

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-013-10 NQF Project: Nursing Homes 2010	
MEASURE DESCRIPTIVE INFORMATION	
De.1 Measure Title: Percent of High Risk Residents with Pressure Ulcers (Long Stay)	
De.2 Brief description of measure: CMS currently has this measure in their QMs but it is based on data from MDS 2.0 assessments and it includes Stage 1 ulcers. This proposed measure will be based on data from MDS 3.0 assessments of long-stay nursing facility residents and will exclude Stage 1 ulcers from the definition. The measure reports the percentage of all long-stay residents in a nursing facility with an annual, quarterly, significant change or significant correction MDS assessment during the selected quarter (3-month period) who were identified as high risk and who have one or more Stage 2-4 pressure ulcer(s). High risk populations are those who are comatose, or impaired in bed mobility or transfer, or suffering from malnutrition.	
Long-stay residents are those who have been in nursing facility care for more than 100 days. This measure is restricted to the population that has long-term needs; a separate pressure ulcer measure is being submitted for short-stay populations. These are defined as having a stay that ends with a discharge within the first 100 days.	
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: 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. 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 <input type="checkbox"/> Y <input type="checkbox"/> N

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

<p>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</p> <p>A.2 Indicate if Proprietary Measure (as defined in measure steward agreement):</p> <p>A.3 Measure Steward Agreement: Government entity and in the public domain - no agreement necessary</p> <p>A.4 Measure Steward Agreement attached:</p>	<p>B</p> <p>Y <input type="checkbox"/></p> <p>N <input type="checkbox"/></p>
<p>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</p>	<p>C</p> <p>Y <input type="checkbox"/></p> <p>N <input type="checkbox"/></p>
<p>C. The intended use of the measure includes <u>both</u> public reporting <u>and</u> quality improvement. ► Purpose: Public reporting, Internal quality improvement</p>	<p>D</p> <p>Y <input type="checkbox"/></p> <p>N <input type="checkbox"/></p>
<p>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.</p> <p>D.1 Testing: No, testing will be completed within 24 months</p> <p>D.2 Have NQF-endorsed measures been reviewed to identify if there are similar or related measures? Yes</p>	<p>Met</p> <p>Y <input type="checkbox"/></p> <p>N <input type="checkbox"/></p>
<p>(for NQF staff use) Have all conditions for consideration been met? Staff Notes to Steward (if submission returned):</p>	<p>Staff Notes to Reviewers (issues or questions regarding any criteria):</p>
<p>Staff Reviewer Name(s):</p>	

TAP/Workgroup Reviewer Name:	
Steering Committee Reviewer Name:	
1. IMPORTANCE TO MEASURE AND REPORT	
<p>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)</p> <p>1a. High Impact _____</p>	<p>Ev al Rat ing</p>
<p>(for NQF staff use) Specific NPP goal:</p> <p>1a.1 Demonstrated High Impact Aspect of Healthcare: Severity of illness, Patient/societal consequences of poor quality, High resource use</p> <p>1a.2</p> <p>1a.3 Summary of Evidence of High Impact: Pressure ulcers typically result from prolonged periods of uninterrupted pressure on the skin, soft tissue, muscle, and bone.(1, 2, 3) Vulnerable patients include the elderly; stroke and diabetic patients; those with dementia, circulatory diseases, dehydration, and malnutrition; and people who use wheelchairs or are bedridden—that is, any patient with impaired mobility or sensation.(2, 4, 5) Pressure ulcers interfere with the activities of daily living, predispose patients to osteomyelitis and septicemia, and are strongly associated with longer hospital stays and mortality.(2)</p> <p>Pressure ulcers are high-volume and high-cost adverse events across the spectrum of health care settings from acute hospitals to home health.(1, 2, 4) The prevalence of pressure ulcers in health care facilities is increasing, with some 2.5 million patients being treated annually for pressure ulcers in acute care facilities.(1,</p>	
	<p>1a</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 [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).

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

3) In 2006, there were 503,300 acute hospital stays during which pressure ulcers were noted—a 78.9% increase from 1993 when there were about 281,300 hospital stays related to pressure ulcers.(1, 5)

Pressure ulcer incidence rates vary considerably by clinical setting—ranging from 0.4% to 38% in acute care, from 2.2% to 23.9% in skilled nursing facilities and nursing homes, and from 0% to 17% in home care.(3,16)

Patients with acute care hospitalizations related to pressure ulcers were more likely to be discharged to long-term care facilities (e.g., a skilled nursing facility, an intermediate care facility, or a nursing home), than hospitalizations for all other conditions.(3, 4) In fact, more than half of principal pressure ulcer stays (53.4%) and secondary pressure ulcer stays (54.5%) were discharged to long-term care—more than 3 times the rate of hospitalizations for all other conditions (16.2%).(4)

Pressure ulcers are serious medical conditions and one of the most important measures of the quality of clinical care in nursing facilities. The CDC conducts the National Nursing Home Survey, a continuing series of national sample surveys of nursing homes, their residents, and their staff. Data for the survey were obtained through personal interviews with facility administrators and designated staff who used administrative records to answer questions about the facilities, staff, services and programs, and medical records to answer questions about the residents. A total of 1,174 nursing home facilities participated in the latest National Nursing Home Survey.(6)

As reported in the 2004 National Nursing Home Survey results, about 159,000 current U.S. nursing home residents (11%) had pressure ulcers. Stage 2 ulcers were the most common, accounting for about 50% of all pressure ulcers. Stages 1, 3, and 4 made up about the other 50% of all ulcers.(6) Stage 1 pressure ulcers are not included in the proposed quality measure, researchers have suggested that inclusion of Stage 1 pressure ulcers in the quality measures adds little value.(17, 18)

See attached Figure 1: Percentage of Nursing Homes Residence with Pressure Ulcers. United States, 2004.

In 2006, Abt Associates examined pressure ulcer incidence and prevalence across post acute settings. For nursing homes, MDS 2.0 assessments were used for April 1, 2006, through July 15, 2006. The prevalence of pressure ulcers Stage 1-4 was 13%, with the prevalence of Stage 3-4 ulcers being 3% nationwide.(4)

Pressure ulcers may cause extreme discomfort to the patient and often lead to serious, life-threatening infections, which substantially increase the total cost of care.(1, 7, 8) The main driver of cost is the presence of complications, which involve diagnostic tests, additional monitoring, more expensive pressure-relieving surfaces, and extended length of stays.(7)

As reported in the Federal Register, in 2006 there were 322,946 reported cases of Medicare patients with a pressure ulcer as a secondary diagnosis—each case had an average charge of \$40,381 for a hospital stay, for an annual total cost of \$13 billion.(9) The Advancing Excellence in America's Nursing Homes Campaign, a national effort launched in 2006 to help nursing homes measurably to improve care, reported that it can cost as much as \$19,000 to treat a single Stage 4 pressure ulcer.(10)

To address this critical clinical issue, there are numerous national healthcare organizations with ongoing efforts and publications to prevent pressure ulcers, monitor prevalence, and improve treatment. Examples listed below are representative but not exhaustive and include the following:

- The Joint Commission on Accreditation of Healthcare Organizations offers National Patient Safety Goals for Long Term Care.(11)
- The Institute for Healthcare Improvement's 5 Million Lives Campaign was a voluntary initiative to protect patients from 5 million incidents of medical harm over the 2006-2008 period.(12)
- CDC's National Center for Health Statistics and National Nursing Home Survey monitor pressure ulcer prevalence.(6)
- The On-Time Quality Improvement for Long-Term Care Program, funded by the Agency for Healthcare Research and Quality (AHRQ) in collaboration with State departments of health, is a Quality Improvement Organization (QIO), or a trade association, to improve nursing home care. This national effort focuses on prevention and timely treatment of pressure ulcers during routine care. New tools to document pressure ulcer healing and treatments and reports to help monitor the healing process have been developed as part of the On-Time Quality Improvement Program.(4, 13)

- The National Pressure Ulcer Advisory Panel (NPUAP) uses research, public policy, and education to improve patient outcomes in pressure ulcer prevention.(14)
- The NQF sponsors the “National Voluntary Consensus Standards for Developing a Framework for Measuring Quality for Prevention and Management of Pressure Ulcers” initiative. This CMS-funded project began in 2008 and has several objectives, including determining how to measure the incidence and prevalence of pressure ulcers and their staging and harmonizing measure specifications across settings of care.(4, 15)
- The Advancing Excellence Campaign is a national campaign to encourage, assist, and empower nursing homes to improve the quality of care and life for residents. Of the eight goals set by the effort, the fourth goal is for nursing home residents receive appropriate care to prevent and appropriately treat pressure ulcers when they develop.(10)

1a.4 Citations for Evidence of High Impact: 1. Russo CA, Steiner C, Spector W. Hospitalizations related to pressure ulcers among adults 18 years and older, 2006 (Healthcare Cost and Utilization Project Statistical Brief No. 64). December 2008. Available from <http://www.hcup-us.ahrq.gov/reports/statbriefs/sb64.pdf>

2. Bates-Jensen BM. Quality indicators for prevention and management of pressure ulcers in vulnerable elders. *Ann Int Med.* 2001;135(8 Part 2), 744-51.

3. Institute for Healthcare Improvement. Relieve the pressure and reduce harm. May 21, 2007. Available from <http://www.ihl.org/IHI/Topics/PatientSafety/SafetyGeneral/ImprovementStories/FSRelieveThePressureandReduceHarm.htm>

4. Hurd D, Moore T, Radley D, Williams C. Pressure ulcer prevalence and incidence across post-acute care settings. Home Health Quality Measures & Data Analysis Project, Report of Findings, prepared for CMS/OCSQ, Baltimore, MD, under Contract No. 500-2005-000181 TO 0002. 2010.

5. MacLean DS. Preventing & managing pressure sores. *Caring for the Ages.* March 2003;4(3):34-7. Available from <http://www.amda.com/publications/caring/march2003/policies.cfm>

6. Park-Lee E, Caffrey C. Pressure ulcers among nursing home residents: United States, 2004 (NCHS Data Brief No. 14). Hyattsville, MD: National Center for Health Statistics, 2009. Available from <http://www.cdc.gov/nchs/data/databriefs/db14.htm>

7. Agency for Healthcare Research and Quality. Agency news and notes: pressure ulcers are increasing among hospital patients. January 2009. Available from <http://www.ahrq.gov/research/jan09/0109RA22.htm>

8. National Pressure Ulcer Advisory Panel Board of Directors; Cuddigan J, Berlowitz DR, Ayello EA (Eds). Pressure ulcers in America: prevalence, incidence, and implications for the future. An executive summary of the National Pressure Ulcer Advisory Panel Monograph. *Adv Skin Wound Care.* 2001;14(4):208-15.

9. CMS. Medicare program: changes to the hospital inpatient prospective payment system and fiscal year 2008 rates. *Fed Regist.* August 22, 2007;72(162):47205.

10. Advancing Excellence in America’s Nursing Homes. Eight goals. n.d. Available from http://www.nhqualitycampaign.org/star_index.aspx?controls=eightgoals

11. The Joint Commission. Accreditation program: long term care patient safety goals (pre-publication version). 2009. Available from http://www.jointcommission.org/NR/rdonlyres/5274F44E-E45B-4A29-8D92-F3500EAC4DE6/0/RevisedChapter_LTC_NPSG_20090924.pdf

12. Institute for Healthcare Improvement. Protecting 5 million lives from harm. 2008. Available from <http://www.ihl.org/IHI/Programs/Campaign/>

13. AHRQ. On-time pressure ulcer healing project. July 2009. Available from <http://www.ahrq.gov/research/pressureulcerhealing/>

14. National Pressure Ulcer Advisory Panel. National Pressure Ulcer Advisory Panel. n.d. Available from <http://www.npuap.org/>

- 15. NQF. Pressure ulcer framework. 2010. Available from http://www.qualityforum.org/Projects/n-r/Pressure_Ulcer/Pressure_Ulcers.aspx
- 16. Duncan KD. Preventing pressure ulcers: The goal is zero. *Jt Comm J Qual Patient Saf.* 2007 Oct;33(10):605-10.
- 17. Brega A, Goodrich G, Hittle D, Conway K, Levy C. Empirical review and validation of refined pressure ulcer quality measures draft. Denver: Division of Health Care Policy and Research University of Colorado at Denver, 2008.
- 18. Lynn J, West J, Hausmann S, Gifford D, Nelson R, McGann P, Bergstrom N, Ryan JA (2007). Collaborative clinical quality improvement for pressure ulcers in nursing homes. *Journal of the American Geriatrics Society*, 55(10), 1663-9.

1b. Opportunity for Improvement

1b.1 Benefits (improvements in quality) envisioned by use of this measure: This measure is intended to encourage nursing facilities to focus on this important clinical issue in order to prevent pressure ulcers and to closely monitor and promote healing of existing pressure ulcers.

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

The high risk pressure ulcer measure is one of the current CMS publicly reported quality measures for nursing facilities and Five-Star Quality Rating System. In its analysis of the current quality measure using MDS 2.0 data from 2006, the University of Colorado found variability across facilities in the rates of pressure ulcers for high risk, long-stay residents, suggesting that it is possible for facilities to improve.(1) As presented in the table below, the national overall nursing facility mean was 12.5% and the standard deviation was 7.0%. The high risk pressure ulcer quality measure demonstrated variability across facilities; from 4.4% at the 10th percentile to 21.7% at the 90th percentile with only 1.7% of facilities reporting high risk residents with no pressure ulcers.

See attached Table 1: Measure Variability Across Facilities.

The most recent state and national averages for the current MDS 2.0 high risk pressure ulcer quality measure are reported on CMS's Nursing Home Compare Web site for the target quarter ending in June 2009.(2) The data continue to demonstrate the ongoing gap in facility performance; the national average was 10%, and state averages ranged from a low of 8.4% to a high of 18.7%.(2)

The Advancing Excellence Campaign in America's Nursing Homes is a national effort begun in 2006 to encourage, assist, and empower nursing homes to improve the quality of care and life for residents. The coalition comprises long-term care providers, medical professionals, consumers, employees, and state and federal agencies and is the largest and first coalition of its kind to measure quality by setting clinical and organizational goals for nursing homes. As of October, 2009, the Advancing Excellence Campaign has recruited over 7,600 nursing homes—47% of all nursing homes in the United States. Of the eight goals set by the effort, the fourth goal is for nursing home residents to receive appropriate care to prevent and appropriately treat pressure ulcers when they occur.(3)

As stated in the Implementation Guide, for this goal, the following objectives have been set for December 31, 2011 as part of Phase 2 efforts:

- A: The national average for high risk pressure ulcers will be at or below 9%.
- B: 30% of nursing homes will report rates of high risk pressure ulcers at or below 6%.
- C: The average of the scores of the nursing homes exceeding the 2009 Q1 90th percentile (n = 1147) will be reduced from 25% to 18%.
- D: Compared with June 2006, there will be 3,000 fewer residents with pressure ulcers per 100,000 nursing home residents. Applying this to the current pressure ulcer denominator of approximately 750,000 results in 22,500 fewer residents with pressure ulcers.
- E. Each state will attain an average facility-level improvement of 1 decile.
- F. Nursing homes will set a specific target to improve the prevalence of pressure ulcers by 1 decile rank over the next 24-month period.

To date, progress has been steady but incremental in meeting these goals as demonstrated by campaign

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.

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objective graphs: http://www.nhqualitycampaign.org/files/reports/results/q2-2009/Goal1_NationalObjectives_2009Q2_1page.pdf (4)

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. CMS. MDS quality measure/indicator report. 2008. Available from http://www.cms.hhs.gov/MDSPubQlandResRep/02_qmreport.asp#TopOfPage
3. Advancing Excellence in America’s Nursing Homes. Goal 4: reducing high risk pressure ulcers, implementation guide 2006. Available from http://www.nhqualitycampaign.org/files/impguides/4_PressureUlcer_TAW_Guide_FINAL_Oct_15.pdf
4. Advancing Excellence in America’s Nursing Homes. Goal 1: Nursing home residents receive appropriate care to prevent and minimize pressure ulcers. Available from http://www.nhqualitycampaign.org/files/reports/results/q2-2009/Goal1_NationalObjectives_2009Q2_4pages.pdf

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

Research suggests racial disparities in quality of care in nursing homes between African Americans and Caucasians (1, 2, 3, 4, 5) and between Hispanics and Caucasians.(6) In 1999, Lapane and colleagues found African American residents, had a lower prevalence of early-stage pressure ulcers but a higher prevalence of later stage pressure ulcers than Caucasian residents (even when controlling for other sociodemographic and clinical variables).(5) However, in 2009, CDC reported in their key findings from the 2004 National Nursing Home Survey that there was no significant difference between white and nonwhite populations with respect to having pressure ulcers.(7)

No research has been conducted on other types of disparities (e.g., ethnicity, rural/urban, or income) specifically for this measure.

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. Fennell ML, Feng Z, Clark MA, Mor V. Elderly Hispanics more likely to reside in poor quality nursing homes. Health Aff (Millwood). 2010;29(1):65-73.
7. Park-Lee E, Caffrey C. Pressure ulcers among nursing home residents: United States, 2004 (NCHS Data Brief No. 14). Hyattsville, MD: National Center for Health Statistics, 2009. Available from <http://www.cdc.gov/nchs/data/databriefs/db14.htm>.

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): The desired outcome is for a low percentage of long-stay, high risk nursing facility residents to have Stage 2-4 pressure ulcers. Pressure ulcers are a significant clinical concern in the nursing home population given that those at risk for developing pressure ulcers include the elderly, stroke and diabetic patients, those with dementia, and people who use wheelchairs or who are bedridden—that is, any patient with impaired mobility or sensation.(1, 3, 4) The most recent state and national averages for the current high risk pressure ulcer quality measure are reported on

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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:
 - 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.

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.

CMS's Nursing Home Compare Web site for the target quarter ending in June 2009.(4) The data continue to demonstrate the ongoing gap in facility performance; the national average was 10% and state averages ranged from a low of 8.4% to a high of 18.7%.(4)

Additionally, there is an increase in pressure ulcers in acute care facilities. In 2006, there were 503,300 acute hospital stays during which pressure ulcers were noted.(4, 5). Acute care hospitalizations related to pressure ulcers were more likely to be discharged to long-term care facilities (e.g., skilled nursing facilities, intermediate care facilities, or nursing homes), as compared with hospitalizations for all other conditions.(5, 6) In fact, over half of principal pressure ulcer stays (53.4%) and secondary pressure ulcer stays (54.5%) were discharged to long-term care—more than 3 times the rate of hospitalizations for all other conditions (16.2%).

1. Bates-Jensen BM. Quality indicators for prevention and management of pressure ulcers in vulnerable elders. *Ann Int Med.* 2001;135(8 Part 2), 744-51.

2. National Pressure Ulcer Advisory Panel Board of Directors; Cuddigan J, Berlowitz DR, Ayello EA (Eds). Pressure ulcers in America: prevalence, incidence, and implications for the future. An executive summary of the National Pressure Ulcer Advisory Panel Monograph. *Adv Skin Wound Care.* 2001;14(4):208-15.

3. Hurd D, Moore T, Radley D, Williams C. Pressure ulcer prevalence and incidence across post-acute care settings. Home Health Quality Measures & Data Analysis Project, Report of Findings, prepared for CMS/OCSO, Baltimore, MD, under Contract No. 500-2005-000181 TO 0002. 2010.

4. MacLean DS. Preventing & managing pressure sores. *Caring for the Ages.* March 2003;4(3):34-5. Available from <http://www.amda.com/publications/caring/march2003/policies.cfm>

5. Park-Lee E, Caffrey C. Pressure ulcers among nursing home residents: United States, 2004 (NCHS Data Brief No. 14). Hyattsville, MD: National Center for Health Statistics, 2009. Available from <http://www.cdc.gov/nchs/data/databriefs/db14.htm>

6. Russo CA, Steiner C, Spector W. Hospitalizations related to pressure ulcers among adults 18 years and older, 2006 (Healthcare Cost and Utilization Project Statistical Brief No. 64). December 2008. Available from <http://www.hcup-us.ahrq.gov/reports/statbriefs/sb64.pdf>

7. Agency for Healthcare Research and Quality. Agency news and notes: pressure ulcers are increasing among hospital patients. January 2009. Available from <http://www.ahrq.gov/research/jan09/0109RA22.htm>

8. Institute for Healthcare Improvement. Relieve the pressure and reduce harm. May 21, 2007. Available from <http://www.ihl.org/IHI/Topics/PatientSafety/SafetyGeneral/ImprovementStories/FSRelievethePressureandReduceHarm.htm>

1c.2-3. Type of Evidence: Evidence-based guideline, Observational study, Systematic synthesis of research, Cohort study, Expert opinion

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

The evidence identifying risk factors, prevention practices, intervention and treatment for pressure ulcers is well documented and supported by a substantial number of studies and practice guidelines across health care settings, clinical disciplines, and health care organizations. Risk factors include being elderly, frail, having a diagnosis of stroke, diabetes or dementia, and being in a wheelchair or being bedridden—that is, or the presence of impaired mobility, sensation or circulation, malnutrition, or weight loss.(1, 2, 3, 4, 5, 6)

Pressure ulcers may cause considerable harm to patients, hindering functional recovery, often causing pain, and often serving as vehicles for the development of serious infections. They have also been associated with an extended length of stay and increased mortality. In fact, an estimated 60,000 patients die each year from complications resulting from hospital-acquired pressure ulcers.(3)

Pressure ulcers are frequently preventable.(3, 4) Pressure ulcer prevention is not a new concept to health care facilities. Many organizations have prevention guidelines which entail essentially two major steps: first,

identifying patients at risk; and second, reliably implementing prevention strategies for all patients who are identified as being at risk.

For years, facilities developed prevention programs using proven techniques to prevent pressure ulcers but often lacked reliable strategies as well as a long-term commitment to prioritize and design caregiver's work so that prevention remains a priority. (3, 4)

Prevention strategies include six key elements: (1) conducting a pressure ulcer admission assessment for all patients, (2) reassessing risk for all patients daily, (3) inspecting skin daily, (4) managing moisture, (5) optimizing nutrition and hydration, and (6) minimizing pressure.(3, 4, 5, 6)

Education and training for staff on identifying pressure ulcer risk, prevention strategies, and treatment are critical to facility success and need to be done routinely to keep staff competent and current. Education should be based on the needs of the staff and appropriate to the patient population.(6)

1c.5 Rating of strength/quality of evidence *(also provide narrative description of the rating and by whom)*: The body of evidence for 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. Bates-Jensen BM. Quality indicators for prevention and management of pressure ulcers in vulnerable elders. *Ann Int Med.* 2001;135(8 Part 2), 744-51.

2. Hurd D, Moore T, Radley D, Williams C. Pressure ulcer prevalence and incidence across post-acute care settings. Home Health Quality Measures & Data Analysis Project, Report of Findings, prepared for CMS/OCSQ, Baltimore, MD, under Contract No. 500-2005-000181 TO 0002. 2010.

3. MacLean DS. Preventing & managing pressure sores. *Caring for the Ages.* March 2003;4(3):34-4. Available from <http://www.amda.com/publications/caring/march2003/policies.cfm>.

4. Advancing Excellence in America's Nursing Homes. Eight goals. n.d. Available from http://www.nhqualitycampaign.org/star_index.aspx?controls=eightgoals.

5. Dorner B, Posthauer ME, Thomas D. The role of nutrition in pressure ulcer prevention and treatment: National Pressure Ulcer Advisory Panel White Paper, 2009. Washington, DC: National Pressure Ulcer Advisory Panel, 2009.

6. Skin safety protocol: risk assessment and prevention of pressure ulcers. Health care protocol. Institute for Clinical Systems Improvement—Private Nonprofit Organization. March 2007. 31 pages. NGC:007033.

1c.9 Quote the Specific guideline recommendation (including guideline number and/or page number): This is an outcome measure and the guidelines listed address pressure ulcer prevention and treatment. Given the clinical importance of this measure, guidelines related to this measure are cited but are too extensive to quote.

1. Pressure ulcer treatment. Health care protocol. Institute for Clinical Systems Improvement—Private Nonprofit Organization. January 2008. 28 pages. NGC:007032.

2. Assessment and management of stage I to IV pressure ulcers. Registered Nurses' Association of Ontario—Professional Association. August 2002 (revised March 2007). 112 pages. NGC:005793.

3. Preventing pressure ulcers and skin tears. In: Evidence-based geriatric nursing protocols for best practice. Hartford Institute for Geriatric Nursing—Academic Institution. 2003 (revised January 2008). 27 pages. NGC:006346.

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.

- 4. Risk assessment & prevention of pressure ulcers. Registered Nurses' Association of Ontario—Professional Association. January 2002 (revised March 2005). 80 pages. NGC:004215.
- 5. Skin safety protocol: risk assessment and prevention of pressure ulcers. Health care protocol. Institute for Clinical Systems Improvement—Private Nonprofit Organization. March 2007. 31 pages. NGC:007033.
- 6. Pressure ulcers in the long-term care setting. American Medical Directors Association—Professional Association. 1996 (revised 2008). 44 pages. NGC:006410.

1c.10 Clinical Practice Guideline Citation: 1. Pressure ulcer treatment. Health care protocol. Institute for Clinical Systems Improvement—Private Nonprofit Organization. January 2008. 28 pages. NGC:007032

- 2. Assessment and management of stage I to IV pressure ulcers. Registered Nurses' Association of Ontario—Professional Association. August 2002 (revised March 2007). 112 pages. NGC:005793
- 3. Preventing pressure ulcers and skin tears. In: Evidence-based geriatric nursing protocols for best practice. Hartford Institute for Geriatric Nursing—Academic Institution. 2003 (revised January 2008). 27 pages. NGC:006346
- 4. Risk assessment & prevention of pressure ulcers. Registered Nurses' Association of Ontario—Professional Association. January 2002 (revised March 2005). 80 pages. NGC:004215

5. Skin safety protocol: risk assessment and prevention of pressure ulcers. Health care protocol. Institute for Clinical Systems Improvement—Private Nonprofit Organization. March 2007. 31 pages. NGC:007033

6. Pressure ulcers in the long-term care setting. American Medical Directors Association—Professional Association. 1996 (revised 2008). 44 pages. NGC:006410

1c.11 National Guideline Clearinghouse or other URL:
<http://www.guideline.gov/browse/browsemode.aspx?node=47462&type=1>

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

The guidelines utilized various rating systems to rate the strength of the recommendations. Specific recommendations were rated, however, the overall guidelines were not. The Institute for Clinical Systems Improvement uses a the following class system to evaluate <<what? Specific recommendations?>>: A (randomized, controlled trial), B (cohort study), C (non-randomized trial with concurrent or historical controls, case-control study, study of sensitivity and specificity of a diagnostic test, population-based descriptive study), D (cross-sectional study, case series, case report), M (meta-analysis, systematic review, decision analysis, cost-effectiveness analysis), R (consensus statement, consensus report, narrative review), X (medical opinion). The Registered Nurses' Association of Ontario utilizes the following levels of evidence: Ia (Evidence obtained from meta-analysis or systematic review of randomized controlled trials), Ib (Evidence obtained from at least one randomized controlled trial), IIa (Evidence obtained from at least one well-designed controlled study without randomization), IIb (Evidence obtained from at least one other type of well-designed quasi-experimental study without randomization), III (Evidence obtained from well-designed non-experimental descriptive studies, such as comparative studies, correlation studies and case studies), IV (Evidence obtained from expert committee reports or opinions and/or clinical experiences of respected authorities). The Hartford Institute for Geriatric Nursing also uses a level grading system: Level I (Systematic reviews (integrative/meta-analyses/clinical practice guidelines based on systematic reviews), Level II (Single experimental study (randomized controlled trials [RCTs]), Level III (Quasi-experimental studies), Level IV (Non-experimental studies), Level V (Care report/program evaluation/narrative literature reviews), Level VI (Opinions of respected authorities/consensus panels). American Medical Directors Association guideline was developed by an interdisciplinary work group using a process that combined evidence- and consensus-based thinking. The type of evidence supporting the recommendations was not specifically stated. Please see attached Table 2: Rating Strength of Recommendation.

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

The guidelines utilized various rating systems to rate the strength of the recommendations. Specific recommendations were rated, not the overall guidelines. Please see attached Table 2: Rating Strength of

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.

Recommendation.	
1c.14 Rationale for using this guideline over others: No particular guideline is recommended in this quality measure. The quality measure focuses on the outcome not on the process by which the facility reaches the outcome.	
TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for <i>Importance to Measure and Report</i> ?	1
Steering Committee: Was the threshold criterion, <i>Importance to Measure and Report</i> , met? Rationale:	1 Y <input type="checkbox"/> N <input type="checkbox"/>
2. SCIENTIFIC ACCEPTABILITY OF MEASURE PROPERTIES	
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)	Ev al Rat ing
2a. MEASURE SPECIFICATIONS	
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 (<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 long-stay residents who have been assessed with annual, quarterly, significant change or significant correction MDS 3.0 assessments during the selected time window and who are defined as high risk with one or more Stage 2-4 pressure ulcer(s). High risk populations are those who are comatose, or impaired in bed mobility or transfer, or suffering from malnutrition.	
2a.2 Numerator Time Window (<i>The time period in which cases are eligible for inclusion in the numerator</i>): The data are collected quarterly. The term "annual" in this sentence refers to one of the various MDS 3.0 assessments utilized to calculate the measure (which may be an admission, annual, quarterly, significant change or correction assessment). Each quarter (3 month window) CMS selects the MDS 3.0 annual, quarterly, significant change or significant correction MDS 3.0 assessments from each nursing facility.	
2a.3 Numerator Details (<i>All information required to collect/calculate the numerator, including all codes, logic, and definitions</i>): The numerator is the number of long-stay residents who have been assessed with annual, quarterly, significant change or significant correction MDS 3.0 assessments during the selected time window and who are reported as having one or more Stage 2-4 pressure ulcer(s) M0300 (current number of unhealed [non-epithelialized] pressure ulcers at each stage); Stage 1 ulcers are not included in this measure because recent studies have identified difficulties in objectively measuring them across different populations (Lynne, 2007). M0300 B. 1 =1 or > (number of Stage 2): Partial thickness loss or dermis presenting as a shallow open ulcer with red or pink wound bed, without slough. May also present as an intact or open/ruptured blister. OR M0300 C.1 =1 or > (number of Stage 3): Full thickness tissue loss. Subcutaneous fat may be visible but bone, tendon, or muscle is not exposed. Slough may be present but does not obscure the depth of tissue loss. May include undermining or tunneling.	

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 NOF's Health Information Technology Expert Panel (HITEP).

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OR

M0300 D.1 =1 or > (number of Stage 4): Full thickness tissue loss with exposed bone, tendon, or muscle. Slough or eschar may be present on some parts of the wound bed. Often includes undermining or tunneling.

OR

Section I—Other—Active Diagnoses in the last 7 days I800 = ICD-9-CM codes for pressure ulcers 707.22 (Stage 2), 707.23 (Stage 3), or 707.24 (Stage 4).

Lynn J, West J, Hausmann S, Gifford D, Nelson R, McGann P, Bergstrom N, Ryan JA (2007). Collaborative clinical quality improvement for pressure ulcers in nursing homes. *Journal of the American Geriatrics Society*, 55(10), 1663-9.

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

The denominator includes all long-stay residents who received an annual, quarterly, or significant change or significant correction assessment during the target quarter and who did not meet 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 long-stay residents in the nursing facility.

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

Every quarter (3-month period) CMS selects the MDS 3.0 annual, quarterly, significant change or significant correction assessments from each nursing facility.

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

The denominator is the number of long-stay residents who have been assessed with annual, quarterly, significant change or significant correction MDS 3.0 assessments (A0310.A=02, 03, 04, 05, 06) during the selected time window and who are defined as high risk by meeting one of the following criteria on the assessment:

1. Impaired in bed mobility or transfer as indicated by item G0110.A.1, Bed mobility (self-performance) or G0110B.1 Transfer (self-performance) = 3(extensive assistance), 4 (total dependence), 7 (activity occurred only once or twice) or 8 (activity [or any part of the ADL was not performed by resident or staff at all over the entire 7 day period)

OR

2. Item B0100 (Comatose) = 1

OR

3. Section I Active Diagnoses Item I5600 (Malnutrition [protein or calorie] or at risk for malnutrition) is checked

2a.9 Denominator Exclusions (*Brief text description of exclusions from the target population*): A long-stay resident is excluded from the denominator if the MDS assessment in the current quarter is an OBRA admission assessment or a 5-day PPS assessment or if there is missing data in the relevant sections of the MDS. The OBRA admission assessment and a 5-day PPS assessment are excluded because pressure ulcers identified on them reflect care received in the previous setting and does not reflect the quality of care provided in the nursing facility.

Nursing facilities with fewer than 30 residents in the sample are excluded from public reporting because of small sample size.

2a.10 Denominator Exclusion Details (*All information required to collect exclusions to the denominator, including all codes, logic, and definitions*):

A0310A = 01 OBRA Admission assessment

OR

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>A0310B = 01 5-day PPS assessment OR Missing data for high-risk including: 1. Impaired in bed mobility or transfer (self performance) as indicated by G0110A.1 or G0110B.1 OR 2. B0100 (Comatose) OR 3. QM not triggered and there is missing data on any of the three pressure ulcer items (if the QM is triggered at least one Stage 2, 3, or 4 pressure ulcer the measure can still be calculated) Stage 2-4 pressure ulcers: M0300 (Current Number of Unhealed [non-epithelialized] Pressure Ulcers at Each Stage): M0300B1, Stage 2: Partial thickness loss or dermis presenting as shallow open ulcer with red or pink wound bed, without slough. May also present as an intact or open/ruptured blister. OR M0300C1, Stage 3: Full thickness tissue loss. Subcutaneous fat may be visible but bone, tendon, or muscle is not exposed. Slough may be present but does not obscure the depth of tissue loss. May include undermining or tunneling. OR M0300D1, Stage 4: Full thickness tissue loss with exposed bone, tendon, or muscle. Slough or eschar may be present on some parts of the wound bed. Often includes undermining or tunneling.</p> <p>Long-stay facilities are excluded from public reporting because of small sample size if their sample includes fewer than 30 residents.</p>
<p>2a.11 Stratification Details/Variables (All information required to stratify the measure including the stratification variables, all codes, logic, and definitions):</p>
<p>2a.12-13 Risk Adjustment Type: No risk adjustment necessary</p>
<p>2a.14 Risk Adjustment Methodology/Variables (List risk adjustment variables and describe conceptual models, statistical models, or other aspects of model or method): 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 2a.20 Interpretation of Score: 2a.21 Calculation Algorithm (Describe the calculation of the measure as a flowchart or series of steps): For each facility, the number of long-stay residents meeting the numerator criteria and the number of (non-excluded) residents meeting the denominator criteria 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 (e.g., significance testing): 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 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): This is not applicable.</p>
<p>2a.24 Data Source (Check the source(s) for which the measure is specified and tested) Electronic clinical data</p>
<p>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.): Nursing Home MDS 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>

2a.29-31 Data dictionary/code table web page URL or attachment: [URL
http://www.cms.hhs.gov/NursingHomeQualityInits/25_NHQIMDS30.asp#TopOfPage](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)
Population: national, 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): Three major tests of the reliability of the high risk pressure ulcer quality 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.(1) This project used a nationwide sample of randomly selected nursing homes using MDS assessments for the period April 1 to December 31, 2006.(1) DAVE 2 performed 173 two-stage reviews.

Second, the University of Colorado used two sources of data: 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.(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.

Third, testing of the reliability of MDS 3.0 data items underlying the high risk pressure ulcer quality measure and a comparison with the MDS 2.0 quality measures were conducted by RAND as part of the MDS 3.0 development process.(3) A representative sample of for-profit and not-for-profit facilities and hospital-based and free-standing facilities was recruited for the study, which included 71 community nursing homes in 8 states, 19 VA nursing homes, and 1,402 nursing home residents for the highrisk pressure ulcer quality measure.

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.
3. 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>.

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

Three sets of analytic methods were used. First, in the DAVE 2 Project, trained nurse reviewers selected a current resident with a recent assessment performed by the nursing home (NH) within the last 14 days.(1) In the first stage of this review, the nurse reviewer conducted a blind reassessment of the resident using standard MDS assessment and coding procedures (e.g., 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, the DAVE 2 nurse reviewer’s assessment was compared with 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.

Second, in terms of measure stability, which is not exactly the same as reliability but is a concept related to

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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it, the University of Colorado examined the percentage of facilities that had a change in ranking from one quarter to the next of at least 3 deciles. (2) This indicator of stability was computed for each of the 12 pairs of adjacent quarters for which data were available (2003 Q3 through 2006 Q3). The range of stability measures across the 12 comparisons was very small (i.e., the difference between the maximum and minimum values), indicating that measure stability is quite constant over time. For high risk pressure ulcers, the minimum percentage was 27.0%, and the maximum percentage was 29.0%.

Third, the national test of MDS 3.0 items examined agreement between assessors (reliability). (2) QIOs were employed to identify gold-standard (research) nurses and recruit community nursing homes to participate in the national evaluation. 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. Quality measures using the MDS 2.0 and the MDS 3.0 were calculated and then compared, with correlations and Kappas calculated.

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.
3. 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>.

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

As part of the DAVE 2 project, Abt Associates used two methods to assess the reliability of the MDS 2.0 quality measures. (1) First, for each MDS data element, the rate of discrepancies between the reconciled and original facility assessments has been reported. For the high risk pressure ulcer items, the two-stage review discrepancy rates for Stage 2, 3, and 4 pressure ulcers were 3.8%, 0.0%, and 0.0% respectively. Second, Abt reported the rate of discrepancies between each quality measure, computed from facility data, and its counterpart, computed from reconciled data. For high risk pressure ulcers, the two-stage discrepancy rate was 13%.

Second, in terms of measure stability, the University of Colorado examined the percentage of facilities that had a change in ranking of at least three deciles from one quarter to the next. (2) For high risk pressure ulcer, 28% of facilities had a change of 3 deciles or more from one quarter to the next.

Third, in their testing of the MDS 3.0, RAND compared the results on the nursing home quality measures using the MDS 3.0 and the MDS 2.0, both at the individual resident level and at the facility level. (3) At the resident level, high risk pressure ulcer rate using the MDS 2.0 was 13.3%; using the MDS 3.0 it was 13.3%; the Kappa was 0.92, the correlation was 0.92, and the percent agreement was 98.1. Kappa is a statistical measure of inter-rater agreement for qualitative data, ranging from 0.0 to 1.0. A rating of 0.70 is considered "substantial agreement." At the facility level, the MDS 2.0 rate of high risk pressure ulcers was 14% and the MDS 3.0 rate was 14.5%, with a correlation of 0.97, which is quite high.

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.
3. 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>.

2c. Validity testing

2c.1 Data/sample (*description of data/sample and size*): The data were validated based on two sources: 1)

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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.

national facility-level quality measure data from 2003 Q3 through 2006 Q3 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, as well as nearly complete data for April 2006 and partial data for May and June 2006.

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. 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):

Yes, the testing is incomplete because the reliability testing for the measure is based on the MDS 2.0. The underlying pressure ulcer items have significantly changed from the MDS 2.0 to the MDS 3.0 although RAND did perform item reliability testing on a national level as part of their MDS 3.0 development work. (1)

Also, the University of Colorado performed limited analysis of the impact of transition to the MDS 3.0.

1. 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>.

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 pressure ulcer 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 pressure ulcer 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 pressure ulcer rates explained in the state in which a facility was located.

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

To evaluate convergent validity, the current MDS 2.0 based quality measure was assessed for correlation with all other measures. The high risk pressure ulcer measure was not well correlated to other quality measures except bedfast.

See attached Table 3: Correlations of Quality Measures.

The analysis found that public reporting appears to have had some influence on the decreased high risk pressure ulcers over time, as evidenced by the decline in the pressure ulcer rate from 13.8 to 12.5. However, the quality measure did demonstrate seasonal and geographic variation, suggesting that the measure is influenced by factors beyond the provision of care.

See attached Table 4: Measure Trends Over Time.

Also, there was variability across facilities in the rates of pressure ulcers for high risk, long-stay residents, suggesting that it is possible for facilities to improve. (1) As presented in the table below, the national overall nursing facility mean in 2006 Q3 was 12.5% and the standard deviation was 7.0%. The high risk pressure ulcer quality measure demonstrated variability across facilities; from 4.4% at the 10th percentile to 21.7% at the 90th percentile with only 1.7% of facilities reporting highrisk residents with no pressure ulcers.

See attached Table 1: Measure Variability Across Facilities.

The most recent state and national averages for the current high risk pressure ulcer quality measure are reported on CMS's Nursing Home Compare website for the target quarter ending in June 2009. (2) The data continue to demonstrate the ongoing gap in facility performance; the national average was 10% and state

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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.

<p>ranged from a low of 8.4% to a high of 18.7%. (2)</p> <p>The statistical limitations of this measure may reflect a limited clinical relationship of high risk pressure ulcers to the other quality 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 assessments of long-stay residents for whom complete data are available are included. Short-term post-acute care residents are excluded because they are likely to have developed their pressure ulcers in the hospital rather than at the nursing facility.</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: The measure is not risk adjusted through a statistical model. However, the measure only applies to long-stay residents. The measure is limited to the long-stay population because post-acute care patients may have developed their pressure ulcers in the hospital rather than the nursing facility. Efforts to develop an adequate risk adjustment, with some success, were undertaken by the University of Colorado (1) as well as Berlowitz (2) based on MDS 2.0 items. The MDS 3.0 pressure ulcer items define Stage 2-4 pressure ulcers differently than the MDS 2.0 and the data needs to be analyzed before risk adjustment can be examined.</p> <p>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.</p> <p>2. Berlowitz DR, Brandeis GH, Anderson JJ, Ash AS, Kader B, Morris JN, et al. Evaluation of a risk-adjustment model for pressure ulcer development using the Minimum Data Set. J Am Geriatr Soc. 2001;49(7):872-6.</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 high risk pressure ulcer rates at the facility level based on the current measure and underlying 2.0 items. (1) Below are the measure scores from testing or current use. For 10,344 facilities, the mean for the high-risk pressure ulcer measure was 12.5% and the standard deviation was 7.0%. The quality measure varied from 4.4% at the 10th percentile to 21.7% at the 90th percentile; only 1.7% of facilities had no highrisk residents with pressure ulcers.</p> <p>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>

- 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. Error! Bookmark not defined. 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>The most recent state and national averages for the current high-risk pressure ulcer quality measure are reported on CMS's Nursing Home Compare Web site for the target quarter ending in June 2009. (2) The data continue to demonstrate the ongoing gap in facility performance; the national average was 10% and state ranged from a low of 8.4% to a high of 18.7%. (2)</p> <p>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. CMS. MDS quality measure/indicator report. 2008. Available from http://www.cms.hhs.gov/MDSPubQlandResRep/02_qmreport.asp#TopOfPage</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 10,344 facilities, the mean pressure ulcer rate was 12.5 percent with a standard deviation of 7.0 percent. The attached Table 1: Measure Variability Across Facilities reports the full results of the analysis.</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 was previously stratified by high risk and low risk. However, the low risk measure will no longer be publicly reported because the measure demonstrated little variability among facilities, the 50th percentile was 1.9% as well as nearly 40% of nursing facilities reported triggering rates of 0%. (1) The measure is not stratified by race, ethnicity, income, or rural/urban location. As noted earlier, the measure is limited to long-stay residents.</p> <p>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.</p> <p>2h.2 If disparities have been reported/identified, but measure is not specified to detect disparities, provide follow-up plans: This is not applicable; however RTI will analyze the proposed quality measure data when MDS 3.0 is implemented.</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, <i>Scientific Acceptability of Measure Properties</i>, 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>

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.

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.

3. USABILITY	
Extent to which intended audiences (e.g., consumers, purchasers, providers, policy makers) can understand the results of the measure and are likely to find them useful for decision making. (evaluation criteria)	Ev 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). If not publicly reported, state the plans to achieve public reporting within 3 years): The highrisk pressure ulcer measure is available on the Nursing Home Compare Web site: http://www.medicare.gov/NHCompare/Include/DataSection/Questions/SearchCriteriaNEW.asp?version=default&brower=IE%7C%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 highrisk quality measure will be used by nursing homes as a tool to improve quality of care by preventing pressure ulcers; when pressure ulcers do occur, nursing homes can use the measure to ensure that they are treated in a timely fashion and according to guidelines. Data on facility performance on the quality measures are also used by surveyors to identify problem areas when they inspect nursing facilities.</p> <p>Testing of Interpretability (Testing that demonstrates the results are understood by the potential users for public reporting and quality improvement)</p> <p>3a.4 Data/sample (description of data/sample and size): A recent study by Castle found that consumers could accurately interpret the quality information given for all the current nursing home quality measures based on MDS 2.0 reported by Nursing Home Compare.(1)</p> <p>In the Castle article, an initial sample of 8,000 family members with elders living in one of 200 randomly selected nursing homes was used.(1) In each facility, one family member (or significant other) was identified as the family contact person for each of 40 residents by nursing home staff. A total of 615 facilities were approached before the target of 200 participating facilities was achieved, giving a facility participation rate of 33%. From these 200 facilities, a total of 4,754 surveys were returned (i.e., family response rate = 59%).</p> <p>1. Castle N. The Nursing Home Compare report card: consumers' use and understanding. J Aging Soc Policy. 2009;21(2), 187-208.</p> <p>3a.5 Methods (e.g., focus group, survey, QI project): A comprehension index was developed to examine whether the information contained in Nursing Home Compare for each currently reported quality measure (based on MDS 2.0) was understood by family members.(1) The measures ranged from 0.0 to 8.0.</p> <p>1. Castle N. The Nursing Home Compare report card: consumers' use and understanding. J Aging Soc Policy. 2009;21(2), 187-208.</p> <p>3a.6 Results (qualitative and/or quantitative results and conclusions): Castle 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 indicated a relatively good understanding of the measures.(1) The comprehension index for the current high risk pressure ulcer measure, based on the MDS 2.0, was 5.47 on a scale of 0.00 to 8.00, slightly above average (5.32) for the non-risk-adjusted measures.</p> <p>1. Castle N. The Nursing Home Compare report card: consumers' use and understanding. J Aging Soc Policy. 2009;21(2), 187-208.</p>	
	3a C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/>

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>3b/3c. Relation to other NQF-endorsed measures</p> <p>3b.1 NQF # and Title of similar or related measures: The proposed measure is intended to replace NQF # 0198 High Risk Residents with Pressure Ulcers because of changes in the underlying items composing the measure as well as the elimination of reporting Stage 1 pressure ulcers. Other related measures are NQF # 0181 Increase in Number of Pressure Ulcers, Centers for Medicare & Medicaid Services (2009) / NQF # 0199 Average Risk Residents with Pressure Ulcers (2003) Centers for Medicare & Medicaid Services / NQF # 0187 Recently Hospitalized Residents with Pressure Ulcers (2003) Centers for Medicare & Medicaid Services / NQF # 0201 Pressure Ulcer Prevalence, The Joint Commission (2009) / NQF # 0538 Pressure Ulcer Prevention Included in Plan of Care, Centers for Medicare & Medicaid Services (2009) / NQF # 0539 Pressure Ulcer Prevention Plans Implemented, Centers for Medicare & Medicaid Services (2009) / NQF # 0540 Pressure Ulcer Risk Assessment Conducted, Centers for Medicare & Medicaid Services (2009).</p>	
<p>(for NQF staff use) Notes on similar/related endorsed or submitted measures:</p>	
<p>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? The measure specifications are not harmonized with any other pressure ulcer measures but the underlying MDS 3.0 items that make up the proposed measure moves towards that goal. The NQF's initiative "National Voluntary Consensus Standards for Developing a Framework for Measuring Quality for Prevention and Management of Pressure Ulcers," begun in 2008, has several objectives, including determining how to measure the incidence, prevalence, and staging of pressure ulcers and harmonizing measure specifications across settings of care. The revised approach to documenting pressure ulcers in the MDS 3.0 is part of that process.</p> <p>The current publicly reported nursing home quality measure reports on Stage 1-4 pressure ulcers based on the MDS 2.0 for long-stay residents identified as high risk (comatose or impaired in bed mobility or transfer or suffering from malnutrition). The MDS 2.0 items for pressure ulcers were problematic for wound care experts because they (1) used reverse staging, which does not reflect the pathophysiology of wound healing; (2) failed to capture size or change in size and therefore missed improvement; (3) inappropriately "staged" stasis ulcers; (4) failed to document pressure ulcers that were present on admission, and (5) did not allow for category "unstageable." The goal of the MDS 3.0 pressure ulcer items was to align MDS 3.0 with accepted best practices.</p> <p>The proposed measure reports Stage 2-4 pressure ulcers based on new items on the MDS 3.0. As Saliba and Buchanan noted during the development of the MDS 3.0, whenever possible, they included items or language used in other health care settings in order to improve communication across settings and providers (e.g., the pressure ulcer items included in the National Pressure Ulcer Advisory Panel's PUSH tool are used to describe pressure ulcers in the MDS 3.0). (1)</p> <p>The variation across populations and measure specification of the range of NQF endorsed pressure ulcer measures will make harmonization challenging. The other NQF endorsed pressure ulcers measures vary by examining only hospital-acquired (nosocomial) Stage 2 or greater pressure ulcers on the day of the prevalence study or by focusing on the home care setting and whether 1) patients with assessed risk for Pressure Ulcers whose physician-ordered plan of care includes intervention(s) to prevent them, 2) patients with assessed risk for Pressure Ulcers for whom interventions for pressure ulcer prevention were implemented during their episode of home care, or 3) patients who were assessed for risk of pressure ulcers at start/resumption of home health care.</p> <p>1. 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>3b C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/> NA <input type="checkbox"/></p>
<p>3c. Distinctive or Additive Value 3c.1 Describe the distinctive, improved, or additive value this measure provides to existing NQF-endorsed measures: The proposed measure reports Stage 2-4 pressure ulcers based on new items on the MDS 3.0. As Saliba and</p>	<p>3c C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/></p>

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).

<p>Buchanan noted during the development of the MDS 3.0, whenever possible, they included items or language consistent with other health care settings in order to improve communication across settings and providers (e.g., the pressure ulcer items included in the National Pressure Ulcer Advisory Panel's PUSH tool are used to describe pressure ulcers in the MDS 3.0).(1) Therefore, the proposed measure, based on the new MDS 3.0 pressure ulcer items, better aligns the measure with accepted best practices. Additionally, Stage 1 ulcers are not included in this measure because recent studies have identified difficulties in objectively measuring them across different populations (Lynn, 2007)</p> <p>This measure is similar to other NQF-endorsed pressure ulcer measures that examine pressure ulcers in other settings. The existing NQF-endorsed pressure ulcer measures focus only on hospital-acquired (nosocomial) Stage 2 or worse pressure ulcers on the day of the prevalence study. Or, they focus on the home care setting and whether: (1) patients with assessed risk for pressure ulcers have a physician-ordered plan of care that includes prevention focused intervention(s), (2) patients with assessed risk for pressure ulcers have interventions for pressure ulcer prevention that were implemented during an episode of home care, or (3) patients were assessed for risk of pressure ulcers at start/resumption of home health care.</p> <p>Lynn J, West J, Hausmann S, Gifford D, Nelson R, McGann P, Bergstrom N, Ryan JA (2007). Collaborative clinical quality improvement for pressure ulcers in nursing homes. <i>Journal of the American Geriatrics Society</i>, 55(10), 1663-9.</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>	<input type="checkbox"/> <input type="checkbox"/> N <input type="checkbox"/> NA <input type="checkbox"/>
<p>TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for <i>Usability</i>?</p>	<p>3</p>
<p>Steering Committee: Overall, to what extent was the criterion, <i>Usability</i>, met? Rationale:</p>	<p>3 <input type="checkbox"/> C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> 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>Ev al Rat ing</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? 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 <input type="checkbox"/> C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/></p>
<p>4b. Electronic Sources</p> <p>4b.1 Are all the data elements available electronically? (<i>elements that are needed to compute measure scores are in defined, computer-readable fields, e.g., electronic health record, electronic claims</i>) No</p> <p>4b.2 If not, specify the near-term path to achieve electronic capture by most providers.</p>	<p>4b <input type="checkbox"/> C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> 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</p>	<p>4c <input type="checkbox"/> C <input type="checkbox"/> P</p>

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.

numerator and denominator specifications? No	M <input type="checkbox"/> N <input type="checkbox"/> NA <input type="checkbox"/>
4c.2 If yes, provide justification.	
4d. Susceptibility to Inaccuracies, Errors, or Unintended Consequences	
<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>The proposed measure strengthens CMS' ability to measure pressure ulcers accurately because of improvements in the underlying items as well as eliminating Stage 1 ulcers from reporting. The goal of the new MDS 3.0 items was to align the pressure ulcer items with accepted best practices using the National Pressure Ulcer Advisory Panel's PUSH tool to describe pressure ulcers. In their validation work, Saliba and Buchanan reported that according to staff feedback, "89% felt that definitions were clear (3% disagreed)." (1)</p> <p>For the updated MDS 3.0 pressure ulcer items, average gold-standard to gold-standard kappa was .905. Average gold-standard to facility-nurse kappa was .937. However, implementation on a nationwide basis does not begin until October 2010, and the data will be analyzed to address any concerns regarding inaccuracies, errors, or unintended consequences.</p> <p>1. 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>	4d C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/>
4e. Data Collection Strategy/Implementation	
<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:</p> <p>The data collection method, the MDS, is already in operation and has been for many years.</p> <p>4e.2 Costs to implement the measure (costs of data collection, fees associated with proprietary measures):</p> <p>The data are collected as part of an existing, legally mandated process. There will be no additional costs to collect this information because it is already collected. However, the pressure ulcer measure items have changed substantially in the MDS 3.0 and require additional training for facility staff.</p> <p>4e.3 Evidence for costs:</p> <p>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>	4e C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/>
TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for Feasibility?	4
Steering Committee: Overall, to what extent was the criterion, Feasibility, met? Rationale:	4 C <input type="checkbox"/> P <input type="checkbox"/> M <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-limit

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).

	ed <input type="checkbox"/>
Steering Committee: Do you recommend for endorsement? Comments:	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 5: Nursing Home Quality Measures Technical Expert Panel (January 2009). This technical expert panel met during 2 days in January 2009 to review the environmental scan of the current quality measures and make recommendations regarding their 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.cms.hhs.gov/NursingHomeQualityInits/downloads/NHQIQMUsersManual.pdf	
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:	
Ad.11 -13 Additional Information web page URL or attachment: Attachment Pressure Ulcers Long Stay tables_FINAL-634045016652767500.doc	
Date of Submission (MM/DD/YY): 07/12/2010	