

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-021-10	NQF Project: Nursing Homes 2010
MEASURE DESCRIPTIVE INFORMATION	
De.1 Measure Title: Percent of Residents Who Were Physically Restrained (Long Stay)	
De.2 Brief description of measure: The measure is based on data from the MDS 3.0 assessment of long-stay nursing facility residents and reports the percentage of all long-stay residents who were physically restrained. The measure reports the percentage of all long-stay residents in nursing facilities with an annual, quarterly, significant change, or significant correction MDS 3.0 assessment during the selected quarter (3-month period) who were physically restrained daily during the 7 days prior to the MDS assessment (which may be annual, quarterly, significant change, or significant correction MDS 3.0 assessment).	
1.1-2 Type of Measure: Process	
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: Safety	
De.5 IOM Quality Domain: Safety	
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 Y <input type="checkbox"/> N <input type="checkbox"/>
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.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: Yes, fully developed and tested D.2 Have NQF-endorsed measures been reviewed to identify if there are similar or related measures? Yes	D Y <input type="checkbox"/> N <input type="checkbox"/>
(for NQF staff use) Have all conditions for consideration been met? Staff Notes to Steward (<i>if submission returned</i>):	Met Y <input type="checkbox"/> N <input type="checkbox"/>
Staff Notes to Reviewers (<i>issues or questions regarding any criteria</i>):	
Staff Reviewer Name(s):	

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 Rat ing
(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: Restraints can pose serious risks for residents. They are used to control behavior for people with disruptive, aggressive, or dangerous behavior, including those with cognitive impairment. (1, 2, 3) Second quarter 2008 statewide averages for the current Chronic Care Restraint Quality Measure (QM) range from 0.0% in Puerto Rico and the Virgin Islands to 8.9% in California, with a 4.3% national average.(4) The negative outcomes of restraints may include strangulation, loss of muscle tone, decreased bone density (with greater susceptibility for fractures), pressure sores, increased infections, decreased mobility, depression, agitation, loss of dignity, social isolation, incontinence, constipation, functional decline, abnormal changes in body chemistry and muscular function, and in some cases, resident death.(5, 6, 7, 8, 9, 10, 11, 12) The use of physical restraints also often constitutes a disproportionate infringement of the autonomy of the resident.(13) The use of restraints also increases the cost of care. One study examining almost 12,000 residents in 276 facilities in seven states found that higher levels of nursing-assistant time were consistently provided to restrained residents, resulting in increased staff costs to the facilities.(14) A 1991 report by the Office of the	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).

Inspector General at the Centers for Medicare & Medicaid Services (CMS) found that nursing homes were able to reduce the use of restraints with no increase in cost of care. (15) Restraints may also impose additional costs on Medicaid; a 2006 analysis of Medicaid reimbursement data for 525 nursing homes found that residents who had experienced greater use of restraints experienced an increased risk of hospitalization. (16)

The Omnibus Budget Reconciliation Act of 1987 (OBRA 87) specifically grants residents the right to freedom from physical restraints. (17) The associated guideline from CMS states that "The resident has the right to be free from any physical or chemical restraints imposed for the purpose of discipline or convenience and not required to treat the resident's medical symptoms." (18) Most nursing facilities have considerably reduced their use of physical restraints since the legislation. However, analysis of the 1996-1999 OSCAR data by researchers showed that a small minority of nursing facilities consistently used physical restraints inappropriately. (18) Congress continues to address this issue; the Health Care Fraud Enforcement Act, introduced in 2009, would strengthen the ability of Civil Rights Division of the Department of Justice to investigate unlawful restraint. (19)

The use of restraints in nursing facilities is a subject of great interest to the public, and the principle of freedom from physical or pharmacological restraint is generally understood and accepted. In addition to the OBRA 87 mandate and the associated CMS regulations limiting restraints, the Food and Drug Administration has recently released clinical guidance for limiting the use of bed rails, reflecting public concern about the safety of restraints. (20) Professional and academic organizations such as the National Citizens' Coalition for Nursing Home Reform (NCCNHR), the Alzheimer's Association, professional organizations such as the American Physical Therapy Association, and numerous nursing home and academic medical research institutions are involved in limiting the use of restraints. (21) The Untie the Elderly campaign has been working since 1989 to raise public awareness of restraint abuse, and Advancing Excellence in America's Nursing Homes has made the reduction of physical restraints one of their major goals. (22, 23) Advancing Excellence in America's Nursing Homes promotes the current CMS Quality Measure, as is noted later in this submission.

1a.4 Citations for Evidence of High Impact: 1. Sullivan-Marx E, Strumpf N, Evans L, et al. Initiation of physical restraint in nursing home residents following restraint reduction efforts. *Res Nurs Health*. 1999;22:369-79.

2. Capezuti E, Evans L, Strumpf N, et al. Physical restraint use and falls in nursing home residents. *J Am Geriatr Soc*. 1996;44:627-33.

3. Castle N, Mor V. Physical restraints in nursing homes: a review of the literature since the Nursing Home Reform Act of 1987. *Med Care Res Rev*. 1998;55(2):139-70.

4. Centers for Medicare & Medicaid Services. MDS quality measure/indicator report. Available from http://www.cms.hhs.gov/MDSPubOlandResRep/02_qmreport.asp#TopOfPage

5. Castle N, Mor V. Physical restraints in nursing homes: a review of the literature since the Nursing Home Reform Act of 1987. *Med Care Res Rev*. 1998;55(2):139-70.

6. Williams C, Finch C. Physical restraints: not fit for woman, man, or beast. *J Am Geriatr Soc*. 1997;45:773-5.

7. Sullivan-Marx E. Achieving restraint-free care of acutely confused older adults. *J Gerontol Nurs*. 2001;27(4):56-61.

8. Evans L, Strumpf N, Allen-Taylor S, et al. A clinical trial to reduce restraints in nursing homes. *J Am Geriatr Soc*. 1997;45(6):675-81.

9. Capezuti E, Maislin G, Strumpf N, et al. Side rail use and bed-related fall outcomes among nursing home residents. *J Am Geriatr Soc*. 2002;50(1):90-6.

10. Parker K, Miles S. Deaths caused by bed rails. *J Am Geriatr Soc*. 1997;45:797-802.

11. Feinsod FM, Moore M, Levenson S. Eliminating full-length bed rails from long term care facilities. *Nurs Home Med*. 1997;5:257-63.

12. Centers for Medicare & Medicaid Services. Revised long-term care resident assessment instrument user's manual, version 2.0. December 2002, with August 2003 and all other subsequent posted updates incorporated.
13. Gastmans C, Milison K. Use of physical restraint in nursing homes: clinical-ethical considerations. J Med Ethics. 2006;32:148-52.
14. Phillips C, Hawes C, Fries B. Reducing the use of physical restraints in nursing homes: will it increase costs? Am J Public Health.1993;83(3):342-8.
15. Kusserow, R. Minimizing restraints in nursing homes: a guide to action. Baltimore, MD: Centers for Medicare & Medicaid Services, 1991.
16. Carter M, Porell F. Nursing home performance on select publicly reported quality indicators and resident risk of hospitalization: grappling with policy implications. J Aging Soc Policy.2006;18(1):17-39.
17. Wiener J, Freiman M, Brown D. Nursing home care quality twenty years after the Omnibus Budget Reconciliation Act of 1987. Research Triangle Park, NC: RTI International, 2007.
18. Castle NG. Nursing homes with persistent deficiency citations for physical restraint use. Med Care. 2002;40:868-78.
19. As reported on the Web site of the United States Senate Special Committee on Aging; accessed January 21, 2010, at <http://aging.senate.gov/record.cfm?id=319434>
20. FDA Hospital Bed Safety Workgroup; accessed January 25, 2010, at <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/MedicalToolsandSupplies/HospitalBeds/default.htm>
21. The "Untie the Elderly" Web site of Kendal Outreach provides an overview of one advocacy organization, including links to the FDA report; <http://ute.kendaloutreach.org/default.aspx>.
22. Untie the Elderly Web site; accessed January 21, 2010, at <http://ute.kendaloutreach.org/Default.aspx>
23. Advancing Excellence in America's Nursing Homes Web site; accessed January 21, 2010, at 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: Reduction in the use of restraints by facilities caring for long-stay nursing facility residents.

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

A version of this quality measure has been used by CMS since 2002, drawing on data from a current MDS 2.0 item. A study of variability for the current measure by the University of Colorado showed that, based on data from the first quarter of 2006, there are still facilities making considerable use of restraints: (1)

See Table 1: Measure Variability Across Facilities.

Research has shown that other clinical interventions usually are more effective than restraints in preventing injuries from falls. Thus, given the negative consequences of restraint use, the practice should be rare. Interventions involving physiologic care, such as positioning and changes in medication or treatment to make the resident more comfortable; psychosocial care involving companionship and supervision; a program of safe activities; and environmental manipulation, such as installing adequate lighting and a more home-like setting, have been shown to be more effective, generally without increasing staff time or overall cost of treatment.(2, 3, 4, 5, 6, 7, 8) Research has also shown that residents with cognitive impairment are more likely to receive physical restraints than those who are cognitively intact.(9)

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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).

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.

1b.3 Citations for data on performance gap:

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.
2. Capezuti E, Talerico K, Cochran E, et al. Individualized interventions to prevent bed-related falls and reduce siderail use. *J Gerontol Nurs.* 1999;25(11):26-34.
3. Sullivan-Marx E. Achieving restraint-free care of acutely confused older adults. *J Gerontol Nurs.* 2001;27(4):56-61.
4. Centers for Medicare & Medicaid Services. Revised long-term care resident assessment instrument user's manual, version 2.0. December 2002, with August 2003 and all other subsequent posted updates incorporated.
5. Capezuti E. Minimizing the use of restrictive devices in dementia patients at risk for falling. *Nurs Clin N Am.* 2004;39:625-47.
6. Ejaz F, Jones J, Rose M. Falls among nursing home residents: an examination of incident reports before and after restraint reduction programs. *J Am Geriatr Soc.* 1994;42:960-4.
7. Neufeld R, Libow L, Foley W, et al. Restraint reduction reduces serious injuries among nursing home residents. *J Am Geriatr Soc.* 1999;47:1202-7.
8. Evans L, Strumpf N, Allen-Taylor S, et al. A clinical trial to reduce restraints in nursing homes. *J Am Geriatr Soc.* 1997;45(6):675-81.
9. Sullivan-Marx E, Strumpf N, Evans L, Baumgarten M, Maislin G. Predictors of continued physical restraint use in nursing home residents following restraint reduction efforts. *J Am Geriatr Soc.* 1999;47(3):342-8.

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

Racial segregation between nursing homes has been shown to be a major factor in racial disparities in the nursing home population, primarily for African Americans, who tend to be concentrated in facilities with higher deficiency ratings for the use of restraints. (1, 2, 3) A 2004 study also found that physical restraints were used at a higher rate in nursing facilities serving mainly Medicaid residents, where most African Americans reside. (4) A 2006 study further showed that the likelihood of African American nursing home residents being restrained was inversely related to the percentage of African Americans among the nursing home's residents. (5)

There is also some research indicating that residents with cognitive impairment are more likely to receive physical restraints than those who are cognitively intact. (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 Aff (Millwood).* 2007;26(5):1448-558.
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? *Am J Public Health.* 2002;92(8):1272-7.
3. Grabowski D. The admission of blacks to high-deficiency nursing homes. *Med Care.* 2004;42(5):456-64
4. Mor V, Zinn J, Angelelli J, Teno J, Miller S. Driven to tiers: socioeconomic and racial disparities in the quality of nursing home care. *Milbank Q.* 2004;82(2):227-56.
5. Miller SC, Papandonatos G, Fennell M, Mor V. Facility and county effects on racial differences in nursing home quality indicators. *Soc Sci Med.* 2006;63(12):3046-59.
6. Sullivan-Marx E, Strumpf N, Evans L, Baumgarten M, Maislin G. Predictors of continued physical restraint use

in nursing home residents following restraint reduction efforts. *J Am Geriatr Soc.* 1999;47(3):342-8.

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*): There are many benefits of employing alternative interventions and refraining from the use of physical restraints to address falls, wandering, and other behaviors. These benefits include improved quality of life, greater autonomy, use of fewer antipsychotic medications, less skin breakdown, and fewer serious injuries due to falls. Research has also shown that restraints do not prevent major adverse consequences for residents; while falls may increase with the removal of physical restraints, studies have found that serious falls do not.

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*):

The benefits of refraining from the use of physical restraints by employing clinically sound interventions to address the causes of falls, wandering, and other behaviors have been well-documented in the long-term care literature; they include improved quality of life, greater autonomy, use of fewer antipsychotic medications, less skin breakdown, and fewer serious injuries resulting from falls. Through multiple clinical trials, case studies, and facility-level intervention studies, research has also shown that restraints do not prevent major adverse consequences for residents; while the number of falls may increase with the removal of physical restraints, studies have consistently found that serious falls resulting in injuries do not. One study found that the risk of serious injury decreased with the removal of physical restraints. (1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13)

1c.5 Rating of strength/quality of evidence (*also provide narrative description of the rating and by whom*): The body of evidence supporting this measure has not been rated.

1c.6 Method for rating evidence:

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

1c.8 Citations for Evidence (*other than guidelines*): 1. Castle N, Mor V. Physical restraints in nursing homes: a review of the literature since the Nursing Home Reform Act of 1987. *Med Care Res Rev.* 1998;55(2):139-70.

2. Engberg J, Castle N, McCaffrey D. Physical restraint initiation in nursing homes and subsequent resident health. *Gerontologist.* 2008;48(4):442-52.

3. Castle N, Engberg J. The health consequences of using physical restraints in nursing homes. *Med Care.* 2009;47(11):1164-73.

4. Williams C, Finch C. Physical restraints: not fit for woman, man, or beast. *J Am Geriatr Soc.* 1997;45:773-5.

5. Sullivan-Marx E. Achieving restraint-free care of acutely confused older adults. *J Gerontol Nurs.* 2001;27(4):56-61.

6. Capezuti E, Talerico K, Cochran E, et al. Individualized interventions to prevent bed-related falls and reduce siderail use. *J Gerontol Nurs.* 1999;25(11):26-34.

7. Capezuti E, Evans L, Strumpf N, Maislin G. Physical restraint use and falls in nursing home residents. *J Am Geriatr Soc.* 1996;44(6):627-33.

8. Centers for Medicare & Medicaid Services. Revised long-term care resident assessment instrument user's manual, version 2.0. December 2002, with August 2003 and all other subsequent posted updates incorporated.

9. Capezuti E. Minimizing the use of restrictive devices in dementia patients at risk for falling. *Nurs Clin N Am.* 2004;39:625-47.

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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.

<p>10. Ejaz F, Jones J, Rose M. Falls among nursing home residents: an examination of incident reports before and after restraint reduction programs. <i>J Am Geriatr Soc.</i> 1994;42:960-4.</p> <p>11. Neufeld R, Libow L, Foley W, et al. Restraint reduction reduces serious injuries among nursing home residents. <i>J Am Geriatr Soc.</i> 1999;47:1202-7.</p> <p>12. Evans L, Strumpf N, Allen-Taylor S, et al. A clinical trial to reduce restraints in nursing homes. <i>J Am Geriatr Soc.</i> 1997;45(6):675-81.</p> <p>13. Neufeld R, Libow L, Foley W, White H. Can physically restrained nursing-home residents be untied safely? Intervention and evaluation design. <i>J Am Geriatr Soc.</i> 1995;43(11):1264-8.</p> <p>1c.9 Quote the Specific guideline recommendation (including guideline number and/or page number): 1. Dementia care practice recommendations for assisted living residences and nursing homes. 2. Practice guideline for the treatment of patients with Alzheimer's disease and other dementias.</p> <p>1c.10 Clinical Practice Guideline Citation: 1. Tilly J, Reed P (eds). Dementia care practice recommendations for assisted living residences and nursing homes. Washington, DC: Alzheimer's Association, 2006. 2. American Psychiatric Association (APA). Practice guideline for the treatment of patients with Alzheimer's disease and other dementias. Arlington, VA: American Psychiatric Association, 2007.</p> <p>1c.11 National Guideline Clearinghouse or other URL: http://www.guideline.gov/summary/summary.aspx?doc_id=10620&nbr=005562&string=physical+AND+restraints and http://www.guideline.gov/summary/summary.aspx?doc_id=11533&nbr=005974&string=physical+AND+restraints</p> <p>1c.12 Rating of strength of recommendation (also provide narrative description of the rating and by whom): The American Psychiatric Association rated the relevant portion of the recommendation as Category I: Recommended with substantial clinical confidence.</p> <p>1c.13 Method for rating strength of recommendation (If different from USPSTF system, also describe rating and how it relates to USPSTF):</p> <p>1c.14 Rationale for using this guideline over others: These are the relevant guidelines registered with the National Guideline Clearinghouse that address the use of physical restraints. Both guidelines recommend that restraints generally not be used.</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 <input checked="" type="checkbox"/> Y <input type="checkbox"/> N <input type="checkbox"/> NA
2. SCIENTIFIC ACCEPTABILITY OF MEASURE PROPERTIES	
<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 Rat ing
2a. MEASURE SPECIFICATIONS	

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.

S.1 Do you have a web page where current detailed measure specifications can be obtained?
 S.2 If yes, provide web page URL:

2a. Precisely Specified

2a.1 Numerator Statement (Brief, text description of the numerator - what is being measured about the target population, e.g. target condition, event, or outcome):

The numerator is the number of long-stay residents (those who have been in the facility for over 100 days) who have been assessed with annual, quarterly, significant change or significant correction MDS 3.0 assessments during the selected time window and who have experienced restraint usage during the 7 days prior to the assessment, as indicated by MDS 3.0, Section P, Item 100, subitems b (P0100B - Trunk restraint used in bed), c (P0100C - Limb restraint used in bed), e (P0100E - Trunk restraint used in chair or out of bed), f (P0100F - limb restraints used in chair or out of bed), or g (P0100G - Chair prevents rising).

2a.2 Numerator Time Window (The time period in which cases are eligible for inclusion in the numerator):

Numerator data come from MDS 3.0 annual, quarterly, significant change or significant correction assessments conducted during each quarter (3-month period).

2a.3 Numerator Details (All information required to collect/calculate the numerator, including all codes, logic, and definitions):

Residents are counted if they are long-stay residents, defined as residents whose length of stay is greater than 100 days. Residents who return to the nursing home following a hospital discharge will not have their stay reset to zero. Residents are counted if any of the following items are coded as "2", meaning that the restraint was used daily during the 7 days prior to the assessment: P0100.B- Trunk restraint used in bed, P0100.C-Limb restraint used in bed, P0100.E- Trunk restraint used in chair or out of bed, P0100.F-Limb restraint used in chair or out of bed, or P0100.G-Chair prevents rising.

2a.4 Denominator Statement (Brief, text description of the denominator - target population being measured):

The denominator is the total of all long-stay residents in the nursing facility who have received an annual, quarterly, significant change or significant correction MDS 3.0 assessment during the quarter and who do not meet the exclusion criteria.

2a.5 Target population gender: Female, Male

2a.6 Target population age range: The target population includes people of all ages who are admitted to the nursing facility.

2a.7 Denominator Time Window (The time period in which cases are eligible for inclusion in the denominator):

Denominator data come from MDS 3.0 annual, quarterly, significant change or significant correction assessments conducted during each quarter (3-month period).

2a.8 Denominator Details (All information required to collect/calculate the denominator - the target population being measured - including all codes, logic, and definitions):

Residents are counted if they are long-stay residents defined as residents whose length of stay is greater than 100 days. Residents who return to the nursing home following a hospital discharge will not have their day count reset to zero. The population includes all long-stay residents who had an annual, quarterly, significant change, or significant correction MDS 3.0 assessment (A0310.A = 02, 03, 04, 05 or 06) during the selected quarter.

2a.9 Denominator Exclusions (Brief text description of exclusions from the target population): An MDS assessment may, on occasion, have incomplete data due to human error in collecting or recording the data. Those records are excluded from the quality calculation because it is not possible to perform the needed calculations when data are missing.

A resident is excluded from the denominator if the selected MDS 3.0 assessment was conducted within 14 days of admission or if there is missing data in the responses to the relevant questions in the MDS.

Long-stay facilities are excluded from public reporting if their samples include fewer than 30 residents.

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) .

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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.

<p>2a.10 Denominator Exclusion Details (<i>All information required to collect exclusions to the denominator, including all codes, logic, and definitions</i>): If the MDS 3.0 assessment is an OBRA admission assessment (A0310a = 01, indicating that the assessment is the OBRA admission assessment, conducted within 14 days of admission) or there is missing data for any of the following restraints items: P0100B - Trunk restraint used in bed, P0100C - Limb restraint used in bed, P0100E - Trunk restraint used in chair or out of bed, P0100F - Limb restraint used in chair or out of bed, or P0100G - Chair prevents rising. Assessments are not included if the data necessary to calculate the rate are missing. The admission assessment is excluded because the 7 days prior would reflect hospital practice and not the use of restraints by the nursing facility for long-stay residents.</p> <p>Long-stay facilities are excluded from public reporting if their samples include fewer than 30 residents.</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 residents meeting the numerator criteria and the number of residents meeting the denominator criteria are counted. The facility prevalence score is calculated as the number of residents in the facility during the selected quarter in the numerator divided by all residents during the selected quarter in the denominator (excluding residents for whom there is missing data).</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>
<p>2a.24 Data Source (<i>Check the source(s) for which the measure is specified and tested</i>) Electronic clinical data</p>
<p>2a.25 Data source/data collection instrument (<i>Identify the specific data source/data collection instrument, e.g. name of database, clinical registry, collection instrument, etc.</i>): Nursing Home Minimum Data Set 3.0</p>
<p>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</p>
<p>2a.29-31 Data dictionary/code table web page URL or attachment: URL http://www.cms.hhs.gov/NursingHomeQualityInits/25_NHQIMDS30.asp#TopOfPage</p>
<p>2a.32-35 Level of Measurement/Analysis (<i>Check the level(s) for which the measure is specified and tested</i>) Facility/Agency</p>
<p>2a.36-37 Care Settings (<i>Check the setting(s) for which the measure is specified and tested</i>) Nursing home (NH) /Skilled Nursing Facility (SNF)</p>
<p>2a.38-41 Clinical Services (<i>Healthcare services being measured, check all that apply</i>)</p>

TESTING/ANALYSIS

2b. Reliability testing

2b.1 Data/sample (*description of data/sample and size*): The proposed measure is based on the restraint item in MDS 3.0, Section P, with the numerator including all those residents who have been assessed with an annual, quarterly, significant change or significant correction MDS assessment during the selected quarter and who have experienced restraint usage during the previous 7 days, as indicated in items P0100B - Trunk restraint used in bed, P0100C - Limb restraint used in bed, P0100E - Trunk restraint used in chair or out of bed, P0100F - Limb restraint used in chair or out of bed, or P0100G - Chair prevents rising.

Two major tests of the reliability of the physical restraint measure have been conducted. First, the MDS 2.0 measure items and the existing 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 April 1 to December 31, 2006; 173 two-stage reviews were performed.(1)

Second, the University of Colorado used national facility-level quality measure data from 2003 Quarter 3 (Q3) through 2006 Q3 came from the QIES MDS Express Reports on the CMS intranet; 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 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, as well as 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.

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

Testing among short stay residents was for other measures. This statement refers to the analytic sample.

The DAVE 2 Project used a two-stage cluster sample design to examine MDS reporting. Trained nurse reviewer selected a current resident with a recent assessment performed by the nursing home (NH) within the last 14 days. In the first stage 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 the second stage of this assessment (Stage 2), the DAVE 2 nurse reviewer's assessment was compared to the corresponding nursing home assessment and each discrepancy was reconciled, with the nursing home 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 et al. examined agreement between assessors (reliability); response rates for interview items; user satisfaction and feedback on changes; and time to complete the assessment. The network of Quality Improvement Organizations was employed identify gold-standard (research) nurses and recruit community nursing homes to participate in the national evaluation, including a representative sample of for-profit and not-for-profit facilities and hospital-based and freestanding facilities. The gold-standard nurses were trained in the MDS 3.0 instrument and, in turn, trained a facility nurse from each participating nursing home 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 an excellent two-stage discrepancy rate of 0.0 percent for the current Physical

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.

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.

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<p>Restraint measure and its associated MDS 2.0 item, indicating no discrepancy.(1)</p> <p>The national pilot test of the proposed MDS 3.0 measure by Saliba et al. showed good reliability with little evidence of confusion. For the restraint item, kappas for gold-standard nurse to gold-standard nurse agreement ranged from .857 to .934 and kappas for gold-standard nurse to facility nurse agreement ranged from .660 to .873.(2)</p> <p>See attached Table 2: Measure Trends Over Time.</p> <p>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.</p> <p>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.</p>	
<p>2c. Validity testing</p> <p>2c.1 Data/sample (description of data/sample and size): The data came from two sources: national facility-level quality measure data from 2003 Quarter 3 (Q3) through 2006 Q3 came from the Quality Improvement and Evaluation System (QIES) MDS Express Reports on the CMS intranet; 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 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, as well as nearly complete data for April 2006 and partial data for May and June 2006.</p> <p>Information for this response and the other responses in regard to Validity Testing is from:</p> <p>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.</p> <p>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.</p> <p>2c.2 Analytic Method (type of validity & rationale, method for testing): The analysis evaluated measure validity in a number of ways; 1) examining the expected positive influence of public reporting on quality of care, 2) assessing the degree to which physical restraint use rates have improved over time; 3) evaluating convergent validity, an assessment of the correlation of the quality measure with all other measures; 4) determining if the quality measure rate was influenced by factors that are unrelated to facility quality, and 5) evaluating seasonal variations in physical restraint use 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 physical restraint use rates explained in the state in which a facility was located.</p> <p>2c.3 Testing Results (statistical results, assessment of adequacy in the context of norms for the test conducted): The analysis found that public reporting appears to have had some influence on the decreased report of restraint use over time as evidenced by the decline in the physical restraint use rate (see attached Table 2: Measure Trends Over Time). The most recent national rate was 3.5 percent for the second quarter of 2009. (Data are available at http://www.cms.hhs.gov/MDSPubQlandResRep/02_qmreport.asp#TopOfPage) In Table 2, seasonal variations are not evident, although the analysis found that 19.6% of the variance in report rate for this measure was explained by the state in which a facility was located. Overall, the steady decline in restraint use reflects an overall trend showing improved quality in nursing facility care over time. Correlations with other current quality measures are not significant and can be seen in the attached Table 3: Correlations of Quality Measures. The statistical limitations of this measure may reflect a limited clinical relationship of physical restraints to</p>	<p>2c C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/></p>

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.

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.

<p>the other measures, and while the variation in rate among states makes it difficult to compare between facilities in different states the measure remains a valuable guide between facilities within the same state.</p>	
<p>2d. Exclusions Justified</p> <p>2d.1 Summary of Evidence supporting exclusion(s): All residents in long-stay for whom 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.</p> <p>2d.2 Citations for Evidence: This is not applicable.</p> <p>2d.3 Data/sample (description of data/sample and size): This is not applicable.</p> <p>2d.4 Analytic Method (type analysis & rationale): This is not applicable.</p> <p>2d.5 Testing Results (e.g., frequency, variability, sensitivity analyses): This is not applicable.</p>	<p>2d C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/> NA <input type="checkbox"/></p>
<p>2e. Risk Adjustment for Outcomes/ Resource Use Measures</p> <p>2e.1 Data/sample (description of data/sample and size): This is not applicable.</p> <p>2e.2 Analytic Method (type of risk adjustment, analysis, & rationale): This is not applicable.</p> <p>2e.3 Testing Results (risk model performance metrics): This is not applicable.</p> <p>2e.4 If outcome or resource use measure is not risk adjusted, provide rationale: This is a process measure and no adequate risk adjustment has been developed. Efforts to develop adequate risk adjustment are described in: 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.</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 (description of data/sample and size): An analytical team at the University of Colorado Health Sciences Center examined the physical restraint use rates for the current measure at the facility level. The data showed meaningful differences. It came from two sources: 1) national facility-level quality measure data from 2003 Quarter 3 (Q3) through 2006 Q3 came from the QIES MDS Express Reports on the CMS intranet; 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</p>	<p>2f C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/></p>

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.

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.

<p>complete MDS data from January 2005 through March 2006, as well as 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 (type of analysis & rationale): 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 (description of scores, e.g., distribution by quartile, mean, median, SD, etc.; identification of statistically significant and meaningfully differences in performance): For 13,837 facilities, the mean physical restraint use rate was 6.2 percent with a standard deviation of 7.4 percent. The attached Table 1: Measure Variability Across Facilities reports the full results of the analysis. A physical restraint use rate of 0% is the desired outcome.</p>	
<p>2g. Comparability of Multiple Data Sources/Methods</p> <p>2g.1 Data/sample (description of data/sample and size): This is not applicable.</p> <p>2g.2 Analytic Method (type of analysis & rationale): This is not applicable.</p> <p>2g.3 Testing Results (e.g., correlation statistics, comparison of rankings): This is not applicable.</p>	<p>2g</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>2h. Disparities in Care</p> <p>2h.1 If measure is stratified, provide stratified results (scores by stratified categories/cohorts): 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: The only disparities reported in the literature in regard to use of restraints relate to the race of the resident. While 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 in any quality measure generally evident in the rating of the facility.(1, 2, 3)</p> <p>1. Smith D, Feng Z, Zinn J, Mor V. 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 Aff (Millwood)</i>. 2007;26(5):1448-558.</p> <p>3. Mor V, Berg K, Angelelli J, Gifford D, Morris J, Moore T. The quality of quality measurement in U.S. nursing homes. <i>Gerontologist</i>. 2003;43(Special Issue II):37-46.</p>	<p>2h</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 Scientific Acceptability of Measure Properties?</p>	<p>2</p>
<p>Steering Committee: Overall, to what extent was the criterion, Scientific Acceptability of Measure Properties, met? Rationale:</p>	<p>2</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 style="text-align: center;">3. USABILITY</p>	
<p>Extent to which intended audiences (e.g., consumers, purchasers, providers, policy makers) can understand</p>	<p>Ev</p>

Comment [kP19]: 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.

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.

<p>the results of the measure and are likely to find them useful for decision making. (evaluation criteria)</p>	al Rat ing
<p>3a. Meaningful, Understandable, and Useful Information</p> <p>3a.1 Current Use: In use</p> <p>3a.2 Use in a public reporting initiative (disclosure of performance results to the public at large) (If used in a public reporting initiative, provide name of initiative(s), locations, Web page URL(s). <u>If not publicly reported</u>, state the plans to achieve public reporting within 3 years): Nursing Home Compare http://www.medicare.gov/NHCompare/Include/DataSection/Questions/SearchCriteriaNEW.asp?version=default&brower=IE%7C6%7CWinXP&language=English&defaultstatus=0&pagelist=Home&CookiesEnabledStatus=True</p> <p>3a.3 If used in other programs/initiatives (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): CMS expects that the quality measure will be used by nursing facilities as a tool to decrease their use of restraints. The national level of use has declined from 6.8 percent in the first quarter of 2005 to 3.5 percent for the second quarter of 2009. (Data are available at http://www.cms.hhs.gov/MDSPubQIandResRep/02_qmreport.asp#TopOfPage) This measure is also cited 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, nursing home practitioners including nurses, health care professionals, medical directors, nursing home administrators, government agencies, quality improvement organizations, and private organizations supporting nursing home education. Based on projection from MDS Quality Measure reporting data, the Advancing Excellence in America's Nursing Homes Campaign set several goals to reduce restraint use by September, 2008. The results to date demonstrate that by the second quarter of 2009 three of the goals were achieved: the national average for physical restraints is under 5%, more than 50% of nursing homes report rates of physical restraints below 3%, and compared to June 2006, approximately 30,000 fewer residents have physical restraints. Progress is also being made on reducing the number of nursing homes reporting a physical restraint rate that exceeds 19%. (http://www.nhqualitycampaign.org/files/reports/results/q2-2009/Goal2_NationalObjectives_2009Q2_4pages.pdf).</p> <p>Testing of Interpretability (Testing that demonstrates the results are understood by the potential users for public reporting and quality improvement) 3a.4 Data/sample (description of data/sample and size): A recent study examined whether consumers could accurately interpret the quality information given for all the measures reported by Nursing Home Compare. Data were collected from 4,754 family members of nursing home residents. (1) 1. Castle N. The Nursing Home Compare report card: consumers' use and understanding. <i>J Aging Soc Policy</i>. 2009;21(2), 187-208.</p> <p>3a.5 Methods (e.g., focus group, survey, QI project): 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 (qualitative and/or quantitative results and conclusions): The study found that 31% of the consumers used the Internet in choosing a nursing home, 12% recalled using Nursing Home Compare, and in general, the consumers' comprehension index scores were high, indicating good understanding. The comprehension index for the physical restraint measure was among the highest at 5.79 on a scale of 1 to 8.</p>	3a C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/>
<p>3b/3c. Relation to other NQF-endorsed measures</p> <p>3b.1 NQF # and Title of similar or related measures: This measure is intended to replace NQF # 0193 Residents who were Physically Restrained Daily during the 7-day Assessment Period because the data source has changed; the MDS 2.0, the data source for NQF #0193, is being replaced with the MDS 3.0. The restraint items in the MDS 3.0 have been refined. NQF # 0203 Physical</p>	

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.

restraint (vest and limb only) is for use in acute care (different population and different definition of restraints).	
(for NQF staff use) Notes on similar/related endorsed or submitted measures:	
3b. Harmonization If this measure is related to measure(s) already endorsed by NQF (e.g., same topic, but different target population/setting/data source or different topic but same target population): 3b.2 Are the measure specifications harmonized? If not, why?	3b C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/> NA <input type="checkbox"/>
3c. Distinctive or Additive Value 3c.1 Describe the distinctive, improved, or additive value this measure provides to existing NQF-endorsed measures: The current measure is being retired due to the change in the data source. The proposed measure will replace it. NQF # 0203 Physical restraint (vest and limb only) is for use in acute care (different population and different definition of restraints). 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:	3c C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/> NA <input type="checkbox"/>
TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for Usability?	3
Steering Committee: Overall, to what extent was the criterion, Usability, met? Rationale:	3 C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/> NA <input type="checkbox"/>
4. FEASIBILITY	
Extent to which the required data are readily available, retrievable without undue burden, and can be implemented for performance measurement. (evaluation criteria)	Ev al Rat ing
4a. Data Generated as a Byproduct of Care Processes 4a.1-2 How are the data elements that are needed to compute measure scores generated? 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)	4a C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/> NA <input type="checkbox"/>
4b. Electronic Sources 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) No 4b.2 If not, specify the near-term path to achieve electronic capture by most providers.	4b C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/> NA <input type="checkbox"/>
4c. Exclusions	4c C <input type="checkbox"/>

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

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.

<p>4c.1 Do the specified exclusions require additional data sources beyond what is required for the numerator and denominator specifications? No</p> <p>4c.2 If yes, provide justification.</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. There is some evidence that decreased use of chair restraints is associated with residents being confined in bed longer, raising the possibility that a facility could be leaving weaker residents in bed as opposed to restraining them in chairs. It should be possible, however, to monitor this kind of lower quality care by watching for any increase in pressure ulcers resulting from the extended time in bed; pressure ulcers are monitored by a different CMS quality measure.(1)</p> <p>Another possible unintended consequence is that chemical restraints may be substituted for physical restraints. Researchers and advocacy organizations have identified improper use of physical and chemical restraints as a form of physical abuse that is associated with other forms of physical abuse in the institutional setting, so that ombudsman reports may provide insight into the potential for this outcome. Further research is needed to determine whether a decrease in improper physical restraints could lead to an increase in chemical restraints and other forms of physical abuse. The measurement of chemical restraints is under consideration as a future CMS quality measure.(2)</p> <p>1. Schnelle J, Bates-Jensen B, Levy-Storms L, Grbic V, Yoshii J, Cadogan M, Simmons S. (2004). The Minimum Data Set prevalence of restraint quality indicator: does it reflect differences in care? <i>Gerontologist</i>. 2004;44(2):245-55.</p> <p>2. Hawes, C. Elder abuse in residential long-term care facilities: what is known about prevalence, causes, and prevention testimony before the U.S. Senate Committee on Finance. June 18, 2002. Available from http://finance.senate.gov/hearings/testimony/061802chtest.pdf.</p>	<p>4d</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>4e. Data Collection Strategy/Implementation</p> <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 there are no issues with these areas.</p> <p>4e.2 Costs to implement the measure (costs of data collection, fees associated with proprietary measures): Data are collected as part of an existing process that incurs 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>	<p>4e</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>TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for Feasibility?</p>	<p>4</p>
<p>Steering Committee: Overall, to what extent was the criterion, Feasibility, met? Rationale:</p>	<p>4</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>

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

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).

	<input type="checkbox"/> N <input type="checkbox"/>
RECOMMENDATION	
(for NQF staff use) Check if measure is untested and only eligible for time-limited endorsement.	Time-limited <input type="checkbox"/>
Steering Committee: Do you recommend for endorsement? Comments:	<input type="checkbox"/> Y <input type="checkbox"/> N <input type="checkbox"/> A <input type="checkbox"/>
CONTACT INFORMATION	
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	
Co.2 Point of Contact Judith, Tobin, PT, MBA, Judith.Tobin@cms.hhs.gov, 410-786-6892-	
Measure Developer If different from Measure Steward Co.3 Organization RTI International, 1440 Main Street, Suite 310, Waltham, Massachusetts, 02451-1623	
Co.4 Point of Contact Roberta, Constantine, RN, MBA, PhD, rconstantine@rti.org, 781-434-1700-1711	
Co.5 Submitter If different from Measure Steward POC Roberta, Constantine, RN, MBA, PhD, rconstantine@rti.org, 781-434-1700-1711, RTI International	
Co.6 Additional organizations that sponsored/participated in measure development	
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. See attached Table 4: Nursing Home Quality Measures Technical Expert Panel (January 2009). This technical expert panel met over 2 days in January 2009 to review the environmental scan of the current quality measures and make recommendations regarding the transition from MDS 2.0 to MDS 3.0.	
Ad.2 If adapted, provide name of original measure: This measure was adapted from the measure of the same name derived from MDS 2.0 data. Ad.3-5 If adapted, provide original specifications URL or attachment http://www.qualitynet.org/dcs/ContentServer?cid=1138050766910&pagename=Medqic%2FOtherResource%2FOtherResourcesTemplate&c=OtherResource	
Measure Developer/Steward Updates and Ongoing Maintenance Ad.6 Year the measure was first released: 2002 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	
Ad.10 Copyright statement/disclaimers: This is not applicable.	
Ad.11 -13 Additional Information web page URL or attachment: Attachment Physical Restraints tables_FINAL-634045018041986250.doc	

Date of Submission (MM/DD/YY): 07/12/2010

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.