NATIONAL QUALITY FORUM

MEASURE WORKSHEET

This document summarizes the evaluation of the measure as it progresses through NQF's Consensus Development Process (CDP). The information submitted by measure developers/stewards is included after the Brief Measure Information, Preliminary Analysis, and Pre-meeting Public and Member Comments sections.

To navigate the links in the worksheet: Ctrl + click link to go to the link; ALT + LEFT ARROW to return

Purple text represents the responses from measure developers.

Red text denotes developer information that has changed since the last measure evaluation review.

Brief Measure Information

NQF #: 0679

Corresponding Measures:

De.2. Measure Title: Percent of High-Risk Residents with Pressure Ulcers (Long Stay)

Co.1.1. Measure Steward: Center for Medicare & Medicaid Services

De.3. Brief Description of Measure: This measure reports the percentage of long-stay, high-risk, residents in a nursing home who have Stage II-IV or unstageable pressure ulcers on a selected target assessment in the target quarter. The long stay nursing home population is defined as residents who have received 101 or more cumulative days of nursing home care by the end of the target assessment period. A nursing home resident is defined as high-risk for pressure ulcer if they meet one or more of the following three criteria:

1. Impaired bed mobility or transfer
2. Comatose
3. Malnourished or at risk of malnutrition.

This measure is based on data obtained through the Minimum Data Set (MDS) 3.0 OBRA, PPS, and/or discharge assessments during the selected quarter(s).

1b.1. Developer Rationale: This outcome-based quality measure reports the percentage of long-stay, high-risk nursing home residents with Stage II-IV pressure ulcers. Pressure ulcers are important to address as they are one of the most unwanted and preventable adverse events in the contexts of severe acute and chronic illnesses, disability, and high care dependency. In the United States, over 2.5 million people experience pressure ulcers with 2% to 24% occurring in long-term care facilities. Typically, pressure ulcers occur in individuals with poor mobility who experience sustained pressure for long periods of time. Elderly individuals are prone to pressure ulcer formation due to the limited mobility that comes with increased age. Additionally, individuals living with disabilities are especially prone to pressure ulcer development due to reduced movement. Therefore, pressure ulcer prevalence is a problem within several nursing homes. Resident characteristics, risk factors, and predictors for pressure

ulcer development include increased age, black race/ethnicity, malnutrition, dehydration, infection, urinary and bowel incontinence, high BMI, low hemoglobin levels, low albumin levels, non-blanchable erythema, mobility limitations, poor moisture status, higher body temperatures, and other comorbidities (e.g., stroke, dementia, Alzheimer's, spina bifida, cerebral palsy, etc.).

Pressure ulcer rates may be indicators of the quality of care offered by long-term care facilities. Although many pressure ulcers are preventable, both facility-level and process-based characteristics can impact pressure ulcer prevalence within nursing homes.

Anrys, Charlotte, Hanne Van Tiggelen, Sofie Verhaeghe, Ann Van Hecke, and Dimitri Beeckman. 2019. "Independent Risk Factors for Pressure Ulcer Development in a High-Risk Nursing Home Population Receiving Evidence-Based Pressure Ulcer Prevention: Results from a Study in 26 Nursing Homes in Belgium." International Wound Journal 16 (2): 325–33. https://doi.org/10.1111/iwj.13032.

Kottner, Jan, Joyce Black, Evan Call, Amit Gefen, and Nick Santamaria. 2018. "Microclimate: A Critical Review in the Context of Pressure Ulcer Prevention." Clinical Biomechanics. 59 (November): 62–70. https://doi.org/10.1016/j.clinbiomech.2018.09.010.

Ahn, Hyochol, Linda Cowan, Cynthia Garvan, Debra Lyon, and Joyce Stechmiller. 2016. "Risk Factors for Pressure Ulcers Including Suspected Deep Tissue Injury in Nursing Home Facility Residents: Analysis of National Minimum Data Set 3.0." Advances in Skin and Wound Care 29 (4): 178–90. https://doi.org/10.1097/01.ASW.0000481115.78879.63.

Refer to footnote 1

Refer to footnote 1

Refer to footnote 3

Alderden, Jenny, Ginette Alyce Pepper, Andrew Wilson, Joanne D. Whitney, Stephanie Richardson, Ryan Butcher, Yeonjung Jo, and Mollie Rebecca Cummins. 2018. "Predicting Pressure Injury in Critical Care Patients: A Machine-Learning Model." American Journal of Critical Care 27 (6): 461–68. https://doi.org/10.4037/ajcc2018525.

Refer to footnote 1

Bauer, Karen, Kathryn Rock, Munier Nazzal, Olivia Jones, and Weikai Qu. 2016. "Pressure Ulcers in the United States' Inpatient Population from 2008 to 2012: Results of a Retrospective Nationwide Study." Ostomy Wound Management 62 (11): 30–38.

Chen, Hong-Lin, Ying-Juan Cao, Wang-Qin Shen, and Bin Zhu. 2017. "Construct Validity of the Braden Scale for Pressure Ulcer Assessment in Acute Care: A Structural Equation Modeling Approach." Ostomy Wound Management 63 (2): 38–41.

Demarre, Liesbet, Sofie Verhaeghe, Ann Van Hecke, Els Clays, Maria Grypdonck, and Dimitri Beeckman. 2015. "Factors Predicting the Development of Pressure Ulcers in an At-Risk Population Who Receive Standardized Preventive Care: Secondary Analyses of a Multicentre Randomised Controlled Trial." Journal of Advanced Nursing 71 (2): 391–403. https://doi.org/10.1111/jan.12497.

Jaul, Efraim, Jeremy Barron, Joshua P. Rosenzweig, and Jacob Menczel. 2018. "An Overview of Co-Morbidities and the Development of Pressure Ulcers among Older Adults." BMC Geriatrics 18 (1): 305. https://doi.org/10.1186/s12877-018-0997-7.

Kwok, Alvin C., Andrew M. Simpson, James Willcockson, Daniel P. Donato, Isak A. Goodwin, and Jayant P. Agarwal. 2018. "Complications and Their Associations Following the Surgical Repair of Pressure Ulcers." American Journal of Surgery 216 (6): 1177–81. https://doi.org/10.1016/j.amjsurg.2018.01.012.

Sprigle, Stephen, Douglas McNair, and Sharon Sonenblum. 2020. "Pressure Ulcer Risk Factors in Persons with Mobility-Related Disabilities." Advances in Skin and Wound Care 33 (3): 146–54. https://doi.org/10.1097/01.ASW.0000653152.36482.7d.

S.4. Numerator Statement: The numerator is the number of long-stay residents identified as high-risk with a selected MDS 3.0 target assessment (OBRA quarterly, annual or significant change/correction assessments or discharge assessment with or without return anticipated) in an episode during the selected target quarter reporting one or more Stage II-IV or unstageable pressure ulcer(s) at the time of assessment. High-risk residents are those who are comatose (B0100 = [1]), or impaired in bed mobility (G0110A1 = [3, 4, 7, 8]) or transfer (G0110B1 = [3, 4, 7, 8]), or either experiencing malnutrition or at risk for malnutrition (I5600 = [1]). Unstageable pressure ulcers are pressure ulcers that are known to be present but are defined as unstageable due to either a non-removable dressing/device (M0300E1 = [1, 2, 3, 4, 5, 6, 7, 8, or 9]), slough or eschar (M0300F1 = [1, 2, 3, 4, 5, 6, 7, 8, or 9]), or a suspected deep tissue injury (M0300G1 = [1, 2, 3, 4, 5, 6, 7, 8, or 9]).

S.6. Denominator Statement: The denominator includes all long-stay nursing home residents who had a target assessment (ORBA, PPS, or discharge) during the selected quarter who were identified as high risk for pressure ulcer, and who do not meet the exclusion criteria.

S.8. Denominator Exclusions: A resident is excluded from the denominator if:

1. The target MDS assessment is an OBRA admission assessment or a PPS 5-day assessment or a PPS readmission/return assessment.

2. The resident did not meet the pressure ulcer conditions for the numerator and any Stage II, III, IV, or unstageable item is missing (M0300B1 = [-] or M0300C1 = [-] or M0300D1 = [-] or M0300E1 = [-] or M0300F1 = [-] or M0300G1 = [-]).

If the facility sample includes fewer than 20 residents, then the facility is excluded from public reporting because of small sample size.

De.1. Measure Type: Outcome

S.17. Data Source: Assessment Data

S.20. Level of Analysis: Facility

IF Endorsement Maintenance – Original Endorsement Date: Mar 03, 2011 **Most Recent Endorsement Date:** Dec 09, 2015

IF this measure is included in a composite, NQF Composite#/title:

IF this measure is paired/grouped, NQF#/title:

De.4. IF PAIRED/GROUPED, what is the reason this measure must be reported with other measures to appropriately interpret results? This measure is not paired/grouped

Preliminary Analysis: Maintenance of Endorsement

To maintain NQF endorsement endorsed measures are evaluated periodically to ensure that the measures still meet the NQF endorsement criteria ("maintenance"). The emphasis for maintaining endorsement is focused on how effective the measure is for promoting improvements in quality. Endorsed measures should have some experience from the field to inform the evaluation. The emphasis for maintaining endorsement is noted for each criterion.

Criteria 1: Importance to Measure and Report

1a. Evidence

Maintenance measures – less emphasis on evidence unless there is new information or change in evidence since the prior evaluation.

1a. Evidence. The evidence requirements for a health outcome measure include providing empirical data that demonstrate a relationship between the outcome and at least one healthcare structure, process, intervention, or service; if these data not available, data demonstrating wide variation in performance, assuming the data are from a robust number of providers and results are not subject to systematic bias. For measures derived from patient report, evidence also should demonstrate that the target population values the measured outcome, process, or structure and finds it meaningful.

Evidence Summary

- The developer provided substantial literature demonstrating that interventions can be implemented to reduce the incidence of pressure ulcers in nursing facilities. Several guidelines were described that recommended several activities including: proper nutrition and hydration, repositioning, early mobilization (e.g., implementing ambulation schedules among residents on bedrest), preventing heel pressure injuries (e.g., regularly assessing the vulnerable heel area, prophylactic dressing of heels, etc.), providing support surfaces to redistribute pressure and provide a proper microclimate, and more.
- Several processes to treat pressure ulcers were also described. These include: (1) assessing and monitoring of the wound, (2) managing pain, (3) supporting wound healing (e.g., promoting a well-vascularized wound bed, moisture balance, and infection and inflammation control), (4) cleansing and debridement (cleansing with normal saline at low pressure for 10 to 20 minutes was associated with greater reduction in pressure injury depth), (5) diagnosing microbial burdens or biofilms (if present) with tissue biopsies or microscopy, (6) administering antibiotics, (7) dressing wounds, (8) conducting biological wound dressing (e.g., skin substitutes, xenografts, collagen dressing, etc.), (9) using biophysical agents (e.g., electrical stimulation), (10) evaluating the need for surgery (usually on stage III or IV pressure injuries), and more.

Changes to evidence from last review

☐ **The developer attests that there have been no changes in the evidence since the measure was last evaluated.**

☒ **The developer provided updated evidence for this measure:**

Updates:

The developer updated the literature review with citations to several systematic reviews the further support the previous evidence of the measure.

Question for the Committee:

Is there at least one thing that the provider can do to achieve a change in the measure results?

If derived from patient report, does the target population value the measured outcome and finds it meaningful?

Guidance from the Evidence Algorithm

Box 1 (Health outcome)? – yes -> Box 2 (One or more action?) yes -> PASS

Preliminary rating for evidence: ☒ Pass ☐ No Pass

1b. Gap in Care/Opportunity for Improvement and 1b. Disparities

Maintenance measures – increased emphasis on gap and variation

1b. Performance Gap. The performance gap requirements include demonstrating quality problems and opportunity for improvement.

The facility-level mean score for this measure in Quarter 4 (Q4) of 2019 was 7.5% and the median score was 6.8%. The standard deviation was 5.1%, the minimum was 0%, and score at the 90th percentile was 14.0%. The interquartile range for this measure was 6.4%, indicating room for improvement on this measure. Of the facilities with adequate sample size to report, 8.0% had perfect scores of 0.
In Q4 2019, there were 13,219 facilities (87.5%) and 749,950 residents (97.0%) that met the denominator inclusion criteria. n (Facilities): 13,219 k (Residents): 749,950

Performance Over Time:

The national facility-level mean and median scores for the Percent of High-Risk Residents with Pressure Ulcers demonstrate slight seasonal variation, with mean and median scores being higher in Quarter 1 and lower in Quarter 4 each year (Figure 1 of NQF Testing Form). Overall, the national facility-level mean and median scores have decreased marginally and indicate a slight improvement in performance over time. The mean score for this measure was 7.53% in quarter 4 of 2017 and the median score was 6.90%. In Q4 2019, the mean and median were 7.45% and 6.82%, respectively. (Data Source: Data are drawn from all United States Nursing Homes with Medicare certified beds and a minimum of 20 long-stay residents in their denominator.)

Disparities

The data were examined to assess for disparities by age, race, and socioeconomic status. Notably all three factors demonstrated significant relationships in performance at the facility-level.

Age: the developer reported that residents below the age of 85 are at higher risk for experiencing pressure ulcers than residents aged 85 years or older.

Race: the developer reported that the non-White population (9.0%) is at higher risk for experiencing pressure ulcers than the White only population (7.0%).

Socioeconomic status: the developer reported that the non-Medicaid population (8.2%) is at higher risk for experiencing pressure ulcers than the Medicaid population (7.4%), indicating there is a relationship between socioeconomic status and prevalence of pressure ulcers among high risk long-stay residents.

Questions for the Committee:

- Is there a gap in care that warrants a national performance measure?
- Based upon the observed differences by age, race, and SES, should this measure be risk-adjusted?

Preliminary rating for opportunity for improvement: ☒ High ☐ Moderate ☐ Low ☐ Insufficient

Committee Pre-evaluation Comments:

Criteria 1: Importance to Measure and Report (including 1a, 1b, 1c)

1a. Evidence to Support Measure Focus: For all measures (structure, process, outcome, patient-reported structure/process), empirical data are required. How does the evidence relate to the specific structure, process, or outcome being measured? Does it apply directly or is it tangential? How does the structure, process, or outcome relate to desired outcomes? For maintenance measures –are you aware of any new studies/information that changes the evidence base for this measure that has not been cited in the submission? For measures derived from a patient report: Measures derived from a patient report must demonstrate that the target population values the measured outcome, process, or structure.

- Evidence is appropriate
- Evidence to support measure is strong and has been updated with systematic reviews since the last iteration. No concerns.
- This outcome measure reports the percentage of long-stay, high-risk, residents in a nursing home who have Stage II-IV pressure ulcers. While the measure was last endorsed in 2015, the evidence to justify this measure remains strong. Up to 24% pressure ulcers occur among elderly who reside in long-term care facilities, and most pressure ulcers are often preventable and can be an indicator of quality of care at the long-term care facilities. So the evidence is directly related to this measure. CMS has provided updated literature including publications since 2015.
- Due to high risk of pressure ulcers in elderly LTC residents, the rate of pressure ulcers are a useful indicator of quality of care offered at LTC facilities.
- Evidence is Pass.
- Unclear to me what the various sources of data may be. Patients would value if they were able to report.
- pass
- No issues
- long state nursing home population - outcome measure

1b. Performance Gap: Was current performance data on the measure provided? How does it demonstrate a gap in care (variability or overall less than optimal performance) to warrant a national performance measure? Disparities: Was data on the measure by population subgroups provided? How does it demonstrate disparities in the care?

- Yes, there is a performance gap. Age and payer were the subgroups measured for disparities
- Substantial variation in measure, with 8% having 0% and the 90th percentile having 14%. This suggests opportunities for improvement. Subgroups of age, race, and SES show different relationships with outcomes, some counterintuitive (younger age and non-Medicaid beneficiaries). Will be interested to hear from developers on this phenomenon.
- The facility-level scores for this measure show a standard deviation of 5.1% and an interquartile range of 6.4%. These numbers demonstrate a performance gap for improvement. Disparities were examined by age, race, and socioeconomic status. All three factors showed significant relationships in performance at the facility-level. In particular, residents below the age of 85 showed higher risk for experiencing pressure ulcers than residents aged 85 years or older; non-

White population showed a higher risk for experiencing pressure ulcers than the White only population; and non-Medicaid population showed a higher risk for experiencing pressure ulcers than the Medicaid population. I am curious about the association between the non-Medicaid population and higher risk pressure ulcers.

- There has been slight improvement from Q4 2017 when mean score for this measure was 7.53% to 7.45% in Q4 2019. Disparities noted in age, face and SES.
- High - existing performance gap.
- Performance gap provided based on incidence variability.
- provided, high gap
- Notable gap
- pass on evidence - there has been slight performance improvement over time. Significant disparities in age and race, and socio economic differences

Criteria 2: Scientific Acceptability of Measure Properties

2a. Reliability: Specifications and Testing

2b. Validity: Testing; Exclusions; Risk-Adjustment; Meaningful Differences; Comparability; Missing Data

Reliability

2a1. Specifications requires the measure, as specified, to produce consistent (reliable) and credible (valid) results about the quality of care when implemented. For maintenance measures – no change in emphasis – specifications should be evaluated the same as with new measures.

2a2. Reliability testing demonstrates if the measure data elements are repeatable, producing the same results a high proportion of the time when assessed in the same population at the same time-period and/or that the measure score is precise enough to distinguish differences in performance across providers. For maintenance measures – less emphasis if no new testing data provided.

Validity

2b2. Validity testing should demonstrate the measure data elements are correct and/or the measure score correctly reflects the quality of care provided, adequately identifying differences in quality. For maintenance measures – less emphasis if no new testing data provided.

2b2-2b6. Potential threats to validity should be assessed/addressed.

Composite measures only:

2d. Empirical analysis to support composite construction. Empirical analysis should demonstrate that the component measures add value to the composite and that the aggregation and weighting rules are consistent with the quality construct.

Complex measure evaluated by Scientific Methods Panel? ☒ **Yes** ☐ **No**

Evaluators: Scientific Methods Panel

Methods Panel Review (Combined)

Methods Panel Evaluation Summary:

This measure was reviewed by the Scientific Methods Panel and discussed on the call. A summary of the measure and the Panel discussion is provided below.
Reliability

- Critical data element testing was performed on 71 community nursing facilities in 8 states (3,822 residents) and 19 VA nursing homes (764 residents). Agreement within gold-standard nurses and between gold-standard nurses and facility nurses both at the resident-level and the facility level. Kappa was 0.92 for the former and 0.97 for the latter.
- Performance measure score testing included nationwide nursing home facilities with an N greater than or equal to 20. Measure score reliability was assessed by split half testing and signal-to- noise analysis. The split-half correlation was 0.33, and 0.50 for the latter.
- Data element reliability was thought by SMP to be excellent, although it was conducted with data from 13 years ago.

Validity

- Performance score validity was assessed by correlation to other quality measures, specifically the Percent of SNF Residents with Pressure Ulcers) and Facility Five-Star Ratings. Variation by state, seasonality, stability analyses and confidence interval analyses were also utilized. Correlation was reported by spearman correlation and was significant for all.
- Spearman correlations ranged from -0.207 to +0.203 for the measure score with the other measures of quality mentioned above. 5.84% of the variation was between-state. Average inter-quartile range of state-level scores was 6.4 percentage points. Of interest was the note that 24.6% of facilities did not change deciles over, 25.7% changed one decile, 19.4% changed two deciles, and 30.4% changed 3 or more deciles. This is attributed to low frequency events and the impact on one event on the decile assignment.

Questions for the Committee regarding reliability:

- Do you have any concerns that the measure can be consistently implemented (i.e., are measure specifications adequate)?
- The Scientific Methods Panel is satisfied with the reliability testing for the measure. Does the Committee think there is a need to discuss and/or vote on reliability?

Questions for the Committee regarding validity:

- Do you have any concerns regarding the validity of the measure (e.g., exclusions, risk-adjustment approach, etc.)?
- The Scientific Methods Panel is satisfied with the validity analyses for the measure. Does the Committee think there is a need to discuss and/or vote on validity?

Preliminary rating for reliability: ☐ **High** ☒ **Moderate** ☐ **Low** ☐ **Insufficient**

Preliminary rating for validity: ☐ **High** ☒ **Moderate** ☐ **Low** ☐ **Insufficient**

Committee Pre-evaluation Comments:
Criteria 2: Scientific Acceptability of Measure Properties (including all 2a, 2b, and 2c)

2a1. Reliability-Specifications: Which data elements, if any, are not clearly defined? Which codes with descriptors, if any, are not provided? Which steps, if any, in the logic or calculation algorithm or other specifications (e.g., risk/case-mix adjustment, survey/sampling instructions) are not clear? What concerns do you have about the likelihood that this measure can be consistently implemented?

- While the comparison between the facility nurse and gold standard nurse showed a high degree of reliability, based on my experience in nursing homes and having run a pressure ulcer collaborative, I believe there is a high degree of variability between nurses within facilities and between facilities. In addition, nurse turnover is an issue in nursing homes, and in general, nurses' understanding of pressure ulcer identification and staging is quite variable. In recent years, while NPUAP has changed its staging system, CMS has not completely aligned with NPUAP.
- No concerns about reliability. This measure appears consistent with other gold standards. Reliability is moderate but appears to discriminate high vs low performers adequately.
- No Concerns.
- Data element reliability was excellent according to SMP however data was old (from 13 years ago).
- Data supporting reliability was 13 years old. Some other concerns as raised by the methods panel, but agree overall reliability is "moderate". One question re definition is how often assessments occur, and if someone who came to the facility with an ulcer, would that be excluded or still counted? what if it's a persistent ulcer, would it be counted each quarter it does not heal?
- none
- moderate level prelim rating
- None
- moderate rating by panel

2a2. Reliability - Testing: Do you have any concerns about the reliability of the measure; reliability testing and results for the measure?

- see previous response
- No
- No Concerns. The SPM rated it as moderate.
- based on old data
- No concerns
- no
- moderate level prelim rating
- No
- moderate rating by panel

2b1. Validity -Testing: Do you have any concerns with the validity testing and results for the measure?

- no concerns
- No concerns. Concurrent validity with mobility was strong, as well as nutritional status.
- No Concerns. The SPM rated it as moderate.
- no concerns

- No concerns, agree with "moderate"
- no
- moderate level prelim rating
- no
- moderate rating by panel

2b4-7. Threats to Validity (Statistically Significant Differences, Multiple Data Sources, Missing Data) 2b4. Meaningful Differences: How do analyses indicate this measure identifies meaningful differences about quality? 2b5. Comparability of performance scores: If multiple sets of specifications: Do analyses indicate they produce comparable results? 2b6. Missing data/no response: Does missing data constitute a threat to the validity of this measure?

- no concerns
- No
- The developer used facility-level quality measure scores to identify meaningful differences in facility performance on NQF 0679. The analyses "show that the quality measure score varies enough to make meaningful distinctions between high- and low-quality facilities. The 90th percentile is more than eight times higher than the 10th percentile, and there is substantial distinction between the first and the third quartile. Moreover, the quality measure scores vary sufficiently from the national mean demonstrating a meaningful difference to differentiate the best and worst performers for this measure." To test the impact of missing data on the validity of this measure, the developer analyzed MDS 3.0 data and found that there was not enough exclusion to test for any kind of differences between facilities and to warrant concern over missing data introducing bias into the measure.
- no concerns
- No concerns.
- May be potential to overlook pressure ulcers that should be reported.
- moderate level prelim rating
- none
- moderate rating by panel

2b2-3. Other Threats to Validity (Exclusions, Risk Adjustment) 2b2. Exclusions: Are the exclusions consistent with the evidence? Are any patients or patient groups inappropriately excluded from the measure? 2b3. Risk Adjustment: If outcome (intermediate, health, or PRO-based) or resource use performance measure: Is there a conceptual relationship between potential social risk factor variables and the measure focus? How well do social risk factor variables that were available and analyzed align with the conceptual description provided? Are all of the risk-adjustment variables present at the start of care (if not, do you agree with the rationale provided)? Was the risk adjustment (case-mix adjustment) appropriately developed and tested? Do analyses indicate acceptable results? Is an appropriate risk-adjustment strategy included in the measure?

- no risk adjustment
- Not risk adjusted. Age appears to be protective, which is counterintuitive.
- To avoid unintended consequences introduced by risk adjusting for advanced age and race, no risk-adjustment is applied for this measure, which is reasonable for a patient safety measure.

- Performance measure score testing included nationwide nursing home facilities with an N greater than or equal to 20.
- I share the same question with one of the members from the methods panel - insufficient justification for not risk adjust is provided. Yes there is always concern for unintended consequences, not sure how this is different compared to other measures where we do risk adjust.
- none apparent
- no concerns
- Concern for the small facility carve out.
- not sure it has been risk adjusted

Criterion 3. Feasibility

Maintenance measures – no change in emphasis – implementation issues may be more prominent

3. Feasibility is the extent to which the specifications including measure logic, require data that are readily available or could be captured without undue burden and can be implemented for performance measurement.

- ALL data elements are in defined fields in electronic clinical data (e.g., clinical registry, nursing home MDS, home health OASIS)
- The general data collection method for the MDS 3.0 is currently in operational use and mandatory for all Medicare/Medicaid certified nursing facilities.

Questions for the Committee:

- Are the required data elements routinely generated and used during care delivery?
- Are the required data elements available in electronic form, e.g., EHR or other electronic sources?

Preliminary rating for feasibility: ☒ **High** ☐ **Moderate** ☐ **Low** ☐ **Insufficient**

Committee Pre-evaluation Comments:

Criteria 3: Feasibility

3. Feasibility: Which of the required data elements are not routinely generated and used during care delivery? Which of the required data elements are not available in electronic form (e.g., EHR or other electronic sources)? What are your concerns about how the data collection strategy can be put into operational use?

- no concerns
- Extractions from MDS and EMR data; no concerns
- No Concerns. The preliminary rating on feasibility is high.
- this data is routinely generated
- No concerns.
- none
- high
- Feasible

- high feasibility

Criterion 4: Usability and Use

Maintenance measures – increased emphasis – much greater focus on measure use and usefulness, including both impact/improvement and unintended consequences

4a. Use (4a1. Accountability and Transparency; 4a2. Feedback on measure)

4a. Use evaluates the extent to which audiences (e.g., consumers, purchasers, providers, policymakers) use or could use performance results for both accountability and performance improvement activities.

4a.1. Accountability and Transparency. Performance results are used in at least one accountability application within three years after initial endorsement and are publicly reported within six years after initial endorsement (or the data on performance results are available). If not in use at the time of initial endorsement, then a credible plan for implementation within the specified timeframes is provided.

Current uses of the measure

Publicly reported? ☒ **Yes** ☐ **No**

Current use in an accountability program? ☒ **Yes** ☐ **No** ☐ **UNCLEAR**

Accountability program details

- Public Reporting
  - Care Compare https://www.medicare.gov/care-compare/
  - Provider Data Catalog https://data.cms.gov/provider-data/
- Quality Improvement (external benchmarking to organizations)
  - Certification and Survey Provider Enhanced Reports (CASPER) https://www.qtso.com/providernh.html

4a.2. Feedback on the measure by those being measured or others. Three criteria demonstrate feedback: 1) those being measured have been given performance results or data, as well as assistance with interpreting the measure results and data; 2) those being measured, and other users have been given an opportunity to provide feedback on the measure performance or implementation; 3) this feedback has been considered when changes are incorporated into the measure.

Feedback on the measure by those being measured or others

- The CASPER reports are available to providers on-demand with quality measure data updated monthly. Care Compare reports the rolling average of four quarters for the quality measure, comparing each nursing home's score to both the state and national average; providers can preview this information before it is publicly reported.

Additional Feedback:

- Upon review of all inquiries submitted to the quality measure support inbox between 10/2019 and 02/2021, other users raised no concerns regarding the performance and implementation of the LS PU measure.

***Questions for the Committee**:*

- How have (or can) the performance results be used to further the goal of high-quality, efficient healthcare?
- How has the measure been vetted in real-world settings by those being measured or others?

Preliminary rating for Use: ☒ **Pass** ☐ **No Pass**

4b. Usability (4a1. Improvement; 4a2. Benefits of measure)

4b. Usability evaluates the extent to which audiences (e.g., consumers, purchasers, providers, policymakers) use or could use performance results for both accountability and performance improvement activities.

4b.1 Improvement. Progress toward achieving the goal of high-quality, efficient healthcare for individuals or populations is demonstrated.

Improvement results

- The national facility-level mean and median scores for the Percent of High-Risk Residents with Pressure Ulcers demonstrate slight seasonal variation, with mean and median scores being higher in Quarter 1 and lower in Quarter 4 each year (See Figure 1 of NQF Testing Form).
- Overall, the national facility-level mean and median scores have decreased marginally and indicate a slight improvement in performance over time. The mean score for this measure was 7.53% in quarter 4 of 2017 and the median score was 6.90%. In Q4 2019, the mean and median were 7.45% and 6.82%, respectively.

4b2. Benefits vs. harms. Benefits of the performance measure in facilitating progress toward achieving high-quality, efficient healthcare for individuals or populations outweigh evidence of unintended negative consequences to individuals or populations (if such evidence exists).

Unexpected findings (positive or negative) during implementation

- During the testing process for NQF #0679, the results of the risk-adjustment model using age as a risk factor demonstrated that the odds of developing pressure ulcers is almost 27% lower for residents over the age of 85 compared to younger residents (see Section 2b3.4a. of the Testing Form). This observation was not in the expected direction, as it was anticipated that advanced aged residents would be at higher risk for pressure ulcers than younger residents.

Potential harms

- None

Additional Feedback:

- None

***Questions for the Committee**:*

- How can the performance results be used to further the goal of high-quality, efficient healthcare?
- Do the benefits of the measure outweigh any potential unintended consequences?

Preliminary rating for Usability and use: ☐ **High** ☒ **Moderate** ☐ **Low** ☐ **Insufficient**

Committee Pre-evaluation Comments:

Criteria 4: Usability and Use

4a1. Use - Accountability and Transparency: How is the measure being publicly reported? Are the performance results disclosed and available outside of the organizations or practices whose performance is measured? For maintenance measures - which accountability applications is the measure being used for? For new measures - if not in use at the time of initial endorsement, is a credible plan for implementation provided? 4a2. Use - Feedback on the measure: Have those being measured been given performance results or data, as well as assistance with interpreting the measure results and data? Have those being measured or other users been given an opportunity to provide feedback on the measure performance or implementation? Has this feedback has been considered when changes are incorporated into the measure?

- Publicly reported and used in accountability programs already
- Publicly reported and used in an accountability program. No concerns.
- The measure is currently being used in CMS public reporting programs, Care compare and Provider Data Catalog; both are posted on the CMS web sites that are publicly accessible.
- The data is publicly reported and used in Care Compare and CASPER for certification surveys.
- No concerns. Rating is "pass".
- no concerns
- In use
- publicly reported and used
- pass on use - built into MDS information system

4b1. Usability – Improvement: How can the performance results be used to further the goal of high-quality, efficient healthcare? If not in use for performance improvement at the time of initial endorsement, is a credible rationale provided that describes how the performance results could be used to further the goal of high-quality, efficient healthcare for individuals or populations? 4b2. Usability – Benefits vs. harms: Describe any actual unintended consequences and note how you think the benefits of the measure outweigh them.

- The finding that younger nursing home residents are at higher risk may be related to the significant number of short-stay patients in nursing homes, particularly post-surgical and post-stroke patients. Generally, the younger patients may have conditions that contribute to their risk level. In addition, this finding could be related to incorrect staging.
- No reports of unintended consequences.
- “Overall, the national facility-level mean and median scores have decreased marginally and indicate a slight improvement in performance over time. The mean score for this measure was 7.53% in quarter 4 of 2017 and the median score was 6.90%. In Q4 2019, the mean and median were 7.45% and 6.82%, respectively.” Thus, the usability of this measure for quality improvement is high.
- This data can be used to design institution level risk reduction programs for reducing harm caused by pressure ulcers in LTC facilities.
- No known unintended consequences. Agree that it's odd that the older age 85 is associated with less risk, agree that adjusting for BMI may be worthwhile.
- Each facility can follow improvements in pressure ulcer occurrences.
- benefits > harms
- reasonable

- moderate usability

Criterion 5: Related and Competing Measures

Related or competing measures
0201: Pressure ulcer prevalence (hospital acquired)
0337: Pressure Ulcer Rate (PDI 2)
0538: Pressure Ulcer Prevention and Care

Harmonization
0201 Pressure ulcer prevalence (hospital acquired). This measure has a similar focus but a different target population (hospital) and data source in addition to only capturing new or worsened pressure ulcers. # 0538 Pressure Ulcer Prevention and Care. This measure has a similar focus, but a different target population (home health patients) in addition to being a process measure focusing on pressure ulcer risk assessment, plan of care development, and prevention implementation. # 0337 Pressure Ulcer Rate (PDI 2). This measure has a similar focus, but a different target population (hospital). The measure only captures stage three and four ulcers and is claims based.
Committee Pre-evaluation Comments: Criterion 5:
Related and Competing Measures

5. Related and Competing: Are there any related and competing measures? If so, are any specifications that are not harmonized? Are there any additional steps needed for the measures to be harmonized?

- there are related measures, but I believe this measure is still needed.
- Overlaps are appropriate, given different settings and populations
- Three other similar pressure ulcer related measures are identified. The biggest difference is that they address different populations, i.e., either hospitalized patients or home-care patients. So I do not think they are competing measures and there is no need for harmonization.
- no
- No concerns.
- no
- several, listed
- None
- 3 completing measures for differing facilities (acute care, home health, etc.)

Public and Member Comments

Comments and Member Support/Non-Support Submitted as of: 06/03/2021

No NQF Members have submitted support/non-support choices as of this date.

No Public or NQF Member comments submitted as of this date.

Scientific Acceptability: Preliminary Analysis Form

Measure Number: 0679

Measure Title: Percent of High-Risk Residents with Pressure Ulcers (Long Stay)

RELIABILITY: SPECIFICATIONS

1. **Are submitted specifications precise, unambiguous, and complete so that they can be consistently implemented? ☒ Yes ☐ No**

   Submission document: "MIF_xxxx" document, items S.1-S.22

   ***NOTE**: NQF staff will conduct a separate, more technical, check of eCQM specifications, value sets, logic, and feasibility, so no need to consider these in your evaluation.*

2. **Briefly summarize any concerns about the measure specifications.**

   Panel Member 1: None.

   Panel Member 2: The developer should provide a distribution of reliability scores among facilities and potentially establish a volume threshold for reporting.

   Panel Member 3: No concerns

   Panel Member 4: No concerns

   Panel Member 5: No Concerns

   Panel Member 6: None

RELIABILITY: TESTING

Type of measure:

☒ Outcome (including PRO-PM) ☐ Intermediate Clinical Outcome ☐ Process

☐ Structure ☐ Composite ☐ Cost/Resource Use ☐ Efficiency

Data Source:

☐ Abstracted from Paper Records ☐ Claims ☐ Registry
☐ Abstracted from Electronic Health Record (EHR) ☐ eMeasure (HQMF) implemented in EHRs
☐ Instrument-Based Data ☐ Enrollment Data ☒ Other (please specify)

Panel Member 1: Assessment data
Panel Member 2: Nursing home MDS
Panel Member 3: Nursing Home Minimum Data Set (MDS) 3.0
Panel Member 4: Assessment Data: Minimum Data Set (MDS) 3.0
Panel Member 5: Percent of High-Risk Residents with Pressure Ulcers (Long Stay)
Panel Member 6: The data source is the Nursing Home Minimum Data Set.
Panel Member 7: Minimum Data Set (MDS) 3.0 OBRA, PPS, and/or discharge assessments
Panel Member 8: MDS

Level of Analysis:

☐ Individual Clinician ☐ Group/Practice ☒ Hospital/Facility/Agency ☐ Health Plan

☐ **Population: Regional, State, Community, County or City** ☐ **Accountable Care Organization**
☐ **Integrated Delivery System** ☐ **Other (please specify)**

Measure is:

☐ **New** ☒ **Previously endorsed (**NOTE: Empirical validity testing is expected at time of maintenance review; if not possible, justification is required.)

Submission document: "MIF_xxxx" document for specifications, testing attachment questions 1.1-1.4 and section 2a2

3. **Reliability testing level** ☒ **Measure score** ☒ **Data element** ☐ **Neither**
4. **Reliability testing was conducted with the data source and level of analysis indicated for this measure** ☒ **Yes** ☐ **No**
5. If score-level and/or data element reliability testing was NOT conducted or if the methods used were NOT appropriate, was **empirical VALIDITY testing** of **patient-level data** conducted?

   ☐ **Yes** ☐ **No**
6. **Assess the method(s) used for reliability testing**

   Submission document: Testing attachment, section 2a2.2

   Panel Member 1: Data element: Used an appropriate method. Assessed inter-rater reliability across different abstractor groups. Measure score: Used appropriate methods. Calculated both signal-to-noise and split-half reliability.

   Panel Member 2: The developer evaluated both data element reliability and measure reliability. Critical data element reliability was established for assessing the agreement between gold-standard nurse abstractor and facility nurse abstractor to ensure critical data element can be uniformly abstracted across facilities. Split-half reliability analysis using r and rho is not the most appropriate approach. Signal-to-noise analysis is appropriate for this purpose; however, the developer need to report more than just average reliability score.

   Panel Member 3: No concerns

   Panel Member 4: Appropriate

   Panel Member 5: All methods appropriate. Facility Nurse agreement using Kappa and Signal to Noise/ Split Half reliability for score level testing and signal to noise.

   Panel Member 6: Critical data element testing was performed on 71 community nursing facilities in 8 states (3,822 residents) and 19 VA nursing homes (764 residents). Agreement within gold-standard nurses and between gold-standard nurses and facility nurses both at the resident-level and the facility level. Kappa was 0.92 for the former and 0.97 for the latter. Performance measure score testing included nationwide nursing home facilities with an N greater than or equal to 20. Measure score reliability was assessed by split half testing and signal-to- noise analysis. The split-half correlation was 0.33, and 0.50 for the latter.

   Panel Member 7: Split-half reliability and SNR

   Panel Member 8: Comparing community nurses to gold standard nurses seems like a test of validity rather than reliability (and is described as such in the validity testing section). Comparing community to community nurses would be a better test of reliability. The Landis and Koch adjectives pertain to evidence against the null hypothesis of zero agreement. Also, interpretation of kappa is difficult in

the presence of asymmetry https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4236536/ The entity-score reliability methods included SNRs and split-sample reliability, which are strong methods. Note that the stability analysis (cast as a test of validity) also directly speaks to reliability.

7. **Assess the results of reliability testing**

Submission document: Testing attachment, section 2a2.3

Panel Member 1: Data element: The Kappa for gold-standard to facility-nurse agreement was 0.92. A rating of 0.92 is considered "substantial agreement." Measure score: The split-half correlation for this measure was positive, and the relationship was moderate ($r = 0.33$, $\rho = 0.30$, $p < .01$), suggesting there is modest evidence of internal reliability. The average signal-to-noise reliability score was 0.50. This suggests that the measure is moderately reliable in separating facility characteristics from variability within facility.

Panel Member 2: Critical data element reliability is high. Mean measure score reliability based on signal-to-noise analysis is moderate. It will be helpful if the developer can describe the distribution of reliability scores among all eligible facilities.

Panel Member 3: Data element reliability was excellent, although it was conducted with data from 13 years ago. As noted, since the data element collection process stayed stable over time, it seems reasonable to not ask for an updated analysis for data element reliability. Only weak/moderate reliability at the score level was supported. Given the low variance expected in these outcomes data, higher reliability scores would be very difficult to achieve. Although I do not think this is a good enough reason to fail this measure from being re-endorsed, these results so suggest limited usefulness of its current scoring method. It may be possible to modify how this measure is scored by raising the bar to create more variability in the outcomes data. Since I am not a clinical expert in the field of pressure ulcers, I will leave it to the developers to consider future modifications, possibly related to the nature of the scoring system. For example, if the measure were to be modified from a binary outcome to an ordered categorical score taking into account the level of the pressure ulcer identified, possibly also including a level 1 pressure ulcer to the numerator, more variability would be expected, with a greater potential to demonstrate higher measure score reliability results. Such a modification, if correctly done, could create a higher impact of the measure on the entities' performance scores, increasing its impact on continued improvements over time. In any case, I am not sure to makes sense to keep endorsing a measure that has little score variability, unless there is no clinically logical way to raise its bar so to speak, and the measure as is important to incentivize providers to maintain the current outcomes. I think this measure is a good example of a measure that should be considered for modifications due to the argument raised here, and I strongly encourage developers to consider this for the next maintenance cycle.

Panel Member 5: Critical Data Element= Correlation between the MDS 2.0 and MDS 3.0 measures was strong at both the resident- ($\rho = 0.92$) and facility-level ($\rho = 0.97$). Performance Measure Score Reliability 7. These analyses demonstrate that the pressure ulcer measure shows moderate evidence of internal reliability. The average signal-to-noise ratio across all providers was 0.50, meaning 50% of the variance in scores for this measure were explained by inter-facility variation.

Panel Member 6: Date element reliability is high but measure score reliability is at best moderate to low. Signal to noise suggest that 50% of the variation comes from inter-facility variation.

Panel Member 7: The split-half correlation for this measure was positive, and the relationship was moderate ($r = 0.33$, $\rho = 0.30$, $p < .01$), suggesting there is modest evidence of internal reliability;

Signal-to-noise analysis: The average signal-to-noise reliability score of this quality measure using facility scores based on FY2019 Q4 data was observed to be 0.50. No breakdowns.

Panel Member 8: Critical data element reliability for gold to community nurses was 0.92. Community to community nurse reliability was not reported. These results are quite old. Median SNR was 0.50. The distribution of SNR was not given. Since half of the entities have reliability <.50, I considered the entity-level reliability to low. The split-sample reliability analysis yielded r = .33 which is also low. We have seen much higher values for measures with similar sample size and skew issues.

8. Was the method described and appropriate for assessing the proportion of variability due to real differences among measured entities? NOTE: If multiple methods used, at least one must be appropriate.

   Submission document: Testing attachment, section 2a2.2

   ☒ **Yes**

   ☐ **No**

   ☐ **Not applicable** (score-level testing was not performed)

9. Was the method described and appropriate for assessing the reliability of ALL critical data elements?

   Submission document: Testing attachment, section 2a2.2

   ☒ **Yes**

   ☐ **No**

   ☒ **Not applicable** (data element testing was not performed)

10. **OVERALL RATING OF RELIABILITY** (taking into account precision of specifications and **all** testing results):

    ☐ **High** (NOTE: Can be HIGH **only if** score-level testing has been conducted)

    ☒ **Moderate** (NOTE: Moderate is the highest eligible rating if score-level testing has **not** been conducted)

    ☒ **Low** (NOTE: Should rate **LOW** if you believe specifications are NOT precise, unambiguous, and complete or if testing methods/results are not adequate)

    ☐ **Insufficient** (NOTE: Should rate **INSUFFICIENT** if you believe you do not have the information you need to make a rating decision)

11. **Briefly explain rationale for the rating of OVERALL RATING OF RELIABILITY and any concerns you may have with the approach to demonstrating reliability.**

    Panel Member 1: Used appropriate methods for testing reliability. The data element reliability testing produced a strong result (Kappa of 0.92). The measure score reliability testing produced more moderate results (signal-to-noise statistic of 0.50).

    Panel Member 2: Data element reliability is very high, measure score reliability is moderate. It will be useful to understand the reliability for low volume facilities.

    Panel Member 3: The moderate rating is due to the weak/moderate reliability demonstrated. As noted above, I strongly recommend that future modifications to the measure scoring is considered as discussed above.

    Panel Member 4: Based on testing results.

Panel Member 5: Critical Data Element Level reliability was high but score level reliability was moderate on the low side with the split-half reliability analysis but slightly better with the signal to noise.

Panel Member 6: Under current measure assessment guidelines, 50% is moderate for performance measure score reliability. Attempts should continue to formally determine causes and opportunities to improve the reliability of the measure score.

Panel Member 8: Results of entity-score reliability suggest low reliability for at least half of the facilities. Also, the stability analysis (reported as a test of validity) shows that in >30% of facilities, Q2Q performance can jump 3 or more deciles.

VALIDITY: TESTING

12. **Validity testing level: ☒ Measure score ☒ Data element ☐ Both**
13. **Was the method described and appropriate for assessing the accuracy of ALL critical data elements?** *NOTE that data element validation from the literature is acceptable.*

    Submission document: *Testing attachment, section 2b1.*

    ☒ **Yes**

    ☐ **No**

    ☐ **Not applicable** (data element testing was not performed)
14. **Method of establishing validity of the measure score:**

    ☐ **Face validity**

    ☒ **Empirical validity testing of the measure score**

    ☐ **N/A (score-level testing not conducted)**
15. **Was the method described and appropriate for assessing conceptually and theoretically sound hypothesized relationships?**

    Submission document: Testing attachment, section 2b1.

    ☒ **Yes**

    ☐ **No**

    ☐ **Not applicable** (score-level testing was not performed)
16. **Assess the method(s) for establishing validity**

    Submission document: Testing attachment, section 2b2.2

    Panel Member 1: Data element: Appropriate method. Assessed inter-rater reliability, comparing gold-standard research nurses to gold-standard nurses and gold-standard nurses to staff nurses. Kappa statistic was calculated. Measure score: Included at least one appropriate method. Compared a facility's performance on this measure with other quality measures for which a hypothesized relationship would exist (risk of developing or worsening a pressure ulcer -and- Facility Five-Star Rating).

    Panel Member 2: Convergent validity analysis is relevant but other analyses are not as relevant.

    Panel Member 3: No concerns

    Panel Member 4: Acceptable.

Panel Member 5: Data Element-The RAND validation of MDS 3.0 study tested the criterion validity of the items by comparing how different nurses assessed the same residents using MDS 3.0 Performance Score-Convergent validity/variation by state/stability analysis and confidence interval analysis.

Panel Member 6: Critical data element validity was assessed by the feedback and comparison of the gold-standard nurse to gold-standard nurse and gold-standard nurse to facility nurse results. Performance score validity was assessed by correlation to other quality measures, specifically the Percent of SNF Residents with Pressure Ulcers) and Facility Five-Star Ratings. Variation by state, seasonality, stability analyses and confidence interval analyses were also utilized. Correlation was reported by spearman correlation and was significant for all.

Panel Member 7: "Convergent" validity; by state; seasonality; stability (Q to Q); CI analysis

Panel Member 8: I appreciate the fact that several tests of validity were performed.

17. **Assess the results(s) for establishing validity**

Submission document: Testing attachment, section 2b2.3

Panel Member 1: Data element: For Stage 2, 3 and 4 ulcers, nurse to gold-standard nurse agreement was perfect and the range of kappas for gold-standard nurse to facility nurse agreement was from 0.945 to 0.993. The items used to identify high risk residents, kappas for bed mobility and transfer self-performance were excellent, ranging from 0.957 to 0.987 Measure score: Found weak to moderate correlations in the expected direction with other quality measures.

Panel Member 2: Correlation analyses with other relevant quality measures provide supportive evidence of measure score validity. Data element validity is high.

Panel Member 3: No concerns

Panel Member 4: Acceptable.

Panel Member 5: Critical Data Elements For the pressure ulcer items for Stage 2, 3 and 4 ulcers used in this measure, nurse to gold-standard nurse agreement was perfect, and the range of kappas for gold-standard nurse to facility nurse agreement was from 0.945 to 0.993. Performance score analysis all indicated validity.

Panel Member 6: Spearman correlations ranged from -0.207 to +0.203 for the measure score with the other measures of quality mentioned above. 5.84% of the variation was between-state. Average inter-quartile range of state-level scores was 6.4 percentage points. Of interest was the note that 24.6% of facilities did not change deciles over, 25.7% changed one decile, 19.4% changed two deciles, and 30.4% changed 3 or more deciles. This is attributed to low frequency events and the impact on one event on the decile assignment.

Panel Member 7: Convergent -OK by state- not sure what to make of this seasonality - same By Percentile ranking - OK (not obvious to me)

Panel Member 8: Critical data element: Validity testing method and results were strong. Correlation with other quality measures: The pattern of correlations with other measures is generally consistent with what might be expected. Variation by state: It unclear if these analyses were done with 3-level hierarchical (patient/facility/state) models or an ANOVA on the facility level scores. The analysis doesn't reveal any obvious concerns. Seasonality: No concerns revealed. Stability analysis: It is concerning that 30% of facilities are jumping 3 or more deciles in performance over a short time interval, likely related to low reliability. This analysis could also have been done in

the split samples used for reliability testing and separately applied to the 3 categories (Lower than average, etc.). Confidence interval analysis: I think this analysis speaks more to NQF's "gap" criteria more than validity evidence.

VALIDITY: ASSESSMENT OF THREATS TO VALIDITY

18. **Please describe any concerns you have with measure exclusions.**

Submission document: Testing attachment, section 2b2.

Panel Member 1: None. The only exclusion is when there is missing data, where missing data is low (0.01% of episodes).

Panel Member 3: No concerns

Panel Member 4: No concerns.

Panel Member 5: No exclusions

Panel Member 6: None

19. **Risk Adjustment**

Submission Document: Testing attachment, section 2b3

19a. **Risk-adjustment method** ☒ **None** ☐ **Statistical model** ☐ **Stratification**

Panel Member 6: Race and age were addressed.

19b. **If not risk-adjusted, is this supported by either a conceptual rationale or empirical analyses?**

☒ Yes ☒ No ☐ Not applicable

19c. **Social risk adjustment:**

19c.1 Are social risk factors included in risk model? ☐ Yes ☒ No ☒ Not applicable

19c.2 Conceptual rationale for social risk factors included? ☐ Yes ☒ No

19c.3 Is there a conceptual relationship between potential social risk factor variables and the measure focus? ☐ Yes ☒ No

19d. **Risk adjustment summary:**

19d.1 All of the risk-adjustment variables present at the start of care? ☐ Yes ☐ No

19d.2 If factors not present at the start of care, do you agree with the rationale provided for inclusion? ☐ Yes ☐ No

19d.3 Is the risk adjustment approach appropriately developed and assessed? ☒ Yes ☐ No

19d.4 Do analyses indicate acceptable results (e.g., acceptable discrimination and calibration) ☐ Yes ☒ No

19d.5. Appropriate risk-adjustment strategy included in the measure? ☒ Yes ☒ No

19e**. Assess the risk-adjustment approach**

Panel Member 1: The measure developers do not provide a clear justification for not risk adjusting the measure but do allude to adjustment for race and age could potentially produce unintended consequences.

Panel Member 2: The developer argued not to adjust for some potential risk factors such as age and race to avoid unintended consequences.

Panel Member 3: I don't think that relatively low explanatory power of potential social risk factors is a good reason for not supporting risk adjustment. However, I do agree with the argument for not

needing to risk-adjust this measure due to its focus on patient safety and the need to encourage to adopt preventative actions instead of statistical adjustment.

Panel Member 4: Justification provided and no evidence that contradicts the developer's rationale,

Panel Member 5: Authors presented analysis and justification for not risk adjusting.

Panel Member 6: Age 85 cutoff and white/non-white were calculated. Age greater than 85 had an odds ratio of 0.73 with a c-statistic of 0.54 and white had an odds ratio of 0.78 with a c-statistic of 0.53. Both suggest weak model performance and are not indicative of high predictive ability.

Panel Member 7: Despite a low C, there may be room for improvement in risk adjustment (as with treatment of age as a risk adjustor) with meaningful adjustment under the curve?

Panel Member 8: The developers tested two variables separately (age and race) and determined that each alone had low predictive power. They state: "Although the results of all of the risk-adjustment models appear to be statistically significant at the 5% level, low C-Statistics were observed for these models. This suggests that the models do not have high predictive ability. Moreover, risk adjusting for advanced age and race may produce unintended consequences." Why weren't other variables such as BMI tested? But more importantly, could the decision to not risk adjust have unintended consequences, such as an adverse impact on patient selection? The decision to not risk adjust the measure seems inconsistent with many other outcome measures. How is this outcome different from (for example) surgical mortality or complication measures?

20. **Please describe any concerns you have regarding the ability to identify meaningful differences in performance.**

    Submission document: Testing attachment, section 2b4.

    Panel Member 1: None. The 90th percentile is more than eight times higher than the 10th percentile, and there is substantial distinction between the first and the third quantile.

    Panel Member 2: Both state level analysis and confidence interval analysis showed that there are substantial variations across facilities.

    Panel Member 3: No concerns

    Panel Member 4: No concerns

    Panel Member 5: No concerns

21. **Please describe any concerns you have regarding comparability of results if multiple data sources or methods are specified.**

    Submission document: Testing attachment, section 2b5.

    Panel Member 1: N/A

    Panel Member 2: Same MDS

    Panel Member 5: No concerns

22. **Please describe any concerns you have regarding missing data.**

    Submission document: Testing attachment, section 2b6.

    Panel Member 1: None. The measure developers identified low levels of missing data (0.01% of episodes).

    Panel Member 2: No concern

    Panel Member 3: No concerns due to the low rates of missing data

Panel Member 4: No concerns

Panel Member 5: No concerns

Panel Member 6: The amount of missing data is insignificant

For cost/resource use measures ONLY:

23. **Are the specifications in alignment with the stated measure intent?**

    ☒ **Yes** ☐ **Somewhat** ☐ **No (If "Somewhat" or "No", please explain)**

24. **Describe any concerns of threats to validity related to attribution, the costing approach, carve outs, or truncation (approach to outliers):**

25. **OVERALL RATING OF VALIDITY taking into account the results and scope of all testing and analysis of potential threats.**

    ☒ **High** (NOTE: Can be HIGH only if score-level testing has been conducted)

    ☒ **Moderate** (NOTE: Moderate is the highest eligible rating if score-level testing has NOT been conducted)

    ☒ **Low** (NOTE: Should rate LOW if you believe that there **are** threats to validity and/or relevant threats to validity were **not assessed OR** if testing methods/results are not adequate)

    ☐ **Insufficient** (NOTE: For instrument-based measures and some composite measures, testing at both the score level and the data element level **is required**; if not conducted, should rate as INSUFFICIENT.)

26. **Briefly explain rationale for rating of OVERALL RATING OF VALIDITY and any concerns you may have with the developers' approach to demonstrating validity.**

    Panel Member 1: The measure developers used appropriate methods for testing. The data element validity testing indicated strong validity, while the measure scoring testing indicated weak to moderate relationships with other quality measures.

    Panel Member 4: Based on testing results.

    Panel Member 5: Authors demonstrated both data element and performance score validity.

    Panel Member 6: Face validity and the nurse's results are the strongest indicator of validity given. There is a small contribution to validity by state. Decile changing is considerable and explained by low event occurrences and impact on scores.

    Panel Member 7: Narrowed denominator.

    Panel Member 8: Poor stability. Also, I question the decision to not risk adjust this outcome.

FOR COMPOSITE MEASURES ONLY: Empirical analyses to support composite construction

27. **What is the level of certainty or confidence that the empirical analysis demonstrates that the component measures add value to the composite and that the aggregation and weighting rules are consistent with the quality construct?**

    ☐ **High**

    ☐ **Moderate**

    ☐ **Low**

    ☐ **Insufficient**

28. **Briefly explain rationale for rating of EMPIRICAL ANALYSES TO SUPPORT COMPOSITE CONSTRUCTION**

ADDITIONAL RECOMMENDATIONS

29. **If you have listed any concerns in this form, do you believe these concerns warrant further discussion by the multi-stakeholder Standing Committee? If so, please list those concerns below.**

    Panel Member 1: None.

    Panel Member 2: Two issues may be worth further discussion. One is if there is a need to establish a volume threshold. Another is about lack of improvement over the years.

    Panel Member 5: None

    Panel Member 6: The low moderate score reliability and low split-half reliability combined with the validity results are concerning. This probably deserves full panel discussion.

Developer Submission

NQF #: 0679

Corresponding Measures:

De.2. Measure Title: Percent of High Risk Residents with Pressure Ulcers (Long Stay)

Co.1.1. Measure Steward: Center for Medicare & Medicaid Services

De.3. Brief Description of Measure: This measure reports the percentage of long-stay, high-risk, residents in a nursing home who have Stage II-IV or unstageable pressure ulcers on a selected target assessment in the target quarter. The long stay nursing home population is defined as residents who have received 101 or more cumulative days of nursing home care by the end of the target assessment period. A nursing home resident is defined as high-risk for pressure ulcer if they meet one or more of the following three criteria:

1. Impaired bed mobility or transfer
2. Comatose
3. Malnourished or at risk of malnutrition

This measure is based on data obtained through the Minimum Data Set (MDS) 3.0 OBRA, PPS, and/or discharge assessments during the selected quarter(s).

1b.1. Developer Rationale: This outcome-based quality measure reports the percentage of long-stay, high-risk nursing home residents with Stage II-IV pressure ulcers. Pressure ulcers are important to address as they are one of the most unwanted and preventable adverse events in the contexts of severe acute and chronic illnesses, disability, and high care dependency. , In the United States, over 2.5 million people experience pressure ulcers with 2% to 24% occurring in long-term care facilities. Typically, pressure ulcers occur in individuals with poor mobility who experience sustained pressure for long periods of time. Elderly individuals are prone to pressure ulcer formation due to the limited mobility that comes with increased age. Additionally, individuals living with disabilities are especially prone to pressure ulcer development due to reduced movement. Therefore, pressure ulcer prevalence is a problem within several nursing homes. Resident characteristics, risk factors, and predictors for pressure ulcer development include increased age, black race/ethnicity, malnutrition, dehydration, infection, urinary and bowel incontinence, high BMI, low hemoglobin levels, low albumin levels, non-blanchable erythema, mobility limitations, poor moisture status, higher body temperatures, and other comorbidities (e.g., stroke, dementia, Alzheimer's, spina bifida, cerebral palsy, etc.). , , , , , , , ,

Pressure ulcer rates may be indicators of the quality of care offered by long-term care facilities. Although many pressure ulcers are preventable, both facility-level and process-based characteristics can impact pressure ulcer prevalence within nursing homes.

Anrys, Charlotte, Hanne Van Tiggelen, Sofie Verhaeghe, Ann Van Hecke, and Dimitri Beeckman. 2019. "Independent Risk Factors for Pressure Ulcer Development in a High-Risk Nursing Home Population Receiving Evidence-Based Pressure Ulcer Prevention: Results from a Study in 26 Nursing Homes in Belgium." International Wound Journal 16 (2): 325–33. https://doi.org/10.1111/iwj.13032.

Kottner, Jan, Joyce Black, Evan Call, Amit Gefen, and Nick Santamaria. 2018. "Microclimate: A Critical Review in the Context of Pressure Ulcer Prevention." Clinical Biomechanics. 59 (November): 62–70. https://doi.org/10.1016/j.clinbiomech.2018.09.010.

Ahn, Hyochol, Linda Cowan, Cynthia Garvan, Debra Lyon, and Joyce Stechmiller. 2016. "Risk Factors for Pressure Ulcers Including Suspected Deep Tissue Injury in Nursing Home Facility Residents: Analysis of National Minimum Data Set 3.0." Advances in Skin and Wound Care 29 (4): 178–90. https://doi.org/10.1097/01.ASW.0000481115.78879.63.

Refer to footnote 1

Refer to footnote 1

Refer to footnote 3

Alderden, Jenny, Ginette Alyce Pepper, Andrew Wilson, Joanne D. Whitney, Stephanie Richardson, Ryan Butcher, Yeonjung Jo, and Mollie Rebecca Cummins. 2018. "Predicting Pressure Injury in Critical Care Patients: A Machine-Learning Model." American Journal of Critical Care 27 (6): 461–68. https://doi.org/10.4037/ajcc2018525.

Refer to footnote 1

Bauer, Karen, Kathryn Rock, Munier Nazzal, Olivia Jones, and Weikai Qu. 2016. "Pressure Ulcers in the United States' Inpatient Population from 2008 to 2012: Results of a Retrospective Nationwide Study." Ostomy Wound Management 62 (11): 30–38.

Chen, Hong-Lin, Ying-Juan Cao, Wang-Qin Shen, and Bin Zhu. 2017. "Construct Validity of the Braden Scale for Pressure Ulcer Assessment in Acute Care: A Structural Equation Modeling Approach." Ostomy Wound Management 63 (2): 38–41.

Demarre, Liesbet, Sofie Verhaeghe, Ann Van Hecke, Els Clays, Maria Grypdonck, and Dimitri Beeckman. 2015. "Factors Predicting the Development of Pressure Ulcers in an At-Risk Population Who Receive Standardized Preventive Care: Secondary Analyses of a Multicentre Randomised Controlled Trial." Journal of Advanced Nursing 71 (2): 391–403. https://doi.org/10.1111/jan.12497.

Jaul, Efraim, Jeremy Barron, Joshua P. Rosenzweig, and Jacob Menczel. 2018. "An Overview of Co-Morbidities and the Development of Pressure Ulcers among Older Adults." BMC Geriatrics 18 (1): 305. https://doi.org/10.1186/s12877-018-0997-7.

Kwok, Alvin C., Andrew M. Simpson, James Willcockson, Daniel P. Donato, Isak A. Goodwin, and Jayant P. Agarwal. 2018. "Complications and Their Associations Following the Surgical Repair of Pressure Ulcers." American Journal of Surgery 216 (6): 1177–81. https://doi.org/10.1016/j.amjsurg.2018.01.012.

Sprigle, Stephen, Douglas McNair, and Sharon Sonenblum. 2020. "Pressure Ulcer Risk Factors in Persons with Mobility-Related Disabilities." Advances in Skin and Wound Care 33 (3): 146–54. https://doi.org/10.1097/01.ASW.0000653152.36482.7d.

S.4. Numerator Statement: The numerator is the number of long-stay residents identified as high-risk with a selected MDS 3.0 target assessment (OBRA quarterly, annual or significant change/correction assessments or discharge assessment with or without return anticipated) in an episode during the selected target quarter reporting one or more Stage II-IV or unstageable pressure ulcer(s) at the time of assessment. . High-risk residents are those who are comatose (B0100 = [1]), or impaired in bed mobility (G0110A1 = [3, 4, 7, 8]) or transfer (G0110B1 = [3, 4, 7, 8]), or either experiencing malnutrition or at risk for malnutrition (I5600 = [1]). Unstageable pressure ulcers are pressure ulcers that are known to be present but are defined as unstageable due to either a non-removable dressing/device (M0300E1 = [1, 2, 3, 4, 5, 6, 7, 8, or 9]), slough or eschar (M0300F1 = [1, 2, 3, 4, 5, 6, 7, 8, or 9]), or a suspected deep tissue injury (M0300G1 = [1, 2, 3, 4, 5, 6, 7, 8, or 9]).

S.6. Denominator Statement: The denominator includes all long-stay nursing home residents who had a target assessment (ORBA, PPS, or discharge) during the selected quarter who were identified as high risk for pressure ulcer, and who do not meet the exclusion criteria.

S.8. Denominator Exclusions: A resident is excluded from the denominator if:

1. The target MDS assessment is an OBRA admission assessment or a PPS 5-day assessment or a PPS readmission/return assessment.

2. The resident did not meet the pressure ulcer conditions for the numerator and any Stage II, III, IV, or unstageable item is missing (M0300B1 = [-] or M0300C1 = [-] or M0300D1 = [-] or M0300E1 = [-] or M0300F1 = [-] or M0300G1 = [-]).

If the facility sample includes fewer than 20 residents, then the facility is excluded from public reporting because of small sample size.

De.1. Measure Type: Outcome

S.17. Data Source: Assessment Data

S.20. Level of Analysis: Facility

IF Endorsement Maintenance – Original Endorsement Date: Mar 03, 2011 **Most Recent Endorsement Date:** Dec 09, 2015

IF this measure is included in a composite, NQF Composite#/title:

IF this measure is paired/grouped, NQF#/title:

De.4. IF PAIRED/GROUPED, what is the reason this measure must be reported with other measures to appropriately interpret results? This measure is not paired/grouped

1. Evidence and Performance Gap – Importance to Measure and Report

Extent to which the specific measure focus is evidence-based, important to making significant gains in healthcare quality, and improving health outcomes for a specific high-priority (high-impact) aspect of healthcare where there is variation in or overall, less-than-optimal performance. ***Measures must be judged to meet all sub criteria to pass this criterion and be evaluated against the remaining criteria.***

1a. Evidence to Support the Measure Focus – See attached Evidence Submission Form

NQF_0679_Evidence_Form_20210402_Upload.docx

1a.1 For Maintenance of Endorsement: Is there new evidence about the measure since the last update/submission?
Do not remove any existing information. If there have been any changes to evidence, the Committee will consider the new evidence. Please use the most current version of the evidence attachment (v7.1). Please use red font to indicate updated evidence.

Yes

1a. Evidence (subcriterion 1a)

Measure Number (*if previously endorsed*)**:** 0679

Measure Title: Percentage of Long-Stay High-Risk Residents with Pressure Ulcers

IF the measure is a component in a composite performance measure, provide the title of the Composite Measure here:

Date of Submission: **4/2/2021**

1a.1. This is a measure of: (*should be consistent with type of measure entered in De.1*)

Outcome

☒ Outcome: **Stage II-IV pressure ulcer development among long-stay, high-risk residents**

☐Patient-reported outcome (PRO):

PROs include HRQoL/functional status, symptom/symptom burden, experience with care, health-related behaviors. (A PRO-based performance measure is not a survey instrument. Data may be collected using a survey instrument to construct a PRO measure.)

☐ Intermediate clinical outcome (*e.g., lab value*):

☐ Process:

☐ Appropriate use measure:

☐ Structure:

☐ Composite:

1a.2 LOGIC MODEL Diagram or briefly describe the steps between the healthcare structures and processes (e.g., interventions, or services) and the patient's health outcome(s). The relationships in the diagram should be easily understood by general, non-technical audiences. Indicate the structure, process or outcome being measured.

Outcomes and risk factors

This outcome-based quality measure reports the percentage of long-stay, high-risk nursing home residents with Stage II-IV pressure ulcers. Pressure ulcers are important to address, as they are among the most unwanted and preventable adverse events for residents with severe acute and chronic illnesses, disability, and high care dependency.[1,2] In the United States, over 2.5 million people experience pressure ulcers with 2% to 24% occurring in long-term care facilities.[3] Typically, pressure ulcers occur in individuals with poor mobility who experience sustained pressure to an area of soft tissue for a prolonged period of time. Elderly individuals are prone to pressure ulcer

[1] Anrys, Charlotte, Hanne Van Tiggelen, Sofie Verhaeghe, Ann Van Hecke, and Dimitri Beeckman. 2019. "Independent Risk Factors for Pressure Ulcer Development in a High-Risk Nursing Home Population Receiving Evidence-Based Pressure Ulcer Prevention: Results from a Study in 26 Nursing Homes in Belgium." International Wound Journal 16 (2): 325–33. https://doi.org/10.1111/iwj.13032.

[2] Kottner, Jan, Joyce Black, Evan Call, Amit Gefen, and Nick Santamaria. 2018. "Microclimate: A Critical Review in the Context of Pressure Ulcer Prevention." Clinical Biomechanics. 59 (November): 62–70. https://doi.org/10.1016/j.clinbiomech.2018.09.010.

[3] Ahn, Hyochol, Linda Cowan, Cynthia Garvan, Debra Lyon, and Joyce Stechmiller. 2016. "Risk Factors for Pressure Ulcers Including Suspected Deep Tissue Injury in Nursing Home Facility Residents: Analysis of National Minimum Data Set 3.0." Advances in Skin and Wound Care 29 (4): 178–90. https://doi.org/10.1097/01.ASW.0000481115.78879.63.

formation due to the limited mobility that comes with increased age.[4] Additionally, individuals living with disabilities are especially prone to pressure ulcer development due to reduced movement. Therefore, pressure ulcer prevalence is a problem within the nursing home population.[5] Resident characteristics, risk factors, and predictors for pressure ulcer development include increased age, black race/ethnicity, malnutrition, dehydration, infection, urinary and bowel incontinence, high BMI, low hemoglobin levels, low albumin levels, non-blanchable erythema, mobility limitations, poor skin moisture status, higher body temperatures, and other comorbidities (e.g., stroke, dementia, Alzheimer's, spina bifida, cerebral palsy, etc.).[6,7,8,9,10,11,12,13,14]

Pressure ulcer rates may be indicators of the quality of care offered by long-term care facilities. Although many pressure ulcers are preventable, both facility-level and process-based characteristics can impact pressure ulcer prevalence within nursing homes.

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[4] Refer to footnote 1

[5] Refer to footnote 1

[6] Refer to footnote 3

[7] Alderden, Jenny, Ginette Alyce Pepper, Andrew Wilson, Joanne D. Whitney, Stephanie Richardson, Ryan Butcher, Yeonjung Jo, and Mollie Rebecca Cummins. 2018. "Predicting Pressure Injury in Critical Care Patients: A Machine-Learning Model." American Journal of Critical Care 27 (6): 461–68. https://doi.org/10.4037/ajcc2018525.

[8] Refer to footnote 1

[9] Bauer, Karen, Kathryn Rock, Munier Nazzal, Olivia Jones, and Weikai Qu. 2016. "Pressure Ulcers in the United States' Inpatient Population from 2008 to 2012: Results of a Retrospective Nationwide Study." Ostomy Wound Management 62 (11): 30–38.

[10] Chen, Hong-Lin, Ying-Juan Cao, Wang-Qin Shen, and Bin Zhu. 2017. "Construct Validity of the Braden Scale for Pressure Ulcer Assessment in Acute Care: A Structural Equation Modeling Approach." Ostomy Wound Management 63 (2): 38–41.

[11] Demarre, Liesbet, Sofie Verhaeghe, Ann Van Hecke, Els Clays, Maria Grypdonck, and Dimitri Beeckman. 2015. "Factors Predicting the Development of Pressure Ulcers in an At-Risk Population Who Receive Standardized Preventive Care: Secondary Analyses of a Multicentre Randomised Controlled Trial." Journal of Advanced Nursing 71 (2): 391–403. https://doi.org/10.1111/jan.12497.

[12] Jaul, Efraim, Jeremy Barron, Joshua P. Rosenzweig, and Jacob Menczel. 2018. "An Overview of Co-Morbidities and the Development of Pressure Ulcers among Older Adults." BMC Geriatrics 18 (1): 305. https://doi.org/10.1186/s12877-018-0997-7.

[13] Kwok, Alvin C., Andrew M. Simpson, James Willcockson, Daniel P. Donato, Isak A. Goodwin, and Jayant P. Agarwal. 2018. "Complications and Their Associations Following the Surgical Repair of Pressure Ulcers." American Journal of Surgery 216 (6): 1177–81. https://doi.org/10.1016/j.amjsurg.2018.01.012.

[14] Sprigle, Stephen, Douglas McNair, and Sharon Sonenblum. 2020. "Pressure Ulcer Risk Factors in Persons with Mobility-Related Disabilities." Advances in Skin and Wound Care 33 (3): 146–54. https://doi.org/10.1097/01.ASW.0000653152.36482.7d.

Evidence for link between structure and quality of care outcomes

Several structural characteristics, including those that are environmental and organizational-focused, may influence pressure ulcer risk among nursing home residents, including seasonality, adequate staffing and staff composition, proper staff education, geographic location, and facility size and ownership type.

First, seasonality may affect pressure ulcer incidence within nursing homes. One study based on a tertiary care hospital in east China found that the incidence of hospital-acquired pressure injuries among hip fracture patients was highest during the summer months compared to lower rates in autumn.[15] Authors suggest these findings are related to higher temperatures and humidity in the summer.[16] The effects of higher humidity and temperatures are inextricably linked to soft tissue deformation.[17] Although, high temperatures may be addressed with air conditioning, facility environmental controls may not be sufficient to reduce high humidity levels, increasing pressure ulcer incidence.[18] The higher summer temperatures and humidity levels resulting from seasonality may impact the pressure ulcer rates of long-term care facilities as well. A subsequent retrospective longitudinal study, which assessed trends and seasonality in unit-level hospital-acquired pressure ulcer rates, suggests that seasonality may be related to patient volume, severity of illness, and nurse staffing levels, all of which may impact pressure ulcer development.[19] This may also be true for nursing-home acquired pressure ulcers.

Adequate staffing and proper staff education is another structural characteristic that may impact pressure ulcer formation among patients. The 2010 multidisciplinary conference hosted by the National Pressure Ulcer Advisory Panel (NPUAP) highlighted the importance of adequate staff numbers and training as crucial components of pressure ulcer prevention programs.[20] One study examined pressure injury prevention among private, for-profit nursing homes in which the experimental group of nursing assistants were given education in pressure ulcer prevention and

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[15] Chen, Hong Lin, Bin Zhu, Rong Wei, and Zhen Yu Zhou. 2018. "A Retrospective Analysis to Evaluate Seasonal Pressure Injury Incidence Differences among Hip Fracture Patients in a Tertiary Hospital in East China." Ostomy Wound Management 64 (2): 40–44. https://doi.org/10.25270/owm.2018.2.4044.

[16] Refer to footnote 15

[17] Refer to footnote 2

[18] Refer to footnote 15

[19] He, Jianghua, Vincent S. Staggs, Sandra Bergquist-Beringer, and Nancy Dunton. 2013. "Unit-Level Time Trends and Seasonality in the Rate of Hospital-Acquired Pressure Ulcers in US Acute Care Hospitals." Research in Nursing and Health 36 (2): 171–80. https://doi.org/10.1002/nur.21527.

[20] Black, Joyce M., Laura E. Edsberg, Mona M. Baharestani, Diane Langemo, Margaret Goldberg, Laurie McNichol, and Janet Cuddigan. 2011. "Pressure Ulcers: Avoidable or Unavoidable? Results of the National Pressure Ulcer Advisory Panel Consensus Conference." Ostomy Wound Management 57 (2): 24–37.

the control group continued with usual care.[21] Residents within nursing homes where nursing assistants received pressure injury prevention had significantly lower resident pressure injury incidence.[22] Staff education may also impact the identification of pressure ulcers. One case study found that only 40% of trained nurses within one hospital were able to accurately identify the presence of a pressure ulcers among newly admitted patients.[23] Furthermore, only 8% of these trained nurses were able to accurately categorize the stage of a patient's pressure ulcers.[24] Evaluating providers' skills in accurately assessing patients is also important among nursing home settings.

Staff composition is also associated with pressure ulcer development. One study concluded that nursing homes with a medical director or director of nursing on board had reduced odds of pressure ulcers.[25] Directors of nursing may offer support and guidance to nursing staff, as well as help with quicker assessments of residents, leading to prompt pressure ulcer identification and resident treatment.[26] Another study emphasized the importance of nursing home leadership.[27] In this study, the visible prioritization and support of pressure ulcer prevention from leadership, as well as the initiation of prevention activities through formal nursing home structures, were components found in nursing homes with improving performance.[28]

Additional facility-level characteristics affecting pressure ulcer incidence include for-profit status, facility size, and geographic location.[29] One study found that residents in for-profit nursing homes were less likely to develop early stage ulcers but were more likely to develop stage IV ulcers; residents in micropolitan facilities, with area populations ranging between 10,000-50,000, were

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[21] Kwong, Enid W.Y., Liang Y. Chen, Rick Y.C. Kwan, and Paul H. Lee. 2020. "The Effectiveness of a Pressure Injury Prevention Program for Nursing Assistants in Private For-Profit Nursing Homes: A Cluster Randomized Controlled Trial." Journal of Advanced Nursing 76 (7): 1780–93. https://doi.org/10.1111/jan.14391.

[22] Refer to footnote 21

[23] Furterer, Sandra L., and Ethling Hernandez. 2019. "Improving the Healthcare Quality Measurement System Using Attribute Agreement Analysis Assessing the Presence and Stage of Pressure Ulcers." International Journal of Statistics and Probability 8 (4): 47–59. https://doi.org/10.5539/ijsp.v8n4p47.

[24] Refer to footnote 23

[25] Kang, Yu, Huey Ming Tzeng, and Nancy A. Miller. 2016. "Facility Characteristics and Risk of Developing Pressure Ulcers in US Nursing Homes." Journal of Nursing Care Quality 31 (1): E9–16. https://doi.org/10.1097/NCQ.0000000000000136.

[26] Refer to footnote 25

[27] Hartmann, Christine W., Jeffrey Solomon, Jennifer A. Palmer, and Carol Vandeusen Lukas. 2016. "Contextual Facilitators of and Barriers to Nursing Home Pressure Ulcer Prevention." Advances in Skin and Wound Care 29 (5): 226–38. https://doi.org/10.1097/01.ASW.0000482113.18800.1c.

[28] Refer to footnote 27

[29] Refer to footnote 25

more likely to develop stage II ulcers but were less likely to experience stage III and IV ulcers; and residents in facilities with more than 200 beds had greater odds of stage III ulcers.[30] Additionally, rural geographic location was associated with greater odds of stage II pressure ulcers.[31]

Lastly, several studies cite the racial/ethnic disparities that cause higher pressure ulcer incidences among black patients.[32,33,34,35,36] In particular, one retrospective cohort study among long-term nursing home residents determined that black residents showed persistently higher pressure ulcer rates compared to white patients, and facilities with higher concentrations of black residents had lower staffing levels of RNs and certified nurse assistants.[37] These facilities were also characterized as large, for-profit, urban nursing homes.[38] Structural health care inequities may cause a disproportionate number of residents from certain racial/ethnic backgrounds to experience negative health outcomes like pressure ulcer development.

Evidence for link between processes and quality of care outcomes

Nursing homes may follow several key processes to both prevent and treat pressure ulcers among residents. Staff may follow recommendations from best practices, clinical guidelines, and evidence-based interventions to improve pressure ulcer incidence within their facilities.

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[30] Refer to footnote 25

[31] Refer to footnote 25

[32] Refer to footnote 3

[33] Refer to footnote 25

[34] Li, Yue, Jun Yin, Xueya Cai, Helena Temkin-Greener, and Dana B. Mukamel. 2011. "Association of Race and Sites of Care with Pressure Ulcers in High-Risk Nursing Home Residents." Journal of the American Medical Association 306 (2): 179–86. https://doi.org/10.1001/jama.2011.942.

[35] Seibert, Julie, Daniel Barch, Amarilys Bernacet, Amy Kandilov, Jennifer Frank, Lindsey Free, Quantesa Roberts, et al. 2020. "Examining Social Risk Factors in a Pressure Ulcer Quality Measure for Three Post-Acute Care Settings." Advances in Skin and Wound Care 33 (3): 156–63. https://doi.org/10.1097/01.ASW.0000651456.30210.8a.

[36] Sprigle, Stephen, Douglas McNair, and Sharon Sonenblum. 2020. "Pressure Ulcer Risk Factors in Persons with Mobility-Related Disabilities." Advances in Skin and Wound Care 33 (3): 146–54. https://doi.org/10.1097/01.ASW.0000653152.36482.7d.

[37] Refer to footnote 34

[38] Refer to footnote 34

1. Processes to prevent pressure ulcers

Several interventions may be implemented by nursing home staff to prevent pressure ulcer formation. The National Pressure Injury Advisory Panel (NPIAP), formerly known as the National Pressure Ulcer Advisory Panel (NPUAP), collaborated with the European Pressure Ulcer Advisory Panel (EPUAP) and the Pan Pacific Pressure Injury Alliance (PPIA) to create an International Guideline of pressure ulcer prevention and treatment strategies.[39] This guideline recommends several prevention strategies, including proper nutrition and hydration, repositioning, early mobilization (e.g., implementing ambulation schedules among residents on bedrest), preventing heel pressure injuries (e.g., regularly assessing the vulnerable heel area, prophylactic dressing of heels, etc.), providing support surfaces to redistribute pressure and provide a proper microclimate, and more.[40] Regarding support surfaces as a prevention strategy, one study recommended using powered active air surfaces and powered hybrid air surfaces to reduce pressure ulcer incidence compared to standard facility surfaces.[41] Additionally, the 2010 NPUAP conference emphasized that staff cannot rely only on pressure redistribution surfaces to replace turning and repositioning of patients.[42]

The American College of Physicians (ACP) recommends additional strategies that staff can use to prevent pressure ulcers. First, the ACP recommends that clinicians should perform a risk assessment to identify patients at risk for developing pressure ulcers. Several instruments can be used to perform risk assessments including the Braden, Cubbin and Jackson, Norton, Ramstadius, and Waterlow scales.[43] The ACP also recommends for clinicians to use advanced static mattresses over advanced static overlays in patients with high risk for pressure ulcer development.[44] Lastly, the ACP does not recommend using alternating-air mattresses or alternating-air overlays in patients who are at a high risk for developing pressure ulcers.[45]

Many of the Wound, Ostomy and Continence Nurse Society (WOCN) pressure ulcer prevention recommendations mirror those offered by the International Guideline and the ACP. Additional

[39] European Pressure Ulcer Advisory Panel (EPUAP), National Pressure Injury Advisory Panel (NPIAP), and Pan Pacific Pressure Injury Alliance (PPPIA). 2019. "Prevention and Treatment of Pressure Ulcers/Injuries: Clinical Practice Guideline. The International Guideline 2019." Emily Haesler (Ed.).

[40] Refer to footnote 39

[41] Shi, Chunhu, Jo C. Dumville, and Nicky Cullum. 2018. "Support Surfaces for Pressure Ulcer Prevention: A Network Meta-Analysis." PLOS ONE 13 (2). https://doi.org/10.1371/journal.pone.0192707.

[42] Refer to footnote 20

[43] Qaseem, Amir, Tanveer P. Mir, Melissa Starkey, and Thomas D. Denberg. 2015. "Risk Assessment and Prevention of Pressure Ulcers: A Clinical Practice Guideline from the American College of Physicians." Annals of Internal Medicine 162 (5): 359–69. https://doi.org/10.7326/M14-1567.

[44] Refer to footnote 43

[45] Refer to footnote 43

WOCN recommendations include implementing measures to reduce risk of developing pressure ulcers, minimizing pressure from medical devices, maintaining head-of-bed elevation at or below 30 degrees, paying special attention to a resident's anatomy when positioning, using heel suspension devices, avoiding foam rings as they concentrate pressure in surrounding tissues, and more.[46]

Although International Guideline, ACP, and WOCN all recommend repositioning and the use of support surfaces as processes to prevent pressure ulcer formation, one study mentions that these tactics are not always effective in reducing pressure ulcer incidence.[47] One systematic review emphasizes that single interventions are not always effective in preventing pressure ulcer formation, and repositioning was only effective when used in combination with other preventive strategies like technological pressure-mapping feedback or by a patient positioning system.[48] Additionally, another study found that repositioning residents more frequently did not result in better outcomes. In this randomized controlled trial, residents were randomly allocated to a repositioning schedule of every two, three, or four hours over a three week period.[49] Ultimately, the study concluded that there was no significant difference in pressure ulcer incidence based on repositioning schedule among high- and medium-risk study participants.[50]

Early detection of pressure ulcers is another notable factor for prevention. One study emphasized the importance of early detection of tissue damage, and recommended using ultrasounds or subepidermal moisture measurement technology to detect early signs of pressure ulcer development.[51]

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[46] Wound, Ostomy and Continence Nurses Society-Wound Guidelines Task Force, Catherine R. Ratliff, Linda R. Droste, Phyllis Bonham, Lea Crestodina, Jan J. Johnson, Teresa Kelechi, Myra F. Varnado, Ronald Palmer, and Becky Carroll. 2017. "WOCN 2016 Guideline for Prevention and Management of Pressure Injuries (Ulcers): An Executive Summary." Journal of Wound, Ostomy and Continence Nursing 44 (3): 241–46. https://doi.org/10.1097/WON.0000000000000321.

[47] Gaspar, Susana, Miguel Peralta, Adilson Marques, Aglécia Budri, and Margarida Gaspar de Matos. 2019. "Effectiveness on Hospital-Acquired Pressure Ulcers Prevention: A Systematic Review." International Wound Journal 16 (5): 1087–1102. https://doi.org/10.1111/iwj.13147.

[48] Refer to footnote 46

[49] Bergstrom, Nancy, Susan D. Horn, Mary Pat Rapp, Anita Stern, Ryan Barrett, and Michael Watkiss. 2013. "Turning for Ulcer Reduction: A Multisite Randomized Clinical Trial in Nursing Homes." Journal of the American Geriatrics Society 61 (10): 1705–13. https://doi.org/10.1111/jgs.12440.

[50] Refer to footnote 48

[51] Oliveira, A. L., Z. Moore, T. O'Connor, and D. Patton. 2017. "Accuracy of Ultrasound, Thermography and Subepidermal Moisture in Predicting Pressure Ulcers: A Systematic Review." Journal of Wound Care. MA Healthcare Ltd. https://doi.org/10.12968/jowc.2017.26.5.199.

Overall, prevention strategies used in combination with each other may help reduce pressure ulcer rates within nursing homes.

2. Processes to treat pressure ulcers

According to the International Guideline, before treating residents for pressure ulcers, it is important for nursing home staff to be able to appropriately assess the wound and properly classify its stage to develop a treatment plan accordingly.[52] As mentioned above, it is important that nursing staff are able to accurately classify pressure ulcer stages.[53] After initial classification, recommendations from the International Guideline and the WOCN offer a comprehensive list of pressure ulcer treatment recommendations. Elements of these recommendations include: (1) assessing and monitoring of the wound, (2) managing pain, (3) supporting wound healing (e.g., promoting a well-vascularized wound bed, moisture balance, and infection and inflammation control), (4) cleansing and debridement (cleansing with normal saline at low pressure for 10 to 20 minutes was associated with greater reduction in pressure injury depth), (5) diagnosing microbial burdens or biofilms (if present) with tissue biopsies or microscopy, (6) administering antibiotics, (7) dressing wounds, (8) conducting biological wound dressing (e.g., skin substitutes, xenografts, collagen dressing, etc.), (9) using biophysical agents (e.g., electrical stimulation), (10) evaluating the need for surgery (usually on stage III or IV pressure injuries), and more.[54,55]

The ACP had additional recommendations that were not mentioned above. First, the ACP recommends that clinicians use protein or amino acid supplementation in patients experiencing pressure ulcers to help reduce wound size.[56] Additionally, the ACP recommends for staff to use hydrocolloid or foam dressing to subsequently reduce wound size.[57]

Ultimately, following multiple clinical recommendations, best practices, and interventions related to pressure ulcer treatment may reduce pressure ulcer rates within nursing homes.

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[52] Refer to footnote 39

[53] Refer to footnote 23

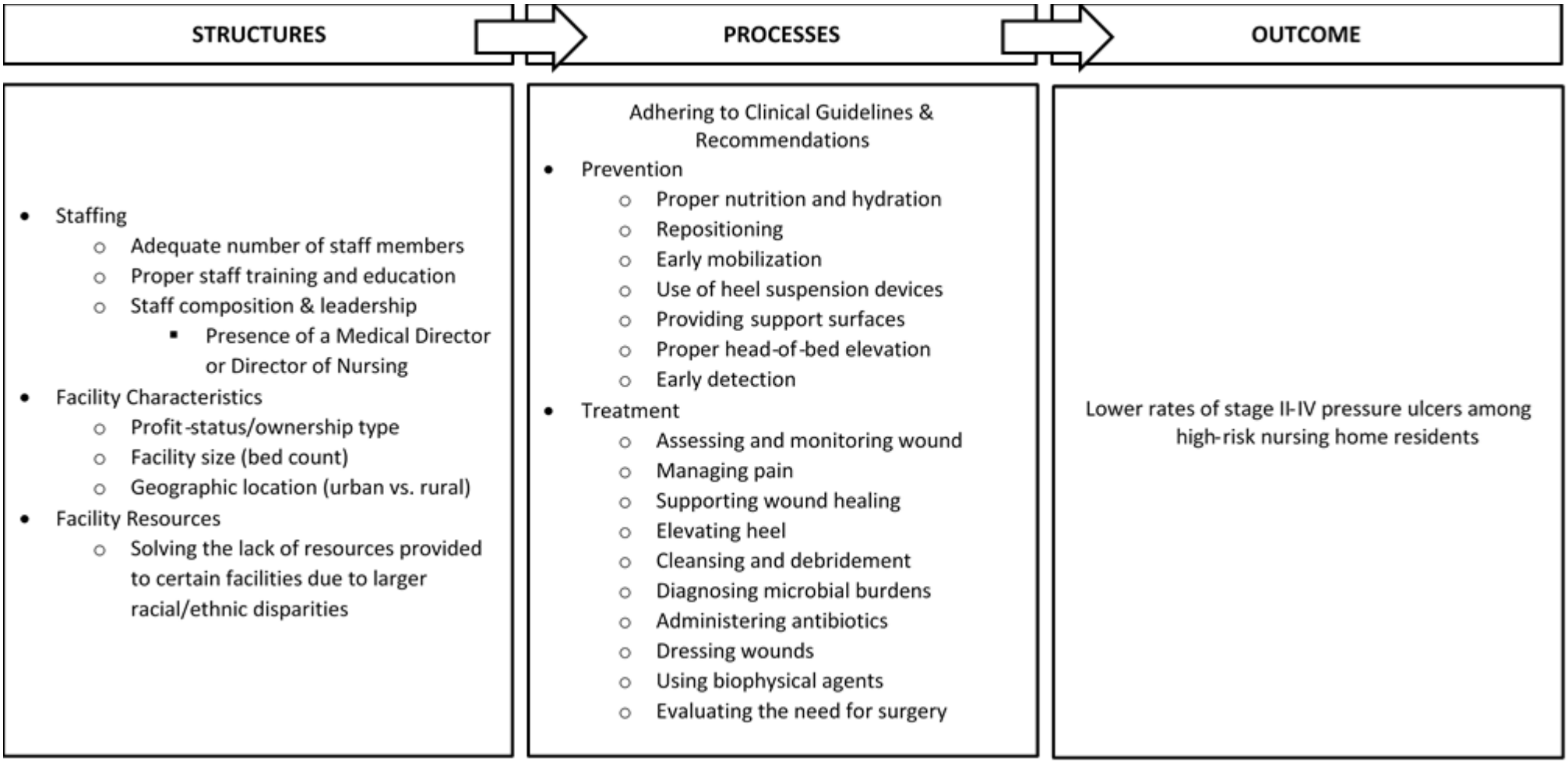
[54] Refer to footnote 39

[55] Refer to footnote 45

[56] Qaseem, Amir, Linda L. Humphrey, Mary Ann Forciea, Melissa Starkey, and Thomas D. Denberg. 2015. "Treatment of Pressure Ulcers: A Clinical Practice Guideline From the American College of Physicians." Annals of Internal Medicine 162 (5): 370–79. https://doi.org/10.7326/M14-1568.

[57] Refer to footnote 55

Figure 1: Role of Nursing Home Structures and Processes in Pressure Ulcer Rates



1a.3 Value and Meaningfulness: IF this measure is derived from patient report, provide evidence that the target population values the measured ***outcome, process, or structure*** and finds it meaningful. (Describe how and from whom their input was obtained.)

Not applicable

****RESPOND TO ONLY ONE SECTION BELOW -EITHER 1a.2, 1a.3 or 1a.4) ****

1a.2 FOR OUTCOME MEASURES including PATIENT REPORTED OUTCOMES - Provide empirical data demonstrating the relationship between the outcome (or PRO) to at least one healthcare structure, process, intervention, or service.

Not applicable

1a.3 SYSTEMATIC REVIEW (SR) OF THE EVIDENCE (for INTERMEDIATE OUTCOME, PROCESS, OR STRUCTURE PERFORMANCE MEASURES, INCLUDING THOSE THAT ARE INSTRUMENT-BASED) If the evidence is not based on a systematic review go to section 1a.4) If you wish to include more than one systematic review, add additional tables.

What is the source of the systematic review of the body of evidence that supports the performance measure? A systematic review is a scientific investigation that focuses on a specific question and uses explicit, prespecified scientific methods to identify, select, assess, and summarize the findings of similar but separate studies. It may include a quantitative synthesis (meta-analysis), depending on the available data. (IOM)

☒ Clinical Practice Guideline recommendation (with evidence review)

☐ US Preventive Services Task Force Recommendation

☐ Other systematic review and grading of the body of evidence (*e.g., Cochrane Collaboration, AHRQ Evidence Practice Center*)

☐ Other

Source of Systematic Review:

- **Title**
- **Author**
- **Date**
- **Citation, including page number**
- **URL**

Title: Treatment of Pressure Ulcers: A Clinical Practice Guideline from the American College of Physicians

Author: Amir Qaseem, MD, PhD, MHA; Linda L. Humphrey, MD, MPH; Mary Ann Forciea, MD; Melissa Starkey, PhD; and Thomas D. Denberg, MD, PhD, for the Clinical Guidelines Committee of the American College of Physicians

Date: 2015

Citation: Qaseem, Amir, Linda L. Humphrey, Mary Ann Forciea, Melissa Starkey, and Thomas D. Denberg. 2015. "Treatment of Pressure Ulcers: A Clinical Practice Guideline from the American College of Physicians." *Annals of Internal Medicine* 162 (5): 370–79. https://doi.org/10.7326/M14-1568.

URL: https://doi.org/10.7326/M14-1568

Quote the guideline or recommendation verbatim about the process, structure or intermediate outcome being measured. If not a guideline, summarize the conclusions from the SR.

Recommendation 1: ACP recommends that clinicians use protein or amino acid supplementation in patients with pressure ulcers to reduce wound size. (Grade: weak recommendation, low quality evidence)

Recommendation 2: ACP recommends that clinicians use hydrocolloid or foam dressings in patients with pressure ulcers to reduce wound size. (Grade: weak recommendation, low-quality evidence)

Recommendation 3: ACP recommends that clinicians use electrical stimulation as adjunctive therapy in patients with pressure ulcers to accelerate wound healing. (Grade: weak recommendation,

Grade assigned to the **evidence** associated with the recommendation with the definition of the grade.

The ACP has a grading system that was adopted from the GRADE (Grading of Recommendations Assessment, Development, and Evaluation) workgroup. The ACP's guideline grading system is outlined in the table below.

Table 1: American College of Physicians' Guideline Grading System

Quality of Evidence	Strength of Recommendation: Benefits clearly outweigh risks and burden or risks and burden clearly outweigh benefits	Strength of Recommendation: Benefits finely balanced with risks and burden
High	Strong	Weak
Moderate	Strong	Weak
Low	Strong	Weak

Insufficient evidence to determine net benefits or risks

Using this grading system, recommendation 1 was graded with low-quality evidence, recommendation 2 was graded with low-quality evidence, and recommendation 3 was graded with moderate-quality evidence.

Provide all other grades and definitions from the evidence grading system.

Not applicable.

Grade assigned to the recommendation with definition of the grade.

All three recommendations were graded as weak. Refer to Table 1 for grading definitions.

Provide all other grades and definitions from the recommendation grading system.

Not applicable.

Body of evidence:

- Quantity – how many studies?
- Quality – what type of studies?

This set of guidelines referenced 110 sources in their review. Authors searched for articles related to pressure ulcer treatment strategies and harms in treatment. Quality of evidence is evaluated using the ACP's Guideline Grading System, displayed in Table 1. This set of guidelines cites more low-quality evidence than moderate-quality evidence, and it does not reference any high-quality evidence. Evidence is reviewed by the ACP's Clinical Guidelines Committee. Additionally, the Annals of Internal Medicine conducted a statistical peer-review process on the evidence.

Estimates of benefit and consistency across studies.

Several benefits were mentioned in this guideline. Moderate-quality evidence showed that air-fluidized beds reduced pressure ulcer size compared to the use of other surfaces. Moderate-quality evidence showed that protein-containing supplements also improved wound healing. Low-quality evidence showed that hydrocolloid dressings reduced pressure ulcer size compared with gauze dressings. Additionally, low-quality evidence showed that platelet-driven growth factor improved wound healing. Low-quality evidence showed that dextranomer paste was inferior to other wound dressings for reducing pressure ulcer area. Moderate-quality evidence supported electrical stimulation as a method to accelerate wound healing. Low-quality evidence showed no difference between adjunctive therapies (e.g., electromagnetic therapy, therapeutic ultrasounds, negative-pressure wound therapy, light therapy, and laser therapy) in improving wound healing.

What harms were identified?

The guidelines state that the reporting of harms was sparse, and comparison among trials was difficult because of the heterogeneity of studies. Overall, there was insufficient evidence to conclude harms about various support surfaces and nutritional supplementation. One harm was associated with medications as more patients had elevated liver enzyme levels when taking oxandrolone than with the placebo. Harms associated with various

wound dressings and topical therapies include skin irritation, inflammation, tissue damage, and maceration. Lastly, the most commonly reported harm from surgery was dehiscence.

Identify any new studies conducted since the SR. Do the new studies change the conclusions from the SR?

Although not mentioned as a primary recommendation, this set of ACP guidelines found moderate-quality evidence to show that air-fluidized beds reduced pressure ulcer size. One 2018 study supported this benefit, stating that low-air-loss and air fluidized beds reduce humidity adjacent to the skin, improving skin microclimate and therefore reducing pressure ulcers. This study supports the benefit mentioned in this set of guidelines and does not change any of its conclusions.

Source: Kottner, Jan, Joyce Black, Evan Call, Amit Gefen, and Nick Santamaria. 2018. "Microclimate: A Critical Review in the Context of Pressure Ulcer Prevention." *Clinical Biomechanics*. 59 (November): 62–70. https://doi.org/10.1016/j.clinbiomech.2018.09.010.

Source of Systematic Review:

- **Title**
- **Author**
- **Date**
- **Citation, including page number**
- **URL**

Title: WOCN 2016 Guideline for Prevention and Management of Pressure Injuries (Ulcers): An Executive summary

Author: Wound, Ostomy and Continence Nurses Society – Wound Guidelines Task Force, Catherine R. Ratliff, Linda R. Droste, Phyllis Bonham, Lea Crestodina, Jan J. Johnson, Teresa Kelechi, Myra F. Varnado, Ronald Palmer, and Becky Carroll

Date: 2016

Citation: Wound, Ostomy and Continence Nurses Society-Wound Guidelines Task Force, Catherine R. Ratliff, Linda R. Droste, Phyllis Bonham, Lea Crestodina, Jan J. Johnson, Teresa Kelechi, Myra F. Varnado, Ronald Palmer, and Becky Carroll. 2017. "WOCN 2016 Guideline for Prevention and Management of Pressure Injuries (Ulcers): An Executive Summary." *Journal of Wound, Ostomy and Continence Nursing* 44 (3): 241–46. https://doi.org/10.1097/WON.0000000000000321.

URL: https://doi.org/10.1097/WON.0000000000000321

Quote the guideline or recommendation verbatim about the process, structure or intermediate outcome being measured. If not a guideline, summarize the conclusions from the SR.

Recommendations related to assessment of pressure ulcers

1. Perform a risk assessment upon the patient's entry to a healthcare setting, and repeat the assessment on a regularly scheduled basis, or when there is a significant change in the individual's condition. Level of Evidence = C (Benefit/Effectiveness/Harm = Class I)

2. Use a valid/reliable risk assessment tool in conjunction with the identification of additional risk factors (e.g., perfusion and oxygenation, increased body temperature, and advanced age), along with clinical judgment. Level of Evidence = C (Benefit/Effectiveness/Harm = Class I)

3. Assess for intrinsic/extrinsic risk factors. Risk factors can be defined as anything that increases the chance of developing a pressure ulcer. Level of Evidence = C (Benefit/Effectiveness/Harm = Class I)

4. Identify high-risk settings and groups to identify where to target prevention efforts to minimize risk. Level of Evidence = C (Benefit/Effectiveness/Harm = Class I)

5. Assess and inspect skin regularly. Level of Evidence = C
(Benefit/Effectiveness/Harm = Class I)

6. Monitor patients who have some degree of immobility frequently to minimize the risk of pressure ulcer formation.
Level of Evidence = C (Benefit/Effectiveness/Harm = Class I)

7. Differentiate pressure ulcers from other types of wounds and moisture-associated skin damage caused by incontinence- associated dermatitis due to exposure to urine and/ or stool, or intertriginous dermatitis due to trapped perspiration.
Level of Evidence = C (Benefit/Effectiveness/Harm = Class I)

8. Assess for incontinence and based on assessment findings, implement an individualized plan for management of incontinence. Level of Evidence = C (Benefit/Effectiveness/Harm = Class I)

9. Perform a nutritional assessment upon the patient's entry to a new healthcare setting, and whenever there is a change in the individual's condition. Level of Evidence = C (Benefit/Effectiveness/Harm = Class I)

10. Utilize laboratory parameters as only one part of the nutritional assessment process, because they should not be considered in isolation. Level of Evidence = C (Benefit/Effectiveness/Harm = Class I)

11. Assess for history of a prior ulcer and/or presence of a current ulcer, previous treatments, and/or surgical interventions.
Level of Evidence = C (Benefit/Effectiveness/Harm = Class I)

12. Assess pressure ulcer(s) on admission to a care setting, and regularly reassess and monitor for any signs of skin or wound deterioration. Level of Evidence = C (Benefit/Effectiveness/Harm = Class I)

13. Assess for factors that impede healing status. Level of Evidence = C (Benefit/Effectiveness/Harm = Class I)

14. Consider the impact of the pressure ulcer on the patient's quality of life. Level of Evidence = C (Benefit/Effectiveness/Harm = Class I)

15. Assess/evaluate healing using a valid and reliable tool. Level of Evidence = C (Benefit/Effectiveness/Harm = Class I)

16. Assess for potential complications associated with pressure ulcer(s). Level of Evidence = C (Benefit/Effectiveness/Harm = Class I)

Recommendations related to prevention of pressure ulcers

17. Implement measures to reduce the risk of developing pressure ulcers: minimize/eliminate pressure, friction, and shear. Level of Evidence = C (Benefit/Effectiveness/Harm = Class I)

18. Minimize/eliminate pressure from medical devices such as oxygen tubing, catheters, cervical collars, casts, and restraints. Level of Evidence = C (Benefit/Effectiveness/Harm = Class I)

19. Maintain the head-of-bed elevation at/or below 30°, or at the lowest degree of elevation consistent with the patient's medical condition to prevent shear-related injury, and use a 30° side-lying position. Level of Evidence = C (Benefit/Effectiveness/Harm = Class I)

20. Schedule regular repositioning and turning for bedbound and chairbound individuals, taking into consideration the condition of the patient and the pressure redistribution support surface in determining the repositioning strategy. Level of Evidence = C (Benefit/Effectiveness/Harm = Class I)

21. Position sitting patients with special attention to the individual's anatomy, postural alignment, distribution of weight, and support of the feet. Level of Evidence = C (Benefit/Effectiveness/Harm = Class I)

22. Consider prophylactic dressings to prevent sacral and heel ulcers in at-risk patients. Level of Evidence = A (Benefit/Effectiveness/Harm = Class I)

23. Use heel suspension devices for patients who are at risk for pressure ulcers that elevate (float) and offload the heel completely, and redistribute the weight of the leg along the calf without putting pressure on the Achilles tendon. Level of Evidence = B (Benefit/Effectiveness/Harm = Class I)

24. Utilize support surfaces (on beds and chairs) to redistribute pressure. Pressure redistribution devices should serve as adjuncts and not replacements for repositioning protocols. Level of Evidence = C (Benefit/Effectiveness/Harm = Class I)

25. Place individuals who are at risk for pressure ulcers on a pressure redistribution surface. Level of Evidence = C
(Benefit/Effectiveness/Harm = Class I)

26. Consider using the WOCN Society's *Evidence- and Consensus-Based Support Surface Algorithm* (http://algorithm.wocn.org) to identify the appropriate support surface (i.e., overlay, mattress, and integrated bed system) for adults (≥ 16 years of age) and bariatric patients in care settings where the length of stay is 24 hours or more. Level of Evidence = C (Benefit/Effectiveness/Harm = Class I)

27. Use a high-specification reactive or alternating pressure support surface in the operating room for individuals at high risk for developing pressure ulcers. Level of Evidence = B (Benefit/Effectiveness/Harm = Class I)

28. Avoid foam rings, foam cut-outs, or donut-type devices for pressure redistribution because they concentrate pressure on the surrounding tissue. Level of Evidence = C (Benefit/Effectiveness/Harm = Class I)

29. Use incontinence skin barriers such as creams, ointments, pastes, and film-forming skin protectants as needed to protect and maintain intact skin in individuals who are incontinent and at risk for pressure ulcers. Level of Evidence = C (Benefit/Effectiveness/Harm = Class I)

30. Offer individuals with nutritional and pressure ulcer risks a minimum of 30 to 35 kcal/kg body weight per day, 1.25 to 1.5 g of protein/kg body weight per day, and 1 mL of fluid intake per kilocalorie per day. Level of Evidence = C (Benefit/Effectiveness/Harm = Class I)

31. Educate the patient/caregiver(s) about the causes and risk factors for developing pressure ulcers and ways to minimize the risk. Level of Evidence = C (Benefit/Effectiveness/Harm = Class I)

Recommendations related to treatment of pressure ulcers

32. Float/elevate the heel(s) completely off the surface with a pillow or heel suspension device for stage 1 and 2 pressure ulcers or a heel suspension device for stage 3 and 4 heel pressure ulcers. Level of Evidence = C (Benefit/Effectiveness/Harm = Class I)

33. Turn and reposition the patient, regularly and frequently. Level of Evidence = C (Benefit/Effectiveness/Harm = Class I)

34. Utilize support surfaces for patients with pressure ulcers (i.e., mattresses, mattress overlays, integrated bed systems, seat cushions, or seat cushion overlays) that meet the individual's needs, and are compatible with the care setting. Level of Evidence = C (Benefit/Effectiveness/Harm = Class I)

35. Consider using the WOCN Society's *Evidence-and Consensus-Based Support Surface Algorithm* (http://algorithm.wocn.org) to identify the appropriate support surface (i.e., overlay, mattress, and integrated bed system) for adults (≥ 16 years of age) and bariatric patients in care settings where the length of stay is 24 hours or more. Level of Evidence = C (Benefit/Effectiveness/Harm = Class I)

36. Utilize seating redistribution support surfaces that meet the needs of sitting individuals who have a pressure ulcer.
Level of Evidence = C (Benefit/Effectiveness/Harm = Class I)

37. Establish an individualized bowel/bladder management program for the patient with incontinence. Level of Evidence = C (Benefit/Effectiveness/Harm = Class I)

38. Screen for nutritional deficiencies at the patient's admission to the care setting, when their condition changes, and/or if the pressure ulcer is not healing. Level of Evidence = C (Benefit/Effectiveness/Harm = Class I)

39. Provide daily calorie and protein intake for adult patients with pressure ulcers: 30 to 35 kcal/kg body weight and 1.25 to 1.5 g of protein/kg body weight. Level of Evidence = B (Benefit/Effectiveness/Harm = Class I)

40. Consider evaluation of laboratory tests such as albumin and prealbumin as only one part of the ongoing assessment of nutritional status. Level of Evidence = C (Benefit/Effectiveness/Harm = Class I)

41. Cleanse the wound and periwound at each dressing change, minimizing trauma to the wound. Level of Evidence = C (Benefit/Effectiveness/Harm = Class I)

42. Choose appropriate solutions for cleaning pressure ulcers, which may include potable tap water, distilled water, cooled boiled water, or saline/salt water. Level of
Evidence = B (Benefit/Effectiveness/Harm = Class I)

43. Determine the bacterial bioburden by tissue biopsy or
Levine quantitative swab technique. Level of Evidence = B (Benefit/Effectiveness/Harm = Class I)

44. Consider a 2-week course of topical antibiotics for nonhealing, clean pressure ulcers. Level of Evidence = C (Benefit/Effectiveness/Harm = Class I)

45. Consider use of antiseptics for "maintenance wounds," which are defined as wounds that are not expected to heal, or for wounds that are critically colonized. Level
of Evidence = C (Benefit/Effectiveness/Harm = Class I)

46. Use systemic antibiotics in the presence of bacteremia, sepsis, advancing cellulitis, or osteomyelitis. Level of Evidence = C (Benefit/Effectiveness/Harm = Class I)

47. Debride the pressure ulcer of devitalized tissue, or when there is a high index of suspicion that biofilm is present (i.e., wound fails to heal despite proper wound care and antimicrobial therapy), and when consistent with the patient's condition and goals of therapy. Level of Evidence = C (Benefit/Effectiveness/Harm = Class I)

48. Modify the type of dressing as appropriate due to changes in the wound during healing or if the pressure ulcer deteriorates. Monitor and assess the wound on a regular basis and at every dressing change to determine whether the type of dressing is appropriate or should be modified. Level of Evidence = C (Benefit/Effectiveness/ Harm = Class I)

49. Consider adjunctive therapies as indicated:

a. Platelet-derived growth factor. Level of Evidence = B (Benefit/Effectiveness/Harm = Class I)

b. Electrical stimulation. Level of Evidence = A (Benefit/ Effectiveness/Harm = Class I)

c. Negative-pressure wound therapy. Level of Evidence =

B (Benefit/Effectiveness/Harm = Class I)

50. Evaluate the need for operative repair for patients with stage 3 and 4 ulcers that do not respond to conservative medical therapy. Level of Evidence = C (Benefit/ Effectiveness/Harm = Class I)

51. Implement measures to eliminate or control the source of pressure ulcer pain. Level of Evidence = C (Benefit/Effectiveness/Harm = Class I)

52. Implement appropriate treatment of pressure ulcers to optimize healing, recognizing that complete healing may be unrealistic in some patients. Level of Evidence = C (Benefit/Effectiveness/Harm = Class I)

53. Educate the patient/caregiver(s) about strategies to prevent pressure ulcers, promote healing, and prevent recurrences of ulcers; and emphasize these are lifelong interventions. Level of Evidence = C (Benefit/ Effectiveness/Harm = Class I)

Grade assigned to the **evidence** associated with the recommendation with the definition of the grade.

See Tables 3 and 4 for grading definitions. Most recommendations were graded with a Level-of-Evidence: C. However, one preventive recommendation (22) was graded with an A rating. Two preventive recommendations were assigned B grades (23 & 27). Four treatment-related recommendations were assigned B grades (42, 43, 49a, and 49c). Lastly, one treatment-related recommendation was graded with an A (49a).

Table 3: Level-of-Evidence Ratings for Research Evidence

Level of Evidence	Criteria
Level I	A randomized controlled trial demonstrating a statistically significant difference in at least one important outcome defined by P<0.05. Level I trials can conclude the difference is not statistically significant if the sample size is adequate to exclude a 25% difference among study arms with 80% power
Level II	A randomized controlled trial not meeting Level I criteria
Level III	A nonrandomized controlled trial with contemporaneous controls selected by some systematic method. A control might have been selected due to its perceived suitability as a treatment option for an individual patient
Level IV	A before-and-after study or a case series of at least 10 patients using historical controls or controls drawn from other studies
Level V	A case series of at least 10 patients with no controls
Level VI	A case report of fewer than 10 patients

Provide all other grades and definitions from the recommendation grading system.

Not applicable.

Body of evidence:

Quantity – how many studies?

Quality – what type of studies?

For this updated guideline, 195 full-text articles were reviewed. Of those, 64 articles were excluded, and 131 new articles were included as references in updated guideline material. The search for studies targeted randomized controlled trials, prospective clinical trials, retrospective studies, meta-analyses, and systematic reviews. 13 questions were used to guide the literature review. All questions were related to pressure ulcer assessment, prevention, and treatment. Based on the judgement of the authors, studies were assessed as acceptable or unacceptable for inclusion and were excluded if there were methodological issues or insufficient detail to evaluate results. Authors evaluated the evidence according to the criteria displayed in Table 3.

Estimates of benefit and consistency across studies.

There is evidence and/or agreement of expert opinion that all recommendations included in this guideline are beneficial and effective with greater benefit than harm. All recommendations were graded as Class I, see Table 5 for more details. Several specific benefits were mentioned in this guideline. For one, conducting periwound cleansing with a pH-balanced skin cleanser was found to decrease wound/periwound microbial counts for 24 hours. Additionally, in relation to adjunctive therapies, electrical stimulation demonstrated to enhance healing of recalcitrant stage 2, 3, and 4 pressure ulcers. In terms of pressure ulcer prevention, prophylactic dressings were shown to prevent sacral and heel ulcers as well as manage microclimate. Additionally, silicone border foam dressings were also shown to decrease incidence of sacral pressure ulcers in a nonexperimental prospective study.

What harms were identified?

Any harms identified in the evidence were outweighed by the benefits and effectiveness of each recommendation as all recommendations were given a Class I grade. However, specific harms were mentioned in the guidelines. One harm identified in this guideline includes positioning a patient directly on a pressure ulcer or deep tissue injury. Instead, positioning or cushioning devices should be used to avoid placing patients on areas affected by pressure ulcers. Additionally, this guideline cautions against using "body-worn" products for fecal incontinence as the use of some products may contribute to the development of incontinence associated dermatitis. Regarding adjunctive therapies, electrical stimulation may be harmful for individuals using pacemakers and should not be used on them. Additionally, electrical stimulation should not be placed over topical substances containing metal ions or over the heart. If surgical intervention is necessary, the patient's mental and physical health should first be evaluated, and factors associated with impaired healing should be minimized. Lastly, conservative sharp debridement should be used with caution among individuals who are immunosuppressed, on anticoagulants, or have bleeding disorders.

Identify any new studies conducted since the SR. Do the new studies change the conclusions from the SR?

One 2019 randomized controlled trial study compared clinical and cost-effectiveness of alternating pressure mattresses and high-specification foam mattresses. Results were not statistically significant; however, the study suggested a benefit of alternating pressure mattresses over high-specification foam mattresses. Alternating pressure mattresses were also more cost-effective. In prevention recommendation 27, the WOCN guidelines recommend using high-specification reactive or alternating pressure support surfaces in the operating room for individuals with high risk for developing pressure ulcers. The WOCN guidelines do not specify which mattress may be more useful than the other.

Source: Nixon, Jane, Isabelle L. Smith, Sarah Brown, Elizabeth McGinnis, Armando Vargas-Palacios, E. Andrea Nelson, Susanne Coleman, et al. 2019. "Pressure Relieving Support Surfaces for Pressure Ulcer Prevention (PRESSURE 2): Clinical and Health Economic Results of a Randomised Controlled Trial." *EClinicalMedicine* 14 (September): 42–52. https://doi.org/10.1016/j.eclinm.2019.07.018.

Source of Systematic Review:

- **Title**
- **Author**
- **Date**
- **Citation, including page number**
- **URL**

Title: Pressure Ulcers and Other Wounds in the Post-Acute and Long-Term Care Setting

Author: AMDA – The Society for Post-Acute and Long-Term Care Medicine

Date: 2017

Citation: AMDA - The Society for Post-Acute Care and Long-Term Care Medicine. Pressure Ulcers and Other Wounds in the Post-Acute and Long-Term Care Setting Clinical Practice Guideline. Columbia, MD: AMDA 2017.

URL: https://paltc.org/product-store/pressure-ulcers-other-wounds-cpg-pocket-guide

Quote the guideline or recommendation verbatim about the process, structure or intermediate outcome being measured. If not a guideline, summarize the conclusions from the SR.

Recognition Recommendations

1. Select and consistently use one predictive scale to identify patients at high risk for the development of pressure ulcers or other wounds. Although predictive scales vary in their predictive value, the consistent use of one scale is the most reliable way to detect change over time (quality of evidence: moderate; strength of recommendation: strong).

2. Write a care plan to address identified risk factors based on minimum data set (MDS) variables (quality of evidence: moderate; strength of recommendation: weak).

Assessment Recommendations

3. Develop a structured program for timely skin assessment (quality of evidence: high; strength of recommendation: strong)

4. Assess nonhealing wounds for infection or biofilm using a tool such as NERDS (Nonhealing, inflammatory Exudate, Red granulation tissue, Debris, and Smell) or clinical observation (quality of evidence: low; strength of recommendation: insufficient).

5. Classify/characterize pressure ulcers based on MDS criteria (quality of evidence: low; strength of recommendation: weak).

Treatment/Prevention/Monitoring Recommendations

6. Employ preventive measures such as promoting hydration and avoiding excessive skin moisture (quality of evidence: moderate; strength of recommendation: strong).

7. Employ repositioning or offloading measures as needed (include support surfaces). For prevention, repositioning and support surfaces should be used (e.g., advanced static mattress, alternating air, sophisticated wheelchair cushion). For treatment, support surfaces should be used (e.g., air-fluidized beds, alternating-pressure beds, low-air-loss mattresses). (quality of evidence: moderate; strength of recommendation: strong)

8. Cleanse wounds with nontoxic products (quality of evidence: low; strength of recommendation: insufficient).

9. Patients with a pressure ulcer nearing the end of life require the balance of best practice in wound treatment and prevention while promoting patient dignity and quality of life (quality of evidence: low; strength of recommendation: strong).

10. Write a facility policy for assessment and treatment of pressure ulcers and other wounds with the goal of using it to develop realistic, individualized, and interdisciplinary care plans (quality of evidence: low; strength of recommendation: strong).

Grade assigned to the **evidence** associated with the recommendation with the definition of the grade.

The recognition-related recommendations were both scored with moderate quality of evidence, see Table 6 for evidence grade criteria. Among the assessment-related recommendations, recommendation 3 was graded with high quality evidence, while recommendations 4 and 5 were graded with low quality evidence. Among the treatment-, prevention-, and monitoring-related recommendations, 6 and 7 were graded with moderate quality of evidence, and 8, 9, and 10 were graded with low quality evidence.

Table 6: AMDA's Clinical Practice Committee Criteria for Assigning Grade of Evidence: Quality of Evidence

Quality of Evidence	Criteria
High	At least 1 randomized controlled trial (RCT) OR 3 pre/post interventions or other prospective interventions or 3 well-structured, relevant observational studies.
Moderate	Studies that use well-tested methods to make comparisons in a fair way, but where the results leave room for uncertainty (e.g., because of the size of the study, losses to follow-up, or the method used for selecting groups for comparison).
Low	Studies in which the results are doubtful because the study design does not guarantee that fair comparisons can be made.

Provide all other grades and definitions from the evidence grading system.

Not applicable.

Grade assigned to the recommendation with definition of the grade.

Among the recognition-related recommendations, recommendation 1 received a strong grade in terms of the strength of recommendation, and recommendation 2 was graded weak, see Table 7 for grade definitions. Under the assessment-based recommendations, recommendation 3 was graded strong, 4 was graded insufficient, and 5 was graded weak. Four of the treatment, prevention, and monitoring recommendations were graded as strong; however, recommendation 8 was graded as insufficient.

Table 7: AMDA's Clinical Practice Committee Criteria for Assigning Grade of Evidence: Strength of Recommendation

Strength of Recommendation	Criteria
Strong	Benefits clearly outweigh risks
Weak	Benefits are balanced with risks
Insufficient	Evidence is inadequate to make a recommendation

Provide all other grades and definitions from the recommendation grading system.

Not applicable.

Body of evidence:

- Quantity – how many studies?
- Quality – what type of studies?

In total, the AMDA guideline referenced 96 sources. Several types of studies were reviewed, including randomized controlled trials, interventions, observational studies, studies with well-tested methods, and studies with less sound designs. Most of the recommendations from this guideline were of moderate or low quality evidence. Therefore, the study may have reviewed less randomized controlled trials and more studies with limitations and uncertain results. Studies reviewed for this guideline were related to pressure ulcer recognition, assessment, prevention, treatment, and monitoring.

Estimates of benefit and consistency across studies.

Most of the recommendations offered by the AMDA were graded as strong, meaning that the benefits of each outweighed their risks. Several benefits were mentioned in this guideline. Regarding nutrition, supplementing zinc deficient patients with zinc, supplementing malnourished patients with Vitamin C, and supplementing patients with L-arginine were found to benefit wound healing. In terms of debridement, several studies support the effectiveness of applying collagenase as a biologic, topical enzymatic debriding agent. Lastly, regarding adjunctive therapies, systematic reviews of chronic ulcers have shown that negative pressure wound therapy has potential for benefit.

What harms were identified?

Most of the recommendations in this guideline have benefits that outweigh their harms. However, one harm identified in the guideline relates to the use of topical antiseptics. Evidence for treating local colonization or infection with antiseptics is lacking. When treating, hydrogen peroxide should not be used as it is highly toxic, iodine products should be avoided in patients with impaired renal failure or thyroid disorders, and Dakin's solution should not be used in concentrations greater than 0.025% as it is cytoxic.

Identify any new studies conducted since the SR. Do the new studies change the conclusions from the SR?

One 2019 systematic review evaluated the effectiveness of pressure ulcer prevention. Although this article researched hospital-acquired pressure ulcers instead of nursing home-acquired ulcers, it recognized the importance of using multiple intervention programs to decrease pressure ulcer incidence instead of just single interventions. This supports the AMDA guidelines as multiple recommendations used in combination may reduce pressure ulcer rates.

Source: Gaspar, Susana, Miguel Peralta, Adilson Marques, Aglécia Budri, and Margarida Gaspar de Matos. 2019. "Effectiveness on Hospital-Acquired Pressure Ulcers Prevention: A Systematic Review." International Wound Journal 16 (5): 1087–1102. https://doi.org/10.1111/iwj.13147.

Source of Systematic Review:

- **Title**
- **Author**
- **Date**
- **Citation, including page number**
- **URL**

Title: Prevention and Treatment of Pressure Ulcers/Injuries: Clinical Practice Guideline – The International Guideline 2019

Author: The European Pressure Ulcer Advisory Panel (EPUAP), the National Pressure Injury Advisory Panel (NPIAP), and the Pan Pacific Pressure Injury Alliance (PPIA)

Date: 2019

Citation: European Pressure Ulcer Advisory Panel (EPUAP), National Pressure Injury Advisory Panel (NPIAP), and Pan Pacific Pressure Injury Alliance (PPPIA). 2019. "Prevention and Treatment of Pressure Ulcers/Injuries: Clinical Practice Guideline. The International Guideline 2019." Emily Haesler (Ed.).

URL: http://www.internationalguideline.com/

Quote the guideline or recommendation verbatim about the process, structure or intermediate outcome being measured. If not a guideline, summarize the conclusions from the SR.

This guideline produced 115 evidence-based recommendations and 61 good practice statements to guide practice in risk assessment, pressure injury prevention and treatment. A list of these recommendations are outlined below, along with symbols that indicate their grade. For more information about grading definitions, see Table 8 and Table 9.

Risk Factors and Risk Assessment

1.1: Consider individuals with limited mobility, limited activity and a high potential for friction and shear to be at risk of pressure injuries.
(Strength of Evidence = A; Strength of Recommendation = ↑↑)

1.2: Consider individuals with a Category/Stage I pressure injury to be at risk of developing a Category/Stage II or greater pressure injury.
(Strength of Evidence = A; Strength of Recommendation = ↑↑)

1.3: Consider the potential impact of an existing pressure injury of any Category/Stage on development of additional pressure injuries.
(Strength of Evidence = C; Strength of Recommendation = ↑)

1.4: Consider the potential impact of a previous pressure injury on additional pressure injury development
(Good Practice Statement)

1.5: Consider the potential impact of alterations to skin status over pressure points on pressure injury risk.
(Good Practice Statement)

1.6: Consider the potential impact of pain at pressure points on pressure injury risk.
(Good Practice Statement)

1.7: Consider the impact of diabetes mellitus on the risk of pressure injuries.
(Strength of Evidence = A; Strength of Recommendation = ↑↑)

1.8: Consider the impact of perfusion and circulation deficits on the risk of pressure injuries.
(Strength of Evidence = B1; Strength of Recommendation = ↑)

1.9: Consider the potential impact of oxygenation deficits on the risk of pressure injuries.
(Strength of Evidence = C; Strength of Recommendation = ↑)

1.10: Consider the impact of impaired nutritional status on the risk of pressure injuries.
(Strength of Evidence = C; Strength of Recommendation = ↑)

1.11: Consider the potential impact of moist skin on the risk of pressure injuries.
(Strength of Evidence = C; Strength of Recommendation = ↑)

1.12: Consider the impact of increased body temperature on the risk of pressure injuries.
(Strength of Evidence = B1; Strength of Recommendation = ↑)

1.13: Consider the potential impact of older age on the risk of pressure injuries.
(Strength of Evidence = C; Strength of Recommendation = ↑)
1.14: Consider the potential impact of impaired sensory perception on the risk of pressure injuries.
(Strength of Evidence = C; Strength of Recommendation = ↑)

1.15: Consider the potential impact of laboratory blood test results on the risk of pressure injuries.
(Strength of Evidence = C; Strength of Recommendation = ↔)

1.16: Consider the potential impact of general and mental health status on pressure injury risk.
(Good Practice Statement)

1.17: Consider the impact of time spent immobilized before surgery, the duration of surgery and the American Society of Anesthesiologists (ASA) Physical Status Classification on surgery-related pressure injury risk.
(Strength of Evidence = B2; Strength of Recommendation = ↑)

1.19: Consider the impact of skin maturity, perfusion and oxygenation, and presence of a medical device on pressure injury risk in neonates and children.
(Strength of Evidence = B1; Strength of Recommendation = ↑↑)

1.20: Consider the impact of illness severity and the duration of critical care unit stay on pressure injury risk in neonates and children.
(Strength of Evidence = B2; Strength of Recommendation = ↑)

1.21: Conduct a pressure injury risk screening as soon as possible after admission to the care service and periodically thereafter to identify individuals at risk of developing pressure injuries.
(Good Practice Statement)

1.22: Conduct a full pressure injury risk assessment as guided by the screening outcome after admission and after any change in status.
(Good Practice Statement)

1.23: Develop and implement a risk-based prevention plan for individuals identified as being at risk of developing pressure injuries.
(Good Practice Statement)

1.24: When conducting a pressure injury risk assessment:

- Use a structured approach
- Include a comprehensive skin assessment
- Supplement use of a risk assessment tool with assessment of additional risk factors
- Interpret the assessment outcomes using clinical judgment.

(Good Practice Statement)

Skin and Tissue Assessment

2.1: Conduct a comprehensive skin and tissue assessment for all individuals at risk of pressure injuries:

- As soon as possible after admission/transfer to the healthcare service
- As a part of every risk assessment
- Periodically as indicated by the individual's degree of pressure injury risk
- Prior to discharge from the care service.

(Good Practice Statement)

2.2: Inspect the skin of individuals at risk of pressure injuries to identify presence of erythema.
(Strength of Evidence = A; Strength of Recommendation = ↑↑)

2.3: Differentiate blanchable from non-blanchable erythema using either finger pressure or the transparent disk method and evaluate the extent of erythema.
(Strength of Evidence = B1; Strength of Recommendation = ↑↑)

2.4: Assess the temperature of skin and soft tissue.
(Strength of Evidence = B1; Strength of Recommendation = ↑)

2.5: Assess edema and assess for change in tissue consistency in relation to surrounding tissues.
(Good Practice Statement)

2.6: Consider using a sub-epidermal moisture/edema measurement device as an adjunct to routine clinical skin assessment.
(Strength of Evidence = B2; Strength of Recommendation = ↔)

2.7: When assessing darkly pigmented skin, consider assessment of skin temperature and sub-epidermal moisture as important adjunct assessment strategies.

(Strength of Evidence = B2; Strength of Recommendation = ↑)

2.8: Evaluate the relevance of performing an objective assessment of skin tone using a color chart when conducting a skin assessment.
(Strength of Evidence = B2; Strength of Recommendation = ↔)

Preventive Skin Care

3.1: Implement a skin care regimen that includes:

- Keeping the skin clean and appropriately hydrated
- Cleansing the skin promptly after episodes of incontinence
- Avoiding use of alkaline soaps and cleansers
- Protecting the skin from moisture with a barrier product.

(Strength of Evidence = B2; Strength of Recommendation = ↑↑)

3.2: Avoid vigorously rubbing skin that is at risk of pressure injuries.
(Good Practice Statement)

3.3: Use high absorbency incontinence products to protect the skin in individuals with or at risk of pressure injuries who have urinary incontinence.
(Strength of Evidence = B1; Strength of Recommendation = ↑)

3.4: Consider using textiles with low friction coefficients for individuals with or at risk of pressure injuries.
(Strength of Evidence = B1; Strength of Recommendation = ↑)

3.5: Use a soft silicone multi-layered foam dressing to protect the skin for individuals at risk of pressure injuries.
(Strength of Evidence = B1; Strength of Recommendation = ↑)

Nutrition Assessment and Treatment

4.1: Conduct nutritional screening for individuals at risk of a pressure injury.
(Strength of Evidence = B1; Strength of Recommendation = ↑↑)

4.2: Conduct a comprehensive nutrition assessment for adults at risk of a pressure injury who are screened to be at risk of malnutrition and for all adults with a pressure injury.
(Strength of Evidence = B2; Strength of Recommendation = ↑↑)

4.3: Develop and implement an individualized nutrition care plan for individuals with or at risk of a pressure injury who are malnourished or who are at risk of malnutrition.
(Strength of Evidence = B2; Strength of Recommendation = ↑↑)

4.4: Optimize energy intake for individuals at risk of pressure injuries who are malnourished or at risk of malnutrition.

(Strength of Evidence = B2; Strength of Recommendation = ↑)

4.5: Adjust protein intake for individuals at risk of pressure injuries who are malnourished or at risk of malnutrition.

(Good Practice Statement)

4.6: Provide 30 to 35 kcalories/kg body weight/day for adults with a pressure injury who are malnourished or at risk of malnutrition.

(Strength of Evidence = B1; Strength of Recommendation = ↑)

4.7: Provide 1.25 to 1.5 g protein/kg body weight/day for adults with a pressure injury who are malnourished or at risk of malnutrition.

(Strength of Evidence = B1; Strength of Recommendation = ↑↑)

4.8: Offer high calorie, high protein fortified foods and/or nutritional supplements in addition to the usual diet for adults who are at risk of developing a pressure injury and who are also malnourished or at risk of malnutrition, if nutritional requirements cannot be achieved by normal dietary intake.

(Strength of Evidence = C; Strength of Recommendation = ↑)

4.9: Offer high calorie, high protein nutritional supplements in addition to the usual diet for adults with a pressure injury who are malnourished or at risk of malnutrition, if nutritional requirements cannot be achieved by normal dietary intake.

(Strength of Evidence = B1; Strength of Recommendation = ↑↑)

4.10: Provide high-calorie, high-protein, arginine, zinc and antioxidant oral nutritional supplements or enteral formula for adults with a Category/Stage II or greater pressure injury who are malnourished or at risk of malnutrition.

(Strength of Evidence = B1; Strength of Recommendation = ↑)

4.11: Discuss the benefits and harms of enteral or parenteral feeding to support overall health in light of preferences and goals of care with individuals at risk of pressure injuries who cannot meet their nutritional requirements through oral intake despite nutritional interventions.

(Good Practice Statement)

4.12: Discuss the benefits and harms of enteral or parenteral feeding to support pressure injury treatment in light of preferences and goals of care for individuals with pressure injuries who cannot meet their nutritional requirements through oral intake despite nutritional interventions.

(Strength of Evidence = B1; Strength of Recommendation = ↑)

4.13: Provide and encourage adequate water/fluid intake for hydration for an individual with or at risk of a pressure injury, when compatible with goals of care and clinical condition.

(Good Practice Statement)

4.14: Conduct age appropriate nutritional screening and assessment for neonates and children at risk of pressure injuries.
(Good Practice Statement)

4.15: For neonates and children with or at risk of pressure injuries who have inadequate oral intake, consider fortified foods, age appropriate nutritional supplements, or enteral or parenteral nutritional support.
(Good Practice Statement)

Repositioning and Early Mobilization

5.1: Reposition all individuals with or at risk of pressure injuries on an individualized schedule, unless contraindicated.
(Strength of Evidence = B1; Strength of Recommendation = ↑↑)

5.2: Determine repositioning frequency with consideration to the individual's level of activity and ability to independently reposition.
(Strength of Evidence = B2; Strength of Recommendation = ↑↑)

5.3: Determine repositioning frequency with consideration to the individual's:

- Skin and tissue tolerance
- General medical condition
- Overall treatment objectives
- Comfort and pain.

(Good Practice Statement)

5.4: Implement repositioning reminder strategies to promote adherence to repositioning regimens.
(Strength of Evidence = B1; Strength of Recommendation = ↑)

5.5: Reposition the individual in such a way that optimal offloading of all bony prominences and maximum redistribution of pressure is achieved.
(Good Practice Statement)

5.6: Reposition the individual to relieve or redistribute pressure using manual handling techniques and equipment that reduce friction and shear.
(Strength of Evidence = B2; Strength of Recommendation = ↑)

5.7: Consider using continuous bedside pressure mapping as a visual cue to guide repositioning.
(Strength of Evidence = C; Strength of Recommendation = ↔)

5.8: Use the 30° side lying position in preference to the 90° side lying position when positioning.
(Strength of Evidence = C; Strength of Recommendation = ↑)

5.9: Keep the head of bed as flat as possible.
(Strength of Evidence = B1; Strength of Recommendation = ↔)

5.10: Avoid extended use of prone positioning unless required for management of the individual's medical condition.
(Strength of Evidence = B1; Strength of Recommendation = ↔)

5.11: Promote seating out of bed in an appropriate chair or wheelchair for limited periods of time.
(Strength of Evidence = B1; Strength of Recommendation = ↑)

5.12: Select a reclined seated position with the individual's legs elevated. If reclining is not appropriate or possible, ensure that the individual's feet are well-supported on the floor or on footrests when sitting upright in a chair or wheelchair.
(Strength of Evidence = B2; Strength of Recommendation = ↑)

5.13: Tilt the seat to prevent the individual sliding forward in the chair or wheelchair.
(Strength of Evidence = B2; Strength of Recommendation = ↑)

5.14: Teach and encourage individuals who spend prolonged durations in a seated position to perform pressure relieving maneuvers.
(Strength of Evidence = C; Strength of Recommendation = ↑)

5.15: Implement an early mobilization program that increases activity and mobility as rapidly as tolerated.
(Strength of Evidence = C; Strength of Recommendation = ↑)

5.16: For individuals with an ischial or sacral pressure injury, evaluate the benefit of periods of bed rest in promoting healing versus the risk of new or worsening pressure injuries and the impact on lifestyle, physical and emotional health.
(Good Practice Statement)

5.17: Reposition unstable critically ill individuals who can be repositioned using slow, gradual turns to allow time for stabilization of hemodynamic and oxygenation status.
(Good Practice Statement)

5.18: Initiate frequent small shifts in body position for unstable critically ill individuals who are too unstable to maintain a regular repositioning schedule, and to supplement regular repositioning.
(Strength of Evidence = C; Strength of Recommendation = ↑)

5.19: Position the individual in such a way as to reduce the risk of pressure injury development during surgery by distributing pressure over a larger body surface area and offloading bony prominences.
(Good Practice Statement)

Heel Pressure Injuries

6.1: Assess the vascular/perfusion status of the lower limbs, heels and feet when performing a skin and tissue assessment, and as part of a risk assessment.
(Strength of Evidence = B2; Strength of Recommendation = ↑↑)

6.2: For individuals at risk of heel pressure injuries and/or with Category/Stage I or II pressure injuries, elevate the heels using a specifically designed heel suspension device or a pillow/ foam cushion. Offload the heel completely in such a way as to distribute the weight of the leg along the calf without placing pressure on the Achilles tendon and the popliteal vein.
(Strength of Evidence = B1; Strength of Recommendation = ↑↑)

6.3: For individuals with a Category/Stage III or greater heel pressure injury, elevate the heels using a device specifically designed for heel suspension, offloading the heel completely in such a way as to distribute the weight of the leg along the calf without placing pressure on the Achilles tendon and the popliteal vein.
(Good Practice Statement)

6.4: Use a prophylactic dressing as an adjunct to heel offloading and other strategies to prevent heel pressure injuries.
(Strength of Evidence = B1; Strength of Recommendation = ↑)

Support Surfaces

7.1: Select a support surface that meets the individual's need for pressure redistribution based on the following factors:

- Level of immobility and inactivity
- Need to influence microclimate control and shear reduction
- Size and weight of the individual
- Number, severity and location of existing pressure injuries
- Risk for developing new pressure injuries.

(Good Practice Statement)

7.2: Ensure that the bed surface area is sufficiently wide to allow turning of the individual.
(Strength of Evidence = C; Strength of Recommendation = ↑)

7.3: For individuals with obesity, select a support surface with enhanced pressure redistribution, shear reduction and microclimate features.
(Good Practice Statement)

7.4: Use a high specification reactive single layer foam mattress or overlay in preference to a foam mattress without high specification qualities for individuals at risk of developing pressure injuries.

(Strength of Evidence = B1; Strength of Recommendation = ↑)

7.5: Consider using a reactive air mattress or overlay for individuals at risk for developing pressure injuries.
(Strength of Evidence = C; Strength of Recommendation = ↑)

7.6: Assess the relative benefits of using a medical grade sheepskin for individuals at risk of developing pressure injuries.
(Strength of Evidence = B1; Strength of Recommendation = ↔)

7.7: Assess the relative benefits of using an alternating pressure air mattress or overlay for individuals at risk of pressure injuries.
(Strength of Evidence = B1; Strength of Recommendation = ↑)

7.8: Use a pressure redistribution support surface on the operating table for all individuals with or at risk of pressure injuries who are undergoing surgery.
(Strength of Evidence = B1; Strength of Recommendation = ↑)

7.9: For individuals with a pressure injury, consider changing to a specialty support surface when the individual:

- Cannot be positioned off the pressure injury
- Has pressure injuries on two or more turning surfaces (e.g., the sacrum and trochanter) that limit repositioning options
- Has a pressure injury that fails to heal or that deteriorates despite appropriate comprehensive care
- Is at high risk for additional pressure injuries
- Has undergone flap or graft surgery
- Is uncomfortable
- 'Bottoms out' on the current support surface.

(Good Practice Statement)

7.10: Assess the relative benefits of using an air fluidized bed to facilitate healing while reducing skin temperature and excess hydration for individuals with Category/Stage III or IV pressure injuries.
(Strength of Evidence = B1; Strength of Recommendation = ↑)

7.11: Select a seat and seating support surface that meets the individual's need for pressure redistribution with consideration to:

- Body size and configuration
- Effects of posture and deformity on pressure distribution
- Mobility and lifestyle needs.

(Good Practice Statement)

7.12: Use a pressure redistribution cushion for preventing pressure injuries in people at high risk who are seated in a chair/wheelchair for prolonged periods, particularly if the individual is unable to perform pressure relieving maneuvers.

(Strength of Evidence = B1, Strength of Recommendation = ↑)

7.13: Assess the relative benefits of using an alternating pressure air cushion for supporting pressure injury healing in individuals who are seated in a chair/wheelchair for prolonged periods, particularly if the individual is unable to perform pressure relieving maneuvers.

(Strength of Evidence = B1, Strength of Recommendation = ↑)

7.14: Use a bariatric pressure redistribution cushion designed for the individuals with obesity on seated surfaces.

(Strength of Evidence = C; Strength of Recommendation = ↑)

7.15: For individuals with or at risk for a pressure injury, consider using a pressure redistributing support surface during transit.

(Good Practice Statement)

7.16: Transfer the individual off a spinal hard board/back board as soon as feasible after admission to an acute care facility in consultation with a qualified health professional.

(Strength of Evidence = C; Strength of Recommendation = ↑)

Device Related Pressure Injuries

8.1: To reduce the risk of medical device related pressure injuries, review and select medical devices with consideration to:

- The device's ability to minimize tissue damage
- Correct sizing/shape of the device for the individual
- Ability to correctly apply the device according to manufacturer's instructions
- Ability to correctly secure the device.

(Strength of Evidence = B2; Strength of Recommendation = ↑↑)

8.2: Regularly monitor the tension of medical device securements and where possible seek the individual's self-assessment of comfort.

(Strength of Evidence = C; Strength of Recommendation = ↑)

8.3: Assess the skin under and around medical devices for signs of pressure related injury as part of routine skin assessment.

(Good Practice Statement)

8.4: Reduce and/or redistribute pressure at the skin-device interface by:

- Regularly rotating or repositioning the medical device and/or the individual
- Providing physical support for medical devices in order to minimize pressure and shear

- Removing medical devices as soon as medically feasible.

(Good Practice Statement)

8.5: Use a prophylactic dressing beneath a medical device to reduce the risk of medical device related pressure injuries.

(Strength of Evidence = B1; Strength of Recommendation = ↑)

8.6: If appropriate and safe, alternate the oxygen delivery device between correctly fitting mask and nasal prongs to reduce the severity of nasal and facial pressure injuries for neonates receiving oxygen therapy.

(Strength of Evidence = B1; Strength of Recommendation = ↑)

8.7: If appropriate and safe, alternate the oxygen delivery device between correctly-fitting mask(s) and nasal prongs to reduce the severity of nasal and facial pressure injuries for older children and adults receiving oxygen therapy.

(Good Practice Statement)

8.8: In consultation with a qualified health professional, replace an extrication cervical collar with an acute care rigid collar as soon as feasible and remove cervical collars as soon as possible, as indicate by clinical condition.

(Strength of Evidence = C; Strength of Recommendation = ↑)

Classification of Pressure Injuries

9.1: Differentiate pressure injuries from other types of wounds.

(Good Practice Statement)

9.2: Use a pressure injury classification system to classify and document the level of tissue loss.

(Good Practice Statement)

9.3: Verify that there is clinical agreement in pressure injury classification amongst the health professionals responsible for classifying pressure injuries.

(Good practice Statement)

Assessment of Pressure Injuries and Monitoring of Healing

10.1: Conduct a comprehensive initial assessment of the individual with a pressure injury.

(Good practice statement)

10.2: Set treatment goals consistent with the value and goals of the individual, with input from the individual's informal caregivers, and develop a treatment plan that supports these values and goals.

(Good practice statement)

10.3: Conduct a comprehensive reassessment of the individual if the pressure injury does not show some signs of healing within two weeks despite appropriate local wound care, pressure redistribution, and nutrition.

(Strength of Evidence = B2, Strength of Recommendation = ↑↑)

10.4: Assess the pressure injury initially and re-assess at least weekly to monitor progress toward healing.
(Good practice statement)

10.5: Select a uniform, consistent method for measuring pressure injury size and surface area to facilitate meaningful comparisons of wound measurements across time.
(Strength of Evidence = B2, Strength of Recommendation = ↑↑)

10.6: Assess the physical characteristics of the wound bed and the surrounding skin and soft tissue at each pressure injury assessment.
(Good practice statement)

10.7: Monitor the pressure injury healing progress.
(Good Practice Statement)

10.8: Consider using a validated tool to monitor pressure injury healing.
(Strength of Evidence = B2, Strength of Recommendation = ↑)

Pain Assessment and Treatment

11.1: Conduct a comprehensive pain assessment for individuals with a pressure injury.
(Strength of Evidence = B1; Strength of Recommendation = ↑↑)

11.2: Use non-pharmacologic pain management strategies as a first line strategy and adjuvant therapy to reduce pain associated with pressure injuries.
(Good Practice Statement)

11.3: Use repositioning techniques and equipment with consideration to preventing and managing pressure injury pain.
(Good Practice Statement)

11.4: Use the principles of moist wound healing to reduce pressure injury pain.
(Good Practice Statement)

11.5: Consider applying a topical opioid to manage wound-related pressure injury pain, if required and when there are no contraindications.
(Strength of Evidence = B1; Strength of Recommendation = ↔)

11.6: Administer analgesia regularly to control pressure injury pain.
(Good Practice Statement)

Cleansing and Debridement

12.1: Cleanse the pressure injury.
(Strength of Evidence = B1; Strength of Recommendation = ↑)

12.2: Use cleansing solutions with antimicrobials to clean pressure injuries with suspected or confirmed infection.
(Good Practice Statement)

12.3: Cleanse the skin surrounding the pressure injury.
(Strength of Evidence = B2; Strength of Recommendation = ↑)

12.4: Avoid disturbing stable, hard, dry eschar in ischemic limbs and heels, unless infection is suspected.
(Strength of Evidence = B2; Strength of Recommendation = ↑↑)

12.5: Debride the pressure injury of devitalized tissue and suspected or confirmed biofilm and perform maintenance debridement until the wound bed is free of devitalized tissue and covered with granulation tissue.
(Strength of Evidence = B2; Strength of Recommendation = ↑↑)

Infection and Biofilms

13.1: Have a high index of suspicion of local infection in a pressure injury in the presence of:

- Delayed healing
- Lack of signs of healing in the preceding two weeks despite appropriate treatment
- Larger size and/or depth
- Wound breakdown/dehiscence
- Necrotic tissue
- Friable granulation tissue
- Pocketing or bridging in the wound bed
- Increased exudate, or change in the nature of the exudate
- Increased warmth in the surrounding tissue
- Increased pain
- Malodor.

(Strength of Evidence = B1; Strength of Recommendation = ↔)

13.2: Have a high index of suspicion of biofilm in a pressure injury in the presence of:

- Failure to heal despite appropriate antibiotic therapy
- Recalcitrance to appropriate antimicrobial therapy
- Delayed healing despite optimal treatment

- Increased exudate
- Increased poor granulation or friable hypergranulation
- Low level erythema and/or low level chronic inflammation
- Secondary signs of infection.

(Good Practice Statement)

13.3: Consider a diagnosis of spreading infection if the individual with a pressure injury has local and/or systemic signs of acute infection including but not limited to:

- Delay in healing
- Erythema extending from the wound edge
- Wound breakdown/dehiscence
- Induration
- Crepitus, fluctuance or discoloration of the surrounding skin
- Lymphangitis
- Malaise/lethargy
- Confusion/delirium and anorexia (particularly in older adults).

(Good Practice Statement)

13.4: Determine presence of microbial burden in the pressure injury by tissue biopsy or semi-quantitative swab technique and microscopy.
(Good Practice Statement)

13.5: Determine presence of biofilm in the pressure injury by tissue biopsy and high resolution microscopy.
(Good Practice Statement)

13.6: Evaluate the pressure injury for presence of osteomyelitis in the presence of exposed bone and/or if the bone feels rough or soft, or if the pressure injury has failed to heal with appropriate treatment.
(Strength of Evidence = B2; Strength of Recommendation = ↑)

13.7: Optimize potential for healing by:

- Evaluating the individual's nutritional status and addressing deficits
- Evaluating the individual's comorbidities and promoting disease control
- Reducing the individual's immunosuppressant therapy if possible
- Preventing contamination of the pressure injury
- Preparing the wound bed through cleansing and debridement.

(Good Practice Statement)

13.8: Use topical antiseptics in tissue-appropriate strengths to control microbial burden and to promote healing in pressure injuries that have delayed healing.
(Strength of Evidence = B1; Strength of Recommendation = ↑)

13.9: Use topical antiseptics that are active against biofilm in tissue-appropriate strengths in conjunction with regular debridement to control and eradicate suspected (or confirmed) biofilm in pressure injuries with delayed healing.

(Strength of Evidence = C; Strength of Recommendation = ↑)

13.10: Use systemic antibiotics to control and eradicate infection in individuals with pressure injuries and clinical evidence of systemic infection.

(Good Practice Statement)

Wound Dressings

14.1: For all pressure injuries, select the most appropriate wound dressing based on goals and self-care abilities of

the individual and/or their informal caregiver and based on clinical assessment, including:

- Diameter, shape and depth of the pressure injury
- Need to address bacterial bioburden
- Ability to keep the wound bed moist
- Nature and volume of wound exudate
- Condition of the tissue in the wound bed
- Condition of the peri-wound skin
- Presence of tunneling and/or undermining
- Pain

(Good Practice Statement)

14.2: Evaluate the cost effectiveness of wound dressings at a local level, with consideration to direct and indirect costs to the health care system and to the individual with a pressure injury. Advanced wound dressings that promote moist wound healing are more likely to be cost-effective due to faster healing times and less frequent dressing changes.

(Good Practice Statement)

14.3: Use hydrocolloid dressings for non-infected Category/Stage II pressure injuries as indicated by the clinical condition of the pressure injury.

(Strength of Evidence = B1; Strength of Recommendation = ↑)

14.4: Use hydrogel dressings for non-infected Category/Stage II pressure injuries as indicated by the clinical condition of the pressure injury.

(Strength of Evidence = B1; Strength of Recommendation = ↑)

14.5: Use polymeric membrane dressings for non-infected Category/Stage II pressure injuries as indicated by the clinical condition of the pressure injury.

(Strength of Evidence = B1; Strength of Recommendation = ↑)

14.6: Use hydrogel dressings for non-infected Category/Stage III and IV pressure injuries with minimal exudate.
(Strength of Evidence = B1; Strength of Recommendation = ↑)

14.7: Use calcium alginate dressings for Category/Stage III and IV pressure injuries with moderate exudate.
(Strength of Evidence = B1; Strength of Recommendation = ↑)

14.8: Use foam dressings (including hydropolymers) for Category/Stage II and greater pressure injuries with moderate/heavy exudate.
(Strength of Evidence = B1; Strength of Recommendation = ↑)

14.9: Use super-absorbent wound dressings with a high capacity for absorption to manage heavily exuding pressure injuries.
(Strength of Evidence = B2; Strength of Recommendation = ↑)

14.10: Use moist gauze dressings to maintain an appropriately moist wound environment when advanced wound dressings are not an option.
(Strength of Evidence = B1; Strength of Recommendation = ↔)

14.11: Use a transparent film dressing as a secondary dressing when advanced wound dressings are not an option.
(Strength of Evidence = B1; Strength of Recommendation = ↔)

14.12: Consider the available evidence and guidance on using local resource dressings when selecting wound dressings in geographic regions with limited access to resources.
(Good Practice Statement)

Biological Dressings

15.1: Consider applying collagen dressings to nonhealing pressure injuries to improve rate of healing and decrease signs and symptoms of wound inflammation.

Growth Factors

(Strength of Evidence = B1; Strength of Recommendation = ↑)

16.1: Consider applying platelet-rich plasma for promoting healing in pressure injuries.
(Strength of Evidence = B1; Strength of Recommendation = ↔)

16.2: Consider applying platelet-derived growth factor for promoting healing in Category/Stage III and IV pressure injuries.
(Strength of Evidence = B1; Strength of Recommendation = ↔)

Biophysical Agents

17.1: Administer pulsed current electrical stimulation to facilitate wound healing in recalcitrant Category/Stage II pressure injuries and Category/Stage III or IV pressure injuries.
(Strength of Evidence = A; Strength of Recommendation = ↑)

17.2: Consider using non-contact low frequency ultrasound therapy as an adjunct therapy to facilitate healing in Category/Stage III and IV pressure injuries and suspected deep tissue injuries.
(Strength of Evidence = B2; Strength of Recommendation = ↔)

17.3: Consider using high frequency ultrasound therapy at 1 MHz as an adjunct therapy to facilitate healing in Category/Stage III and IV pressure injuries.
(Strength of Evidence = B1; Strength of Recommendation = ↔)

17.4: Consider negative pressure wound therapy as an early adjunct therapy for reducing the size and depth of Category/Stage III or IV pressure injuries.
(Strength of Evidence = B1; Strength of Recommendation = ↑)

Pressure Injury Surgery

18.1: Obtain a surgical consultation for an individual with a pressure injury that:

- Has advancing cellulitis or is a suspected source of sepsis
- Has undermining, tunneling, sinus tracts and/or extensive necrotic tissue not easily removed by conservative debridement
- Is Category/Stage III or IV and not closing with conservative treatment.

(Good Practice Statement)

18.2: Consider the following factors when assessing the individual's eligibility for pressure injury surgery:

- Likelihood of healing with conservative treatment versus surgical intervention
- The individual's goals of care
- The individual's clinical condition
- Motivation and ability of the individual to comply with the treatment regimen
- Risk of surgery for the individual.

(Good Practice Statement)

18.3: Evaluate and mitigate physical and psychosocial factors that may impair surgical wound healing or influence recurrence of a pressure injury.
(Strength of Evidence = B2; Strength of Recommendation = ↑)

18.4: Fully excise the pressure injury, including abnormal skin, granulation and necrotic tissue, sinus tracts, bursa and involved bone to the extent possible.
(Strength of Evidence = B2; Strength of Recommendation = ↑)

18.5: When designing a flap:

- Select tissue with a good quality blood supply
- Use composite tissues to increase durability
- Use a flap as large as possible
- Minimize violation of adjacent skin and tissue
- Locate the suture line away from areas of direct pressure
- Minimize tension on the incision at closure.

(Good Practice Statement)

18.6: Regularly monitor the wound and immediately report signs of flap failure.
(Good Practice Statement)

18.7: Use a specialty support surface in the immediate post-operative period.
(Strength of Evidence = B1; Strength of Recommendation = ↑)

18.8: Position and transfer the individual in such a way as to avoid pressure on, and disruption to, the surgical site.
(Good Practice Statement)

18.9: When the surgical site is sufficiently healed commence a progressive sitting protocol.
(Strength of Evidence = B1; Strength of Recommendation = ↑)

Measuring Pressure Injury Prevalence and Incidence

19.1: Use a rigorous methodological design and consistent measurement variables when conducting and reporting pressure injury prevalence and incidence studies.
(Good Practice Statement)

Implementing Best Practices in Clinical Settings

20.1: At an organizational level, assess and maximize workforce characteristics as part of a quality improvement plan to reduce pressure injury incidence.
(Strength of Evidence = C; Strength of Recommendation = ↑)

20.2: At the organizational level, assess the knowledge health professionals have about pressure injuries to facilitate implementation of an education program and a quality improvement program.
(Strength of Evidence = B1; Strength of Recommendation = ↑)

20.3: At an organizational level, assess and maximize workforce attitudes and cohesion to facilitate implementation of a quality improvement program.

(Good Practice Statement)

20.4: At an organizational level, assess and maximize the availability and quality of equipment and standards for its use as part of a quality improvement plan to reduce the incidence of pressure injuries.

(Strength of Evidence = B1; Strength of Recommendation = ↑↑)

20.5: At an organizational level, develop and implement a structured, tailored and multi-faceted quality improvement program to reduce the incidence of pressure injuries.

(Strength of Evidence = A; Strength of Recommendation = ↑↑)

20.6: At an organizational level, engage all key stakeholders in oversight and implementation of the quality improvement program to reduce the incidence of pressure injuries.

(Strength of Evidence = B1; Strength of Recommendation = ↑↑)

20.7: At an organizational level, include evidence-based policies, procedures and protocols and standardized documentation systems to reduce the incidence of pressure injuries.

(Strength of Evidence = B1; Strength of Recommendation = ↑↑)

20.8: At an organizational level, provide clinical decision support tools as part of a quality improvement plan to reduce the incidence of pressure injuries.

(Strength of Evidence = B1; Strength of Recommendation = ↑↑)

20.9: Provide clinical leadership in pressure injury prevention and treatment as part of a quality improvement plan to reduce pressure injuries.

(Strength of Evidence = B1; Strength of Recommendation = ↑↑)

20.10: At a professional level, provide education in pressure injury prevention and treatment as part of a quality improvement plan to reduce the incidence of pressure injuries.

(Strength of Evidence = A; Strength of Recommendation = ↑↑)

20.11: At an organizational level, regularly monitor, analyze and evaluate performance against quality indicators for pressure injury prevention and treatment.

(Strength of Evidence = B1; Strength of Recommendation = ↑↑)

20.12: At an organizational level, use feedback and reminder systems to promote the quality improvement program and its outcomes to stakeholders.

(Strength of Evidence = B2; Strength of Recommendation = ↑)

21.1: At the organizational level, assess the knowledge health professionals have about pressure injuries to facilitate implementation of an education program and a quality improvement program.

(Strength of Evidence = B1; Strength of Recommendation = ↑↑)

21.2: At an organizational level, develop and implement a multi-faceted education program for pressure injury prevention and treatment.
(Strength of Evidence = B2; Strength of Recommendation = ↑↑)

22.1: Assess the health-related quality of life, knowledge and self-care skills of individuals with or at risk of pressure injuries to facilitate the development of a pressure injury care plan and education program.
(Good Practice Statement)

22.2: Provide pressure injury education, skills training and psychosocial support to individuals with or at risk of pressure injuries.
(Strength of Evidence = C; Strength of Recommendation = ↑)

Grade assigned to the **evidence** associated with the recommendation with the definition of the grade.

Overall, the evidence in this guideline had seven A grades, 58 B1 grades, 28 B2 grades, and 22 C grades. See Table 8 for grade definitions. The majority of evidence used in this guideline have consistent outcomes, and any identified inconsistencies can be explained.

Table 8: Grading Guideline – Strengths of Evidence*

Grade	**Strength of Evidence**
A	• More than one high quality Level I study providing direct evidence • Consistent body of evidence
B1	• Level 1 studies of moderate or low quality providing direct evidence • Level 2 studies of high or moderate quality providing direct evidence • Most studies have consistent outcome sand inconsistencies can be explained
B2	• Level 2 studies of low quality providing direct evidence • Level 3 or 4 studies (regardless of quality) providing direct evidence • Most studies have consistent outcomes and inconsistencies can be explained

Grade	Strength of Evidence
C	• Level 5 studies (indirect evidence) e.g., studies in normal human subjects, humans with other types of chronic wounds, animal models • A body of evidence with inconsistencies that cannot be explained, reflecting genuine uncertainty surrounding the topic
GPS	Good Practice Statement • Statements that are not supported by a body of evidence as listed above but considered by the Guideline Governance Group (GGG) to be significant for clinical practice.

*Individual studies were assigned a level of evidence based on study design. The body of evidence supporting each recommendation was given a strength of evidence grade based on evidence quantity, levels, and consistency.

Provide all other grades and definitions from the evidence grading system.

Not applicable.

Grade assigned to the recommendation with definition of the grade.

Overall, most recommendations from this guideline were positive, see Table 9 for grade definitions. There were 68 weak positive recommendations (↑), 32 strong positive recommendations (↑↑), and 15 neutral recommendations (↔). Negative recommendations were not included in this guideline (↓ or ↓↓).

Table 9: Grading Guideline – Strengths of Recommendations**

Symbol for Recommendation	Recommendation and Description
↑↑	Strong positive recommendation: Definitely do it
↑	Weak positive recommendation: Probably do it
↔	No specific recommendation
↓	Weak negative recommendation: Probably don't do it
↓↓	Strong negative recommendation: Definitely don't do it.

**A consensus voting process was used to assign a strength of recommendation grade that indicates the confidence a health professional can have that the recommended practice will improve outcomes (i.e., do more good than harm). The strength of recommendation can be used by health professionals to prioritize interventions.

Provide all other grades and definitions from the recommendation grading system.

Not applicable.

Body of evidence:

- Quantity – how many studies?
- Quality – what type of studies?

In total, over 2,000 references were cited in this guideline. To be included in the study, articles must be primarily focused on pressure injury prevention, risk assessment, or pressure injury treatment in human subjects; articles must have been published in a peer reviewed journal; and an abstract of the article should be available. Numerous study types were included as evidence, such as randomized controlled trials, prospective controlled clinical trials, prospective cohort studies with a control group, pre-test/post-test studies, retrospective cohort studies, observational studies, cross-sectional studies, survey studies, case-control studies, and case series (with 10 or more subjects). Systematic reviews and meta-analyses were only used for comparative discussions.

Estimates of benefit and consistency across studies.

Several benefits were mentioned in this guideline. For example, negative pressure wound therapy has been used as a first-line treatment for wounds that could achieve benefit. Additionally, dressing changes are associated with benefits of reduction in pain and discomfort. Educational interventions are also seen as beneficial in preventing pressure ulcers. One small trial, which provided written, evidence-based patient resources at patients' bedsides, was associated with significantly more individuals reporting to receive education about pressure injury risks and preventive strategies. Overall, since most of the evidence-based recommendations included in this guideline were graded with positive recommendations, most of them would be considered beneficial in reducing pressure ulcers.

What harms were identified?

Harms identified in this guideline are as follows. Prolonged bed rest may cause muscle wasting, joint contracture, loss of bone density, deconditioning, respiratory complications, malnutrition, psychological harm, social isolation, and financial challenges. Some antiseptics are cytotoxic to skin and tissue cells in higher concentrations. Additionally, some antiseptics can be painful on application. Using too much of a topical antibiotic on an infected pressure injury could cause side effects and antibiotic resistance. Wound dressings could impact the fragile skin of older adults. Lastly, hydrocolloid dressings should be used cautiously in older adults who are at a higher risk for skim trauma.

Identify any new studies conducted since the SR. Do the new studies change the conclusions from the SR?

One 2020 article sought expert opinion to assess COVID-19's potential impact on pressure ulcer development. The article concluded that since the virus affects oxygen perfusion in combination with vascular system effects, it could devastate the skin and increase the rate of pressure injury formation. Therefore, additional recommendations may need to be added to future clinical practice guidelines to address COVID-19.

Source: Britton, Julie, Tony Costa, Clive Horrocks, Loretta Kaes, Karen Kennedy-Evans, Diane Krasner, Janine Maguire, et al. 2020. "How COVID-19 Is Changing Skin: Post-Acute Care Wound Experts from Across the United States Speak Out." Wound Management & Prevention 66 (9): 5–7.

1a.4 OTHER SOURCE OF EVIDENCE

If source of evidence is NOT from a clinical practice guideline, USPSTF, or systematic review, please describe the evidence on which you are basing the performance measure.

Not applicable

1a.4.1 Briefly SYNTHESIZE the evidence that supports the measure. A list of references without a summary is not acceptable.

Not applicable

1a.4.2 What process was used to identify the evidence?

Not applicable

1a.4.3.Provide the citation(s) for the evidence.

Not applicable

1b. Performance Gap

Demonstration of quality problems and opportunity for improvement, i.e., data demonstrating:

- considerable variation, or overall, less-than-optimal performance, in the quality of care across providers; and/or
- Disparities in care across population groups.

1b.1. Briefly explain the rationale for this measure *(e.g., how the measure will improve the quality of care, the benefits or improvements in quality envisioned by use of this measure)*

If a COMPOSITE *(e.g., combination of component measure scores, all-or-none, any-or-none), SKIP this question and answer the composite questions.*

This outcome-based quality measure reports the percentage of long-stay, high-risk nursing home residents with Stage II-IV pressure ulcers. Pressure ulcers are important to address as they are one of the most unwanted and preventable adverse events in the contexts of severe acute and chronic illnesses, disability, and high care dependency. , In the United States, over 2.5 million people experience pressure ulcers with 2% to 24% occurring in long-term care facilities. Typically, pressure ulcers occur in individuals with poor mobility who experience sustained pressure for long periods of time. Elderly individuals are prone to pressure ulcer formation due to the limited mobility that comes with increased age. Additionally, individuals living with disabilities are especially prone to pressure ulcer development due to reduced movement. Therefore, pressure ulcer prevalence is a problem within several nursing homes. Resident characteristics, risk factors, and predictors for pressure ulcer development include increased age, black race/ethnicity, malnutrition, dehydration, infection, urinary and bowel incontinence, high BMI, low hemoglobin levels, low albumin levels, non-blanchable erythema, mobility limitations, poor moisture status, higher body temperatures, and other comorbidities (e.g., stroke, dementia, Alzheimer's, spina bifida, cerebral palsy, etc.). , , , , , , , ,

Pressure ulcer rates may be indicators of the quality of care offered by long-term care facilities. Although many pressure ulcers are preventable, both facility-level and process-based characteristics can impact pressure ulcer prevalence within nursing homes.

Anrys, Charlotte, Hanne Van Tiggelen, Sofie Verhaeghe, Ann Van Hecke, and Dimitri Beeckman. 2019. "Independent Risk Factors for Pressure Ulcer Development in a High-Risk Nursing Home Population Receiving Evidence-Based Pressure Ulcer Prevention: Results from a Study in 26 Nursing Homes in Belgium." International Wound Journal 16 (2): 325–33. https://doi.org/10.1111/iwj.13032.

Kottner, Jan, Joyce Black, Evan Call, Amit Gefen, and Nick Santamaria. 2018. "Microclimate: A Critical Review in the Context of Pressure Ulcer Prevention." Clinical Biomechanics. 59 (November): 62–70. https://doi.org/10.1016/j.clinbiomech.2018.09.010.

Ahn, Hyochol, Linda Cowan, Cynthia Garvan, Debra Lyon, and Joyce Stechmiller. 2016. "Risk Factors for Pressure Ulcers Including Suspected Deep Tissue Injury in Nursing Home Facility Residents: Analysis of National Minimum Data Set 3.0." Advances in Skin and Wound Care 29 (4): 178–90. https://doi.org/10.1097/01.ASW.0000481115.78879.63.

Refer to footnote 1

Refer to footnote 1

Refer to footnote 3

Alderden, Jenny, Ginette Alyce Pepper, Andrew Wilson, Joanne D. Whitney, Stephanie Richardson, Ryan Butcher, Yeonjung Jo, and Mollie Rebecca Cummins. 2018. "Predicting Pressure Injury in Critical Care Patients: A Machine-Learning Model." American Journal of Critical Care 27 (6): 461–68. https://doi.org/10.4037/ajcc2018525.

Refer to footnote 1

Bauer, Karen, Kathryn Rock, Munier Nazzal, Olivia Jones, and Weikai Qu. 2016. "Pressure Ulcers in the United States' Inpatient Population from 2008 to 2012: Results of a Retrospective Nationwide Study." Ostomy Wound Management 62 (11): 30–38.

Chen, Hong-Lin, Ying-Juan Cao, Wang-Qin Shen, and Bin Zhu. 2017. "Construct Validity of the Braden Scale for Pressure Ulcer Assessment in Acute Care: A Structural Equation Modeling Approach." Ostomy Wound Management 63 (2): 38–41.

Demarre, Liesbet, Sofie Verhaeghe, Ann Van Hecke, Els Clays, Maria Grypdonck, and Dimitri Beeckman. 2015. "Factors Predicting the Development of Pressure Ulcers in an At-Risk Population Who Receive Standardized

Preventive Care: Secondary Analyses of a Multicentre Randomised Controlled Trial." Journal of Advanced Nursing 71 (2): 391–403. https://doi.org/10.1111/jan.12497.

Jaul, Efraim, Jeremy Barron, Joshua P. Rosenzweig, and Jacob Menczel. 2018. "An Overview of Co-Morbidities and the Development of Pressure Ulcers among Older Adults." BMC Geriatrics 18 (1): 305. https://doi.org/10.1186/s12877-018-0997-7.

Kwok, Alvin C., Andrew M. Simpson, James Willcockson, Daniel P. Donato, Isak A. Goodwin, and Jayant P. Agarwal. 2018. "Complications and Their Associations Following the Surgical Repair of Pressure Ulcers." American Journal of Surgery 216 (6): 1177–81. https://doi.org/10.1016/j.amjsurg.2018.01.012.

Sprigle, Stephen, Douglas McNair, and Sharon Sonenblum. 2020. "Pressure Ulcer Risk Factors in Persons with Mobility-Related Disabilities." Advances in Skin and Wound Care 33 (3): 146–54. https://doi.org/10.1097/01.ASW.0000653152.36482.7d.

1b.2. Provide performance scores on the measure as specified (current and over time) at the specified level of analysis. *(**This is required for maintenance of endorsement**. Include mean, std dev, min, max, interquartile range, scores by decile. Describe the data source including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities include.) This information also will be used to address the sub-criterion on improvement (4b1) under Usability and Use.*

Current performance: Table 7 of the NQF Testing Form describes the national facility score distribution for Percent of High Risk Residents with Pressure Ulcers. The facility-level mean score for this measure in Quarter 4 (Q4) of 2019 was 7.5% and the median score was 6.8%. The standard deviation was 5.1%, the minimum was 0%, and score at the 90th percentile was 14.0%. The interquartile range for this measure was 6.4%, indicating room for improvement on this measure. Of the facilities with adequate sample size to report, 8.0% had perfect scores of 0. This analysis is restricted to facilities that had at least 20 residents in the denominator, the minimum denominator threshold for public reporting. In Q4 2019, there were 13,219 facilities (87.5%) and 749,950 residents (97.0%) that met the denominator inclusion criteria.

n (Facilities): 13,219

k (Residents): 749,950

Mean score: 7.5%

Std dev.: 5.1%

10th percentile: 1.7%

25th percentile: 3.8%

50th percentile: 6.8%

75th percentile: 10.3%

90th percentile: 14.0%

Interquartile range: 6.4%.

% of facilities with "perfect scores": 8.0%

Performance Over Time: The national facility-level mean and median scores for the Percent of High Risk Residents with Pressure Ulcers demonstrate slight seasonal variation, with mean and median scores being higher in Quarter 1 and lower in Quarter 4 each year (Figure 1 of NQF Testing Form). Overall, the national facility-level mean and median scores have decreased marginally and indicate a slight improvement in performance over time. The mean score for this measure was 7.53% in quarter 4 of 2017 and the median score was 6.90%. In Q4 2019, the mean and median were 7.45% and 6.82%, respectively. (Data Source: Data are drawn from all United States Nursing Homes with Medicare certified beds and a minimum of 20 long-stay residents in their denominator.)

1b.3. If no or limited performance data on the measure as specified is reported in 1b2, then provide a summary of data from the literature that indicates opportunity for improvement or overall, less than optimal performance on the specific focus of measurement.

This is not applicable (data are available and described in 1b.2).

1b.4. Provide disparities data from the measure as specified (current and over time) by population group, e.g., by race/ethnicity, gender, age, insurance status, socioeconomic status, and/or disability. ***(This is required for maintenance of endorsement****. Describe the data source including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included.) For measures that show high levels of performance, i.e., "topped out", disparities data may demonstrate an opportunity for improvement/gap in care for certain sub-populations. This information also will be used to address the sub-criterion on improvement (4b1) under Usability and Use.*

Age

To examine whether facilities with higher percentages of residents aged 85 or older have different performance scores for LS PUs, analyses were completed comparing the performance of facilities based on their percentage of residents aged 85 or older and residents below the age of 85. First, the percentage of high-risk residents with pressure ulcers was stratified by age. Residents below the age of 85 represented the highest mean (8.4%) followed by residents aged 85 or older (6.3%). Next, a 2-way chi-squared test for statistical dependence was run that assessed the association between quality measure score and age. The results were significant (p=<.0001) indicating that there is a statistically significant relationship between age and QM score for the measure. The results suggested that residents below the age of 85 are at higher risk for experiencing pressure ulcers than residents aged 85 years or older.

Race

To examine whether facilities with higher percentages of non-White residents have different performance scores for LS PUs, analyses were completed comparing the performance of facilities based on their percentage of White only and non-White residents. First, the percentage of high-risk residents with pressure ulcers was stratified by racial identification. Black or African American residents represented the highest mean (9.92%), followed by Hispanic or Latino residents (7.44%), and White residents (6.99%). Next a 2-way chi-squared test for statistical dependence was run that assessed the association between quality measure score and race/ethnicity. The results were significant (p=<.0001) indicating that there is a statistically significant relationship between racial composition and QM score. The results suggested that the non-White population (9.0%) is at higher risk for experiencing pressure ulcers than the White only population (7.0%).

Socioeconomic status

To examine whether facilities with higher percentages of Medicaid-enrolled residents have different performance scores for LS PUs, analyses were completed comparing the performance of facilities based on their percentage of Medicaid-enrolled residents and residents not enrolled in Medicaid. First, the percentage of high-risk residents with pressure ulcers was stratified by Medicaid enrollment. Residents not enrolled in Medicaid represented the highest mean (8.48%), followed by Medicaid-enrolled residents (7.20%), indicating there are more high-risk residents not enrolled in Medicaid who experience pressure ulcers than Medicaid-enrolled high-risk residents. Next a 2-way chi-squared test for statistical dependence was run that assessed the association between quality measure score and Medicaid enrollment. The results were significant (p=<.0001) indicating that that there is a statistically significant relationship between Medicaid enrollment and QM score for this measure. The results suggested that the non-Medicaid population (8.2%) is at higher risk for experiencing pressure ulcers than the Medicaid population (7.4%), indicating there is a relationship between socioeconomic status and prevalence of pressure ulcers among high risk long-stay residents.

SOURCE: Acumen analysis of Q4 2019 MDS 3.0 data

1b.5. If no or limited data on disparities from the measure as specified is reported in 1b.4, then provide a summary of data from the literature that addresses disparities in care on the specific focus of measurement. Include citations. Not necessary if performance data provided in 1b.4

This is not applicable.

2. Reliability and Validity—Scientific Acceptability of Measure Properties

Extent to which the measure, **as specified**, produces consistent (reliable) and credible (valid) results about the quality of care when implemented. ***Measures must be judged to meet the sub criteria for both reliability and validity to pass this criterion and be evaluated against the remaining criteria.***

2a.1. Specifications The measure is well defined and precisely specified so it can be implemented consistently within and across organizations and allows for comparability. eMeasures should be specified in the Health Quality Measures Format (HQMF) and the Quality Data Model (QDM).

De.5. Subject/Topic Area *(check all the areas that apply):*

De.6. Non-Condition Specific*(check all the areas that apply):*

Primary Prevention, Safety, Safety : Complications

De.7. Target Population Category *(Check all the populations for which the measure is specified and tested if any):*

Elderly, Populations at Risk, Populations at Risk : Individuals with multiple chronic conditions

S.1. Measure-specific Web Page *(Provide a URL link to a web page specific for this measure that contains current detailed specifications including code lists, risk model details, and supplemental materials. Do not enter a URL linking to a home page or to general information.)*

http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/NHQIQualityMeasures.html Please see "MDS-3.0-QM-User's-Manual-v14.0.pdf" in the "Users-Manuals-Updated-10-19-2020.zip" zipped folder in the Downloads

S.2a. If this is an eMeasure, HQMF specifications must be attached. Attach the zipped output from the eMeasure authoring tool (MAT) - if the MAT was not used, contact staff. (Use the specification fields in this online form for the plain-language description of the specifications)

This is not an eMeasure **Attachment:**

S.2b. Data Dictionary, Code Table, or Value Sets *(and risk model codes and coefficients when applicable) must be attached. (Excel or csv file in the suggested format preferred - if not, contact staff)*

No data dictionary **Attachment:**

S.2c. Is this an instrument-based measure (i.e., data collected via instruments, surveys, tools, questionnaires, scales, etc.)? Attach copy of instrument if available.

Attachment : mds-3.0-rai-manual-v1.17.1_october_2019-637453804297029010.pdf

S.2d. Is this an instrument-based measure (i.e., data collected via instruments, surveys, tools, questionnaires, scales, etc.)? Attach copy of instrument if available.

Clinician

S.3.1. For maintenance of endorsement: Are there changes to the specifications since the last updates/submission. If yes, update the specifications for S1-2 and S4-22 and explain reasons for the changes in S3.2.

No

S.3.2. For maintenance of endorsement, please briefly describe any important changes to the measure specifications since last measure update and explain the reasons.

There have been no changes to the measure specifications since the last measure update.

S.4. Numerator Statement *(Brief, narrative description of the measure focus or what is being measured about the target population, i.e., cases from the target population with the target process, condition, event, or outcome) DO NOT include the rationale for the measure.*

***IF an OUTCOME MEASURE**, state the outcome being measured. Calculation of the risk-adjusted outcome should be described in the calculation algorithm (S.14).*

The numerator is the number of long-stay residents identified as high-risk with a selected MDS 3.0 target assessment (OBRA quarterly, annual or significant change/correction assessments or discharge assessment with or without return anticipated) in an episode during the selected target quarter reporting one or more Stage II-IV or unstageable pressure ulcer(s) at the time of assessment.. High-risk residents are those who are comatose (B0100 = [1]), or impaired in bed mobility (G0110A1 = [3, 4, 7, 8]) or transfer (G0110B1 = [3, 4, 7, 8]), or either experiencing malnutrition or at risk for malnutrition (I5600 = [1]). Unstageable pressure ulcers are pressure ulcers that are known to be present but are defined as unstageable due to either a non-removable dressing/device (M0300E1 = [1, 2, 3, 4, 5, 6, 7, 8, or 9]), slough or eschar (M0300F1 = [1, 2, 3, 4, 5, 6, 7, 8, or 9]), or a suspected deep tissue injury (M0300G1 = [1, 2, 3, 4, 5, 6, 7, 8, or 9]).

S.5. Numerator Details *(All information required to identify and calculate the cases from the target population with the target process, condition, event, or outcome such as definitions, time period for data collection, specific data collection items/responses, code/value sets – Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format at S.2b)*

***IF an OUTCOME MEASURE**, describe how the observed outcome is identified/counted. Calculation of the risk-adjusted outcome should be described in the calculation algorithm (S.14).*

Residents are counted in the numerator if they are long-stay residents, defined as residents whose length of stay is 101 days or more, and identified as at high risk for pressure ulcer(s). Residents who return to the nursing home following a hospital discharge may not have their length of stay within the episode of care reset to zero. The numerator is the number of long-stay residents with a selected target assessment (OBRA quarterly, annual or significant change/correction assessments or discharge assessment with or without return anticipated) that meets both of the following conditions:

1. There is a high risk for pressure ulcers, where high-risk is defined in the denominator definition below.
2. Stage II-IV or unstageable pressure ulcers are present, as indicated by any of the following six conditions:

2.1 Current number of unhealed Stage II ulcers (M0300B1) = [1, 2, 3, 4, 5, 6, 7, 8, 9, or more] or

2.2 Current number of unhealed Stage III ulcers (M0300C1) = [1, 2, 3, 4, 5, 6, 7, 8, 9, or more] or

2.3 Current number of unhealed Stage IV ulcers (M0300D1) = [1, 2, 3, 4, 5, 6, 7, 8, 9, or more] or

2.4 Current number of unstageable ulcers due to non-removable dressing/device (M0300E1) = [1, 2, 3, 4, 5, 6, 7, 8, 9, or more] or

2.5 Current number of unstageable ulcers due to wound bed being covered by slough and/or eschar (M0300F1) = [1, 2, 3, 4, 5, 6, 7, 8, 9, or more] or

2.6 Current number of unstageable ulcers presenting as deep tissue injury (M0300G1) = [1, 2, 3, 4, 5, 6, 7, 8, 9, or more]

Stage 1 pressure ulcers are not included in this measure because studies have identified difficulties in objectively measuring them across different populations (Lynn et al., 2007).

Stage 2 pressure ulcer: 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.

Stage 3 pressure ulcer: 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.

Stage 4 pressure ulcer: Full thickness tissue loss with exposed bone or tendon, or muscle. Slough or eschar may be present on some parts of the wound bed. Often includes undermining or tunneling.

Non-removable dressing/device: Includes, for example, a primary surgical dressing that cannot be removed, an orthopedic device, or cast.

Slough tissue: Non-viable yellow, tan, gray, green or brown tissue; usually moist, can be soft, stringy and mucinous in texture. Slough may be adherent to the base of the wound or present in clumps throughout the wound bed.

Eschar tissue: Dead or devitalized tissue that is hard or soft in texture; usually black, brown, or tan in color, and may appear scab-like. Necrotic tissue and eschar are usually firmly adherent to the base of the wound and often the sides/ edges of the wound.

Suspected deep tissue injury: Purple or maroon area of discolored intact skin due to damage of underlying soft tissue. The area may be preceded by tissue that is painful, firm, mushy, boggy, warmer or cooler as compared to adjacent tissue.

(Target assessments may be OBRA quarterly, annual or significant change/correction assessments (A0310A = 02, 03, 04, 05, 06) or discharge assessment with or without return anticipated (A0310F = 10, 11)).

Reference

1. 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.

S.6. Denominator Statement *(Brief, narrative description of the target population being measured)*

The denominator includes all long-stay nursing home residents who had a target assessment (ORBA, PPS, or discharge) during the selected quarter who were identified as high risk for pressure ulcer, and who do not meet the exclusion criteria.

S.7. Denominator Details *(All information required to identify and calculate the target population/denominator such as definitions, time period for data collection, specific data collection items/responses, code/value sets – Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format at S.2b.)*

***IF an OUTCOME MEASURE**, describe how the target population is identified. Calculation of the risk-adjusted outcome should be described in the calculation algorithm (S.14).*

Residents are counted in the denominator if they are long-stay residents, defined as residents whose length of stay is 101 days or more. Residents who return to the nursing home following a hospital discharge may not have their length of stay within the episode of care reset to zero. The denominator is the number of long-stay residents with a selected target assessment (assessment types include: a quarterly, annual, significant change/correction admission OBRA assessment (A0310A = 02, 03, 04, 05, 06); or discharge with or without return anticipated (A0310F = 10, 11)) during the selected quarter, except those with exclusions. Residents must be high risk for pressure ulcer where high risk is defined by meeting one of the following criteria on the selected target assessment:

1. Impaired bed mobility or transfer:

1.1 This is indicated by a level of assistance reported on either item G0110A1, Bed mobility (self-performance) or G0110B1 Transfer (self-performance) at the level of: extensive assistance (3), total dependence

(4), activity occurred only once or twice (7) OR activity or any part of the ADL was not performed by resident or staff at all over the entire 7 day period (8), or

2. Comatose (B0100 = [1] (yes)), or

3. Malnutrition [protein or calorie] or at risk for malnutrition (I5600 = [1])

S.8. Denominator Exclusions *(Brief narrative description of exclusions from the target population)*

A resident is excluded from the denominator if:

1. The target MDS assessment is an OBRA admission assessment or a PPS 5-day assessment or a PPS readmission/return assessment.

2. The resident did not meet the pressure ulcer conditions for the numerator and any Stage II, III, IV, or unstageable item is missing (M0300B1 = [-] or M0300C1 = [-] or M0300D1 = [-] or M0300E1 = [-] or M0300F1 = [-] or M0300G1 = [-]).

If the facility sample includes fewer than 20 residents, then the facility is excluded from public reporting because of small sample size.

S.9. Denominator Exclusion Details *(All information required to identify and calculate exclusions from the denominator such as definitions, time period for data collection, specific data collection items/responses, code/value sets – Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format at S.2b.)*

A long-stay resident is excluded from the denominator if the MDS assessment in the current quarter is an OBRA admission assessment or a PPS 5-day assessment:

1. OBRA admission assessment (A0310A = [01]), or

2. 5-Day PPS assessment (A0310B = [01]), or

In addition, a resident is excluded if the resident did not meet the pressure ulcer conditions for the numerator AND any of the following conditions are true:

1. M0300B1 (Current number of unhealed Stage II ulcers) = [-] (missing)

2. M0300C1 (Current number of unhealed Stage III ulcers) = [-] (missing)

3. M0300D1 (Current number of unhealed Stage IV ulcers) = [-] (missing)

4. M0300E1 (Current number of unstageable ulcers due to non-removable dressing/device) = [-] (missing)

5. M0300F1 (Current number of unstageable ulcers due to coverage of wound bed by slough or eschar) = [-] (missing)

6. M0300G1 (Current number of unstageable ulcers with suspected deep tissue injury in evolution) = [-] (missing)

Nursing homes are excluded from public reporting because of small sample size if their sample includes fewer than 20 residents.

S.10. Stratification Information *(Provide all information required to stratify the measure results, if necessary, including the stratification variables, definitions, specific data collection items/responses, code/value sets, and the risk-model covariates and coefficients for the clinically-adjusted version of the measure when appropriate – Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format with at S.2b.)*

This measure is not stratified.

S.11. Risk Adjustment Type (Select type. Provide specifications for risk stratification in measure testing attachment)

Other

If other: Other: Sample restriction - this measure is restricted to residents who are at high risk for pressure ulcers. Residents are identified as high risk if they meet any of the following three criteria: 1. Impaired in bed mobility or transfer, or 2. Comatose, or 3. Active diagnosis of malnutrition [protein or calorie] identified, or resident is at risk for malnutrition. (See denominator details for more information) This measure was originally developed as one of a pair of stratified pressure ulcer measures – one low-risk and one high-risk. The low-risk measure is no longer reported or maintained.

S.12. Type of score:

Rate/proportion

If other:

S.13. Interpretation of Score *(Classifies interpretation of score according to whether better quality is associated with a higher score, a lower score, a score falling within a defined interval, or a passing score)*

Better quality = Lower score

S.14. Calculation Algorithm/Measure Logic (*Diagram or describe the calculation of the measure score as an ordered sequence of steps including identifying the target population; exclusions; cases meeting the target process, condition, event, or outcome; time period for data, aggregating data; risk adjustment; etc.)*

Step 1: For each facility, identify the total number (sum) of high risk long-stay residents with a target assessment meeting the denominator criteria.

Step 2: Starting with the set of residents identified in Step 1, determine the number of high-risk long-stay residents in the numerator (i.e., the total number with stage II, III, IV, or unstageable ulcers at target assessment).

Step 3: Divide the result of Step 2 by the result of Step 1.

S.15. Sampling *(If measure is based on a sample, provide instructions for obtaining the sample and guidance on minimum sample size.)*

IF an instrument-based performance measure (e.g., PRO-PM), identify whether (and how) proxy responses are allowed.

This is not applicable because the data are not estimated based on samples. Rather, the data include all nursing home residents nationally who do not meet the exclusion criteria.

S.16. Survey/Patient-reported data *(If measure is based on a survey or instrument, provide instructions for data collection and guidance on minimum response rate.)*

Specify calculation of response rates to be reported with performance measure results.

This is not applicable because this measure is not based on survey/patient-reported data.

S.17. Data Source *(Check ONLY the sources for which the measure is SPECIFIED AND TESTED).*

If other, please describe in S.18.

Assessment Data

S.18. Data Source or Collection Instrument *(Identify the specific data source/data collection instrument (e.g., name of database, clinical registry, collection instrument, etc., and describe how data are collected.)*

IF instrument-based, identify the specific instrument(s) and standard methods, modes, and languages of administration.

The data source is the Minimum Data Set (MDS) 3.0, and the collection instrument is the Resident Assessment Instrument (RAI). For MDS 3.0 item sets used to calculate the quality measure, please see "MDS3.0_Final_Item_Sets_v1.17.2 for October 1 2020 zip (ZIP)" under the "Downloads" section of the following webpage:

https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/NHQIMDS30TechnicalInformation

S.19. Data Source or Collection Instrument *(available at measure-specific Web page URL identified in S.1 OR in attached appendix at A.1)*

Available at measure-specific web page URL identified in S.1

S.20. Level of Analysis *(Check ONLY the levels of analysis for which the measure is SPECIFIED AND TESTED)*

Facility

S.21. Care Setting *(Check ONLY the settings for which the measure is SPECIFIED AND TESTED)*

Post-Acute Care

If other:

S.22. COMPOSITE Performance Measure - Additional Specifications *(Use this section as needed for aggregation and weighting rules, or calculation of individual performance measures if not individually endorsed.)*

This is not applicable because this is not a composite performance measure.

2. Validity – See attached Measure Testing Submission Form

NQF_0679_Testing_20210126_ToUpload.docx

2.1 For maintenance of endorsement

Reliability testing: If testing of reliability of the measure score was not presented in prior submission(s), has reliability testing of the measure score been conducted? If yes, please provide results in the Testing attachment. Please use the most current version of the testing attachment (v7.1). Include information on all testing conducted (prior testing as well as any new testing); use red font to indicate updated testing.

Yes

2.2 For maintenance of endorsement

Has additional empirical validity testing of the measure score been conducted? If yes, please provide results in the Testing attachment. Please use the most current version of the testing attachment (v7.1). Include information on all testing conducted (prior testing as well as any new testing); use red font to indicate updated testing.

Yes

2.3 For maintenance of endorsement

Risk adjustment: For outcome, resource use, cost, and some process measures, risk-adjustment that includes social risk factors is not prohibited at present. Please update sections 1.8, 2a2, 2b1, 2b4.3 and 2b5 in the Testing attachment and S.140 and S.11 in the online submission form. NOTE: These sections must be updated even if social risk factors are not included in the risk-adjustment strategy. You MUST use the most current version of the Testing Attachment (v7.1) -- older versions of the form will not have all required questions.

No - This measure is not risk-adjusted

Measure Testing (subcriteria 2a2, 2b1-2b6)

Measure Number (*if previously endorsed*)**:** 0679

Measure Title: Percent of High-Risk Residents with Pressure Ulcers (Long Stay)

Date of Submission: 1/5/2021

Type of Measure:

Measure	Measure (continued)
X Outcome (*including PRO-PM*)	☐ Composite – ***STOP – use composite testing form***
☐ Intermediate Clinical Outcome	☐ Cost/resource
☐ Process *(including Appropriate Use)*	☐ Efficiency
☐ Structure	*

*cell intentionally left blank

1. DATA/SAMPLE USED FOR ALL TESTING OF THIS MEASURE

Often the same data are used for all aspects of measure testing. In an effort to eliminate duplication, the first five questions apply to all measure testing. ***If there are differences by aspect of testing****, (e.g., reliability vs. validity) be sure to indicate the specific differences in question 1.7.*

1.1. What type of data was used for testing? (*Check all the sources of data identified in the measure specifications and data used for testing the measure. Testing must be provided for* ***all*** *the sources of data specified and intended for measure implementation.* ***If different data sources are used for the numerator and denominator, indicate N [numerator] or D [denominator] after the checkbox.***)

Measure Specified to Use Data From: (*must be consistent with data sources entered in S.17*)	Measure Tested with Data From:
☐ abstracted from paper record	☐ abstracted from paper record
☐ claims	☐ claims
☐ registry	☐ registry
☐ abstracted from electronic health record	☐ abstracted from electronic health record
☐ eMeasure (HQMF) implemented in EHRs	☐ eMeasure (HQMF) implemented in EHRs
X other: Nursing Home Minimum Data Set (MDS) 3.0	X other: Nursing Home Minimum Data Set (MDS) 3.0

1.2. If an existing dataset was used, identify the specific dataset (*the dataset used for testing must be consistent with the measure specifications for target population and healthcare entities being measured; e.g., Medicare Part A claims, Medicaid claims, other commercial insurance, nursing home MDS, home health OASIS, clinical registry*).

The dataset used for testing was the Nursing Home Minimum Data Set (MDS) 3.0, which is one of three components of the Resident Assessment Instrument (RAI). The RAI is a tool used by nursing home staff to collect information on residents' strengths and needs. The MDS contains screening, clinical, and functional status elements, such as definitions and coding categories. These elements form the foundation of the comprehensive RAI for all eligible Medicare and Medicaid beneficiaries who are residents of nursing homes. The MDS items standardize how information about resident status and condition is recorded and shared within the facility, between facilities, and between facilities and outside agencies. Nursing homes are required to complete assessments on a regular basis, and the assessment requirements for the MDS are applicable to all residents in Medicare and/or Medicaid certified long-term care facilities, regardless of payment source or payer source.

1.3. What are the dates of the data used in testing?

Critical Data Element Testing

The RAND Development and Validation study from August 2006 to February 2007 on the development and validation of a revised nursing home assessment tool was used for the testing of critical data elements.

Saliba, D., & Buchanan, J. (2008, April). *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. Retrieved from

https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/downloads/MDS30FinalReport.pdf.

Performance Measure Score Testing

MDS 3.0 data from FY2019 Quarter 4 was used to construct this measure and calculate the QM scores. The seasonal trend analysis in **Section 2b1** was conducted using data from FY2017 Quarter 1 to FY2019 Quarter 4. The split-half analysis in **Section 2a2** was conducted using data from FY2019 Quarter 3 to FY2019 Quarter 4. The signal-to-noise analysis in **Section 2a2** and the 95% confidence interval analysis in **Section 2b1** were conducted using data from FY2019 Quarter 4.

1.4. What levels of analysis were tested? (*testing must be provided for **all** the levels specified and intended for measure implementation, e.g., individual clinician, hospital, health plan*)

Measure Specified to Measure Performance of: (*must be consistent with levels entered in item S.20*)	Measure Tested at Level of:
☐ individual clinician	☐ individual clinician
☐ group/practice	☐ group/practice
X hospital/facility/agency	X hospital/facility/agency
☐ health plan	☐ health plan
☐ other:	☐ other:

Measure Specified to Measure Performance of: (*must be consistent with levels entered in item S.20*)

1.5. How many and which measured entities were included in the testing and analysis (by level of analysis and data source)? (*identify the number and descriptive characteristics of measured entities included in the analysis (e.g., size, location, type); if a sample was used, describe how entities were selected for inclusion in the sample*)

Critical Data Element Testing

The RAND Development and Validation of MDS 3.0 study sample included a representative sample of for-profit and not-for-profit facilities, and hospital-based and freestanding facilities, which were recruited for the study. The sample included 71 community nursing facilities in 8 states and 19 Veterans Affairs (VA) nursing homes (Saliba & Buchanan, 2008).

Saliba, D., & Buchanan, J. (2008, April). *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. Retrieved from https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/downloads/MDS30FinalReport.pdf.

Performance Measure Score Testing

The analysis of MDS 3.0 data included all nationwide nursing home facilities with sufficient denominator size ($n \geq 20$) to publicly report this measure in FY2019 Quarter 4 ($k = 13,219$), unless otherwise noted.

1.6. How many and which patients were included in the testing and analysis (by level of analysis and data source)? (*identify the number and descriptive characteristics of patients included in the analysis (e.g., age, sex, race, diagnosis); if a sample was used, describe how patients were selected for inclusion in the sample*)

Critical Data Element Testing

The RAND Development and Validation of MDS 3.0 study sample included 3,822 residents from community nursing homes and 764 residents from VHA nursing homes (Saliba & Buchanan, 2008).

Saliba, D., & Buchanan, J. (2008, April). *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. Retrieved from https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/downloads/MDS30FinalReport.pdf.

Performance Measure Score Testing

This measure is for residents who are at high risk for pressure ulcers in nursing facilities, including residents who have impaired bed mobility, have impaired transfer, are comatose, or have malnutrition or risk of malnutrition. The analysis of MDS 3.0 data included all long-stay residents who met the denominator inclusion criteria for this measure in facilities with sufficient sample size ($n \geq 20$, $k = 13,219$) to report this measure in FY2019 Quarter 4. 749,950 residents met the denominator inclusion criteria out of a total of 1,032,864 long-stay residents in these facilities. Of these 749,950 residents, 704,193 had impaired bed mobility, 695,926 had impaired transfer, 3,002 were comatose, and 75,476 had malnutrition or were at risk for malnutrition.

Table 1 describes the characteristics of the residents who were counted in the denominator after applying facility sample size restrictions to FY2019 Quarter 4 data (n = 749,950). The majority of residents who met the denominator criteria were female (66.2%) and white (72.6%), while a smaller proportion of residents were male (33.8%) and Black or African American (16.4%). A majority of residents were dual-eligible for Medicare and Medicaid (74.2%). More than 41% of residents were over the age of 85, and approximately 27% were between the ages of 75-84. The most frequently reported diagnoses were Hypertension (78.1%), Depression (54.0%), and Non-Alzheimer's Dementia (51.6%). Other common diagnoses reported for more than a quarter of residents were Arthritis (33.3%), Anemia (32.2%), Diabetes Mellitus (35.6%), and Anxiety Disorders (32.6%). Table 1 also outlines the characteristics of the residents who were counted in the numerator. Compared to the denominator, the numerator had a higher share of males, Black or African American residents, non-dual residents, residents under the age of 75, residents with hip fractures and other fracture, and residents with cancer, anemia, diabetes mellitus and malnutrition or at risk for malnutrition.

Table 1. Characteristics of Long-Stay Residents Included in Analyses, NQF #0679 (FY2019 Q4)

Resident characteristics	NQF #0679 Denominator: Frequency (n)	NQF #0679 Denominator: Total Observations (N)	NQF #0679 Denominator: Percentage (%)	NQF #0679 Numerator: Frequency (n)	NQF #0679 Numerator: Total Observations (N)	NQF #0679 Numerator: Percentage (%)	Percentage Ratio (% Numerator/% Denominator)
Sex: Female	496,105	749,950	66.2	33,519	53,531	59.3	0.9
Sex: Male	253,845	749,950	33.8	23,012	53,531	40.7	1.2
Race/Ethnicity: White Only	544,542	749,950	72.6	38,104	53,531	67.4	0.9
Race/Ethnicity: Black or African American Only	123,026	749,950	16.4	12,210	53,531	21.6	1.3
Race/Ethnicity: Hispanic or Latino Only	44,146	749,950	5.9	3,287	53,531	5.8	1.0
Race/Ethnicity: Asian Only	17,348	749,950	2.3	1,056	53,531	1.9	0.8
Race/Ethnicity: American Indian/Alaska Native Only	2,971	749,950	0.4	318	53,531	0.6	1.4
Race/Ethnicity: Native Hawaiian or Other Pacific Islander Only	2,864	749,950	0.4	189	53,531	0.3	0.9
Race/Ethnicity: Multi-race	2,474	749,950	0.3	183	53,531	0.3	1.0
Medicare-Medicaid Dual Eligibility: Dual-Eligible	556,457	749,950	74.2	40,073	53,531	70.9	1.0
Medicare-Medicaid Dual Eligibility: Non-Dual	182,157	749,950	24.3	15,452	53,531	27.3	1.1
Medicare-Medicaid Dual Eligibility: Missing	11,336	749,950	1.5	1,006	53,531	1.8	1.2

Resident characteristics	NQF #0679 Denominator: Frequency (n)	NQF #0679 Denominator: Total Observations (N)	NQF #0679 Denominator: Percentage (%)	NQF #0679 Numerator: Frequency (n)	NQF #0679 Numerator: Total Observations (N)	NQF #0679 Numerator: Percentage (%)	Percentage Ratio (% Numerator/% Denominator)
Age: <65	105,086	749,950	14.0	10,722	53,531	19.0	1.4
Age: 65-74	134,438	749,950	17.9	11,174	53,531	19.8	1.1
Age: 75-84	201,388	749,950	26.9	15,284	53,531	27.0	1.0
Age: 85+	309,038	749,950	41.2	19,351	53,531	34.2	0.8
Diagnoses: Arthritis	68,608	206,220	33.3	5,694	18,354	31.0	0.9
Diagnoses: Osteoporosis	27,710	206,220	13.4	2,113	18,354	11.6	0.9
Diagnoses: Hip Fracture	16,390	689,819	2.4	1,821	47,891	3.8	1.6
Diagnoses: Other Fracture	26,700	689,814	3.9	2,163	47,890	4.5	1.2
Diagnoses: Depression	372,163	689,783	54.0	23,785	47,887	49.7	0.9
Diagnoses: Stroke	131,786	689,805	19.1	8,900	47,891	18.6	1.0
Diagnoses: Alzheimer's Disease	116,083	689,814	16.8	6,535	47,891	13.6	0.8
Diagnoses: Non-Alzheimer's Dementia	356,203	689,785	51.6	21,420	47,889	44.7	0.9
Diagnoses: Malnutrition or at risk for malnutrition	75,476	749,882	10.1	8,615	56,523	15.2	1.5
Diagnoses: Cancer	45,860	676,506	6.8	3,703	46,343	8.0	1.2
Diagnoses: Anemia	221,921	689,792	32.2	19,413	47,892	40.5	1.3
Diagnoses: Heart Failure	156,721	689,803	22.7	12,076	47,889	25.2	1.1

Resident characteristics	NQF #0679 Denominator: Frequency (n)	NQF #0679 Denominator: Total Observations (N)	NQF #0679 Denominator: Percentage (%)	NQF #0679 Numerator: Frequency (n)	NQF #0679 Numerator: Total Observations (N)	NQF #0679 Numerator: Percentage (%)	Percentage Ratio (% Numerator/% Denominator)
Diagnoses: Hypertension	538,463	689,782	78.1	36,481	47,891	76.2	1.0
Diagnoses: Diabetes Mellitus	267,039	749,932	35.6	24,710	56,528	43.7	1.2
Diagnoses: Anxiety Disorder	244,420	749,853	32.6	17,318	56,524	30.6	0.9
Diagnoses: Asthma, Chronic Obstructive Pulmonary Disease, or Chronic Lung Disease	160,517	689,804	23.3	11,245	47,891	23.5	1.0

1.7. If there are differences in the data or sample used for different aspects of testing (e.g., reliability, validity, exclusions, risk adjustment), identify how the data or sample are different for each aspect of testing reported below.

Data for Critical Data Elements

RAND reliability analysis of data elements used the same sample as described in **Sections 1.5** and **1.6** (Saliba & Buchanan, 2008).

Saliba, D., & Buchanan, J. (2008, April). 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. Retrieved from https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/downloads/MDS30FinalReport.pdf.

Data for Measure Performance Score Testing

All analyses used the same data as described above in **Sections 1.2, 1.3, 1.5, and 1.6**.

1.8 What were the social risk factors that were available and analyzed? For example, patient-reported data (e.g., income, education, language), proxy variables when social risk data are not collected from each patient (e.g., census tract), or patient community characteristics (e.g., percent vacant housing, crime rate) which do not have to be a proxy for patient-level data.

Resident-level social risk factor variables related to pressure ulcers that were available in the MDS 3.0 dataset were selected, including age, race, Medicaid status, and gender. The descriptive statistics for all of these characteristics are listed in Table 1 under item 1.6 in response to NQF prompting for sample resident characteristics.

2a2. RELIABILITY TESTING

***Note**: If accuracy/correctness (validity) of data elements was empirically tested, separate reliability testing of data elements is not required – in 2a2.1 check critical data elements; in 2a2.2 enter "see section 2b2 for validity testing of data elements"; and skip 2a2.3 and 2a2.4.*

2a2.1. What level of reliability testing was conducted? (*may be one or both levels*)

☒ **Critical data elements used in the measure** (*e.g., inter-abstractor reliability; data element reliability must address ALL critical data elements*)

☒ **Performance measure score (e.g., signal-to-noise analysis)**

2a2.2. For each level checked above, describe the method of reliability testing and what it tests

(*describe the steps—do not just name a method; what type of error does it test; what statistical analysis was used*)

Critical Data Element Reliability

1. The national test of MDS 3.0 items examined the agreement between assessors (reliability). Quality Improvement Organizations were employed to identify gold-standard (research) nurses and recruit community nursing facilities to participate in the national evaluation (Saliba & Buchanan, 2008). The gold-standard nurses were trained in the MDS 3.0 instrument, and they, in turn, trained a facility nurse from each participating nursing facility in their home states. Residents participating in the test were selected to capture a representative sample of short- and long-stay residents. In this national test of the Pressure Ulcer item, the agreement between the MDS 2.0 item, coded by facility nurses, and the MDS 3.0 item, coded by gold-standard nurses was examined. Saliba and Buchanan (2008) present Pressure Ulcer rates using the MDS 2.0 and MDS 3.0 items at the resident- and facility-level, as well as Cohen's kappas, which were calculated to assess item reliability. Kappa is a statistical measure of inter-rater agreement for qualitative data, ranging from 0.0 to 1.0, where a rating of greater than 0.60 is considered substantial agreement (Landis & Koch, 1977).

Landis, JR, Koch, GG. The measurement of observer agreement for categorical data. *Biometrics 33*(1), p 159-174, 1977.

Saliba, D., & Buchanan, J. (2008, April). *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. Retrieved from https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/downloads/MDS30FinalReport.pdf.

Performance Measure Score Reliability

1. Split-half reliability analysis: Split-half reliability assesses the internal consistency of a quality measure by randomly dividing the residents within each nursing facility into two halves and calculating the correlation between each facility's quality measure scores on the basis of the two divided halves. When a nursing facility's residents, randomly divided, have a score similar to one another, the quality measure score is more likely to reflect systematic differences in nursing home-level quality rather than random variation. In this analysis, a split-half reliability analysis was conducted on all facilities with 40 or more residents counted in the measure denominator across the two quarters (ensuring at least 20 residents could be used in each randomly selected half of a facility's residents). Data from 2019Q3 - 2019Q4 were used to calculate the Spearman Rank Correlation and Pearson Correlation to measure the internal reliability.

2. Signal-to-noise analysis: The signal-to-noise ratio gives the proportion of variability in measure performance that can be explained by between-provider differences in provider performance rather than variability within a provider (e.g., through measurement or sampling error). Since having a pressure ulcer is a binary outcome, the reliability was estimated using a beta-binomial model. The beta-binomial model assumes that the provider QM score for the pressure ulcer measure is a binomial random variable, conditional on the provider's true value that comes from a beta distribution. Data from FY2019 Q4 were used to conduct this analysis by fitting the beta binomial model to the data. The estimated alpha and beta parameters from the model were used to calculate the provider-to-provider variance:

$$\sigma^2_{\text{provider-to-provider}} = \frac{\alpha\beta}{(\alpha+\beta+1)(\alpha+\beta)^2}$$

The provider-specific error was calculated using the following formula, where "p" is each facility's QM score and "n" is the number of residents in each facility:

$$\sigma^2_{\text{provider-specific-error}} = \frac{p\,(1-p)}{n}$$

The reliability score for each facility was then calculated using the following formula:

$$\text{reliability} = \frac{\sigma^2_{\text{provider-to-provider}}}{\sigma^2_{\text{provider-to-provider}} + \sigma^2_{\text{provider-specific-error}}}$$

A reliability score closer to 1 implies that most of the variability is attributable to between-provider differences in performance, and a score closer to 0 implies that most of the variability in the measure is attributable to variation within providers.

2a2.3. For each level of testing checked above, what were the statistical results from reliability testing? (e.*g., percent agreement and kappa for the critical data elements; distribution of reliability statistics from a signal-to-noise analysis*)

Critical Data Element Reliability

1. In their testing of the MDS 3.0, RAND calculated the Pressure Ulcer rate using the MDS 3.0 and the MDS 2.0, both at the individual resident-level and at the facility-level (Saliba & Buchanan, 2008). At the resident-level, the Pressure Ulcer rate using the MDS 2.0 was 13.3% and using the MDS 3.0 was 13.3%. At the facility-level, the MDS 2.0 rate of Pressure Ulcers was 14.0% and the MDS 3.0 rate was 14.5%. Correlation between the MDS 2.0 and MDS 3.0 measures was strong at both the resident- ($\rho = 0.92$) and facility-level ($\rho = 0.97$). The Kappa for gold-standard to facility-nurse agreement on the MDS 3.0 and MDS 2.0 item was 0.92. Kappa is a statistical measure of inter-rater agreement for qualitative data, ranging from 0.0 to 1.0. A rating of 0.92 is considered "substantial agreement." These results are indicative of data element reliability.

Saliba, D., & Buchanan, J. (2008, April). *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. Retrieved from https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/downloads/MDS30FinalReport.pdf.

Performance Measure Score Reliability

1. Split-half reliability analysis: The split-half correlation for this measure was positive, and the relationship was moderate ($r = 0.33$, $\rho = 0.30$, $p < .01$), suggesting there is modest evidence of internal reliability. These moderate correlations were expected due to a modest amount of variation in performance among providers. Since correlations are calculated using the covariance of the data and the individual variances to naturalize the covariance to report a value range between -1 and 1, the modest amount of variance in performance was expected to yield moderate correlation coefficients. **Table 6** in **Section 2b4.2** demonstrates that the variation in scores is still sufficient to distinguish high-performers and low-performers.
2. Signal-to-noise analysis: The average signal-to-noise reliability score of this quality measure using facility scores based on FY2019 Q4 data was observed to be 0.50. This suggests that the measure is moderately reliable in separating facility characteristics from variability within facility. This moderate variability is expected for this outcome measure because of modest variability in measure scores.

2a2.4 What is your interpretation of the results in terms of demonstrating reliability? (i.*e., what do the results mean and what are the norms for the test conducted?*)

Critical Data Element Reliability

The RAND Development and Validation of MDS 3.0 national pilot test study demonstrated excellent reliability for MDS 3.0 items used to calculate this measure. Although the RAND testing was conducted 13 years ago, the MDS 3.0 forms used in the RAND study are similar to the latest MDS 3.0 forms used in the testing of this measure. The MDS 3.0 item set has remained stable since RAND created the recommended MDS 3.0 form in 2008, with the exception of select changes in item specifications and the addition of some new items. In particular, the Pressure Ulcer item has the same item wording in the latest MDS 3.0 form and the 2008 recommended form.

Performance Measure Score Reliability

These analyses demonstrate that the pressure ulcer measure shows moderate evidence of internal reliability. The average signal-to-noise ratio across all providers was 0.50, meaning 50% of the variance in scores for this measure were explained by inter-facility variation. This suggests that the measure is moderately reliable in separating provider characteristics from variability within provider.

2b1. VALIDITY TESTING

2b1.1. What level of validity testing was conducted? (*may be one or both levels*)

☐ **Critical data elements** (*data element validity must address ALL critical data elements*)

☒ **Performance measure score**

☒ **Empirical validity testing**

☐ **Systematic assessment of face validity of performance measure score as an indicator** of quality or resource use (*i.e., is an accurate reflection of performance on quality or resource use and can distinguish good from poor performance*) **NOTE**: Empirical validity testing is expected at time of maintenance review; if not possible, justification is required.

2b1.2. For each level of testing checked above, describe the method of validity testing and what it tests (*describe the steps—do not just name a method; what was tested, e.g., accuracy of data elements compared to authoritative source, relationship to another measure as expected; what statistical analysis was used)*

Critical Data Element Validity

The RAND validation of MDS 3.0 study tested the criterion validity of the items by comparing how different nurses assessed the same residents using MDS 3.0. They compared gold-standard research nurses to gold-standard nurses, and they compare gold-standard nurses to staff nurses trained by the gold-standard nurses. Kappa statistic was calculated.

Performance Measure Score Validity

a. Convergent validity: Groups of quality measures that reflect similar care processes or outcomes were examined with the hypothesis that a facility's percentile ranking (compared to all facilities reporting the measure) may be somewhat consistent among related quality measures. A related MDS Quality Measure (Percent of SNF Residents with Pressure Ulcers That Are New or Worsened) that is associated with the risk of developing or worsening a pressure ulcer and Facility Five-Star Ratings were examined for this purpose. Public reporting data was used to calculate these correlations between NQF #0679 (Percent of High-Risk Residents with Pressure Ulcers (long stay)) and related quality measures.

b. Variation by state: Analyses investigated whether or not variation in scores on this measure was substantially attributable to state-by-state differences. If a measure is subject to variation caused by other factors beyond facility control, such as state-level payment policies or demographics, this variation can be a threat to the validity of the measure. At the same time, it is expected that state variation may explain a small portion of measure variation due to differences in quality across states.

c. Seasonality: Another potential threat to the validity of a quality measure is seasonal variation. If a quality measure score varies substantially from quarter to quarter in a consistent pattern over time corresponding to changes in seasons, it is possible that the validity of the measure is being compromised due to influences not within a nursing home's control. To address whether seasonal variation might play a role, the trend in the national mean and median for this quality measure score between FY2017 Q1 and FY2019 Q4 was examined.

d. Stability analysis: The extent to which relative facility rank changed on this quality measure from FY2019 Q3 to FY2019 Q4 was also assessed by evaluating the percentage of facilities that changed in their percentile ranking (i.e., relative quality measure score) within 1 decile, between 1 and 2 deciles, between 2 and 3 deciles, and 3 or more deciles. Dramatic changes in the quality measure score or facility rank based on the score over time may indicate measure instability, rather than true changes in quality. An important caveat is that some degree of variation in performance across time is to be expected: very poor performance in one quarter may lead to immediate changes that improve performance in subsequent quarters, and some movement in performance becomes more likely with rare event outcomes.

e. Confidence interval analysis: Proportions of facilities with scores for this measure that are significantly different from the national facility-level mean were examined and stratified by facility denominator size. For this analysis, statistical significance was determined by using 95% confidence intervals. A facility's quality measure score was significantly different from the national mean if the national mean was not included in the facility's 95% confidence interval. High-performing facilities should have scores that are significantly better than average, and scores of low-performing facilities should be significantly below average. The analysis was stratified by facility denominator size to examine whether this feature of the measure varies by size.

2b1.3. What were the statistical results from validity testing? (*e.g., correlation; t-test*)

Critical Data Elements

For the pressure ulcer items for Stage 2, 3 and 4 ulcers used in this measure, nurse to gold-standard nurse agreement was perfect, and the range of kappas for gold-standard nurse to facility nurse agreement was from 0.945 to 0.993. The unstageable item had perfect gold-standard to gold-standard nurse agreement and gold-standard to facility nurse agreement.

Regarding the items used to identify high risk residents, kappas for bed mobility and transfer self-performance were excellent, ranging from 0.957 to 0.987. Rates of agreement reported for comatose for ratings by gold-standard to gold-standard nurse was over 98%. Malnutrition or malnutrition risk had perfect gold-standard to gold-standard nurse agreement and 99% agreement and a kappa of 0.697 for gold-standard to facility ratings.

References:

1. Saliba, D., & Buchanan, J. (2008, April). *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. Retrieved from https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/downloads/MDS30FinalReport.pdf.

Performance Measure Score Validity

a. Convergent Validity: Among facilities that could report both measures, the analysis found statistically significant positive correlation between Percent of High-Risk Residents with Pressure Ulcers (NQF #0679) and Percent of SNF Residents with Pressure Ulcers That Are New or Worsened (NQF #0678). Statistically significant negative correlations between Percent of High-Risk Residents with Pressure Ulcers and Overall Facility Five-Star Ratings, Staffing Ratings, and Registered Nurse Staffing Ratings were also observed. The coefficient estimates and associated p-values are summarized in **Table 2** below.

Table 2. Correlations between NQF #0679 and other related MDS Quality Measures, Facility Five-Star Ratings and Claims-based Quality Measures (FY2019 Q4)

Quality Measure	Spearman Correlation	P Value
MDS Quality Measures	*	*
Percent of SNF Residents with Pressure Ulcers That Are New or Worsened (NQF #0678)	0.203	<.0001
Facility Five Star Ratings	*	*
Overall facility ratings	-0.207	<.0001
Staffing ratings	-0.122	<.0001
Registered nurse staffing ratings	-0.123	<.0001

*cell intentionally left blank

b. Variation by State: The proportion of variation in this measure explained by the state that facilities are located in was small though significant ($p < .001$). An analysis of variance showed that just 5.84% of the overall variance in this measure can be attributed to the state in which the facility is located. The average inter-quartile range of state-level scores was 6.4 percentage points. Washington DC had the highest mean, median and interquartile range for NQF #0679 compared to the other states but had a relatively low number of nursing facilities located in the state. The state-level average scores and percentile distributions are summarized in **Table 3** below.

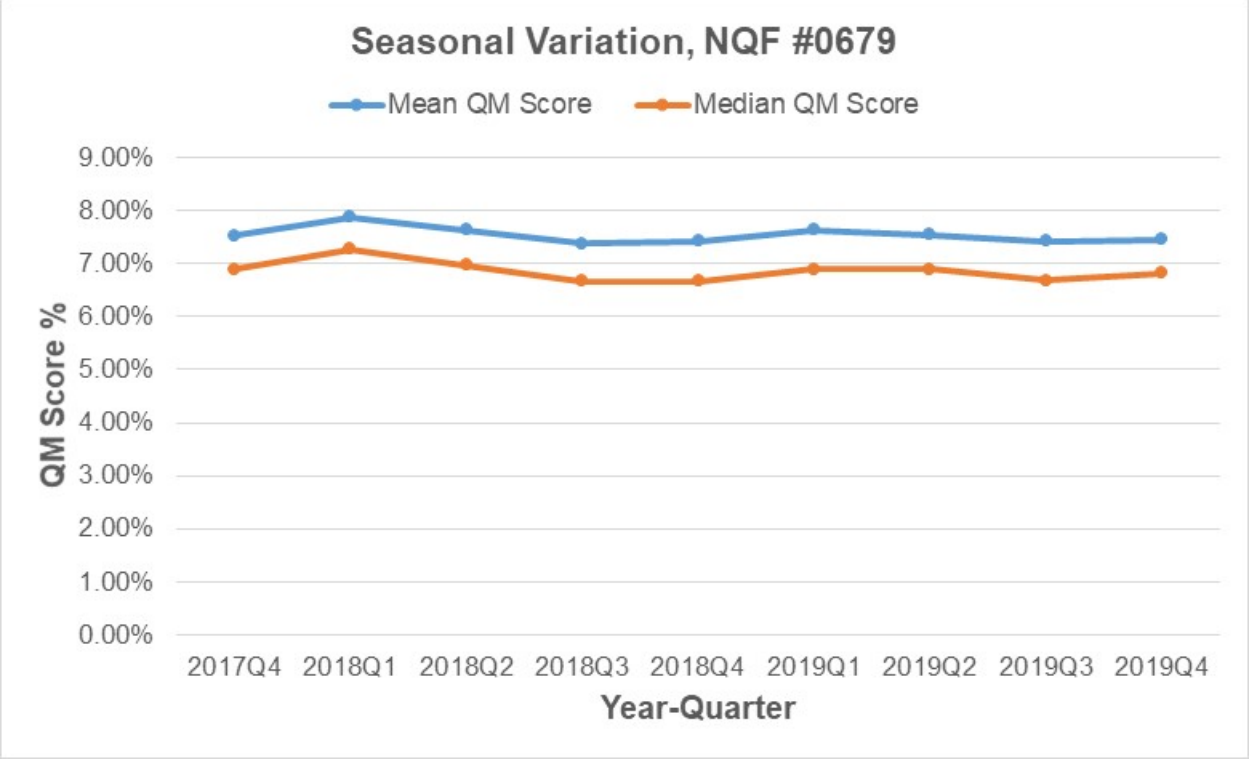
Table 3. State-level NQF #0679 QM score summary (FY2019 Q4)

State	Number of facilities	Mean score	Std dev.	10th percentile	25th percentile	50th percentile	75th percentile	90th percentile	Interquartile range
DC	16	13.3%	7.2%	2.1%	7.3%	14.3%	18.1%	23.0%	10.9%
AK	6	11.8%	5.8%	2.9%	8.9%	12.0%	15.0%	20.0%	6.1%
GA	344	9.9%	5.2%	4.3%	6.5%	9.1%	12.6%	15.9%	6.2%
MS	190	9.7%	6.7%	2.7%	5.4%	8.7%	13.1%	18.2%	7.8%
SC	160	9.4%	4.8%	3.0%	6.3%	9.3%	12.4%	15.5%	6.1%
LA	258	9.2%	5.1%	3.3%	5.8%	8.3%	11.3%	15.6%	5.6%
NC	390	9.0%	5.1%	3.0%	5.0%	8.9%	11.9%	15.6%	6.9%
KY	259	8.9%	5.5%	2.3%	5.3%	8.2%	12.5%	16.3%	7.2%
NJ	328	8.8%	4.7%	3.3%	5.6%	8.5%	11.2%	14.7%	5.7%
MD	209	8.8%	5.4%	2.8%	4.9%	8.1%	12.0%	16.9%	7.1%
NY	591	8.8%	4.9%	2.9%	5.5%	8.1%	11.6%	15.0%	6.2%
MO	384	8.8%	6.2%	2.4%	4.0%	7.9%	12.1%	17.9%	8.1%
OK	211	8.7%	5.7%	2.2%	4.5%	8.2%	12.5%	16.0%	8.0%
NV	43	8.6%	4.8%	2.6%	5.1%	7.7%	13.6%	15.2%	8.5%
NM	57	8.5%	5.3%	2.5%	4.5%	7.7%	11.1%	16.0%	6.6%
WV	111	8.4%	5.0%	2.6%	4.7%	7.7%	12.3%	15.0%	7.6%
AZ	109	8.4%	6.1%	2.0%	3.9%	7.5%	11.4%	17.0%	7.5%
MT	44	8.1%	6.4%	0.0%	3.8%	6.4%	14.3%	17.9%	10.4%
FL	640	8.0%	4.6%	2.7%	4.5%	7.3%	10.9%	14.2%	6.4%
VA	266	8.0%	4.6%	2.5%	4.9%	7.3%	10.5%	14.5%	5.6%
IL	601	7.8%	5.3%	2.0%	4.0%	7.1%	10.5%	14.5%	6.5%
AL	221	7.8%	4.8%	1.9%	4.5%	7.4%	10.3%	13.5%	5.8%
OR	95	7.7%	5.7%	0.0%	3.1%	7.7%	11.1%	15.4%	8.0%
TN	286	7.7%	4.5%	2.4%	4.6%	7.1%	10.0%	13.3%	5.4%
MI	380	7.5%	4.7%	2.1%	4.0%	6.9%	10.0%	13.5%	6.0%
TX	1065	7.3%	4.9%	2.1%	4.0%	6.7%	10.0%	13.7%	6.0%
CA	987	7.3%	5.3%	1.2%	3.4%	6.5%	10.0%	13.8%	6.6%
AR	212	7.2%	5.0%	2.0%	3.4%	6.4%	10.5%	13.3%	7.0%
PA	638	6.8%	4.4%	2.0%	3.8%	6.3%	8.9%	12.3%	5.1%

State	Number of facilities	Mean score	Std dev.	10th percentile	25th percentile	50th percentile	75th percentile	90th percentile	Interquartile range
IN	475	6.7%	4.7%	1.3%	3.2%	6.1%	9.5%	12.5%	6.3%
OH	848	6.7%	4.7%	0.0%	3.3%	5.9%	9.2%	12.8%	5.9%
DE	43	6.6%	4.3%	2.2%	3.6%	5.6%	8.6%	13.0%	5.0%
WA	174	6.3%	4.1%	1.7%	2.9%	5.5%	9.1%	12.0%	6.1%
SD	79	6.1%	5.2%	0.0%	2.6%	4.8%	8.3%	13.6%	5.7%
NH	66	6.0%	4.8%	0.0%	2.8%	5.1%	9.1%	11.8%	6.3%
WI	292	6.0%	5.1%	0.0%	2.2%	5.1%	9.1%	12.0%	6.9%
KS	205	5.9%	5.0%	0.0%	2.5%	4.8%	9.3%	12.8%	6.8%
VT	31	5.8%	4.1%	2.1%	3.4%	4.5%	7.7%	11.4%	4.2%
MA	351	5.8%	3.9%	1.6%	3.1%	5.4%	8.0%	10.5%	4.9%
IA	317	5.8%	5.2%	0.0%	1.8%	4.8%	8.3%	12.0%	6.6%
MN	298	5.7%	4.6%	0.0%	2.6%	4.9%	8.1%	11.5%	5.5%
ID	61	5.7%	4.8%	0.0%	2.6%	4.3%	7.4%	11.4%	4.8%
RI	73	5.7%	3.9%	1.3%	2.9%	4.7%	8.5%	11.1%	5.6%
CO	175	5.5%	4.4%	0.0%	2.2%	4.8%	8.3%	11.1%	6.1%
ND	66	5.5%	3.4%	0.0%	3.7%	5.0%	8.0%	10.2%	4.3%
UT	64	5.4%	4.1%	0.0%	2.5%	5.1%	8.1%	10.3%	5.5%
ME	87	5.3%	4.1%	0.0%	2.5%	4.5%	8.0%	10.8%	5.5%
NE	151	5.3%	5.2%	0.0%	1.9%	4.3%	7.4%	12.2%	5.5%
WY	28	5.2%	4.5%	0.0%	2.2%	4.1%	8.0%	14.0%	5.7%
CT	199	5.1%	3.7%	0.0%	2.5%	4.8%	7.2%	9.4%	4.7%
HI	35	4.8%	3.4%	0.0%	2.3%	4.8%	7.1%	9.5%	4.9%

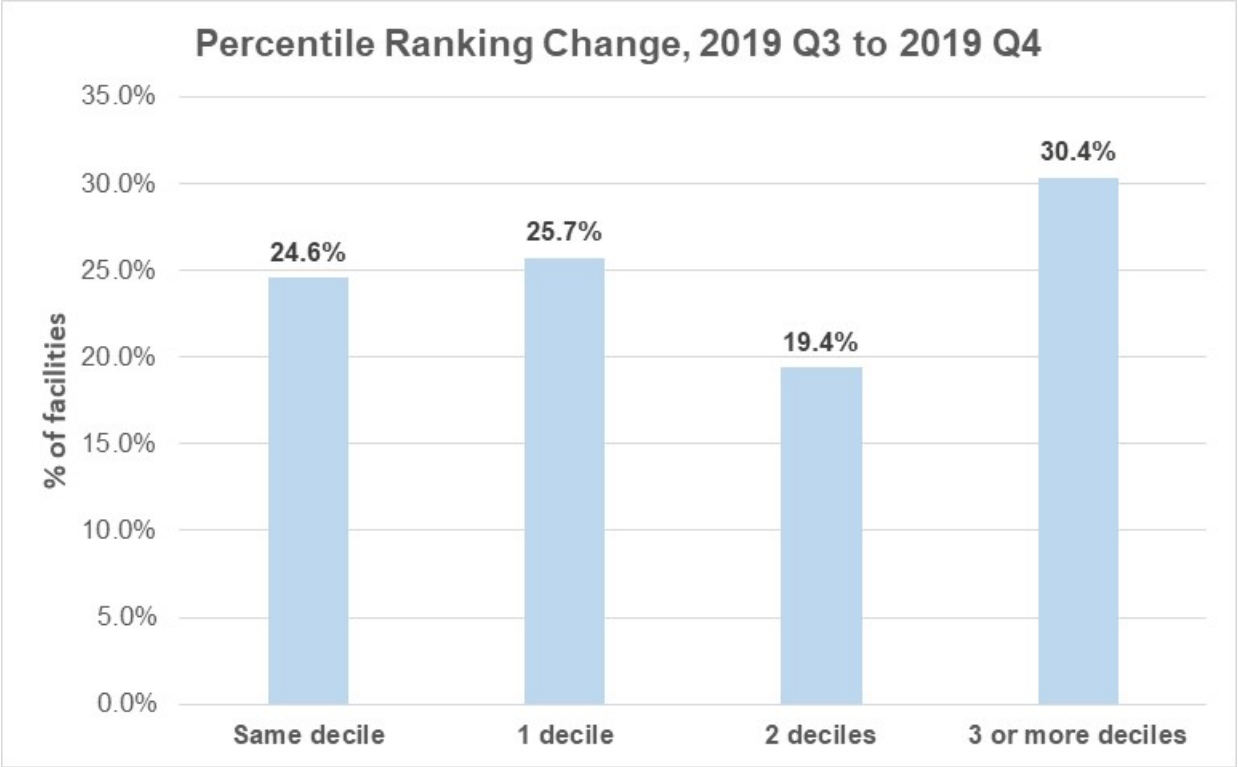
c. Seasonality: The seasonal variation in the measure score was examined by plotting the mean and median national level scores for each quarter from FY2017 Q4 to FY2019 Q4. Slight seasonal variation was observed, as the mean score for this measure was higher in Quarter 1 and lower in Quarter 4. The highest mean score was 7.88% in FY2018 Q1 and the lowest mean score was 7.42% in FY2018 Q4. The results are presented in **Figure 1** below.

Figure 1. Trends over time for NQF #0679 Percent of High-Risk Residents with Pressure Ulcers (Long Stay)



d. Stability analysis: **Figure 2** illustrates the changes in facility rank by quality measure score from FY2019 Q3 to FY2019 Q4. Comparing ranks for these two quarters, 24.6% of facilities' percentile rankings were constant within the same decile, 25.7% of facilities changed rank within 1 decile, 19.4% changed rank within 2 deciles, and 30.4% changed rank by 3 or more deciles.

Figure 2. Decile Change in QM Ranks from FY2019 Q3 to FY2019 Q4, NQF #0679 Percent of High-Risk Residents with Pressure Ulcers (Long Stay)



e. Confidence interval analysis: **Table 4** shows the proportions of facilities that scored significantly higher or lower than the national facility-level mean in FY2019 Q4. For this analysis, statistical significance was determined using 95% confidence intervals. A facility's quality measure score was statistically significantly different from the national mean if the national mean was not within that facility's 95% confidence interval. This analysis was also stratified by decile of facility size based on the number of residents who qualify for the denominator count

14.5% of facilities had a score that was statistically significantly different from the national mean with 95% confidence. Approximately 9.3% of facilities had scores that were statistically significantly lower than the national mean, and 5.2% of facilities had scores that were statistically significantly higher than the national mean with 95% confidence. The percentage of facilities with scores significantly different from the mean decreased with the number of residents until the 8th decile, in which the percentage of facilities with scores significantly different from the mean began increasing with the number of residents. These findings indicate that there were higher proportions of small and large facilities that were statistically different from the mean than medium sized facilities. Small facilities are more likely to have perfect performance. On the other hand, their performance is more heavily affected by a single occurrence of pressure ulcer. Increases in the facility-level sample size lead to reductions in the standard error of facility-level scores.

Table 4. Proportion of Facilities with Scores Significantly Different from the National Facility-Level Mean, Stratified by Facility Denominator Size for NQF #0679, FY2019 Q4

Decile of denominator size in residents	Number of facilities	Number of facilities with 95% confidence interval lower than national mean (%): N	Number of facilities with 95% confidence interval lower than national mean (%): %	Number of facilities with 95% confidence interval higher than national mean (%): N	Number of facilities with 95% confidence interval higher than national mean (%): %	Total number of facilities with scores significantly different from mean (%): N	Total number of facilities with scores significantly different from mean (%): %
1st Decile	1,264	313	24.8%	48	3.8%	361	28.6%
2nd Decile	1,353	255	18.8%	40	3.0%	295	21.8%
3rd Decile	1,193	145	12.2%	41	3.4%	186	15.6%
4th Decile	1,351	121	9.0%	46	3.4%	167	12.4%
5th Decile	1,253	65	5.2%	55	4.4%	120	9.6%
6th Decile	1,334	64	4.8%	53	4.0%	117	8.8%
7th Decile	1,355	36	2.7%	79	5.8%	115	8.5%
8th Decile	1,413	32	2.3%	107	7.6%	139	9.8%
9th Decile	1,360	76	5.6%	87	6.4%	163	12.0%
10th Decile	1,343	125	9.3%	135	10.1%	260	19.4%
Total	**13,219**	**1,232**	**9.3%**	**691**	**5.2%**	**1,923**	**14.5%**

2b1.4. What is your interpretation of the results in terms of demonstrating validity? (i.e., *what do the results mean and what are the norms for the test conducted?*)

Performance Measure Score Validity

This measure has satisfactory item level validity, with some limited seasonal variation in which the highest mean score occurred in FY2018 Quarter 1 and the lowest mean score occurred in FY2018 Quarter 4. Higher rates of pressure ulcers occurring in winter months may be attributed to drier skin in the winter and/or winter illnesses that can lead to residents being bedridden. In addition, lower facility staffing levels during winter months could contribute to the higher rates of pressure ulcers. Nevertheless, seasonal variation is minimal in magnitude.

State-level variation is also a minimal source of variation. The proportion of variance in this measure explained by the state in which facilities are located was only 5.84% ($p < 0.001$).

The measure's correlation with related quality measures are all in the expected direction, which demonstrates strong convergence validity. This measure has modest negative correlations with Overall Facility Five-Star Ratings, Staffing Ratings, and Registered Nurse Staffing Ratings. This measure is modestly and positively correlated with Percent of SNF Residents with Pressure Ulcers That Are New or Worsened

(NQF #0678). There may be several reasons for the relatively low correlation between NQF #0679 and NQF #0678, including that they are focused on distinct patient populations (high-risk long-stay residents versus residents requiring skilled nursing care) and are both low frequency measures.

The confidence interval analysis for this measure indicates that 14.5% of facilities had a mean score for which the 95% confidence intervals did not overlap with the national mean. The proportion of facilities with scores that were significantly different from the national mean varied as a function of the number of residents included in the denominator for this measure. In general, more facilities with a lower number of residents had scores significantly lower than the mean than those with larger number of residents. As the facility size increased, a greater proportion of facilities had scores that were significantly higher than the national mean (i.e. worse performers). However, a greater share of the largest size facilities (10th deciles) were observed to have performance significantly lower than the mean than the proportion of mid-size facilities (i.e. those in the 5th and 6th deciles).

The stability analysis shows that while there were some changes from one quarter to another, 24.6% of facilities remained in the same decile and an additional 45.1% of facilities had score changes of 2 deciles or less in the next quarter.

2b2. EXCLUSIONS ANALYSIS

NA ☐ no exclusions — *skip to section 2b3*

2b2.1. Describe the method of testing exclusions and what it tests (*describe the steps—do not just name a method; what was tested, e.g., whether exclusions affect overall performance scores; what statistical analysis was used*)

Please see **Section 2b6**. "Missing data analysis and minimizing bias for analysis of this measure's exclusions," which are only for missing data on the applicable pressure ulcer items.

2b2.2. What were the statistical results from testing exclusions? (*include overall number and percentage of individuals excluded, frequency distribution of exclusions across measured entities, and impact on performance measure scores*)

Please see **Section 2b6**. "Missing data analysis and minimizing bias for analysis of this measure's exclusions," which are only for missing data on the applicable pressure ulcer items.

2b2.3. What is your interpretation of the results in terms of demonstrating that exclusions are needed to prevent unfair distortion of performance results? (*i.e., the value outweighs the burden of increased data collection and analysis.* ***Note****:* ***If patient preference is an exclusion****, the measure must be specified so that the effect on the performance score is transparent, e.g., scores with and without exclusion*)

Please see **Section 2b6**. "Missing data analysis and minimizing bias for analysis of this measure's exclusions," which are only for missing data on the applicable pressure ulcer items.

2b3. RISK ADJUSTMENT/STRATIFICATION FOR OUTCOME OR RESOURCE USE MEASURES

If not an intermediate or health outcome, or PRO-PM, or resource use measure, skip to section 2b4.

2b3.1. What method of controlling for differences in case mix is used?

☒ **No risk adjustment or stratification**

☐ **Statistical risk model with risk factors**

☐ **Stratification by risk categories**

☐ **Other,**

2b3.1.1 If using a statistical risk model, provide detailed risk model specifications, including the risk model method, risk factors, coefficients, equations, codes with descriptors, and definitions.

Not applicable. This measure is not risk-adjusted.

2b3.2. If an outcome or resource use component measure is not risk adjusted or stratified, provide rationale and analyses to demonstrate that controlling for differences in patient characteristics (case mix) is not needed to achieve fair comparisons across measured entities.

The measure is not risk adjusted through a statistical model nor through stratification. However, clinical factors for risk adjustment were explored and a relevant clinical factor was tested statistically. The discussion is presented in **Section 2b3.3a** below.

2b3.3a. Describe the conceptual/clinical and statistical methods and criteria used to select patient factors (clinical factors or social risk factors) used in the statistical risk model or for stratification by

risk (*e.g., potential factors identified in the literature and/or expert panel; regression analysis; statistical significance of p<0.10; correlation of x or higher; patient factors should be present at the start of care*). **Also discuss any "ordering" of risk factor inclusion**; for example, are social risk factors added after all clinical factors?

Risk Adjustor Selection – Conceptual Rationale and Statistical Testing

Social Risk Factors

- Age: Older residents may be at higher risk for developing pressure ulcers due to their frail skin (Siebert et al., 2020).
- Race: White residents may be at lower risk for developing pressure ulcers than Black residents because facilities with higher concentrations of Black residents tend to have lower staffing levels of registered nurses and certified nursing assistants, and tend to be larger, for-profit, urban facilities (Li, et al., 2011)

References:

1. Seibert, Julie, Daniel Barch, Amarilys Bernacet, Amy Kandilov, Jennifer Frank, Lindsey Free, Quantesa Roberts, et al. (2020). Examining social risk factors in a pressure ulcer quality measure for three post-acute care settings. Advances in Skin and Wound Care 33 (3): 156–63. https://doi.org/10.1097/01.ASW.0000651456.30210.8a.
2. Li, Yue, Jun Yin, Xueya Cai, Helena Temkin-Greener, and Dana B. Mukamel. (2011). Association of race and sites of care with pressure ulcers in high-risk nursing home residents. Journal of the American Medical Association 306 (2): 179–86. https://doi.org/10.1001/jama.2011.942.

2b3.3b. How was the conceptual model of how social risk impacts this outcome developed? Please check all that apply:

☒ **Published literature**

☒ **Internal data analysis**

☐ **Other (please describe)**

2b3.4a. What were the statistical results of the analyses used to select risk factors?

Internal data analysis

Variables were created for the risk factor described above as follows:

- Age: Defined by the birth date reported on item A0900 on the MDS. A resident was defined as being aged if they were 85 years of age or older (as of the target assessment).
- Race: Defined by item A1000 on the MDS. A resident was defined as being white if item A1000F was checked in the MDS and non-white otherwise (as of the target assessment).

The results of the risk-adjustment model using age as a risk factor are summarized in **Table 5** below. Overall, the odds ratio for residents over the age of 85 is 0.73 and is statistically significant at the 5% level. The odds of developing pressure ulcers is almost 27% lower for residents over the age of 85 compared to younger residents. However, the C-statistic (0.54) of the model indicates weak model performance and suggests that the model does not have high predictive ability.

Table 5. Assessment of Alternate Risk Adjustment Specifications: Age as the Covariate, NQF #0679 (FY2019 Q4)

Model Covariates	Frequency of high risk residents w/ covariate value	Frequency of high risk residents with pressure ulcers	% of high risk residents with pressure ulcers	Odds Ratio	95% CI	95% CI	C statistic
Candidate model: (Base case: Age < 85)	440,912	37,180	8.4%	*	*	*	0.54
Age >= 85	309,038	19,351	6.3%	0.73	0.71	0.74	*

*cell intentionally left blank

The results of the risk-adjustment model using race as a risk factor are summarized in **Table 6** below. Overall, the odds ratio for non-white residents is 0.76 and is statistically significant at the 5% level. The odds of developing pressure ulcers is almost 24% lower for white high-risk residents compared to non-white high-risk residents. However, the C-statistic (0.53) of the model indicates weak model performance and suggests that the model does not have high predictive ability.

Table 6. Assessment of Alternate Risk Adjustment Specifications: Race as the Covariate, NQF #0679 (FY2019 Q4)

Model Covariates	Frequency of high risk residents w/ covariate value	Frequency of high risk residents with pressure ulcers	% of high risk residents with pressure ulcers	Odds Ratio	95% CI	95% CI	C statistic
Candidate model: (Base case: Non-White Residents)	205,408	18,427	9.0%	*	*	*	0.53
White Residents	544,542	38,104	7.0%	0.76	0.75	0.78	*

*cell intentionally left blank

2b3.4b. Describe the analyses and interpretation resulting in the decision to select social risk factors *(e.g., prevalence of the factor across measured entities, empirical association with the outcome, contribution of unique variation in the outcome, assessment of between-unit effects and within-unit effects.)* **Also describe the impact of adjusting for social risk (or not) on providers at high or low extremes of risk.**

The analysis in **Section 2b3.4a** indicates that residents over the age of 85 are less likely to develop pressure ulcers than younger residents. This observation is not in the expected direction, as we anticipated that advanced aged residents would be at higher risk for pressure ulcers than younger residents. We hypothesize that this is because younger residents receiving care in nursing homes are likely experiencing disabilities that leave them less mobile and at higher risk for developing pressure ulcers. Additionally, non-white residents are more likely to develop pressure ulcers than white residents. We hypothesize that this is because facilities with higher concentrations of Black residents tend to have lower staffing levels of registered nurses and certified nursing assistants, and therefore provide less care to residents who need assistance with their mobility (Li, et al., 2011). Although the results of all of the risk-adjustment models appear to be statistically significant at the 5% level, low C-Statistics were observed for these models. This suggests that the models do not have high predictive ability. Moreover, risk adjusting for advanced age and race may produce unintended consequences. The effect of advanced age is contrary to initial expectation, suggesting a more complicated mechanism. Given existing literature, the effect of race may be the result of facility-level decisions (e.g., staffing levels), and the purpose of the measure is to encourage improved decision-making for patient safety.

2b3.5. Describe the method of testing/analysis used to develop and validate the adequacy of the statistical model or stratification approach (*describe the steps—do not just name a method; what statistical analysis was used*). *Provide the statistical results from testing the approach to controlling for differences in patient characteristics (case mix) below*.

If stratified, skip to 2b3.9

This is not applicable. This measure is not risk-adjusted.

2b3.6. Statistical Risk Model Discrimination Statistics (*e.g., c-statistic, R-squared*)**:**

This is not applicable. This measure is not risk-adjusted.

2b3.7. Statistical Risk Model Calibration Statistics (*e.g., Hosmer-Lemeshow statistic*):

This is not applicable. This measure is not risk-adjusted.

2b3.8. Statistical Risk Model Calibration – Risk decile plots or calibration curves:

This is not applicable. This measure is not risk-adjusted.

2b3.9. Results of Risk Stratification Analysis:

This is not applicable. This measure is not risk-adjusted.

2b3.10. What is your interpretation of the results in terms of demonstrating adequacy of controlling for differences in patient characteristics (case mix)? (i.*e., what do the results mean and what are the norms for the test conducted*)

This is not applicable.

2b3.11. Optional Additional Testing for Risk Adjustment (***not required****, but would provide additional support of adequacy of risk model, e.g., testing of risk model in another data set; sensitivity analysis for missing data; other methods that were assessed*)

This is not applicable. This measure is not risk-adjusted.

2b4. IDENTIFICATION OF STATISTICALLY SIGNIFICANT & MEANINGFUL DIFFERENCES IN PERFORMANCE

2b4.1. Describe the method for determining if statistically significant and clinically/practically meaningful differences in performance measure scores among the measured entities can be identified (*describe the steps—do not just name a method; what statistical analysis was used? Do not just repeat the information provided related to performance gap in 1b)*

In order to identify meaningful differences in facility performance on NQF #0679, the current variability in the facility-level quality measure scores was explored (see 2b4.2). The proportions of facilities with scores for this measure that are significantly different from the national facility-level mean were also explored and stratified by facility denominator size (see 2b1.3). For this analysis, statistical significance was determined using 95% confidence intervals: a facility's quality measure score was significantly different from the national mean if the national mean was not included in the facility's 95% confidence interval. High-performing facilities should have scores that are significantly above average, and scores of low-performing facilities should be significantly below average. The analysis was stratified by facility denominator size to examine whether this feature of the measure varies by size.

2b4.2. What were the statistical results from testing the ability to identify statistically significant and/or clinically/practically meaningful differences in performance measure scores across measured entities? (e.g., *number and percentage of entities with scores that were statistically significantly different from mean or some benchmark, different from expected; how was meaningful difference defined*)

Table 7 describes the current variability in the quality measure scores of facilities nationally. The mean facility-level score for this quality measure was 7.5% in Quarter 4, 2019 with a median score of 6.8%. The interquartile range for this measure was 6.4 percentage points. Among facilities who were eligible to publicly report this measure, 8.0% (*k* = 1,058) had perfect scores of 0%.

Table 7. National Facility-Level Score Distribution, NQF #0679 Percent of High-Risk Residents with Pressure Ulcers (Long Stay), FY2019 Q4

K	Mean score	Std dev.	10th percentile	25th percentile	50th percentile	75th percentile	90th percentile	% of facilities with perfect score	Interquartile range
13,219	7.5%	5.1%	1.7%	3.8%	6.8%	10.3%	14.0%	8.0%	6.4 % points

Table 4 in Section 2b1.3 above shows the proportions of facilities that scored statistically significantly higher or lower than the national facility-level mean in FY2019 Q4. Overall, 14.5% of facilities scored significantly differently than the national mean from in FY2019 Q4. The data were also stratified by the facility denominator size to examine the relationship between facility size and the reliability of facility scores. The proportions of facilities with scores that were significantly different from the national mean varied as a function of the number of residents included in the denominator for this measure. In this 95% confidence interval analysis the percentage of facilities with scores that were statistically significantly different from the mean decreased as the number of residents increased up until the 6th decile where the percentage of facilities began increasing, indicating that there were higher proportions of small and large facilities that were statistically different from the mean than medium sized facilities.

2b4.3. What is your interpretation of the results in terms of demonstrating the ability to identify statistically significant and/or clinically/practically meaningful differences in performance across measured entities? (i.*e., what do the results mean in terms of statistical and meaningful differences?*)

These analyses show that the quality measure score varies enough to make meaningful distinctions between high- and low-quality facilities. The 90th percentile is more than eight times higher than the 10th percentile, and there is substantial distinction between the first and the third quantile. Moreover, the quality measure scores vary sufficiently from the national mean that there are meaningful differences to differentiate the best and worst performers for this measure.

2b5. COMPARABILITY OF PERFORMANCE SCORES WHEN MORE THAN ONE SET OF SPECIFICATIONS *If* only one set of specifications, this section can be skipped.

Note*: This item is directed to measures that are risk-adjusted (with or without social risk factors)* ***OR*** *to measures with more than one set of specifications/instructions (e.g., one set of specifications for how to identify and compute the measure from medical record abstraction and a different set of specifications for claims or eMeasures). It does not apply to measures that use more than one source of data in one set of*

specifications/instructions (e.g., claims data to identify the denominator and medical record abstraction for the numerator). ***Comparability is not required when comparing performance scores with and without social risk factors in the risk adjustment model. However, if comparability is not demonstrated for measures with more than one set of specifications/instructions, the different specifications (e.g., for medical records vs. claims) should be submitted as separate measures.***

2b5.1. Describe the method of testing conducted to compare performance scores for the same entities across the different data sources/specifications (*describe the steps—do not just name a method; what statistical analysis was used*)

This is not applicable.

2b5.2. What were the statistical results from testing comparability of performance scores for the same entities when using different data sources/specifications? (*e.g., correlation, rank order*)

This is not applicable.

2b5.3. What is your interpretation of the results in terms of the differences in performance measure scores for the same entities across the different data sources/specifications? (i.*e., what do the results mean and what are the norms for the test conducted*)

This is not applicable.

2b6. MISSING DATA ANALYSIS AND MINIMIZING BIAS

2b6.1. Describe the method of testing conducted to identify the extent and distribution of missing data (or nonresponse) and demonstrate that performance results are not biased due to systematic missing data (or differences between responders and non-responders) and how the specified handling of missing data minimizes bias (*describe the steps—do not just name a method; what statistical analysis was used*)

> Missing data represent a potential threat to the validity of a quality measure. Bias may be introduced if missing data is associated with resident or facility characteristics. Therefore, the rate of missing data per total number of assessments was examined. The results of this assessment are discussed in **Section 2b6.2.**

2b6.2. What is the overall frequency of missing data, the distribution of missing data across providers, and the results from testing related to missing data? (*e.g., results of sensitivity analysis of the effect of various rules for missing data/nonresponse;* ***if no empirical sensitivity analysis****, identify the approaches for handling missing data that were considered and pros and cons of each*)

Based on analyses of MDS 3.0 data, missing data is not a threat to validity for this measure as very few resident episodes were excluded from the QM calculation due to missing data (an episode is excluded if the resident's target (latest qualifying) assessment is an OBRA Admission assessment (A0310A = [1]) ***or*** a PPS 5-Day assessment (A0310B = [1]), or if the number of various staged pressure ulcers were not assessed (M0300B1 = [-] ***or*** M0300C1 = [-] ***or*** M0300D1 = [-] ***or*** M0300E1 = [-] ***or*** M0300F1 = [-] ***or*** M0300G1 = [-])). Only 25 episodes in the FY2019 Q4 high-risk long stay resident sample were excluded from the denominator for this measure, which accounts for 0.01% of the total episodes.

2b6.3. What is your interpretation of the results in terms of demonstrating that performance results are not biased due to systematic missing data (or differences between responders and non-responders) and how the specified handling of missing data minimizes bias**?** (i.*e., what do the results mean in terms of supporting the selected approach for missing data and what are the norms for the test conducted;* ***if no empirical analysis****, provide rationale for the selected approach for missing data*)

There were too few residents excluded due to missing data to warrant concern over missing data introducing bias into the measure. Additionally, the number of excluded cases was too small to test for any kind of differences between facilities. Therefore, no further analyses were performed regarding missing data and this measure.

3. Feasibility

Extent to which the specifications including measure logic, require data that are readily available or could be captured without undue burden and can be implemented for performance measurement.

3a. Byproduct of Care Processes

For clinical measures, the required data elements are routinely generated and used during care delivery (e.g., blood pressure, lab test, diagnosis, medication order).

3a.1. Data Elements Generated as Byproduct of Care Processes.

Generated or collected by and used by healthcare personnel during the provision of care (e.g., blood pressure, lab value, diagnosis, depression score)

If other:

3b. Electronic Sources

The required data elements are available in electronic health records or other electronic sources. If the required data are not in electronic health records or existing electronic sources, a credible, near-term path to electronic collection is specified.

3b.1. To what extent are the specified data elements available electronically in defined fields (*i.e., data elements that are needed to compute the performance measure score are in defined, computer-readable fields*) Update this field for **maintenance of endorsement**.

ALL data elements are in defined fields in electronic clinical data (e.g., clinical registry, nursing home MDS, home health OASIS)

3b.2. If ALL the data elements needed to compute the performance measure score are not from electronic sources, specify a credible, near-term path to electronic capture, OR provide a rationale for using other than electronic sources. For **maintenance of endorsement**, if this measure is not an eMeasure (eCQM), please describe any efforts to develop an eMeasure (eCQM).

3b.3. If this is an eMeasure, provide a summary of the feasibility assessment in an attached file or make available at a measure-specific URL. Please also complete and attach the NQF Feasibility Score Card.

Attachment:

3c. Data Collection Strategy

Demonstration that the data collection strategy (e.g., source, timing, frequency, sampling, patient confidentiality, costs associated with fees/licensing of proprietary measures) can be implemented (e.g., already in operational use, or testing demonstrates that it is ready to put into operational use). For eMeasures, a feasibility assessment addresses the data elements and measure logic and demonstrates the eMeasure can be implemented or feasibility concerns can be adequately addressed.

3c.1. Required for maintenance of endorsement. Describe difficulties (as a result of testing and/or operational use of the measure) regarding data collection, availability of data, missing data, timing and frequency of data collection, sampling, patient confidentiality, time and cost of data collection, other feasibility/implementation issues.

IF instrument-based, consider implications for both individuals providing data (patients, service recipients, respondents) and those whose performance is being measured.

The general data collection method for the MDS 3.0 is currently in operational use and mandatory for all Medicare/Medicaid certified nursing facilities.

3c.2. Describe any fees, licensing, or other requirements to use any aspect of the measure as specified *(e.g., value/code set, risk model, programming code, algorithm)*.

This is not applicable.

4. Usability and Use

Extent to which potential audiences (e.g., consumers, purchasers, providers, policy makers) are using or could use performance results for both accountability and performance improvement to achieve the goal of high-quality, efficient healthcare for individuals or populations.

4a. Accountability and Transparency

Performance results are used in at least one accountability application within three years after initial endorsement and are publicly reported within six years after initial endorsement (or the data on performance results are available). If not in use at the time of initial endorsement, then a credible plan for implementation within the specified timeframes is provided.

4.1. Current and Planned Use

NQF-endorsed measures are expected to be used in at least one accountability application within 3 years and publicly reported within 6 years of initial endorsement in addition to performance improvement.

Specific Plan for Use	Current Use (for current use provide URL)
*	Public Reporting Care Compare https://www.medicare.gov/care-compare/ Provider Data Catalog https://data.cms.gov/provider-data/ Care Compare https://www.medicare.gov/care-compare/ Provider Data Catalog https://data.cms.gov/provider-data/ Quality Improvement (external benchmarking to organizations) Certification and Survey Provider Enhanced Reports (CASPER) https://www.qtso.com/providernh.html Quality Improvement (Internal to the specific organization) Certification and Survey Provider Enhanced Reports (CASPER) https://www.qtso.com/providernh.html

*cell intentionally left blank

4a1.1 For each CURRENT use, checked above (update for maintenance of endorsement), provide:

- Name of program and sponsor
- Purpose
- Geographic area and number and percentage of accountable entities and patients included
- Level of measurement and setting

Public Reporting:
•Program and sponsor: Care Compare and Provider Data Catalog/Centers for Medicare and Medicaid
•Purpose: Consumer information
•Geographic area and number and percentage of accountable entities and patients included: All United States Nursing Homes with Medicare-eligible long-stay residents. In quarter 4 of 2019 there were 15,104 eligible facilities and 773,332 residents with target assessments, and 13,219 facilities (87.5%) had sufficient sample size (20 or more long-stay residents included in the denominator) to report on this measure, and 749,950 residents (97.0%) were included in the calculation of this measure. Four individual quarter scores are publicly reported on Provider Data Catalog. To enhance measurement stability and reliability beyond a one-quarter measure, a four-quarter average version of the measure is publicly reported as part of the Five-Star Quality Rating System through Care Compare and Provider Data Catalog. Five-Star is a rating system CMS created to help consumers, families and care givers compare nursing homes more easily.
Quality Improvement with Benchmarking (external benchmarking to multiple organizations):
•Program and sponsor: Certification and Survey Provider Enhanced Reports (CASPER)/Centers for Medicare and Medicaid
•Purpose: Quality improvement
•Geographic area and number and percentage of accountable entities and patients included: All United States Medicare/Medicaid certified Nursing Homes with eligible long-stay residents regardless of denominator sample size. In quarter 4 of 2019 there were 15,104 eligible facilities and 773,332 residents with target assessments.
Quality Improvement (internal to the specific organization):
•Program and sponsor: Certification and Survey Provider Enhanced Reports (CASPER)/Centers for Medicare and Medicaid
•Purpose: Quality improvement
•Geographic area and number and percentage of accountable entities and patients included: All United States Medicare/Medicaid certified Nursing Homes with eligible long-stay residents regardless of denominator sample size. In quarter 4 of 2019 there were 15,104 eligible facilities and 773,332 residents with target assessments.

4a1.2. If not currently publicly reported OR used in at least one other accountability application (e.g., payment program, certification, licensing) what are the reasons? (*e.g., Do policies or actions of the developer/steward or accountable entities restrict access to performance results or impede implementation?*)
This is not applicable; this measure is publicly reported.

4a1.3. If not currently publicly reported OR used in at least one other accountability application, provide a credible plan for implementation within the expected timeframes -- any accountability application within 3 years and publicly reported within 6 years of initial endorsement. (*Credible plan includes the specific program, purpose, intended audience, and timeline for implementing the measure within the specified timeframes. A plan for accountability applications addresses mechanisms for data aggregation and reporting.*)

This is not applicable; this measure is publicly reported.

4a2.1.1. Describe how performance results, data, and assistance with interpretation have been provided to those being measured or other users during development or implementation.

How many and which types of measured entities and/or others were included? If only a sample of measured entities were included, describe the full population and how the sample was selected.

This quality measure (NQF #0679, Percent of High-Risk Residents with Pressure Ulcers (Long Stay) is part of the Nursing Home Quality Initiative (NHQI). Information on this measure is available to both nursing home providers and to the public.

All United States Medicare and/or Medicaid certified nursing home providers may view their performance results for this and other NHQI measures via the Certification and Survey Provider Enhanced Reports (CASPER) system. These CASPER MDS 3.0 QM reports are intended to provide nursing home providers with feedback on their quality measure scores, helping them to improve the quality of care delivered to their residents. CASPER

MDS 3.0 reports also include Resident-Level Quality Measure Reports, which allow providers to identify the residents that trigger a particular quality measure (by scanning a column of interest and looking for the residents with an "X") and to identify residents who trigger multiple quality measures. Providers can use this information to target residents for quality improvement activities. Quality measure reports are also available to state surveyors and facility staff through the CASPER reporting system.

Consumers, including current and prospective nursing home residents and their families/caregivers, may access nursing home performance scores on this quality measure via the Care Compare website (https://www.medicare.gov/care-compare/?providerType=NursingHome) or the Provider Data Catalog (https://data.cms.gov/provider-data/). The Care Compare site reports the four-quarter average, while the Provider Data Catalog site reports the one-quarter version of the measure alongside the four-quarter average.

CMS also publishes composite quality ratings on Care Compare via the Five-Star Rating System. Five-Star features an overall quality rating of one to five stars based on nursing home performance on three domains, each of which has its own rating. The four-quarter version of this quality measure (NQF #0679, Percent of High-Risk Residents with Pressure Ulcers (Long Stay)) is one of the clinical measures that contribute to the rating of the Quality Measures domain of Five-Star. The Five-Star program requires the measure denominator to include at least 20 residents' assessments across four quarters of data.

Further, providers have an opportunity to review their performance prior to public reporting on the Nursing Home Compare website via Provider Preview Reports, also available through the CASPER system. These reports allow providers to view their quality measure scores for each NHQI measure, along with state and national averages for comparison, to identify potential errors in data submission or other information and request an update. These reports also allow providers to view their Five-Star rating. Detailed instructions on how to view and interpret reports, including an explanation of differences between the quality measure reports and publicly reported information, are provided in the CASPER Reporting MDS Provider Users Guide, Section 11, which can be found at the following website:
https://qtso.cms.gov/system/files/qtso/cspr_sec11_mds_prvdr_0.pdf

4a2.1.2. Describe the process(es) involved, including when/how often results were provided, what data were provided, what educational/explanatory efforts were made, etc.

The CASPER reports are available to providers on-demand with quality measure data updated monthly. Care Compare reports the rolling average of four quarters for the quality measure, comparing each nursing home's score to both the state and national average; providers can preview this information before it is publicly reported.

Detailed instructions on how to view and interpret reports, including an explanation of differences between the quality measure reports and publicly reported information, are provided in the CASPER Reporting MDS Provider Users Guide, Section 11, at the following website:
https://qtso.cms.gov/system/files/qtso/cspr_sec11_mds_prvdr_0.pdf

CMS provides technical users' guides (https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/CertificationandComplianc/Downloads/usersguide.pdf) on how the quality measures are used in the 5-star rating system, as well as a Help Line, which is accessible by telephone and email, to answer provider questions about the NHQI quality measures and reporting requirements.

4a2.2.1. Summarize the feedback on measure performance and implementation from the measured entities and others described in 4d.1.

Describe how feedback was obtained.

CMS is committed to receiving ongoing feedback on measures implemented as part of the NHQI. CMS takes into consideration feedback and input on measure performance and implementation through the appropriate sub-regulatory communication channels, including but not limited to: NQF public comment periods held as part of endorsement processes; feedback from providers submitted to the CMS quality measure support inboxes; and feedback from the provider community on Open Door Forums (ODFs).

4a2.2.2. Summarize the feedback obtained from those being measured.

Upon review of all inquiries submitted to the quality measure support inbox between 10/2019 and 02/2021, those being measured raised no concerns regarding the performance and implementation of NQF 0679.

4a2.2.3. Summarize the feedback obtained from other users

Upon review of all inquiries submitted to the quality measure support inbox between 10/2019 and 02/2021, other users raised no concerns regarding the performance and implementation of the LS PU measure.

4a2.3. Describe how the feedback described in 4a2.2.1 has been considered when developing or revising the measure specifications or implementation, including whether the measure was modified and why or why not.

This is not applicable.

Improvement

Progress toward achieving the goal of high-quality, efficient healthcare for individuals or populations is demonstrated. If not in use for performance improvement at the time of initial endorsement, then a credible rationale describes how the performance results could be used to further the goal of high-quality, efficient healthcare for individuals or populations.

4b1. Refer to data provided in 1b but do not repeat here. Discuss any progress on improvement (trends in performance results, number and percentage of people receiving high-quality healthcare; Geographic area and number and percentage of accountable entities and patients included.)

If no improvement was demonstrated, what are the reasons? If not in use for performance improvement at the time of initial endorsement, provide a credible rationale that describes how the performance results could be used to further the goal of high-quality, efficient healthcare for individuals or populations.

Progress (trends in performance results, number and percentage of people receiving high-quality healthcare)

- The national facility-level mean and median scores for the Percent of High Risk Residents with Pressure Ulcers demonstrate slight seasonal variation, with mean and median scores being higher in Quarter 1 and lower in Quarter 4 each year (See Figure 1 of NQF Testing Form). Overall, the national facility-level mean and median scores have decreased marginally and indicate a slight improvement in performance over time. The mean score for this measure was 7.53% in quarter 4 of 2017 and the median score was 6.90%. In Q4 2019, the mean and median were 7.45% and 6.82%, respectively.

Geographic area and number and percentages of accountable entities and patients included:

- All United States Nursing Homes with Medicare-eligible long-stay residents. In quarter 4 of 2019 there were 15,104 eligible facilities and 773,332 residents with target assessments, and 13,219 facilities (87.5%) had sufficient sample size (20 or more long-stay residents included in the denominator) to report on this measure, and 749,950 residents (97.0%) were included in the calculation of this measure.

4b2. Unintended Consequences

The benefits of the performance measure in facilitating progress toward achieving high-quality, efficient healthcare for individuals or populations outweigh evidence of unintended negative consequences to individuals or populations (if such evidence exists).

4b2.1. Please explain any unexpected findings (positive or negative) during implementation of this measure including unintended impacts on patients.

During the testing process for NQF #0679, the results of the risk-adjustment model using age as a risk factor demonstrated that the odds of developing pressure ulcers is almost 27% lower for residents over the age of 85 compared to younger residents (see Section 2b3.4a. of the Testing Form). This observation was not in the expected direction, as it was anticipated that advanced aged residents would be at higher risk for pressure ulcers than younger residents.

4b2.2. Please explain any unexpected benefits from implementation of this measure.

This is not applicable; there are no unexpected benefits from the implementation of NQF #0679.

5. Comparison to Related or Competing Measures

If a measure meets the above criteria **and** there are endorsed or new related measures (either the same measure focus or the same target population) or competing measures (both the same measure focus and the same target population), the measures are compared to address harmonization and/or selection of the best measure.

5. Relation to Other NQF-endorsed Measures

Are there related measures (conceptually, either same measure focus or target population) or competing measures (conceptually both the same measure focus and same target population)? If yes, list the NQF # and title of all related and/or competing measures.

Yes

5.1a. List of related or competing measures (selected from NQF-endorsed measures)

0201 : Pressure ulcer prevalence (hospital acquired)

0337 : Pressure Ulcer Rate (PDI 2)

0538 : Pressure Ulcer Prevention and Care

5.1b. If related or competing measures are not NQF endorsed please indicate measure title and steward.

n/a

5a. Harmonization of Related Measures

The measure specifications are harmonized with related measures;

OR

The differences in specifications are justified

5a.1. If this measure conceptually addresses EITHER the same measure focus OR the same target population as NQF-endorsed measure(s):

Are the measure specifications harmonized to the extent possible?

No

5a.2. If the measure specifications are not completely harmonized, identify the differences, rationale, and impact on interpretability and data collection burden.

0201 Pressure ulcer prevalence (hospital acquired). This measure has a similar focus but a different target population (hospital) and data source in addition to only capturing new or worsened pressure ulcers. # 0538 Pressure Ulcer Prevention and Care. This measure has a similar focus, but a different target population (home health patients) in addition to being a process measure focusing on pressure ulcer risk assessment, plan of care development, and prevention implementation. # 0337 Pressure Ulcer Rate (PDI 2). This measure has a similar focus, but a different target population (hospital). The measure only captures stage three and four ulcers and is claims based.

5b. Competing Measures

The measure is superior to competing measures (e.g., is a more valid or efficient way to measure);

OR

Multiple measures are justified.

5b.1. If this measure conceptually addresses both the same measure focus and the same target population as NQF-endorsed measure(s):

Describe why this measure is superior to competing measures (e.g., a more valid or efficient way to measure quality); OR provide a rationale for the additive value of endorsing an additional measure. (Provide analyses when possible.)

Not applicable. There are no competing measures.

Appendix

A.1 Supplemental materials may be provided in an appendix. All supplemental materials (such as data collection instrument or methodology reports) should be organized in one file with a table of contents or bookmarks. If material pertains to a specific submission form number, that should be indicated. Requested information should be provided in the submission form and required attachments. There is no guarantee that supplemental materials will be reviewed.

Attachment **Attachment:** NQF_0679_Measure_Submission_Appendix_20210402_Upload.docx

Contact Information

Co.1 Measure Steward (Intellectual Property Owner): Center for Medicare & Medicaid Services

Co.2 Point of Contact: Rebekah, Natanov, Rebekah.Natanov@cms.hhs.gov, 202-205-2913-

Co.3 Measure Developer if different from Measure Steward: Acumen LLC

Co.4 Point of Contact: Aathira, Santhosh, asanthosh@sphereinstitute.org, 650-558-8882-1256

Additional Information

Ad.1 Workgroup/Expert Panel involved in measure development

Provide a list of sponsoring organizations and workgroup/panel members' names and organizations. Describe the members' role in measure development.

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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.

Measure Developer/Steward Updates and Ongoing Maintenance

Ad.2 Year the measure was first released: 2002

Ad.3 Month and Year of most recent revision: 04, 2015

Ad.4 What is your frequency for review/update of this measure? Every 3 years

Ad.5 When is the next scheduled review/update for this measure? 04, 2021

Ad.6 Copyright statement: n/a

Ad.7 Disclaimers: n/a

Ad.8 Additional Information/Comments: n/a