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 <u>evaluation criteria</u> 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 #: 0674 NQF Project: Nursing Homes 2010

MEASURE DESCRIPTIVE INFORMATION

De.1 Measure Title: Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay)

De.2 Brief description of measure: This measure is based on data from all non-admission MDS 3.0 assessments of long-stay nursing facility residents which may be annual, quarterly, significant change, significant correction, or discharge assessment. It reports the percent of residents who experienced one or more falls with major injury (e.g., bone fractures, joint dislocations, closed head injuries with altered consciousness, and subdural hematoma) in the last year (12-month period). The measure is based on MDS 3.0 item J1900C, which indicates whether any falls that occurred were associated with major injury.

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. 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. A.1 Do you attest that the measure steward holds intellectual property rights to the measure and the right to use aspects of the measure owned by another entity (e.g., risk model, code set)? Yes	
A.2 Indicate if Proprietary Measure (as defined in measure steward agreement):	Α
A.3 Measure Steward Agreement: Government entity and in the public domain - no agreement necessary	Y□
A.4 Measure Steward Agreement attached:	N

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B. The measure owner/steward verifies there is an identified responsible entity and process to maintain and update the measure on a schedule that is commensurate with the rate of clinical innovation, but at least every 3 years. Yes, information provided in contact section	B Y□ N□		
C. The intended use of the measure includes <u>both</u> public reporting <u>and</u> quality improvement. ▶Purpose: Public Reporting			
D. The requested measure submission information is complete. Generally, measures should be fully developed and tested so that all the evaluation criteria have been addressed and information needed to evaluate the measure is provided. Measures that have not been tested are only potentially eligible for a time-limited endorsement and in that case, measure owners must verify that testing will be completed within 12 months of endorsement.			
D.1Testing: No, testing will be completed within 12 months D.2 Have NQF-endorsed measures been reviewed to identify if there are similar or related measures? Yes	D Y□ N□		
(for NQF staff use) Have all conditions for consideration been met? Staff Notes to Steward (if submission returned):			
Staff Notes to Reviewers (issues or questions regarding any criteria):			
Staff Reviewer Name(s):			
TAP/Workgroup Reviewer Name:			
Steering Committee Reviewer Name:			
1. IMPORTANCE TO MEASURE AND REPORT			
Extent to which the specific measure focus is important to making significant gains in health care quality (safety, timeliness, effectiveness, efficiency, equity, patient-centeredness) and improving health outcomes for a specific high impact aspect of healthcare where there is variation in or overall poor performance. <i>Measures must be judged to be important to measure and report in order to be evaluated against the remaining criteria</i> . (evaluation criteria) 1a. High Impact			
(for NQF staff use) Specific NPP goal:			
1a.1 Demonstrated High Impact Aspect of Healthcare: Leading cause of morbidity/mortality, Patient/societal consequences of poor quality, High resource use 1a.2			
1a.3 Summary of Evidence of High Impact: Research findings indicate that approximately 75% of nursing facility residents fall at least once a year; twice the rate of their counterparts in the community.(1) Further, it is estimated that 10%-25% of nursing facility resident falls result in fractures and/or hospitalization.(2) Saliba and Buchanan tested the proposed MDS 3.0 items, including those assessing the prevalence of any falls and falls with major injuries. Their study included 4,586 residents from 71 community nursing facilities and 19 Veteran's Administration nursing facilities in 8 different states and found rates of falls and falls with injury similar to those reported in the literature. During their six month data collection period, they found that approximately 24% of patients reported at least one fall since the prior assessment. Among the 24% who experienced a fall, 9% had at least one fall with major injury and an additional 30% had at least one fall with minor injury.(3)	1a C		
The effort to monitor the prevalence of injurious falls at the facility level is very important for protecting the			

- Comment [KP1]: 1a. The measure focus addresses:

 •a specific national health goal/priority identified by NOF'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).

Falls also represent a significant cost burden to the entire health care system, with injurious falls accounting for 6% of medical expenses among those age 65 and older.(6) Studies have shown that falls account for 10% of visits to the emergency department and 6% of urgent hospitalizations among elderly people. (7) In addition, a 1993 review estimated the lifetime costs associated with fall-related injuries (direct, morbidity and mortality) to be \$12.6 billion, or approximately 6% of all medical care expenses for the elderly US population.(8) Among the skilled nursing facility population, the average 6 month cost of a patient with a hip fracture was estimated at \$11,719 in 1996 U.S. dollars.(9)

In their 2006 work, Sorensen et al. document the costs associated with falls of varying severity in acute care hospitals, as well as in post-acute and long-term care settings. Their work suggests that in acute care hospitals, the costs incurred for falls with major injury range from \$979 for a typical case with a simple fracture to \$14,716 for a typical case with multiple injuries.(10) In addition, Sorensen et al. also compared the cost of post-falls care in long-term care settings with the cost of patient care prior to hospitalization. They found that patients who experienced a fall with major injury, had an additional post-fall Resource Utilization Group (RUG) III per diem cost ranging from \$1,999 per year for a typical case with a simple fracture to \$15,992 per year for a case with multiple injuries.(10)

- **1a.4 Citations for Evidence of High Impact:** 1. Rubenstein LZ, Josephson KR, Robbins AS. Falls in the nursing home. Ann Intern Med. 1994 Sep 15; 121(6):442-51. Review.
- 2. Vu MQ, Weintraub N, Rubenstein LZ. Falls in the nursing home: are they preventable? J Am Med Dir Assoc. 2004 Nov-Dec; 5(6):401-6. Review.
- 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.
- 4. Magaziner J, Lydick E, Hawkes W, Fox KM, Zimmerman SI, Epstein RS, Hebel JR. Excess mortality attributable to hip fracture in white women aged 70 years and older. Am J Public Health. 1997 Oct;87(10):1630-6.
- 5. Yardley L, Smith H. A prospective study of the relationship between feared consequences of falling and avoidance of activity in community-living older people. Gerontologist. 2002 Feb;42(1):17-23.
- 6. Tinetti ME, Williams CS. The effect of falls and fall injuries on functioning in community-dwelling older persons. J Gerontol A Biol Sci Med Sci. 1998 Mar;53(2):M112-9.
- 7. Tinetti ME. Clinical practice. Preventing falls in elderly persons. N Engl J Med. 2003 Jan 2;348(1):42-9. Review
- 8. Runge JW. The cost of injury. Emerg Med Clin North Am. 1993;11 (1):241-53.
- 9. Kramer AM, Steiner JF, Schlenker RE, et al. Outcomes and costs after hip fracture and stroke: a comparison of rehabilitation settings. JAMA. 1997;277 (5):396-404.
- 10. Sorensen SV, de Lissovoy G, Kunaprayoon D, Resnick B, Rupnow MF, Studenski S. A taxonomy and economic consequence of nursing home falls. Drugs Aging. 2006;23(3):251-62.

1b. Opportunity for Improvement

- 1b.1 Benefits (improvements in quality) envisioned by use of this measure: The anticipated improvement in quality is a reduction of falls with major injury. Facilities can use this information to identify the rate of falls with major injury and develop falls prevention quality improvement programs.
- 1b.2 Summary of data demonstrating performance gap (variation or overall poor performance) across providers:

While the evidence gathered from multiple studies indicates a generally high rate of falls with major injury among nursing facility residents, clear variation between facilities is also evident. The literature on this topic dates back to a 1994 review by Rubenstein et al. which analyzed the annual incidence of falls and percentage

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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of falls with serious injury from 17 different studies. The annual incidence of falls reported per 1000 beds among these studies ranged from 220 (Gostynski, 1991) to 3,600 (Blake & Morfitt, 1986).(1, 2, 3) In turn, the percentage of falls with serious injury ranged from 1% (Cacha, 1979) to 35% (Svensson et al., 1991).(1, 4, 5) Such variation between facilities suggests the potential for improvement in this area; similarly in 2005, the U.S. Public Health Service estimated that approximately two-thirds of deaths due to falls are potentially preventable.(6)

In recognition of the effects of falls on morbidity, functioning, quality of life and health care utilization, the Department of Health and Human Services included injury prevention, which incorporates falls prevention, as one of the 10 leading health indicators in the Healthy People 2010 initiative. (6) To date, studies have identified a number of risk factors for falls within the nursing facility population, including history of falls, impaired cognitive function, postural hypotension, psychotropic and cardiovascular medications, use of restraints, balance problems during transfer and ambulation, and insomnia. (7-11)

While evidence for various falls prevention strategies has been mixed, a 2004 meta-analysis conducted by Chang et al. found that the use of a multifactorial falls risk assessment and management program resulted in significantly fewer falls among older adults. (12) Within this meta-analysis, a multifactorial falls risk assessment was defined as a focused post-fall assessment or systematic risk factor screening among individuals at risk tied to intervention recommendations and follow-up on uncovered risks. Review of drugs was also an important component of all programs. Exercise programs included both general activities such as walking, cycling, aerobic movements, and other endurance activities. Specific physical activity included training intended to improve balance, gait, and strength. (12) Such results support earlier findings published jointly by the American Geriatrics Society, British Geriatrics Society and American Academy of Orthopedic in 2001. (13) The multifactorial interventions considered in their review featured similar activities including staff education, gait training and advice on use of assistive devices, and review and modification of medications. (13)

In addition, some of the evidence reviewed in the 2003 Cochrane Review by Gillespie et al. also suggested that multifactorial risk assessments decreased the risk of subsequent falls and further identified trends in fall reduction when targeted exercise or physical therapy programs were employed. (14) For example, the intervention evaluated in the 2002 Jensen et al. study included educating staff, modifying the environment, implementing exercise programs, and reviewing drug regimens. The exercise programs used for this study included strength and balance exercises designed to improve strength, balance, gait, and transfer ability. (15) Ray et al. in their 1997 study, evaluated a similar approach in nursing facilities referred to as the "Falls Consultation Service." This service included a review of the patient's ability with ambulation and transfer and subsequent environmental modifications, altered physical therapy regimens or orders for routine assistance. Similar to other studies, these targeted physical therapy interventions were complemented by reviews of psychotropic drug use, wheelchair use, and personal safety. (16) Additional elements included in other nursing facility-based multifactorial falls reduction programs included medication withdrawal/adjustment, and cognitive/behavioral components.

1b.3 Citations for data on performance gap:

- 1. Rubenstein LZ, Josephson KR, Robbins AS. Falls in the nursing home. Ann Intern Med. 1994 Sep 15; 121(6):442-51. Review.
- 2. Gostynski M. Haufigkeit, Umstande und Konsequenzen von Sturzen institutionalisierter Betagter; eine Pilotstudie. Soz Praventivmed. 1991; 36:341-5.
- 3. Blake C, Morfitt JM. Falls and staffing in a residential home for elderly people. Public Health. 1986;100:385-
- 4. Cacha CA. An analysis of the 1976 incident reports of the Carillon nursing home. J Am Health Care Assoc. 1979;5:29-33.
- 5. Svensson ML, Rundgren A, Larsson M, Oden A, Sund Y, Landahl S. Accidents in the institutionalized elderly: a risk analysis. Aging (Milano). 1991;3:181-92.
- 6. Department of Health and Human Services. Healthy people 2010. Retrieved August 1, 2005, from http://www.healthypeople.gov/

- 7. Rothschild JM, Bates DW, Leape LL. Preventable medical injuries in older patients. Arch Intern Med. 2000 Oct 9; 160(18):2717-28. Review.
- 8. Morris JN, Moore T, Jones R, et al. Validation of long-term and post-acute care quality indicators. CMS Contract No: 500-95-0062/T.O. #4. Cambridge, MA: Abt Associates, Inc., June 2003.
- 9. Avidan AY, Fries BE, James ML, Szafara KL, Wright GT, Chervin RD. Insomnia and hypnotic use, recorded in the minimum data set, as predictors of falls and hip fractures in Michigan nursing homes. J Am Geriatr Soc. 2005 Jun; 53(6):955-62.
- 10. Fonad E, Wahlin TB, Winblad B, Emami A, Sandmark H. Falls and fall risk among nursing home residents. J Clin Nurs. 2008 Jan; 17(1):126-34.
- 11. van Doorn C, Gruber-Baldini AL, Zimmerman S, Hebel JR, Port CL, Baumgarten M, Quinn CC, Taler G, May C, Magaziner J, Epidemiology of Dementia in Nursing Homes Research Group. Dementia as a risk factor for falls and fall injuries among nursing home residents. J Am Geriatr Soc. 2003 Sep; 51(9):1213-8.
- 12. Chang JT, Morton SC, Rubenstein LZ, Mojica WA, Maglione M, Suttorp MJ, Roth EA, Shekelle PG. Interventions for the prevention of falls in older adults: systematic review and meta-analysis of randomised clinical trials. BMJ. 2004 Mar 20; 328(7441):680. Review.
- 13. Guideline for the prevention of falls in older persons. American Geriatrics Society, British Geriatrics Society, and American Academy of Orthopaedic Surgeons Panel on Falls Prevention. J Am Geriatr Soc. 2001 May; 49(5):664-72.
- 14. Gillespie LD, Gillespie WJ, Robertson MC, Lamb SE, Cumming RG, Rowe BH. Interventions for preventing falls in elderly people. Cochrane Database Syst Rev. 2003;(4):CD000340. Review.
- 15. Jensen J, Lundin-Olsson L, Nyberg L, Gustafson Y. Fall and injury prevention in older people living in residential care facilities: a cluster randomized trial. Ann Int Med. 2002;136(10):733-41.
- 16. Ray WA, Taylor JA, Meador KG, Thapa PB, Brown AK, Kajihara HK, et al. A randomized trial of a consultation service to reduce falls in nursing homes. JAMA. 1997;278(7):557-62.

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

Although research suggests racial disparities in the quality of care in nursing facilities between African Americans and whites (1, 2, 3, 4, 5), no analyses have been conducted specifically examining falls related to racial disparities. No research has been conducted on other types of disparities (e.g., ethnicity, urban/rural, and income) 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.
- 1c. Outcome or Evidence to Support Measure Focus

Comment [k4]: 1c. The measure focus is:
•an outcome (e.g., morbidity, mortality,
function, health-related quality of life) that is
relevant to, or associated with, a national
health goal/priority, the condition, population,
and/or care being addressed;
OR

•if an intermediate outcome, process, structure, etc., there is evidence that supports the specific measure focus as follows: oIntermediate outcome - evidence that the measured intermediate outcome (e.g., blood pressure, Hba1c) leads to improved health/avoidance of harm or cost/benefit. $o\underline{Process}$ - 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 multistep care process, it measures the step that has the greatest effect on improving the specified desired outcome(s). oStructure - evidence that the measured structure supports the consistent delivery of effective processes or access that lead to improved health/avoidance of harm or cost/benefit. oPatient experience - evidence that an association exists between the measure of patient experience of health care and the outcomes, values and preferences of

individuals/ the public.
oAccess - evidence that an association exists between access to a health service and the outcomes of, or experience with, care.
oEfficiency - 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.

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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): This measure of any fall with injury among nursing facility residents is an important health outcome to monitor in the nursing facility population. Research has shown that falls that result in serious injury, such as hip fracture, are a leading cause of death and disability in this population.

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

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

Numerous studies have identified risk factors for falls within the nursing facility population, including history of falls, impaired cognitive function, postural hypotension, psychotropic and cardiovascular medications, use of restraints, balance problems during transfer and ambulation, and insomnia. (1-5) The identification of such risk factors suggests the potential for nursing facilities to reduce and prevent the incidence of falls among their residents.

A 2004 meta-analysis by Chang et al. found that using a multifactorial falls risk assessment and management program resulted in significantly less falls among older adults. (6) Their review included a total of 40 randomized controlled trials that included falls outcomes. A random effects analysis combining trials with risk ratio data showed an overall reduction in fall risk of 0.88 (95% confidence interval [CI]: 0.82-0.95), while combining trials with incidence rate data showed a reduction in the monthly rate of falls of 0.80 (95% CI: 0.72-0.88). The effect of individual components by meta-regression revealed that a multifactorial falls risk assessment and management program to be the most effective method of intervention, reducing falls risk to 0.82 (95% CI: 0.72-0.94), while exercise interventions were also show to have a beneficial effect (0.86 risk, 95% CI: 0.75-0.99).

A 2003 Cochrane Review by Gillespie et al. similarly identified trends in fall reduction when a multifactorial risk factor screening and intervention were employed. (7) This review considered a total of 62 randomized controlled trials. Of these trials, 47 focused on populations living in the community, 8 were set in long term care facilities, 4 focused on rehabilitation or geriatric hospital wards, and 3 had participants with specific conditions from a mix of residential settings. The majority (71%) examined either the effect of exercise/physical therapy interventions or multifactorial risk factor screening and intervention. The exercise and physical therapy interventions were shown to have no significant effect, while the multifactorial falls interventions were shown to reduce falls risk in the community-dwelling population. The evidence on multifactorial falls interventions within institutional settings was mixed, with some studies reporting no effect (8, 9) and others (10, 11) reporting significant reductions in falls incidence of up to 0.60 (95% CI: 0.50-0.73).

In September 2000, the American Geriatrics Society, British Geriatrics Society, and American Academy of Orthopaedic Surgeons convened an expert Panel on Falls Prevention. (12) Panel participants considered evidence related to falls prevention from meta-analyses, systematic literature reviews, randomized controlled trials, nonrandomized control trials, case control studies, cohort studies, and other sources providing epidemiological data. A narrative summary was used to grade the evidence because the heterogeneity of evidence precluded meta-analytic techniques. As with the meta-analyses carried out by Chang and Gillepsie, the majority of evidence considered by the Panel concerned multifactorial interventions. In long-term care and assisted living settings, the Panel concluded that multifactorial interventions should include staff education programs, gait training, and review and modification of medications, with particular attention to psychotropic medications. (12)

- 1. Rothschild JM, Bates DW, Leape LL. Preventable medical injuries in older patients. Arch Intern Med. 2000 Oct 9; 160(18):2717-28. Review.
- 2. Morris JN, Moore T, Jones R, et al. Validation of long-term and post-acute care quality indicators. CMS Contract No: 500-95-0062/T.O. #4. Cambridge, MA: Abt Associates, Inc., June 2003.
- 3. Avidan AY, Fries BE, James ML, Szafara KL, Wright GT, Chervin RD. Insomnia and hypnotic use, recorded in the minimum data set, as predictors of falls and hip fractures in Michigan nursing homes. J Am Geriatr Soc. 2005 Jun; 53(6):955-62.

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

- 4. Fonad E, Wahlin TB, Winblad B, Emami A, Sandmark H. Falls and fall risk among nursing home residents. J Clin Nurs. 2008 Jan; 17(1):126-34.
- 5. van Doorn C, Gruber-Baldini AL, Zimmerman S, Hebel JR, Port CL, Baumgarten M, Quinn CC, Taler G, May C, Magaziner J, Epidemiology of Dementia in Nursing Homes Research Group. Dementia as a risk factor for falls and fall injuries among nursing home residents. J Am Geriatr Soc. 2003 Sep; 51(9):1213-8.
- 6. Chang JT, Morton SC, Rubenstein LZ, Mojica WA, Maglione M, Suttorp MJ, Roth EA, Shekelle PG. Interventions for the prevention of falls in older adults: systematic review and meta-analysis of randomised clinical trials. BMJ. 2004 Mar 20; 328(7441):680. Review.
- 7. Gillespie LD, Gillespie WJ, Robertson MC, Lamb SE, Cumming RG, Rowe BH. Interventions for preventing falls in elderly people. Cochrane Database Syst Rev. 2003;(4):CD000340. Review.
- 8. McMurdo ME, Millar AM, Daly F. A randomized controlled trial of fall prevention strategies in old peoples' homes. Gerontology. 2000;46(2):83-7.
- 9. Rubenstein LZ, Robbins AS, Josephson KR, Schulman BL, Osterweil D. The value of assessing falls in an elderly population. A randomized clinical trial. Ann Int Med. 1990;113:308-16.
- 10. Jensen J, Lundin-Olsson L, Nyberg L, Gustafson Y. Fall and injury prevention in older people living in residential care facilities: a cluster randomized trial. Ann Int Med. 2002;136(10):733-41.
- 11. Vassallo M, Vignaraja R, Sharma JC, Briggs RS, Allen SC. Can intervention prevent falls and injury in geriatric wards? Hospital injury prevention (HIP) study [abstract]. Age Ageing. 2001;30(Suppl 2):15.
- 12. Guideline for the prevention of falls in older persons. American Geriatrics Society, British Geriatrics Society, and American Academy of Orthopaedic Surgeons Panel on Falls Prevention. J Am Geriatr Soc. 2001 May;49(5):664-72.
- 1c.5 Rating of strength/quality of evidence (also provide narrative description of the rating and by whom):

 The meta-analysis by Chang et al. used Jadad scoring (0-5) to assess quality of the individual studies but did not rate the overall strength of the evidence. Using this methodology, four trials scored 1, 22 scored 2, and 14 scored 3.(1) As this scoring system gives up to 2 points for double-blinding and double-blinding is not conceptually possible for falls intervention studies, the maximum possible score for these studies is effectively 3. An overall score was not assigned. The Cochrane Review conducted by Gillespie et al. did not attempt to create an overall score for the strength or quality of evidence, however scores ranging from 3-1 were assigned to individual studies in 11 categories.(2) The scores across these categories were not compiled into an overall score for each study, however, individual study scores did range from 3-1. The expert Panel on Falls Prevention convened by the American Geriatrics Society rated both the categories of evidence as well as the strength of recommendation. The evidence for the recommendations concerning components of multifactorial interventions in long-term care and assisted living settings was all rated a "B," meaning that it was directly based on Class II evidence or extrapolated from Class I evidence. This grade is generally considered good.

1c.6 Method for rating evidence: The meta-analysis by Chang et al. used Jadad scoring (0-5) to assess quality of the evidence. The Jadad scoring method assigns these scores based on the following criteria:

Was the study described as randomized?

Was the study described as double blind?

Was there a description of withdrawals and dropouts?

The Cochrane Review used the following criteria to assign scores:

Was the assigned treatment adequately concealed prior to allocation?

Were the outcomes of the patients who withdrew described and included in this analysis (intention to treat)?

Were the outcome assessors blinded to treatment status?

Were the treatment and control group comparable at entry?

Were the subjects blind to assignment status after allocation?

Were the treatment providers blind to assignment status?

Were care programs, other than the trial options, identical?

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

http://www.ahrq.gov/clinic/uspstf07/method/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.

Were the inclusion and exclusion criteria clearly defined? Were the outcome measures used clearly defined?

Was ascertainment of fall and other outcomes reliable?

Was the duration of surveillance clinically appropriate?

The Panel on Falls Prevention rated both the category of evidence and strength of recommendation as follows: Categories of Evidence

Class I: Evidence from at least one randomized control trial or meta-analysis of randomized controlled trials Class II: Evidence from at least one controlled study without randomization or evidence from at least one other type of quasi-experimental study

Class III: Evidence from nonexperimental studies, such as comparative studies, correlation studies and casecontrol studies

Class IV: Evidence from expert committee reports or opinions and/or clinical experience of respected authorities

Strength of Recommendation

- A. Directly based on Class I evidence
- B. Directly based on Class II evidence or extrapolated recommendation from Class I evidence
- C. Directly based on Class III evidence or extrapolated recommendation from Class I or II evidence
- D. Directly based on Class IV evidence or extrapolated recommendation from Class I, II or III evidence
- **1c.7** Summary of Controversy/Contradictory Evidence: Although Chang et al. indicate that multifactorial falls interventions had a significant effect, Gillespie et al. report mixed evidence on multifactorial falls interventions. Within institutional settings, Gillespie et al. found that some studies reported no effect (4, 5) and others (6, 7) reported significant reductions in falls incidence of up to 0.60 (95% CI: 0.50-0.73).
- **1c.8 Citations for Evidence (***other than guidelines***):** 1. Chang JT, Morton SC, Rubenstein LZ, Mojica WA, Maglione M, Suttorp MJ, Roth EA, Shekelle PG. Interventions for the prevention of falls in older adults: systematic review and meta-analysis of randomised clinical trials. BMJ. 2004 Mar 20; 328(7441):680. Review.
- 2. Gillespie LD, Gillespie WJ, Robertson MC, Lamb SE, Cumming RG, Rowe BH. Interventions for preventing falls in elderly people. Cochrane Database Syst Rev. 2003;(4):CD000340. Review.
- 3. Guideline for the prevention of falls in older persons. American Geriatrics Society, British Geriatrics Society, and American Academy of Orthopaedic Surgeons Panel on Falls Prevention. J Am Geriatr Soc. 2001 May; 49(5):664-72.
- 4. McMurdo ME, Millar AM, Daly F. A randomized controlled trial of fall prevention strategies in old peoples' homes. Gerontology. 2000;46(2):83-7.
- 5. Rubenstein LZ, Robbins AS, Josephson KR, Schulman BL, Osterweil D. The value of assessing falls in an elderly population. A randomized clinical trial. Ann Int Med. 1990;113:308-16.
- 6. Jensen J, Lundin-Olsson L, Nyberg L, Gustafson Y. Fall and injury prevention in older people living in residential care facilities: a cluster randomized trial. Ann Int Med. 2002;136(10):733-41.
- 7. Vassallo M, Vignaraja R, Sharma JC, Briggs RS, Allen SC. Can intervention prevent falls and injury in geriatric wards? Hospital injury prevention (HIP) study [abstract]. Age Ageing. 2001;30(Suppl 2):15.
- **1c.9** Quote the Specific guideline recommendation (including guideline number and/or page number): The American Geriatrics Society Panel on Falls in Older Persons issued a guideline on falls prevention in 2001. This guideline recommends first an assessment step, followed by multifactorial falls intervention if appropriate. The recommended assessment process is further differentiated for individuals with or without risk factors, as follows:
- 1. Routine Care of Older Persons (not presenting after a fall)
- Clinicians caring for older persons should ask about fall history annually
- Those patients who report a single fall should undergo a balance and gait screening. This is done by observing the ability to stand up from a chair without using arms, walk several paces and return. (i.e. the "get up and go test")

- Those having difficulty require further assessment and appropriate intervention such as referral to physical and or occupational therapy.
- 2. Evaluation of Older Persons Presenting with One or More Falls or Having Abnormalities Gait and or Balance or who report Recurrent Falls:
- History of the fall circumstances, medications (prescribed and over the counter), acute or chronic medical problems, and mobility levels
- An examination of vision, muscle strength, gait, balance, and neurological function including lower extremity peripheral nerves, proprioception, reflexes, cortical and extrapyramidal and cerebellar functions should be done. An assessment of cognitive function and a basic cardiovascular evaluation including heart rate and rhythm, orthostatic pulse and blood pressure should be done.

As the results of the assessment process dictate, multifactorial interventions should then be employed as follows:

- For community living older persons should include:
- a. Gait training by physical therapists and prescription and teaching the use of assistive devices by occupational therapists (level B).
- b. Exercise programs including balance training (level B).
- c. Review and modification of medication especially psychotropic and sympathomimetic varieties (level B).
- d. Treatment of postural hypotension (level B).
- e. Modification of environmental hazards (level C).
- f. Treatment of cardiovascular disorders including arrhythmia (level D).
- In long term care and assisted living settings multifactorial interventions should include all of the above and:
- a. Staff education programs to enhance sensitivity to identify risks for falls among all levels of caregivers (level B).
- b. Gait training and advice on the appropriate use of assistive device (level B).
- c. Review and modification of medications, especially psychotropic medications (level B).

In addition, the Institute for Clinical Systems Improvement (ICSI) issued an ICSI Health Care Protocol concerning falls prevention in acute care settings titled, "Prevention of Falls (Acute Care)." This protocol includes four main components:

- 1. Perform risk assessment to identify risk factors
- 2. Communicate risk factors
- 3. Perform risk factor interventions
- 4. Continuously monitor and reassess

While these recommendations were issued for the acute care setting, they are also helpful for improving quality in the long-term care setting.

1c.10 Clinical Practice Guideline Citation: The American Geriatrics Society Guideline citation is:

Guideline for the prevention of falls in older persons. American Geriatrics Society, British Geriatrics Society, and American Academy of Orthopaedic Surgeons Panel on Falls Prevention. J Am Geriatr Soc. 2001 May; 49(5):664-72.

1c.11 National Guideline Clearinghouse or other URL:

http://www.americangeriatrics.org/products/positionpapers/abstract.shtml and http://www.icsi.org/falls__acute_care___prevention_protocol_/falls__acute_care___prevention_of__protocol

__24255.html

1c.12 Rating of strength of recommendation (also provide narrative description of the rating and by whom): The expert Panel on Falls Prevention convened by the American Geriatrics Society rated both the categories of evidence as well as the strength of recommendation. The evidence for the recommendations concerning components of multifactorial interventions in long-term care and assisted living settings was all rated a "B," meaning that it was directly based on Class II evidence or extrapolated from Class I evidence. This grade is generally considered good. Although individual studies used to develop the ICSI guideline were rated for strength of evidence, no overall rating was assigned to this recommendation.

Comment [k7]: USPSTF grading system http://www.ahrq.gov/clinic/uspstf/grades.ht m: 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.

iver "	
1c.13 Method for rating strength of recommendation (<i>If different from <u>USPSTF system</u></i> , also describe rating and how it relates to <i>USPSTF</i>):	
The method used to rate the strength of the American Geriatrics Society recommendation uses a similar approach to the USPSTF system, but has four categories (ranging from the best, A, to the worst, D) for rating the evidence. In this approach, a rating of "A" should be considered analogous to the USPSTF rating of "good," while a rating of "B" would be deemed comparable to a USPSTF rating of "fair/good."	
1c.14 Rationale for using this guideline over others: This is not applicable.	
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 N
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. (<u>evaluation criteria</u>)	Eva <u>I</u> 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 based on the number of long-stay nursing facility residents who experienced one or more falls that resulted in major injury (J1900c = 1 or 2) on any non-admission MDS assessment in the last 12 months which may be an annual, quarterly, significant change, significant correction or discharge assessment. In the MDS 3.0, major injury is defined as bone fractures, joint dislocations, closed head injuries with altered consciousness, or subdural hematoma.	
2a.2 Numerator Time Window (<i>The time period in which cases are eligible for inclusion in the numerator</i>): The denominator time window is a 12-month look-back period. It is updated quarterly based on MDS 3.0 annual, quarterly, significant change, significant correction or discharge assessments. Annual percentages are reported to ensure adequate sample size.	
2a.3 Numerator Details (All information required to collect/calculate the numerator, including all codes, logic, and definitions): Residents are counted if they are long-stay residents, defined as residents whose length of stay is greater than 100 days. Residents who return to the nursing home following a hospital discharge will not have their stay reset to zero. Residents are counted if J1900 = 1 or 2 (resident had had one fall with major injury, or two or more falls with major injury.	2a- sp ec s
2a.4 Denominator Statement (<i>Brief, text description of the denominator - target population being measured</i>): The denominator is the total number of long-stay residents in the nursing facility who were assessed during the selected time window and who did not meet the exclusion criteria.	C P M
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.	N

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).

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

The denominator time window is a 12-month look-back period. It is updated quarterly based on MDS 3.0 annual, quarterly, or significant change or correction assessments. Annual percentages are reported to ensure adequate sample size.

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

Residents are counted if they are long-stay residents defined as residents whose length of stay is greater than 100 days. Residents who return to the nursing home following a hospital discharge will not have their day count reset to zero. The target population includes all long-stay residents who had an annual, quarterly, significant change, significant correction, or discharge assessment during the previous 12 months (A0310.A = 02, 03, 04, 05 or 06).

2a.9 Denominator Exclusions (*Brief text description of exclusions from the target population*): Residents with MDS admission assessments (OBRA or a 5-day PPS assessment) from the current quarter are exclude. Also excluded are residents for whom data from the relevant section of the MDS are missing. Residents must be present for at least 100 days to be included in long-stay measures.

Long-stay facilities are excluded from the public reporting if their sample includes fewer than 30 residents.

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

A0310.A = 01 OBRA Admission assessment OR

A0310.B = 01 PPS Medicare Part A 5-day scheduled assessment OR

J1900C = missing when J1800 = 1 (resident had falls since admission or the prior assessment but it is unknown whether they had a major injury)

Long-stay facilities with fewer than 30 residents are excluded because of small sample size.

2a.11 Stratification Details/Variables (All information required to stratify the measure including the stratification variables, all codes, logic, and definitions): This is not applicable.

2a.12-13 Risk Adjustment Type: No risk adjustment necessary

2a.14 Risk Adjustment Methodology/Variables (*List risk adjustment variables and describe conceptual models, statistical models, or other aspects of model or method*):

2a.15-17 Detailed risk model available Web page URL or attachment:

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 long-stay residents meeting the denominator criteria are reported for the last 12 months. This measure is updated every quarter. The facility score is calculated as the number of long-stay residents in the numerator during the last 12 months divided by the number of long-stay residents in the denominator during the last 12 months.

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.

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.

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

2a.25 Data source/data collection instrument (Identify the specific data source/data collection instrument,

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.

e.g. name of database, clinical registry, collection instrument, etc.): Nursing Home Minimum Data Set 3.0

2a.26-28 Data source/data collection instrument reference web page URL or attachment: URL http://www.cms.hhs.gov/NursingHomeQualityInits/25_NHQIMDS30.asp#TopOfPage This URL provides specifications for the most current version of the MDS 3.0 and will be updated as required.

2a.29-31 Data dictionary/code table web page URL or attachment: URL

http://www.cms.hhs.gov/NursingHomeQualityInits/25_NHQIMDS30.asp#TopOfPage This URL provides specifications for the existing measure based on MDS 2.0

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

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): Although the reliability of the falls with major injury measure has not yet been tested because the proposed MDS 3.0 assessment has yet to be implemented, Saliba and Buchanan did test the reliability of the items on which this measure is based (J1800 – J1900) and found them to be a marked improvement over the MDS 2.0 fall item. Their work included a sample of 71 community and 19 Veteran's Administration (VA) nursing homes distributed throughout the United States. (1) Residents were selected in these facilities to capture a representative sample of short- and long-stay residents, and in order to maximize the number of MDS 2.0 items assessed, the selection algorithms included a strong preference for capturing cases scheduled for MDS 2.0 admission assessments (OBRA and PPS 5 day scheduled assessments).

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

First, the national test of MDS 3.0 items by Saliba and Buchanan examined agreement between assessors (reliability) (1). Quality Improvement Organizations were employed to identify gold-standard (research) nurses and recruit community nursing facilities 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 facilities in their home states. Residents participating in the test were selected to capture a representative sample of short- and long-stay residents. Quality measures/quality indicators using the MDS 2.0 and the MDS 3.0 were calculated and then compared, with correlations and Kappas calculated.

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

Among nurses who participated in the MDS 3.0 national study, 88% reported that the fall-related injury definitions were clear, and 94% felt that facility falls documentation would provide the necessary information to complete these items. Saliba and Buchanan further demonstrated that the revised MDS 3.0 fall items had excellent reliability both for gold-standard to gold-standard comparisons (alpha = 0.967) as well as gold-standard to facility-nurse comparisons (alpha = 0.945).(1) These results indicate marked improvement over the moderate reliability found for the corresponding MDS 2.0 fall item, J4a (alpha = 0.52).(1) Therefore, the reliability of the proposed measure appears promising.

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.

2c. Validity testing

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.

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.

2b

C P

M

N

2c

С

2c.1 Data/sample (description of data/sample and size): This is not applicable.	ļ
2c.2 Analytic Method (type of validity & rationale, method for testing):	P
This is not applicable.	M
2c.3 Testing Results (statistical results, assessment of adequacy in the context of norms for the test conducted): This is not applicable.	N
2d. Exclusions Justified	
2d.1 Summary of Evidence supporting exclusion(s)	
2d.2 Citations for Evidence: This is not applicable.	2d C D
2d.3 Data/sample (description of data/sample and size): This is not applicable.	M
2d.4 Analytic Method (type analysis & rationale): This is not applicable.	N
2d.5 Testing Results (e.g., frequency, variability, sensitivity analyses): This is not applicable.	NA
2e. Risk Adjustment for Outcomes/ Resource Use Measures	
2e.1 Data/sample (description of data/sample and size): This is not applicable.	
2e.2 Analytic Method (type of risk adjustment, analysis, & rationale): This is not applicable.	
2e.3 Testing Results (risk model performance metrics): This is not applicable.	
2e.4 If outcome or resource use measure is not risk adjusted, provide rationale: The decision not to recommend risk adjustment for this proposed quality measure was based on careful review of the existing literature and feedback from the October, 2009 Technical Expert Panel (TEP). While risk adjustment, when properly employed, can ensure that facilities with higher acuity patients aren't unfairly penalized because of case mix differences, too much adjustment can render a statistic meaningless or even mask inadequate care. This delicate balance is acknowledged by Abt Associates in their recent work developing a quality indicator for falls-related injuries in nursing homes.(1) Their proposed indicator adjusts for a total of 35 covariates, including Activities of Daily Living (ADL) functional abilities, common conditions such as dysrhythmia, arthritis, cataracts, and glaucoma, and medication use, among others.	
While this approach is not without its strengths, the TEP convened to review the proposed quality measures felt very strongly that adjustment was inappropriate for a falls-related quality measure. The TEP participants considered risk adjustment for falls to be a very slippery slope; as one participant noted, "Once you start risk adjusting, where would you stop?" Further, many participants echoed the sentiment by another TEP member, a physician who stated, "you could risk-adjust out things that facilities should be paying attention to. One of the first things [facilities] should do is screen for high falls risks." Similarly, it was noted by another TEP participant that by admitting a patient, "[a facility is] assuming responsibility for them; if they're high risk [the facility] should deal with it." Given this feedback, as well as the very challenging task of achieving an appropriate level of adjustment given the wide variety of falls risk factors, no adjustment is currently recommended.	2e C P M Z
Williams, C., Moore, T., Spector, W., Limcangco, R., & Mukamel, D. (2009, November). Nursing home quality measure for serious fall-related injuries. Presented at the annual scientific meeting of the Gerontological Society of America, Atlanta, GA.	NA

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

Comment [KP14]: 2d. Clinically necessary measure exclusions are identified and must be:
•supported by evidence of sufficient frequency of occurrence so that results are distorted without the exclusion;
AND

•a clinically appropriate exception (e.g., contraindication) to eligibility for the measure focus;

AND

precisely defined and specified:
 if there is substantial variability i

-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 [....[1]

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; Frort Bowlands 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.

2f. Identification of Meaningful Differences in Performance		_
2f.1 Data/sample from Testing or Current Use (description of data/sample and size): This measure has not been tested or evaluated yet, so there is no information available.		
2f.2 Methods to identify statistically significant and practically/meaningfully differences in performance (type of analysis & rationale):	2f C	-
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	
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):	M N	
2g. Comparability of Multiple Data Sources/Methods	2g	
2g.1 Data/sample (description of data/sample and size): This is not applicable.	2g C P	ľ
2g.2 Analytic Method (type of analysis & rationale): This is not applicable.	M	
2g.3 Testing Results (e.g., correlation statistics, comparison of rankings):	N	
This is not applicable.	NA	
2h. Disparities in Care	2h C	
2h.1 If measure is stratified, provide stratified results (scores by stratified categories/cohorts): This is not applicable.	P	
2h.2 If disparities have been reported/identified, but measure is not specified to detect disparities,	M	
provide follow-up plans: This is not applicable.	N N	
	NA	
TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for <i>Scientific</i>		
Acceptability of Measure Properties? Steering Committee: Overall, to what extent was the criterion, Scientific Acceptability of Measure	2	
Properties, met? Rationale:	c □	
Nationale.	P	
	M	
	N	
3. USABILITY		
Extent to which intended audiences (e.g., consumers, purchasers, providers, policy makers) can understand	Eva	
the results of the measure and are likely to find them useful for decision making. (evaluation criteria)	Eva L Rat	
	ing	
3a. Meaningful, Understandable, and Useful Information	3a	/
3a.1 Current Use: Testing not yet completed	C P	

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

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

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

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

Comment [KP22]: 3a. Demonstration that information produced by the measure is meaningful, understandable, and useful to the intended audience(s) for <u>both</u> public reporting (e.g., focus group, cognitive testing) <u>and</u> 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.

	NQF #	:0674
2 <u>re</u> N	a.2 Use in a public reporting initiative (disclosure of performance results to the public at large) (If used in public reporting initiative, provide name of initiative(s), locations, Web page URL(s). If not publicly eported, state the plans to achieve public reporting within 3 years): ursing Home Compare	M N
	tp://www.medicare.gov/NHCompare/Include/DataSection/Questions/SearchCriteriaNEW.asp?version=defaul&browser=IE%7C6%7CWinXP&language=English&defaultstatus=0&pagelist=Home&CookiesEnabledStatus=True	
n.	a.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 OI, state the plans to achieve use for OI within 3 years): The proposed measure is similar to the NQF-endorsed measure "Acute care prevention of falls: rate of	
in ar m qr Sy TI	patient falls with injury per 1,000 patient days," but differs in that it focuses on nursing facility residents and is reported as a percentage, rather than a rate. Nonetheless, the current uses of the inpatient falls easure suggests that the proposed nursing facility falls measure could also easily be employed to improve uality of care. For example, the inpatient falls measure led to the development of Institute of Clinical restems Improvement (ICSI) guidelines that are designed to reduce falls with injury in the acute care setting. These guidelines were developed for use by physicians, nurses, therapists, provider organizations, health care eaching institutions, health plans, and health systems, as well as a variety of other health care professionals	
ar et	nd groups. In addition, this measure is also being used to measure the success of voluntary quality and safety forts intended to reduce inpatient falls, including that of "Patients First," an initiative among Massachusetts ospitals. (http://www.patientsfirstma.org/)	
3a di in	esting of Interpretability (Testing that demonstrates the results are understood by the potential users for ublic reporting and quality improvement) a.4 Data/sample (description of data/sample and size): A recent study by Tinetti et al found that sseminating evidence on falls prevention strategies reduced falls within a given geographical area. This effort volved clinical staff from nursing homes and other local healthcare providers, and evaluated the ease of use quality improvement efforts.	
ha ha Za ch	ne intervention region encompassed 58 Zip Code Tabulation Areas (ZCTAs) in the Hartford, CT area. This area as 212 primary care offices, 133 outpatient rehabilitation facilities, 26 home care agencies, 7 acute care ospitals with emergency departments and 41 senior centers. The usual care or control region included 53 cTAs in southern Connecticut, and was similar to the intervention region in terms of size, sociodemographic naracteristics of the 70+ population, pre-intervention rates of falls-related use of medical services, and umbers of clinicians and healthcare providers.(1)	
ac fc	ith regards to use for public reporting, a separate study by N. Castle evaluated consumers' ability to curately interpret quality information given for all the measures reported by Nursing Home Compare and bund they were useful. For this study, data were collected from 4,754 family members of nursing home scidents. (2)	
	Tinetti ME, Baker DI, King M, Gottschalk M, Murphy TE, Acampora D, Carlin BP, Leo-Summers L, Allore HG. fect of dissemination of evidence in reducing injuries from falls. N Engl J Med. 2008 Jul 17;359(3):252-61.	
	Castle N. The Nursing Home Compare report card: consumers' use and understanding. J Aging Soc Policy. 309;21(2), 187-208.	
TI ar m ar ar ol	a.5 Methods (e.g., focus group, survey, Ol project): ne intervention evaluated by Tinetti at al involved a multifaceted approach. First, in order to raise patient nd clinical awareness of the problem, media attention, websites, posters, bus advertisements and educational aterials were introduced into the region. Local opinion leaders were also recruited to influence colleagues, nd visits were conducted with local healthcare providers to explain evidence-based falls prevention practices and demonstrate how to incorporate these practices into normal workflow. In addition, targeted outreach to der adults was accomplished through visits to senior centers, assisted living facilities, adult day centers, enior housing sites, and other community locations.	

Castle used a comprehension index to examine whether the information contained in Nursing Home Compare for each quality measure was understood by family members.

3a.6 Results (qualitative and/or quantitative results and conclusions): During the evaluation period, Tinetti et al found that the rates of serious fall-related injuries among people 70 years or older per 1000 person-years were 31.4 in the usual care region and 28.6 in the intervention region. This represents a 9% decline in the rate of serious fall-related injuries in the intervention region relative to the usual care region (adjusted rate ratio, 0.91; 95% credibility interval, 0.88 to 0.94). The study by Castle found that 31% of the consumers used the Internet in choosing a nursing facility, 12% recalled using Nursing Home Compare, and in general, the consumers' comprehension index scores were high, indicating good understanding. However, as this is a newly proposed quality measure, there is no information about the ability of consumers to comprehend this information.		
3b/3c. Relation to other NQF-endorsed measures		
3b.1 NQF # and Title of similar or related measures: NQF #0202 - Acute care prevention of falls: rate of inpatient falls with injury per 1,000 patient days		
(for NQF staff use) Notes on similar/related endorsed or submitted measures:		
3b. Harmonization If this measure is related to measure(s) already endorsed by NOF (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 proposed measure is similar to the NQF endorsed measure, Acute care prevention of falls: rate of inpatient falls with injury per 1,000 patient days. The proposed measure focuses on nursing facility residents and reports the results as a percentage of long-stay residents with falls over a 12-month period which is used to account for the relatively small sample size and lower resident turnover in these facilities compared to acute care.	3b C P M N N	
3c. Distinctive or Additive Value 3c.1 Describe the distinctive, improved, or additive value this measure provides to existing NQF-endorsed measures: While the endorsed measure reports on falls with injury in the acute care setting, the proposed measure applies the same logic to the long-stay nursing facility population. In addition, the proposed measure considers falls with major injury, rather than all falls or falls with only minor injury. While any fall is concerning, falls with major injury cause significant levels of morbidity and mortality among nursing facility residents, particularly compared to their counterparts in the community. Moreover, because the likelihood of sustaining a fall in a nursing facility is substantial, the risk of incurring a fall with major injury is also relatively high. 5.1 If this measure is similar to measure(s) already endorsed by NQF (i.e., on the same topic and the same target population), Describe why it is a more valid or efficient way to measure quality:	3c C P M N NA	`\
TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for <i>Usability?</i>	3	
Steering Committee: Overall, to what extent was the criterion, <i>Usability</i> , met? Rationale:	3 C P M N	
4. FEASIBILITY		
Extent to which the required data are readily available, retrievable without undue burden, and can be implemented for performance measurement. (evaluation criteria)	Eva I	

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 HbAtc 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).

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	Rat ing	
4a. Data Generated as a Byproduct of Care Processes 4a.1-2 How are the data elements that are needed to compute measure scores generated? Data generated as byproduct of care processes during care delivery (Data are generated and used by healthcare personnel during the provision of care, e.g., blood pressure, lab value, medical condition), Coding/abstraction performed by someone other than person obtaining original information (E.g., DRG, ICD-9 codes on claims, chart abstraction for quality measure or registry)	4a C P M N	 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.)
4b. Electronic Sources 4b.1 Are all the data elements available electronically? (elements that are needed to compute measure scores are in defined, computer-readable fields, e.g., electronic health record, electronic claims) No 4b.2 If not, specify the near-term path to achieve electronic capture by most providers. http://www.cms.gov/MDSPubQlandResRep/01_Overview.asp	4b C P M N	 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.
4c. Exclusions 4c.1 Do the specified exclusions require additional data sources beyond what is required for the numerator and denominator specifications? No 4c.2 If yes, provide justification.	4c C P M N NA	 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.
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. This measure has a low likelihood of being susceptible to problems in accuracy. The proposed measure is based on the new MDS 3.0 item J1900c, which asks for the frequency of any falls with major injury. Major injury is defined to include bone fractures, joint dislocations, closed head injuries with altered consciousness or subdural hematoma. In contrast, item J1900b defines a fall with a non-major injury to be any fall that results in skin tears, abrasions, lacerations, superficial bruises, hematomas and sprains, or any fall-related injury that causes the resident to complain of pain. To the extent that these two items may not include all the possible categories of injurious falls that may occur (major or non-major), the potential for misclassification exists. This potential source of error will need to be further considered as the MDS 3.0 is implemented nationally and areas of potential confusion are identified.	4d C P M N	 Comment [KP29]: 4d. Susceptibility to inaccuracies, errors, or unintended consequences and the ability to audit the data items to detect such problems are identified.
4e. Data Collection Strategy/Implementation 4e.1 Describe what you have learned/modified as a result of testing and/or operational use of the measure regarding data collection, availability of data/missing data, timing/frequency of data collection, patient confidentiality, time/cost of data collection, other feasibility/ implementation issues: The data collection method is already in operational use and there are no issues with these areas. While the items are slightly changed from those in the MDS 2.0, the training needs to use the new MDS 3.0 items are expected to be minimal and facility staff participating in the pilot tests considered these items to be an improvement over the current MDS 2.0 items and easy to complete. 4e.2 Costs to implement the measure (costs of data collection, fees associated with proprietary measures):	4e C P M N	 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).

Data are collected as part of an existing process with no additional cost.	
4e.3 Evidence for costs: This is not applicable.	
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.	
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, <i>Feasibility</i> , met? Rationale:	4 C P M N
RECOMMENDATION	
(for NQF staff use) Check if measure is untested and only eligible for time-limited endorsement.	Tim e- limi ted
Steering Committee: Do you recommend for endorsement? Comments:	Y N A
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 Cheryl, Wiseman, MS, MPH, Cheryl.wiseman2@cms.hhs.gov, 410-786-1175-	
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 Karen, Reilly, ScD, kreilly@rti.org, 781-434-1700-1791	
Co.5 Submitter If different from Measure Steward POC Karen, Reilly, ScD, kreilly@rti.org, 781-434-1700-1791, 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 1: Nursing Home Quality Measures Technical Expert Panel (October 2009).

This TEP met over 2 days in October of 2009 to review the environmental scan and deliberate on the importance and validity of potential new nursing home measures for further development.

Ad.2 If adapted, provide name of original measure: This is not applicable. Ad.3-5 If adapted, provide original specifications URL or attachment

Measure Developer/Steward Updates and Ongoing Maintenance

Ad.6 Year the measure was first released:

Ad.7 Month and Year of most recent revision:

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 Falls tables_FINAL.doc

Date of Submission (MM/DD/YY): 04/27/2011

Page 13: [1] Comment [KP14]

Karen Pace

10/5/2009 8:59:00 AM

- 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;
- 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).