intermediate outcome, process, structure, etc., there is evidence that supports the specific measure focus as follows:
 - Intermediate outcome - evidence that the measured intermediate outcome (e.g., blood pressure, Hba1c) leads to improved health/avoidance of harm or cost/benefit.
 - Process - evidence that the measured clinical or administrative process leads to improved health/avoidance of harm and
if the measure focus is on one step in a multi-step care process, it measures the step that has the greatest effect on improving the specified desired outcome(s).
 - Structure - evidence that the measured structure supports the consistent delivery of effective processes or access that lead to improved health/avoidance of harm or cost/benefit.
 - Patient experience - evidence that an association exists between the measure of patient experience of health care and the outcomes, values and preferences of individuals/ the public.
 - Access - evidence that an association exists between access to a health service and the outcomes of, or experience with, care.
 - Efficiency - demonstration of an association between the measured resource use and level of performance with respect to one or more of the other five IOM aims of quality.