

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**

Brief Measure Information

NQF #: 0680

Measure Title: Percent of Residents Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short-Stay)

Measure Steward: Centers for Medicare and Medicaid Services

Brief Description of Measure: This measure captures the percentage of short-stay nursing home residents who were assessed and appropriately given the influenza vaccine during the most recent influenza season. The influenza vaccination season (IVS) is defined as beginning on October 1, or when the vaccine first becomes available, and ends on March 31 of the following year. This measure is based on the NQF's National Voluntary Standards for Influenza and Pneumococcal Immunizations. The measure denominator consists of short-stay residents. Short-stay residents are identified as those who have had 100 or fewer days of nursing home care.

Note: While the IVS officially begins when the vaccine becomes available, which may be before October 1, the target period for the quality measure and references to the IVS for the denominator specification is from October 1 to March 31 of the following year. The numerator time window and references to the IVS in the numerator specifications may include residents who were assessed and offered the vaccine before October 1. This is based on how the influenza items were coded by the facility.

Developer Rationale: This process-based quality measure reports the percentage of short-stay nursing home residents who were assessed and appropriately given the seasonal influenza vaccine. Seasonal influenza vaccination is important to monitor in the nursing home population because of the substantial health threat that influenza poses to elderly populations. The Centers for Disease Control and Prevention (CDC) reports that influenza and pneumonia together have remained among the top ten most common causes of death for people aged 65 and older in the United States since 1999 (CDC, 2021). In fact, influenza alone caused 176,924 hospitalizations and 13,673 deaths among adults aged 65 and older during the 2019-2020 season (CDC, 2021). In addition to older age, influenza infection is also particularly threatening to people with comorbidities. Therefore, nursing home residents, who are older in age and likely to have comorbidities, are at high-risk for experiencing the adverse outcomes of influenza. In the short-stay nursing home population these comorbidities include impaired functional status, some cardiovascular conditions (atrial fibrillation, heart failure), and respiratory illnesses (pneumonia, asthma/COPD, respiratory failure) (Moyo et al, 2020).

Influenza vaccination is an effective preventative measure against infection, as well as hospitalization and mortality due to influenza. The CDC estimates that influenza vaccination averted 61,115 hospitalizations and 4,723 deaths in adults aged 65 years and older during the 2019-2020 influenza season (2020). This observation holds true in the nursing home population, as one recent prospective cohort study found that residents who received the influenza vaccine experienced a significant reduction in mortality compared to the unvaccinated nursing home population (Poscia et al, 2017). These researchers observed a 38% reduction (P<0.001) in the crude hazard ratio (CHR) for mortality in influenza vaccinated nursing home residents aged 65 and older as compared to their unvaccinated counterparts (Poscia et al, 2017). Furthermore, when adjusting for age, sex, number of diseases, cognitive performance, activities of daily living (ADL), and depression, influenza vaccination (CHR = 0.80; 95% CI 0.66–0.97) was associated with a statistically significant reduction in mortality for vaccinated residents compared to the unvaccinated population (Poscia et al, 2017). These findings were further corroborated in a retrospective cohort study that evaluated the effectiveness of influenza vaccination during multiple outbreaks in long term care facilities in 2017. Ng et al determined vaccine effectiveness by estimating the ratio of the odds of testing positive for influenza among vaccinated individuals to the odds among unvaccinated individuals and then adjusted for age, gender, calendar month, and number of days from illness onset to date of sample collection (2017). The results demonstrated that vaccine effectiveness varies by the length of the post-vaccination period, with the highest vaccine effectiveness occurring between 15 and 180 days post vaccination (59.3%; p=0.01). The findings from Ng et al, as well as Poscia et al, suggest that vaccination is highly effective at reducing infection and mortality in the nursing home population.

References:

Centers for Disease Control and Prevention, National Center for Health Statistics. Underlying Cause of Death 1999-2020 on CDC WONDER Online Database, released in 2021. Data are from the Multiple Cause of Death Files, 1999-2020, as compiled from data provided by the 57 vital statistics jurisdictions through the Vital Statistics Cooperative Program. Accessed at http://wonder.cdc.gov/ucd-icd10.html

Centers for Disease Control and Prevention (CDC). (2020). Estimated influenza illnesses, medical visits, and hospitalizations averted by vaccination in the United States – 2019–2020 influenza season. https://www.cdc.gov/flu/about/burden-averted/2019-2020.htm.

Moyo, P., Zullo, A.R., McConeghy, K.W. Bosco, E., van Aalst, R., Chit, A., & Gravenstein, S. (2020). Risk factors for pneumonia and influenza hospitalizations in long-term care facility residents: a retrospective cohort study. BMC Geriatrics, 20(47). https://doi.org/10.1186/s12877-020-1457-8

Ng, Y., Nandar, K., Chua, L., Mak, T. M., Foo, K., Muhammad, I. R., Low, C., Ma, S., Ooi, S. P., Lin, R., James, L., & Lee, V. (2019). Evaluating the effectiveness of the influenza vaccine during respiratory outbreaks in Singapore's long term care facilities, 2017. Vaccine, 37(29): 3925–3931. https://doi.org/10.1016/j.vaccine.2019.03.054

Poscia, A., Collamati, A., Carfi, A., Topinkova, E., Richter, T., Denkinger, M., Pastorino, R., Landi, F., Ricciardi, W., Bernabei, R., & Onder, G. (2017). Influenza and pneumococcal vaccination in older adults living in nursing home: a survival analysis on the shelter study. European Journal of Public Health, 27(6): 1016–1020. https://doi.org/10.1093/eurpub/ckx15.

Numerator Statement: The numerator is the number of residents in the denominator sample who, during the numerator time window, meet any one of the following criteria:

- 1. Resident received the influenza vaccine during the most recent influenza season, either in the facility or outside the facility; or
- 2. Resident was offered and declined the influenza vaccine; or
- 3. Resident was ineligible due to medical contraindication(s).

The numerator time window coincides with the most recently-completed seasonal IVS which begins on October 1 and ends on March 31 of the following year. However, the measure selection period uses a June 30 end date to ensure residents who do not have an assessment completed until after March 31 but were vaccinated between October 1 and March 31 are captured in the sample.

Denominator Statement: The denominator consists of residents 180 days of age and older on the target date of the assessment who were in the facility for at least one day during the most recently completed IVS, from October 1 to March 31 of the following year. If a nursing home resident has more than one episode during this time window, only the more recent episode is included in this measure.

Denominator Exclusions: Residents whose age is 179 days or less on the target date of the selected influenza vaccination assessment are excluded from this measure. Nursing homes with denominator counts of less than 20 short-stay residents in the sample are excluded from public reporting for the corresponding population due to small sample size.

Measure Type: Process Data Source: Assessment Data Level of Analysis: Facility IF Endorsement Maintenance – Original Endorsement Date: 03-03-2011 Most Recent Endorsement Date: 01-17-2017

Preliminary Analysis: Maintenance of Endorsement

To maintain NQF endorsement, endorsed measures are evaluated periodically to ensure that the measure still meets 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 *structure, process or intermediate outcome* measure are that it is based on a systematic review (SR) and grading of the body of empirical evidence where the specific focus of the evidence matches what is being measured. For measures derived from patient report, evidence also should demonstrate that the target population values the measured process or structure and finds it meaningful.

The developer provides the following description for this measure:

- This is a maintenance process measure at the facility level of analysis that measure captures the percentage of short-stay nursing home residents who were assessed and appropriately given the influenza vaccine during the most recent influenza season.
- The developer provides a logic model that depicts routine influenza immunization leads to prevention of and reduction in the severity of influenza illness.

The developer provides the following evidence for this measure:

- Systematic Review of the evidence specific to this measure? Xes
- Quality, Quantity and Consistency of evidence provided?
- Evidence graded?

- ☑ Yes
 □ Yes
 ☑ Yes
 ☑ No
- 3

Summary of prior review in 2016

- The developer cited guideline recommendations from the Centers for Disease Control (CDC) Advisory Committee on Immunization Practices ACIP recommendations published in the Morbidity and Mortality Weekly Report 64 (MMWR 64) in August 2015 that stated that vaccination should occur before onset of influenza activity in the community and continue to be offered as long as influenza viruses are circulating.
- The developer also cited evidence-based data that depicts the death rate for influenza and pneumonia in people 65 to 74 years old is 2.4 times that of a person 55 to 64 and the death rate for a person over the age of 85 is 36.1 times that of people 65 to 74 years of age.
- The developer also highlighted CDC findings which indicate that more than 200,000 people are hospitalized in the United States each year as a result of complications from influenza and influenza vaccine effectiveness (VE) rates have ranged from 50 to 60 percent in influenza-related hospitalization or pneumonia prevention and 30 to 40 percent in influenza illness prevention.
- Developer did not illustrate specific grading assigned to specific recommendations cited in the evidence submission, but the developer stated that ACIP unanimously voted during its October 2010 meeting to adopt the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach for developing evidence-based recommendations. The developer explained that the GRADE approach takes into account key factors for developing recommendations include the balance of benefits and harms, type or quality of evidence, values and preferences, and health economic analyses.

Changes to evidence from last review

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

 \boxtimes The developer provided updated evidence for this measure:

- The developer continued to indicate the Center for Disease Control's (CDC) Advisory Committee on Immunization Practices (ACIP) as the main source of support for this measure and is the basis of evidence for recommendations published most recently in Morbidity and Mortality Weekly Report (MMWR) 70 in August 2021.
- The developer noted inclusion of more recent evidence for the association between influenza and higher risk of hospitalization and increased mortality in the nursing home population.
 - The developer cited several recent studies that demonstrated that residents aged 65 and older who received the influenza vaccine experienced reduced mortality in influenza than their unvaccinated counterparts.
- The developer cites CDC findings which indicate that vaccination has proven to be an effective intervention for preventing hospitalization and mortality due to influenza. The developer adds CDC finding that estimates that influenza vaccination averted 61,115 hospitalizations and 4,723 deaths in adults aged 65 years and older during the 2019-2020 influenza season.
- The developer cites examination of 14 studies that investigated waning influenza vaccine effectiveness and found a significant decline in effectiveness within 180 days following vaccination for influenza A (H3N2) and influenza B, but not for influenza A(H1N1).

Exception to evidence

• N/A

- The evidence provided by the developer is updated, directionally the same, and stronger compared to that for the previous NQF review. Does the Committee agree there is no need for repeat discussion and vote on Evidence?
- What is the relationship of this measure to patient outcomes?
- How strong is the evidence for this relationship?
- Is the evidence directly applicable to the process of care being measured?

Guidance from the Evidence Algorithm

Not an outcome measure (Box 1) -> Process measure based on systematic review (Box 3) -> QQC not presented (Box 4)

*Without QQC from systematic review, moderate is the highest potential rating.

Preliminary rating for evidence:	🗌 High	🛛 Moderate	🗆 Low	Insufficient

1b. Gap in Care/Opportunity for Improvement and 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 developer provided summary statistics for the 2018-2019 influenza season. The developer displays performance within the 2018-2019 influenza season and compares 2018-2019 influenza season performance to the 2013-2014 influenza season performance.
 - Mean facility score: 83.9 percent (2018 2019); 81.6 percent (2013-2014)
 - 25th percentile: 78.4 (2018 2019); 75.3 (2013-2014)
 - 50th percentile: 90.0 (2018 2019); 87.1 (2013-2014)
 - 90th percentile: 98.9 (2018 2019); 97.4 (2013-2014)
 - Standard Deviation: 17.4 (2018 2019); 17.5 (2013-2014)
 - Interquartile range: 17.4 (2018 2019); 18.5 (2013-2014)
 - Percentage of facilities with a perfect score of 100 percent: 7.8 (2018 2019); 3.6 (2013-2014)
- The developer states that the national facility-level mean scores have remained relatively stable with a small increase between the 2013-2014 influenza season and the 2018-2019 influenza season. The developer cites the interquartile range of 17.4 percent for the 2018-2019 influenza season as an indication of the opportunity for improvement.

Disparities

- The developer presented performance scores for seasonal influenza vaccination by age, race, and socioeconomic status by proxy of Medicare eligibility status.
 - Mean influenza vaccination performance was higher for residents aged 85 or older (87.5 percent) than residents below the age of 85 (85.5 percent)
 - Mean influenza vaccination performance was highest for native Hawaiian or other pacific islander residents (89.15 percent) and lowest for black or African American residents (80.61 percent)

- Mean influenza vaccination performance was highest for residents who were Medicareeligible only (87.61 percent) and lowest for residents who were Medicaid-eligible only (79.27 percent)
 - Developer asserts that the Medicaid-eligible only population is less likely to be assessed and appropriately given a seasonal influenza vaccine than the Medicareeligible only population, indicating there is a relationship between socioeconomic status and influenza vaccination among short-stay residents.

Questions for the Committee:

• Is there a gap in care that warrants a national performance measure?

Preliminary rating for opportunity for improvement:	🗌 Hig	h 🛛 Moderate	🗆 Low 🗆
Insufficient			

Committee Pre-evaluation Comments:

1a. Evidence

- The evidence offered supports the importance of the measure to be maintained.
- Am not aware of new data that would impact this measure.
- There is evidence to support this measure. The measure continues to meet the NQF endorsement criteria.
- Additional evidence strengthens support for the measure.
- Rating moderate: Supported by systematic review w/o QQC, recent CDC ACIP recommendation, focused on high-risk group.
- There was strong evidence, based on systematic reviews and practice guidelines, in support of annual influenza vaccines for older individuals, and the evidence base has been strengthened since this measure was last approved. The developer does not, however, cite any specific practice guidelines for nursing home residents. It should be noted, however, that the numerator includes individuals who were offered and declined influenza vaccination essentially as successes. The guidelines, on the other hand, everyone be vaccinated. Thus, the measure is not consistent with the guidelines.
- They make a clear, logical, strong case for the measure.
- This is a process measure quality measure reports the percentage of short-stay nursing home residents who were assessed and appropriately given the seasonal influenza vaccine. The evidence is an updated systematic literature review, examining 14 studies, CDC findings, about the association between influenza and risk of hospitalization and increased mortality in the NH population.

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

- Disparity analyses were provided suggesting a moderate opportunity for improvement.
- Relatively high rates of vaccinations is there data that shows that increase from these rates would change morbidity/mortality outcomes? what is minimum population percent vaccine for meaningful change?
- The performance gap is measured by race, ethnicity, and even Medicaid versus Medicare status.
- Demonstrates gap in care, though gap is narrowing. Disparity evident in that Medicaid-eligible (lower SES) subgroup reflected lowest performance level.
- Rating moderate: Age/income/ethnic Gap disparities still exist

- Overall performance is below universal coverage. In addition, the develop cites evidence of disparities by age, race, Medicaid eligibility status (as a proxy for socio-economic status).
- Solid evidence of gaps; Strong evidence of economic, racial inequities
- The developer presented performance scores for seasonal influenza vaccination by age, race, and socioeconomic status by proxy of Medicare eligibility status.

Criteria 2: Scientific Acceptability of Measure Properties

Complex measure evaluated by Scientific Methods Panel? \Box Yes \boxtimes No

Evaluators: NQF Staff

2a. Reliability: Specifications and Testing

For maintenance measures – no change in emphasis – specifications should be evaluated the same as with new measures.

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 – less emphasis if no new testing data provided.

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 in the same time period and/or that the measure score is precise enough to distinguish differences in performance across providers.

Specifications:

- Measure specifications are clear and precise.
- The developer attests that there have been no changes to the measure specifications since the last measure update.

Reliability Testing:

- Reliability testing was conducted at the Patient/Encounter Level:
 - The developer conducted inter-rater reliability measures the extent to which two data collectors achieve the same results when assessing the same resident within the same time frame.
 - Two types of reliability were tested: gold-standard nurse to gold-standard nurse, and gold-standard nurse to facility-nurse.
 - Quality Improvement Organizations were employed to identify gold-standard (research) nurses and recruit community nursing facilities to participate in the national evaluation.
 - The gold-standard nurses were trained in the MDS 3.0 instrument, and they, in turn, trained a facility nurse from each participating nursing facility in their home states.
 - The gold-standard to gold-standard comparisons provided information on instrument performance with highly trained nurses using research protocols.
 - The gold-standard to facility-nurse comparisons measured item performance in a more operational environment in which one assessor had ongoing facility responsibilities.
 - Residents participating in the test were selected to capture a representative sample of short- and long-stay residents.
 - Kappa statistics were calculated to assess item reliability.

- The developer found kappa for gold-standard to gold-standard assessments of the influenza vaccination received in the facility item was 0.989; and the kappa for gold-standard nurse assessment to facility nurse assessment of the influenza vaccination received in the facility item was 0.941.
- The developer also found the kappa for gold-standard to gold-standard assessments of no influenza vaccination received and associated why item was 0.976; and the kappa for gold-standard nurse assessment to facility nurse assessment of no influenza vaccination received and associated why item was 0.815.
- The developer stated that kappa is a statistical measure of inter-rater agreement for qualitative data, ranging from 0.0 to 1.0, and a rating of 0.989 is considered "substantial agreement."
- Reliability testing was conducted at the Accountable Entity Level:
 - Data evaluation occurred in 12,907 nursing home facilities between 2018Q3 and 2019Q2 using the minimum data set (MDS) 3.0 data. The developer used two types of analyses:
 - Developer conduct split-half reliability in the short-stay population on all facilities with 40 or more residents (with at least 20 residents in each randomly selected half of a facility's residents) to determine the strength of internal consistency reliability and assess the correlation between each facility's measure scores.
 - R = 0.91; ICC = 0.91; p-value < .01
 - The developer notes these results suggest a position and strong correlative relationship between providers and substantial internal reliability. Developer conducted signal to noise analysis using a beta-binomial model.
 - Signal to noise ratio: 0.94
 - 25th percentile: 0.91
 - 50th percentile: 0.96
 - o 75th percentile: 0.99
- The developer notes these reliability testing results indicate strong reliability. The data reveals consistency in measures scores across percentiles and allows for the assertion that the influenza vaccination measure is reliable in its distinction of performance across and within facilities; variability is strongly attributable to between-provider differences in performance because of a signal to noise ratio that is near the value of one.

Questions for the Committee regarding reliability:

• Do you have any concerns that the measure cannot be consistently implemented (i.e., are measure specifications adequate)?

Preliminary rating for reliability: 🛛 High 🛛 Moderate 🖓 Low 🖓 Insufficient

2b. Validity: <u>Validity testing</u>; <u>Exclusions</u>; <u>Risk-Adjustment</u>; <u>Meaningful Differences</u>; <u>Comparability</u>; <u>Missing Data</u>

For maintenance measures – less emphasis if no new testing data provided.

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.

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

Validity Testing:

- Validity testing conducted at the Patient/Encounter Level:
 - Using the same method as outlined in reliability testing, the developer conducted criterion validity testing by comparing facility nurses and gold-standard nurses who assessed the same residents using the MDS 3.0. The developer conducted inter-rater reliability, comparing 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.
 - Two types of reliability were tested: gold-standard nurse to gold-standard nurse, and goldstandard nurse to facility-nurse.
- The developer found the kappa score for gold-standard nurse assessment to facility nurse assessment of the influenza vaccination received in the facility item (0.941) and for gold-standard nurse assessment to facility nurse assessment of no influenza vaccination received and associated why item (0.815) demonstrated high consistency and nearly perfect agreement among nurses completing the assessment.
- The developer stated that the results also indicate strength in the quality and correctness of the data element.
- Validity testing conducted at the Accountable Entity Level:
 - Developer uses convergent validity testing to correlate the scores between comparative assessment tools. The assumption of this testing method is that measures which share similar constructs should be highly correlated.
 - The developer derived its testing results from publicly reported data and generated Spearman correlation coefficients.
 - Developer formed three distinct hypotheses:
 - A facility's percentile ranking should be consistent among related vaccination measures
 - Developer attributes the modest strength of correlation to the likelihood of differences in the vaccination schedules for the pneumococcal and influenza vaccines and population differences between the short-stay and long-stay influenza vaccination measures. Correlations between NQF #0680 and the related vaccination measures will be higher than the correlations with other measures
 - The developer states results indicate moderate convergent validity and confirm the hypothesis
 - Percent of Residents Assessed and Appropriately Given the Pneumococcal Vaccine (Short-Stay) – 0.728
 - Percent of Residents Assessed and Appropriately Given the Influenza Vaccine (Long-Stay) 0.586
 - Discharge to Community 0.200A facility's percentile ranking (compared to all facilities reporting the measure) should be consistent among those facility Five-Star ratings
 - The developer states Spearman correlation coefficients between NQF #0680 and Facility Five-Star Ratings (all generate p-value < .0001) results indicate low to moderate convergent validity.
 - Overall facility ratings: 0.299
 - Quality ratings: 0.236
 - Staffing ratings: 0.157
 - Registered nurse staffing ratings: 0.110
 - Survey ratings: 0.258

Exclusions

• The developer notes one qualifier for resident episode exclusion, which is resident's age on target date of selected target assessment as 179 days or less. This exclusion accounts for a negligible proportion (0.009%) of the total resident episodes.

Risk-Adjustment

• The measure is not risk adjusted or stratified.

Meaningful Differences

- The developer assessed variability in the facility-level quality measure scores and analyzed the corresponding intervals to indicate meaningful differences in facility-level scores for this measure.
 - 83.9 percent mean facility-level score and 60.2 percent of facilities had a mean score for which the 95 percent confidence intervals did not overlap with the national mean.
 - The 90th percentile is more than 1.5 times higher than the 10th percentile.
- The developer suggests that the analyses demonstrates that the quality measure score varies enough to make meaningful distinctions between high- and low-quality facilities.

Missing Data

- The developer advised that, based on the Minimum Data Set (MDS) 3.0 data, missing data is not a threat to validity.
- The developer notes no concerns and explains that nursing homes are required, via the MDS form, 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 and the likelihood for missing data is low.
- The developer assessed the rate of missing data per total number of assessments on the basis of exclusions and determined that there are no concerns regarding missing data.

Comparability

• The measure only uses one set of specifications for this measure.

Questions for the Committee regarding validity:

• Do you have any concerns regarding the validity of the measure (e.g., exclusions, risk-adjustment approach, etc.)?

Preliminary rating for validity: 🛛 High 🗆 Moderate 🗆 Low 🗆 Insufficient

Committee Pre-evaluation Comments:

2a1. Reliability – Specifications

- Reliability analyses were provided that document the measure's reliability.
- No issue.

- No concerns. The reliability rating is high.
- No concerns re: reliability.
- Rating: High, Kappa stat range 0.815 to 0.989 nurse/facility, ACO level stat range 0.91 to 0.99.
- Reliability testing conducted at the patient/encounter and accountable entity levels, with good results.
- All clear.
- High level of reliability. The developer notes these reliability testing results indicate strong reliability. The data reveals consistency in measures scores across percentiles and allows for the assertion that the influenza vaccination measure is reliable in its distinction of performance across and within facilities; variability 8 is strongly attributable to between-provider differences in performance because of a signal to noise ratio that is near the value of one.

2a2. Reliability – Testing

- No concerns.
- No concerns.
- No concerns.
- No.
- No concerns.
- No concerns.
- No.

2b1. Validity – Testing

- No concerns.
- No.
- No concerns.
- Rating: kappa at nurse/facility 0.815 to 0.941, Spearman at ACO level 0.586, able to show meaningful differences w/o significant missing data.
- The developers report results from "Validity testing conducted at the Patient/Encounter Level" that are essentially the same as those reported for reliability testing. These results are appropriate for reliability, but not validity. However, the developers report appropriate convergent validity analyses at the accountable entity level.
- No concerns.
- No concerns.

2b2-2b3. Threats to validity (Exclusions, Risk Adjustment)

- No concerns.
- Risk adjustment is not used.
- No concerns.
- Lacks risk adjustment which would likely inform & be helpful in future refinements.
- No concerns.
- No concerns.
- No threats to validity. Data is not risk adjusted. Overall validity rated high.

2b4-2b7. Threats to validity (Statistically Significant Differences, Multiple Data Sources, Missing Data)

- No threats to validity noted.
- Intersectional data would be helpful next step (race+gender rates for Black women v white men, etc)
- No.
- No concerns.

- No, as mentioned above.
- No concerns.
- No concerns here; strong testing results; missing data not an issue.
- No threats to validity...Data is recorded in MDS 3.0. No issues / concerns with missing data.

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.

- The developer indicates that the data elements are generated or collected and used by healthcare personnel during the provision of care and are coded by someone other than person obtaining original information.
- The developer states that the measure relies on data elements that are defined in a combination of electronic sources and cites no difficulties in the collection of data.
- The developer notes that the general data collection method for the Minimum Data Set (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?
- Is the data collection strategy ready to be put into operational use?

Preliminary rating for feasibility: 🛛 High 🛛 Moderate 🖓 Low 🖓 Insufficient

Committee Pre-evaluation Comments:

3. Feasibility

- No concerns.
- No issues.
- The required elements are routinely generated.
- No concerns.
- Rating: high since existing active measurement with history
- Measure currently in wide use.
- No concerns.
- The general data collection method for the Minimum Data Set (MDS) 3.0 is currently in operational use and mandatory for all Medicare/Medicaid certified nursing facilities.

Criterion 4: Use and Usability

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?	\boxtimes Yes \square	No 🗆 UNCLEAR
Planned use in an accountability program?	🗆 Yes 🗆	No 🛛 NA

Accountability program details

- The developer reports that the measure is in use for public reporting in the Centers for Medicare and Medicaid Services (CMS) Care Compare and Provider Data Catalog.
- The developer reports that the measure is in use for internal and external quality improvement benchmarking via the Centers for Medicare & Medicaid Services Certification and Survey Provider Enhanced Reports (CASPER) program.

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 developer reported no feedback or concerns received by those being measured or other users regarding the performance and implementation of NQF #0680.

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 developer reports small increase between the 2013-2014 influenza season (2013Q3-2014Q2) and the 2018-2019 influenza season (2018Q3-2019Q2).
 - The developer reiterates that the mean score for this measure was 81.6 percent and the median score was 87.1 percent during the 2013-2014 season; the mean score for the measure was 83.9 percent and the median score was 90 percent during the 2018-2019 season.

4b2. Benefits vs. harms. Benefits of the performance measure in facilitating progress toward achieving highquality, 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

• Developer reports no unexpected findings during implementation.

Potential harms

• Developer reports no potential harms as a result of implementation.

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
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Committee Pre-evaluation Comments:

4a. Use

- The criteria for the measure for Accountability and Transparency are acceptable and have a preliminary rating passing it for use.
- This is an easily understood measure. Those being measured have been given performance results.
- No concerns.
- Rating: Moderate, since it is considered stable in data trend-probably needs measure refinement/evolution on next review date.
- No comments.
- No concerns.
- Publicly reported and accountability programs. The developer reports that the measure is in use for public reporting in the Centers for Medicare and Medicaid Services (CMS) Care Compare and Provider Data Catalog. The developer reports that the measure is in use for internal and external quality improvement benchmarking via the Centers for Medicare & Medicaid Services Certification and Survey Provider Enhanced Reports (CASPER) program.

4b. Usability

- Usability is acceptable.
- None.
- No identified unintended consequences.
- No concerns. Used for performance improvement and public reporting.

- Rating: likely moderate as an improvement tool as evidenced by the flat performance curve & ongoing disparities.
- No comments.
- No concerns.
- Developer did not report any potential harms. The benefits outweigh the harms.

Criterion 5: Related and Competing Measures

Related measures

• NQF #1659 Influenza Immunization

Harmonization

• The developer identified the differences, rationale, and impact on interpretability and data collection burden of NQF #1659. The developer explained that NQF #1659 targets a different population in multiple settings and does not include residents who experienced an influenza vaccination assessment but were not given the vaccine. The developer further states that NQF #1659 has a broader numerator that includes inpatients age six months and older who were screened for influenza vaccine status and were vaccinated prior to discharge if indicated.

Committee Pre-evaluation Comments:

5: Related and Competing Measures

- The measure developer noted that NQF #1659 is a related measure, but it targets a different population.
- None.
- There are related measures regarding vaccination for healthcare workers and the general public. They are being harmonized.
- Do not think harmonization is appropriate.
- Should measures # 1659 +0431 +0041 + 0680 be harmonized with a gap analysis to suggest new measure related refinements?
- All flu vaccine measures should have the same inclusion and exclusion criteria, consistent with NQF report of a few years ago.
- No concerns.
- Only one related measure #1659.

Public and NQF Member Comments (Submitted as of June 15, 2022)

Member Expression of Support

• No member submitted an expression of support.

Comments

 No NQF member and public comments were received in advance of the Standing Committee evaluation

RELIABILITY: SPECIFICATIONS

- 1. Have measure specifications changed since the last review? \Box Yes \boxtimes No
- 2. Are submitted specifications precise, unambiguous, and complete so that they can be consistently implemented? 🛛 Yes 🗌 No
- 3. Briefly summarize any changes to the measure specifications and/or concerns about the measure specifications.
 - The measure specifications are clear and precise and the developer attests that there have been no changes to the measure specifications since the last measure update.

RELIABILITY: TESTING

4. Did the developer conduct new reliability testing? 🛛 Yes 🛛 🗋 No

4a. If no, summarize the Standing Committee's previous feedback:

• N/A

4b. If yes, describe any differences between the new and old testing and summarize any relevant Standing Committee's feedback from the previous review:

- In the previous testing, developer conducted both critical data element reliability and performance measure score reliability. At the data element reliability level of testing, the developer reports on what it indicates as nearly perfect scores (i.e. the kappa statistic) for the item indicating whether the influenza vaccine was given gold-standard nurse to gold-standard nurse agreement. The corresponding kappa statistic for that item was .989, and the kappa for gold-standard nurse to facility nurse agreement was .941. The kappa statistic for the item requesting the reason the vaccine was not given for gold-standard nurse to gold-standard nurse agreement was .976, and the kappa for gold-standard nurse to facility nurse agreement was .820.
- At the performance measure score level, the developer conducted, in the previous testing, a confidence interval analysis. As a part of this analysis, the developer ran summary statistics on Inpatient Rehabilitation Facility Patient Assessment Instrument (IRF-PAI) v 1.2 data from October 1, 2014 to March 31, 2015 to show how many facilities and what proportions of the facilities differ from the nation mean facility score, by facility size. The developer found that two-thirds (66%) of facilities had measure scores that were either significantly better than or worse than the national mean. The developer suggests that there are meaningful differences in facility-level scores for this measure and that regardless of the facility size, the measure is able to identify those facilities that are performing well (higher than the national mean) and those that are performing less well (lower than the national mean).
- 5. Reliability testing level: 🛛 Accountable-Entity Level 🔲 Patient/Encounter Level 🔲 Neither
- 6. Reliability testing was conducted with the data source and level of analysis indicated for this measure: ☑ Yes □ No
- 7. If accountable-entity level and/or patient/encounter level reliability testing was NOT conducted or if the methods used were NOT appropriate, was **empirical VALIDITY testing** of patient-level data conducted?

🗆 Yes 🛛 No

- 8. Assess the method(s) used for reliability testing:
 - At the patient/encounter level, the developer conducted inter-rater reliability measures the extent to which two data collectors achieve the same results when assessing the same resident within the same time frame.

- Two types of reliability were tested: gold-standard nurse to gold-standard nurse, and gold-standard nurse to facility-nurse.
- Quality Improvement Organizations were employed to identify gold-standard (research) nurses and recruit community nursing facilities to participate in the national evaluation.
- The gold-standard nurses were trained in the MDS 3.0 instrument, and they, in turn, trained a facility nurse from each participating nursing facility in their home states.
- The gold-standard to gold-standard comparisons provided information on instrument performance with highly trained nurses using research protocols.
- The gold-standard to facility-nurse comparisons measured item performance in a more operational environment in which one assessor had ongoing facility responsibilities.
- Residents participating in the test were selected to capture a representative sample of short- and long-stay residents.
- Kappa statistics were calculated to assess item reliability.
 - The developer found kappa for gold-standard to gold-standard assessments of the influenza vaccination received in the facility item was 0.989; and the kappa for gold-standard nurse assessment to facility nurse assessment of the influenza vaccination received in the facility item was 0.941.
 - The developer also found the kappa for gold-standard to gold-standard assessments of no influenza vaccination received and associated why item was 0.976; and the kappa for gold-standard nurse assessment to facility nurse assessment of no influenza vaccination received and associated why item was 0.815.
 - The developer stated that kappa is a statistical measure of inter-rater agreement for qualitative data, ranging from 0.0 to 1.0, and a rating of 0.989 is considered "substantial agreement.".
- At the accountable entity Level, data evaluation occurred in 12,907 nursing home facilities between 2018Q3 and 2019Q2 using the minimum data set (MDS) 3.0 data. The developer used two types of analyses:
 - Developer conduct split-half reliability in the short-stay population on all facilities with 40 or more residents (with at least 20 residents in each randomly selected half of a facility's residents) to determine the strength of internal consistency reliability and assess the correlation between each facility's measure scores.

9. Assess the results of reliability testing

- The developer conducted validity testing at the patient or encounter level; additional reliability testing is not required. Developer conducted signal to noise analysis as influenza vaccination is a binary outcome, therefore, the developer estimates reliability using a beta-binomial model.
 - \circ ~ Signal to noise ratio: 0.94 ~
 - 25th percentile: 0.91
 - 50th percentile: 0.96
 - 75th percentile: 0.99
 - \circ $\;$ Developer provides the random split-half correlation in the short-stay population
 - R = 0.91; ICC = 0.91; p-value < .01
- The developer noted these results suggest a position and strong correlative relationship between providers and substantial internal reliability
- The developer noted these reliability testing results indicate strong reliability. The data reveals consistency in measures scores across percentiles and allows for the assertion that the influenza vaccination measure is reliable in its distinction of performance across and within facilities; variability

is strongly attributable to between-provider differences in performance because of a signal to noise ratio that is near the value of one.

10. 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.

 \boxtimes Yes \square No \square Not applicable

- 11. Was the method described and appropriate for assessing the reliability of ALL critical data elements?
 - □ Yes □ No ⊠ Not applicable (patient/encounter level testing was not performed)
- 12. **OVERALL RATING OF RELIABILITY** (taking into account precision of specifications and all testing results):

High (NOTE: Can be HIGH only if accountable-entity level testing has been conducted)

□ **Moderate** (NOTE: Moderate is the highest eligible rating if accountable-entity 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)

- 13. Briefly explain rationale for the rating of OVERALL RATING OF RELIABILITY and any concerns you may have with the approach to demonstrating reliability.
 - The developer demonstrates reliability testing at the accountable-entity level. Furthermore, the reliability testing methodology is deemed appropriate for the indicated level of analysis, and the results demonstrate strength in performance differentiation.

VALIDITY: TESTING

14. Did the developer conduct new validity testing? \boxtimes Yes \Box No

14a. If no, summarize the Standing Committee's previous feedback:

• N/A

14b. If yes, describe any differences between the new and old testing and summarize any relevant Standing Committee's feedback from the previous review:

• In the previous testing and similar to the current testing, developer conducted both critical data element and measure score validity. The measure score validity testing was supported by both empirical validity testing and a systematic assessment of face validity of performance measure score; the latter is a component unique to the old testing information. The developer noted that similar to the data element reliability testing conducted in the old testing, previous findings of the validity of the MDS items are applicable to the Inpatient Rehabilitation Facility Patient Assessment Instrument (IRF-PAI) items due to overlap in the IRF and nursing home population and nearly identical influenza assessment items.

15. Validity testing level (check all that apply):

NOTE: Empirical validity testing is expected at time of maintenance review; if not possible, justification is required.

- 16. If patient/encounter level validity testing was provided, was the method described and appropriate for assessing the accuracy of ALL critical data elements? NOTE: Data element validation from the literature is acceptable.
 - 🛛 Yes
 - 🗆 No

□ **Not applicable** (patient/encounter level testing was not performed)

- 17. Method of establishing validity at the accountable-entity level:
 - □ Face validity
 - Empirical validity testing at the accountable-entity level
 - □ N/A (accountable-entity level testing not conducted)
- 18. Was the method described and appropriate for assessing conceptually and theoretically sound hypothesized relationships?
 - oxtimes Yes
 - 🗆 No
 - □ Not applicable (accountable-entity level testing was not performed)
- 19. Assess the method(s) for establishing validity
 - The developer conducted validity testing at the patient/encounter Level. Via the RAND validation of the MDS 3.0 study, the developer compared nurses' assessments of the same residents using the MDS 3.0. The developer compared gold-standard research nurses to gold-standard nurses and compared gold-standard nurses to staff nurses trained by the gold-standard nurses and derived a kappa statistic.
 - The developer found a 0.941 Kappa score for gold-standard nurse assessment to facility nurse assessment of the influenza vaccination received in this facility.
 - The developer found a 0.815 Kappa for gold-standard nurse assessment to facility nurse assessment of the influenza if no influenza vaccination was received then why item.
 - The developer advised that a high kappa statistic demonstrates high consistency and nearly perfect agreement among nurses completing the assessment. The results also indicate strength in the quality and correctness of the data element. Data demonstrates sufficient validity at the data element level.
 - The developer conducted validity testing at the accountable entity level. The developer uses convergent validity testing to correlate the scores between comparative assessment tools. The assumption of this testing method is that measures which share similar constructs should be highly correlated. Developer derived its testing results from publicly reported data and generated Spearman correlation coefficients between NQF #0680 and the following three groups of measures be vaccination measures, Five-Star ratings, and other quality measures based on clinician recommendation or relevant literature.
 - Developer formed three distinct hypotheses:
 - A facility's percentile ranking should be consistent among related vaccination measures
 - Correlations between NQF #0680 and the related vaccination measures will be higher than the correlations with other measures
 - A facility's percentile ranking (compared to all facilities reporting the measure) should be consistent among those facility Five-Star ratings

20. Assess the results (s) for establishing validity

- At the patient/encounter level, the developer found a 0.941 Kappa score for gold-standard nurse assessment to facility nurse assessment of the influenza vaccination received in this facility. The developer found a 0.815 Kappa for gold-standard nurse assessment to facility nurse assessment of the influenza if no influenza vaccination was received then why item.
- In relation to the accountable entity level testing, the developer advised that a high kappa statistic demonstrates high consistency and nearly perfect agreement among nurses completing the assessment. The results also indicate strength in the quality and correctness of the data element. Data demonstrates sufficient validity at the data element level.
 - Correlations between NQF #0680 and Facility Five-Star Ratings (all generate p-value < .0001)

Facility Five Star Rating	Spearman Correlation		
Overall facility ratings	0.299		
Quality ratings	0.236		
Staffing ratings	0.157		
Registered nurse staffing ratings	0.110		
Survey ratings	0.258		

- The developer suggests low to moderate convergent validity as indicated by the low but statistically significant positive correlations between NQF #0680 and overall facility five-star ratings, quality ratings, staffing ratings, registered nurse staffing ratings, and survey ratings.
- Correlations between NQF #0680 and other MDS Quality Measures
 - The highest correlations that were found between NQF #0680 among other MDS Quality Measures are listed below and suggest moderate convergent validity. Results confirm the hypothesis that correlations between NQF #0680 and related vaccination measures are higher than the correlations with other measures due to the similar measure processes.
 - Percent of Residents Assessed and Appropriately Given the Pneumococcal Vaccine (Short-Stay) – 0.728
 - Percent of Residents Assessed and Appropriately Given the Influenza Vaccine (Long-Stay) 0.586
 - \circ Discharge to Community 0.200
- Developer attributes the modest strength of correlation to the likelihood of differences in the vaccination schedules for the pneumococcal and influenza vaccines and population differences between the short-stay and long-stay influenza vaccination measures.

VALIDITY: ASSESSMENT OF THREATS TO VALIDITY

21. Please describe any concerns you have with measure exclusions.

• The developer notes one qualifier for resident episode exclusion, which is resident's age on target date of selected target assessment as 179 days or less. This exclusion accounts for a negligible proportion (0.009%) of the total resident episodes.

22. Risk Adjustment

22a. Risk-adjustment method

\boxtimes	None (only answer Question 22b and	22e) [Statistical model		Stratification
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□ Other method assessing risk factors (please specify)

22b. If not risk-adjusted, is this supported by either a conceptual rationale or empirical analyses?

 \Box Yes \Box No \boxtimes Not applicable

22c. Social risk adjustment:

22c.1 Are social risk factors included in risk model?	🗆 Yes	🗌 No	🛛 Not applicable
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22c.2 Conceptual rationale for social risk factors included?

22c.3 Is there a conceptual relationship between potential social risk factor variables and the measure focus?
Yes No

22d. Risk adjustment summary:

22d.1 All of the risk-adjustment variables present at the start of care? \Box Yes \Box No

22d.2 If factors not present at the start of care, do you agree with the rationale provided for inclusion?

🗆 Yes 🛛 No

22d.3 Is the risk adjustment approach appropriately developed and assessed? □ Yes □ No
22d.4 Do analyses indicate acceptable results (e.g., acceptable discrimination and calibration)
□ Yes □ No

22d.5.Appropriate risk-adjustment strategy included in the measure?
Yes No

22e. Assess the risk-adjustment approach

- This measure does not use risk-adjustment.
- 23. Please describe any concerns you have regarding the ability to identify meaningful differences in performance.

For cost/resource use measures, does this measure identify meaningful differences about cost and resource use between the measured entities?

- The developer assessed variability in the facility-level quality measure scores and analyzed the corresponding intervals to indicate meaningful differences in facility-level scores for this measure. 83.9 percent mean facility-level score and 60.2 percent of facilities had a mean score for which the 95 percent confidence intervals did not overlap with the national mean. The 90th percentile is more than 1.5 times higher than the 10th percentile. The developer suggests that the analyses demonstrates that the quality measure score varies enough to make meaningful distinctions between high- and low-quality facilities.
- 24. Please describe any concerns you have regarding comparability of results if multiple data sources or methods are specified.
 - The measure uses one set of specifications for this measure.
- 25. Please describe any concerns you have regarding missing data.
 - There are no concerns regarding missing data.
- 26. 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 accountable-entity level testing has been conducted)

□ **Moderate** (NOTE: Moderate is the highest eligible rating if accountable-entity 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 accountable-entity level and the patient/encounter level is required; if not conducted, should rate as INSUFFICIENT.)
- 27. Briefly explain rationale for rating of OVERALL RATING OF VALIDITY and any concerns you may have with the developers' approach to demonstrating validity.
 - The developer demonstrates validity testing at both the patient/encounter level and the accountableentity level. The validity testing methodology is deemed appropriate for the indicated level of analysis. The developer demonstrates that the validity testing of data elements analyzes agreement with another authoritative source of the same information. The measure developer demonstrates that the measure data elements are correct and/or the measure score correctly reflects the quality of care provided, adequately identifying differences in quality.

ADDITIONAL RECOMMENDATIONS

- 28. 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.
 - No additional recommendations.

Criteria 1: 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

1ma.01. Indicate whether there is new evidence about the measure since the most recent maintenance evaluation. If yes, please briefly summarize the new evidence, and ensure you have updated entries in the Evidence section as needed.

[Response Begins]

Yes

[Yes Please Explain]

More recent literature (2016 - 2021) has been included in Section 1a.01 as evidence of the association between influenza and higher risk of hospitalization and increased mortality in the nursing home population. Evidence described in the most recent maintenance evaluation that was not mentioned in past maintenance cycles includes the link between facility characteristics, such as ownership status, facility size, and geographic location, and vaccination rates in the short-stay population. The updated evidence also addresses corollary outcomes, such as decreased infection, hospitalization, and mortality rates, as well as how staffing plays an important role in addressing such outcomes. For more details on new evidence about the influenza vaccine measure, please see the red text in Section 1a.01.

[Response Ends]

Please separate added or updated information from the most recent measure evaluation within each question response in the Importance to Measure and Report: Evidence section. For example:

2021 Submission:

Updated evidence information here.

2018 Submission:

Evidence from the previous submission here.

1a. Evidence

1a.01. Provide a logic model.

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.

[Response Begins]

2016 Submission: Evidence from the Previous Submission

Influenza is associated with increased morbidity and mortality in high-risk adult populations and the elderly (CDC, 2015). The death rate for influenza and pneumonia in people 65 to 74 years old is 2.4 times that of a

person 55 to 64; for a person over the age of 85, the death rate is 36.1 times that (Xu, Murphy, Kochanek, and Bastian, 2016). Influenza is particularly threatening to people with comorbidities, nursing home residents, who are more likely to have comorbidities, are especially susceptible to adverse outcomes of influenza. Nursing home residents frequently have two or more chronic conditions which, together with gradual deterioration of the immune system, make them more susceptible to influenza infection (Fulop et al., 2009). Annual seasonal vaccination is an essential element of a multi-faceted approach for preventing the spread of influenza and is an effective preventative measure against influenza-related hospitalization and death. According to the Centers for Disease Control and Prevention (CDC), more than 200,000 people are hospitalized in the United States each year as a result of complications from influenza (CDC, 2008). Among older persons, influenza vaccine effectiveness (VE) rates recently reported by the CDC have ranged from 50 to 60 percent in preventing influenza influenza ranged from 30 to 40 percent in preventing influenza illness, and have stayed constant at 80 percent in preventing influenza-related death (CDC, 2013; Chaves et al., 2015).

References:

Centers for Disease Control and Prevention (CDC). (2008, September). Influenza e-brief: 2008–2009 flu facts for policymakers. Retrieved from <u>http://www.cdc.gov/washington/pdf/flu_newsletter.pdf</u>.

Centers for Disease Control and Prevention (CDC). (2013). Prevention and control of seasonal influenza with vaccines. Recommendations of the Advisory Committee on Immunization Practices--United States, 2013-2014. *MMWR Recommendations and Reports*, *62*(RR-07), 1–43. Retrieved from http://www.ncbi.nlm.nih.gov/pubmed/24048214.

Centers for Disease Control and Prevention (CDC). (2015, December 10). Estimated influenza illnesses and hospitalizations averted by vaccination—United States, 2014–15 influenza season. http://www.cdc.gov/flu/about/disease/2014-15.htm.

Chaves, S. S., Perez, A., Miller, L., Bennett, N. M., Bandyopadhyay, A., Farley, and M. M., Finelli, L. (2015). Impact of prompt influenza antiviral treatment on extended care needs after influenza hospitalization among community-dwelling older adults. *Clinical Infectious Diseases*, *61*(12), 1807–1814. doi:10.1093/cid/civ733

Fulop, T., Pawelec, G., Castle, S., and Loeb, M. (2009) Immunosenescence and Vaccination in Nursing Home Residents *Aging and Infectious Diseases*, (48), 443-8. doi: 10.1086/596475

Xu, J., Murphy, S. L., Kochanek, K. D., and Bastian, B. A. (2016). Deaths: final data for 2013. *National Vital Statistics Report, 64*(2). Atlanta, GA: Centers for Disease Control and Prevention (CDC), Division of Vital Statistics.

2022 Submission: Updated Evidence Information

Outcomes and Risk Factors

This process-based quality measure assesses the percent of short-stay nursing home residents who were assessed and appropriately given the seasonal influenza vaccine. Influenza vaccination is important to monitor in the nursing home population because of the impact of influenza on health outcomes, as the virus is associated with higher risk of hospitalization and increased mortality (CDC, 2020).

Some nursing home residents are at higher risk for contracting influenza and experiencing hospitalization or mortality, as certain resident characteristics influence their susceptibility. Short-stay residents who are 85 years or older, have impaired functional status, and have certain cardiovascular (atrial fibrillation, heart failure) and respiratory conditions (pneumonia, asthma/COPD, respiratory failure) are at risk for hospitalization from influenza (Moyo et al, 2020). Furthermore, being admitted to the nursing home from a post-acute care (PAC) setting and receiving antibiotics or Beers criteria medications (potentially inappropriate medications that are not recommended for use among older adults in most circumstances) are also risk factors for hospitalization from influenza in the short-stay population (Moyo et al, 2020). In addition to these resident characteristics, the geographic region in which a facility is located also influences a resident's risk for contracting influenza. A recent retrospective cohort study observed that facilities located in the South and Midwest had the highest rates of influenza among all long term care facilities in the United States between

2013 and 2015 (Bosco et al, 2020). Researchers suggest that geographic variation in vaccination rates may explain the geographic variation in influenza infection rates among facilities (Bosco et al, 2020).

Vaccination has proven to be an effective intervention for preventing hospitalization and mortality due to influenza. In fact, the CDC estimates that influenza vaccination averted 61,115 hospitalizations and 4,723 deaths in adults aged 65 years and older during the 2019-2020 influenza season (2020). In fact, nursing home residents who receive the influenza vaccine experience a significant reduction in mortality compared to the unvaccinated nursing home population (Poscia et al, 2017). A recent prospective cohort study of European nursing home residents aged 65 and older observed a 38% reduction (P<0.001) in the crude hazard ratio (CHR) for mortality in influenza vaccinated residents as compared to unvaccinated residents (Poscia et al, 2017). Furthermore, when adjusting for age, sex, number of diseases, cognitive performance, activities of daily living (ADL), and depression, influenza vaccination (CHR = 0.80; 95% CI 0.66–0.97) was associated with a statistically significant reduction in mortality compared to the unvaccinated population (Poscia et al, 2017). These findings from Poscia et al are further corroborated by Ng et al, who evaluated the effectiveness of influenza vaccination during multiple outbreaks in Singapore's long term care facilities in 2017. Ng et al determined vaccine effectiveness by estimating the ratio of the odds of testing positive for influenza among vaccinated individuals to the odds among unvaccinated individuals and then adjusted for age, gender, calendar month, and number of days from illness onset to date of sample collection (2017). The results demonstrated that vaccine effectiveness varies by the length of the post-vaccination period, with the highest vaccine effectiveness occurring between 15 and 180 days post vaccination (59.3%; p=0.01). The findings from Ng et al, as well as Poscia et al, suggest that vaccination is highly effective at reducing infection and mortality in the nursing home population.

Despite the proven effectiveness of influenza vaccines in preventing infection and mortality, not all nursing home residents receive the vaccine during the influenza season. There are several clinical and social factors associated with lower vaccination rates among the short-stay population. At the facility level, higher percentages of residents who were physically restrained and higher percentages of residents experiencing a pressure ulcer are associated with lower influenza vaccination rates (Silva et al, 2021). At the patient level, one major indicator for influenza vaccine uptake is whether or not the resident refused the vaccine during the previous influenza season, as residents who refused the vaccine during the previous season are likely to refuse the vaccine during the current season (OR 0.04, 95% CI 0.01–0.15) (Tan et al, 2019). In addition to these clinical factors, race is a social risk factor that is associated with vaccination status among the short-stay population. Several studies have found that non-White nursing home residents are less likely to be vaccinated against influenza than White residents (Tan et al, 2019; Riester et al, 2021; Bardenheier et al, 2020). Bardenheier et al assessed the White-Black gap in influenza vaccination among US nursing home residents between the 2008–2009 and 2018–2019 influenza seasons and found a gap of 9.9 percentage points in vaccination rates (2020). This White-Black gap in influenza vaccination rates was most pronounced at the facility level, where facilities with a majority of Black residents generally had the lowest vaccination rates (Bardenheier et al, 2020). Furthermore, the racial disparity in influenza vaccination is greater in the short-stay population than the long-stay population. Riester et al investigated the Minimum Data Set (MDS) assessments of more than 1.5 million nursing home residents during the 2013-2014 influenza season and found that 67.2% of White, 55.1% of Black, and 54.5% of Hispanic short-stay residents received the influenza vaccine compared to 84.2%, 76.7%, and 80.8% of long-stay residents, respectively (2021). This evidence suggests that race plays a major role in influenza vaccination uptake among nursing home residents.

Evidence for link between structure and quality of care outcomes

Several nursing home characteristics may influence the uptake of influenza vaccines among nursing home residents, such as ownership status, facility size, and geographic location. Studies have found that government and non-profit nursing homes have higher influenza vaccination rates among residents than for-profit nursing homes (Pu et al, 2016; Travers et al, 2016). There is also evidence of small facilities (0-85 beds) and facilities located in the Northeastern states of the US having higher influenza vaccination rates among their residents (Pu et al, 2016; Travers et al, 2016). Furthermore, influenza vaccination rates increase as a nursing home's

overall five-star rating increases (Pu et al, 2016). These findings suggest facilities that provide higher quality of care also have higher resident vaccination rates against influenza.

In addition to resident influenza vaccination rates, corollary outcomes such as the rates of influenza infections, hospitalizations, and mortality are influenced by facility characteristics. Staffing levels, hours, specialties, and vaccination status all play a critical role in reducing influenza-related morbidity and mortality. To prevent the incidence of influenza among the short-stay population it is essential for facilities to ensure adequate staffing, as facilities that employ more licensed independent practitioners (physician assistants (PAs) and nurse practitioners (NPs)) and maintain higher registered nurse (RN) hours per resident per day have lower influenza incidence rates (Bosco et al, 2019). Staffing in a facility is also an important factor in influenza rates because of the risk that staff pose to nursing home residents. In fact, a recent observational study found that 42% of workers had gone to work while sick, and 54% of workers stated that facility policies posed challenges to their ability to remain home while sick (O'Neil et al, 2017). These findings highlight the risk that staff pose to nursing home residents, as well as the necessity of influenza vaccination for both nursing home residents and healthcare workers. Literature suggests that vaccinating healthcare workers in a facility against influenza decreases infection rates and increases protection against all-cause mortality for residents, as having 100% of workers vaccinated prevents up to 60% of influenza infections among residents (Jenkin et al, 2019). Beyond influenza infection, the vaccination of healthcare personnel (HCP) within a facility has also been found to reduce hospitalizations and deaths due to influenza among residents (Hayward et al, 2006; Lemaitre et al, 2009; Frentzel et al, 2020). This is why the Centers for Disease Control and Prevention (CDC) recommends all HCP, paid and unpaid, who have the potential for exposure to patients or infectious materials while working in any healthcare setting should receive the seasonal influenza vaccine (Grohskopf et al, 2021).

Despite the CDC's guidance and ample evidence supporting the importance of influenza vaccination among healthcare workers, vaccine uptake remains lower among HCP in long term care settings (LTC) compared to other settings. Vaccination coverage among LTC workers in the US has continuously decreased from 69.2% during the 2015–2016 influenza season to 68.0% and 67.4% during the 2016–2017 and 2017–2018 influenza seasons respectively (Black et al, 2016; Black et al, 2017; Black et al, 2018). One factor in the decreasing rates of HCP vaccination against influenza is prior vaccination history, as many studies have found that past vaccination history is one of the strongest determinants of vaccine uptake among HCP in LTC settings (Lai et al, 2020; Wong et al, 2018; Kenny et al, 2020). To increase vaccination uptake among HCP who did not previously receive the influenza vaccine, facilities must implement multifaceted interventions that involve establishing educational programs, developing new facility policies, scheduling kick-off events for staff, and providing incentives for vaccination to HCP in LTC settings (Ofstead et al, 2017). Such interventions have led to considerable increases in influenza vaccine uptake among HCP, with the majority citing education about resident protection as the main driver for receiving the vaccine (Ofstead et al, 2017; Boey et al, 2021).

Evidence for link between processes and quality of care outcomes

Key nursing home processes can be implemented to increase influenza vaccine uptake and reduce rates of infection, hospitalization, and mortality among nursing home residents. Although the CDC recognizes nursing home and LTC residents as high-risk and recommends vaccination for this population, vaccine effectiveness can vary widely during each influenza season (Grohskopf et al, 2021). In fact, the CDC estimates the vaccine effectiveness was between 34% and 42% for adults 65 years and older during the 2019-2020 influenza season (Grohskopf et al, 2021). Moreover, vaccination becomes less effective as people age because their immune systems become less responsive (Frentzel et al, 2020). This means that vaccination of nursing home residents is essential but not sufficient for preventing influenza infections, hospitalizations, and deaths. To address this gap in influenza prevention processes, the Society for Post-Acute and Long-Term Care (AMDA) and the CDC both argue that influenza vaccination among HCP is an important process for facilities to follow.

AMDA recommends that all HCP receive the influenza vaccination annually, regardless of whether or not their responsibilities require direct patient contact (Frentzel et al, 2020). To adhere to this recommendation and increase HCP influenza vaccination rates, Belgian researchers developed a ready-to-use instruction manual containing 24 possible interventions targeting barriers towards vaccinations in healthcare settings that could

be applied by LTC facilities (Boey et al, 2021). After the manual was implemented by 11 LTC facilities, researchers observed an increase in vaccination rates among healthcare workers from 54% in 2016 to 68% in 2017 (Boey et al, 2021). These results indicate that interventions at the facility level can improve influenza vaccination rates considerably among LTC staff. Another method for adhering to AMDA's recommendation is mandatory vaccination, as there is evidence for the effectiveness of mandates in increasing influenza vaccine uptake among LTC healthcare workers. However, the majority of facilities do not require influenza vaccination for staff, and HCP cite the lack of a mandate as the main reason for not receiving the vaccine (O'Neil et al, 2017; Black et al, 2018; Wong et al, 2018). Recent literature indicates that employer vaccine mandates have proven to be the most useful intervention for increasing vaccination uptake among HCP in the LTC setting (Yue et al, 2019; Bechini et al, 2020). However, employer vaccine mandates are more prevalent in US hospitals than in LTC facilities, as 28.4% of LTC personnel reported an employer mandate compared to 61.0% of hospital personnel (Yue et al, 2019). In addition to employer mandates, some studies have found evidence of a positive association between the availability of vaccination on-site at the workplace and increased vaccination (Yue et al, 2019; Nunn et al, 2017). This was one finding from a recent cross-sectional study that evaluated a LTC facility policy requiring healthcare workers to either receive the influenza vaccine annually or wear a mask in patient care areas during the influenza season (Nunn et al, 2017). Researchers observed an increased demand for influenza vaccines among 35% of LTC facilities that participated in the study (Nunn et al, 2017). These findings suggest that instituting policies that provide choices to HCP rather than mandates still increase uptake of the influenza vaccine in the facility, which can reduce the risk of infection and mortality for its residents.





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[Response Ends]

1a.02. Select the type of source for 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.

[Response Begins]

Clinical Practice Guideline recommendation (with evidence review)

[Response Ends]

If the evidence is not based on a systematic review, skip to the end of the section and do not complete the repeatable question group below. If you wish to include more than one systematic review, add additional tables by clicking "Add" after the final question in the group.

Evidence - Systematic Reviews Table (Repeatable)

Group 1 - Evidence - Systematic Reviews Table

1a.03. Provide the title, author, date, citation (including page number) and URL for the systematic review.

[Response Begins]

Guideline recommendations are from the Center for Disease Control's (CDC) Advisory Committee on Immunization Practices (ACIP) recommendations published most recently in MMWR 70 in August 2021. These guidelines are available at https://www.cdc.gov/mmwr/volumes/70/rr/pdfs/rr7005a1-H.pdf

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[Response Ends]

1a.04. Quote the guideline or recommendation verbatim about the process, structure or intermediate outcome being measured. If not a guideline, summarize the conclusions from the systematic review.

[Response Begins]

Summary of Recommendations, Changes, and Updates for the 2021-2022 Influenza Season (pp.7-8)

- Routine annual influenza vaccination is recommended for all persons aged ≥6 months who do not have contraindications. For each recipient, a licensed and age-appropriate vaccine should be used. ACIP makes no preferential recommendation for a specific vaccine when more than one licensed, recommended, and age-appropriate vaccine is available. During the 2021–22 influenza season, the following types of vaccines are expected to be available: inactivated influenza vaccines (IIV4s), recombinant influenza vaccine (RIV4), and live attenuated influenza vaccine (LAIV4).
- The 2021–22 influenza season is expected to coincide with continued circulation of SARS-CoV-2, the virus that causes COVID-19. Influenza vaccination of persons aged ≥6 months to reduce prevalence of illness caused by influenza will reduce symptoms that might be confused with those of COVID-19. Guidance for vaccine planning during the pandemic is available at https://www.cdc.gov/vaccines/pandemic-guidance/index.html. Recommendations for the use of COVID-19 vaccines are available at https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/covid-19.html, and additional clinical guidance is available at https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html.

- Current guidance for the use of COVID-19 vaccines indicates that these vaccines can be coadministered with other vaccines, including influenza vaccines. Providers should consult current COVID-19 vaccine recommendations and guidance for up-todate information.
- One labeling change is described. In March 2021, FDA granted approval for the use of Flucelvax Quadrivalent (cell culture–based quadrivalent inactivated influenza vaccine [ccIIV4]) for children aged 2 through <4 years. Flucelvax Quadrivalent had previously been approved for persons aged ≥4 years; approval for those aged 4 through <18 years was based on immunogenicity data and required a postmarketing efficacy study. The new approval is based on a randomized observer-blinded clinical efficacy study conducted among children aged 2 through <18 years over three seasons, in which Flucelvax Quadrivalent demonstrated efficacy against laboratory-confirmed influenza of 54.6% (95% confidence interval [CI] = 45.7%–62.1%) compared with a noninfluenza control vaccine. Flucelvax Quadrivalent is now approved for persons aged ≥2 years.
- Guidance concerning timing of vaccination has been modified. For women in the third trimester of
 pregnancy, vaccination soon after vaccine becomes available can now be considered. As in previous
 seasons, children who need 2 doses of influenza vaccine administered ≥4 weeks apart (those aged 6
 months through 8 years who have never received influenza vaccine or who have not previously
 received a lifetime total of ≥2 doses) are recommended to receive the first dose as soon as possible
 after vaccine becomes available. For nonpregnant adults, early vaccination (i.e., in July and August)
 should be avoided unless there is concern that later vaccination might not be possible.
- Contraindications and precautions to the use of ccIIV4 and RIV4 have been modified, specifically with regard to persons with a history of severe allergic reaction (e.g., anaphylaxis) to an influenza vaccine. A history of a severe allergic reaction (e.g., anaphylaxis) to a previous dose of any egg-based IIV, LAIV, or RIV of any valency is a precaution to use of ccIIV4. A history of a severe allergic reaction (e.g., anaphylaxis) to a previous dose of any egg-based IIV, LAIV, or RIV of any valency is a precaution to use of ccIIV4. A history of a severe allergic reaction (e.g., anaphylaxis) to a previous dose of any egg-based IIV, ccIIV, or LAIV of any valency is a precaution to use of RIV4. Use of ccIIV4 and RIV4 in such instances should occur in an inpatient or outpatient medical setting under supervision of a provider who can recognize and manage a severe allergic reaction; providers can also consider consulting with an allergist to help identify the vaccine component responsible for the reaction. For ccIIV4, history of a severe allergic reaction (e.g., anaphylaxis) to any ccIIV of any valency or any component of ccIIV4 is a contraindication to future use of ccIIV4. For RIV4, history of a severe allergic reaction (e.g., anaphylaxis) to any cCIIV of any valency or any component of RIV4.

The MMWR article also outlines more specific guidance for use in specific populations and situations. For the 2021–2022 IVS, ACIP recommends the following guidelines, verbatim:

- Populations at Higher Risk for Medical Complications Attributable to Severe Influenza
 - All children aged 6 through 59 months;
 - All persons aged \geq 50 years;
 - Adults and children who have chronic pulmonary (including asthma), cardiovascular (excluding isolated hypertension), renal, hepatic, neurologic, hematologic, or metabolic disorders (including diabetes mellitus);
 - Persons who are immunocompromised due to any cause (including but not limited to immunosuppression caused by medications or HIV infection);
 - Women who are or will be pregnant during the influenza season;
 - Children and adolescents (aged 6 months through 18 years) who are receiving aspirin- or salicylate-containing medications and who might be at risk for experiencing Reye syndrome after influenza virus infection;
 - Residents of nursing homes and other long-term care facilities;
 - American Indians/Alaska Natives; and

- Persons who are extremely obese (body mass index \geq 40 for adults).
- Persons Who Live with or Care for Persons at Higher Risk for Influenza-Related Complications
 - Health care personnel, including all paid and unpaid persons working in health care settings who have the potential for exposure to patients or to infectious materials. These personnel might include (but are not limited to) physicians, nurses, nursing assistants, nurse practitioners, physician assistants, therapists, technicians, emergency medical service personnel, dental personnel, pharmacists, laboratory personnel, autopsy personnel, students and trainees, contractual staff, and other persons not directly involved in patient care but who might be exposed to infectious agents (e.g., clerical, dietary, housekeeping, laundry, security, maintenance, administrative, and billing staff and volunteers). ACIP guidance for vaccination of health care personnel has been published previously;
 - Household contacts (including children aged ≥6 months) and caregivers of children aged ≤59 months (i.e., aged <5 years) and adults aged ≥50 years, particularly contacts of children aged <6 months; and
 - Household contacts (including children aged ≥6 months) and caregivers of persons with medical conditions that put them at higher risk for severe complications from influenza.
- Influenza Vaccination of Persons with COVID-19
 - Considerations regarding vaccination of persons who have tested positive for COVID-19 or who are in quarantine after an exposure should include whether bringing the recipient into a vaccination setting could expose others to COVID-19, whether the person is acutely ill and the severity of the illness, presence of risk factors for severe influenza illness, the likelihood of being able to vaccinate at a later date, and the desire to avoid confusing postvaccination symptoms with those of COVID-19 illness.
 - In general, those who are in quarantine or isolation should not be brought to a vaccination setting if doing so could expose others to COVID-19.
 - For those who have moderate or severe COVID-19, vaccination should generally be deferred until they have recovered, which is consistent with ACIP General Best Practice Guidelines for Immunization.
 - For persons who have mild or asymptomatic COVID-19, further deferral might be considered to avoid confusing COVID-19 illness symptoms with postvaccination reactions.
 - Because recommendations for vaccination of this population might continue to evolve, clinicians should check current CDC guidance (https://www.cdc.gov/vaccines/pandemic-guidance/index.html) for up-todate information.
- Children Aged 6 Months Through 8 Years
 - Four IIV4s are approved for ages ≥6 months; one is approved for ages ≥2 years. The appropriate dose volumes for some of these vaccines differ for children aged. For these vaccines, approved age indications and dose volumes are as follows:
 - Afluria Quadrivalent is approved for ages ≥6 months. The approved dose volume for children aged 6 through 35 months is 0.25 mL per dose. Persons aged ≥36 months (≥3 years) should receive 0.5 mL per dose.
 - Fluarix Quadrivalent is approved for ages ≥6 months. The approved dose volume is
 0.5 mL per dose for all persons aged ≥6 months.
 - FluLaval Quadrivalent is approved for ages ≥6 months. The approved dose volume is 0.5 mL per dose for all persons aged ≥6 months.
 - Fluzone Quadrivalent is approved for ages ≥6 months. The approved dose volume for children aged 6 through 35 months is either 0.25 mL or 0.5 mL per dose. Persons aged ≥36 months should receive 0.5 mL per dose.

- Flucelvax Quadrivalent is approved for ages ≥2 years. The approved dose volume is
 0.5 mL per dose for all persons aged ≥24 months (≥2 years).
- Children aged 6 months through 8 years require 2 doses of influenza vaccine administered a minimum of 4 weeks apart during their first season of vaccination for optimal protection. Determination of the number of doses needed is based on 1) the child's age at the time of the first dose of 2021–22 influenza vaccine and 2) the number of doses of influenza vaccine received in previous influenza seasons:
 - For those aged 6 months through 8 years, the number of doses of influenza vaccine needed for the 2021–22 influenza season is determined as follows:
 - Those who have previously received ≥2 total doses of trivalent or quadrivalent influenza vaccine ≥4 weeks apart before July 1, 2021, require only 1 dose for the 2021–22 season. The 2 previous doses of influenza vaccine do not need to have been administered in the same season or consecutive seasons.
 - Those who have not previously received ≥2 doses of trivalent or quadrivalent influenza vaccine ≥4 weeks apart before July 1, 2021, or whose previous influenza vaccination history is unknown, require 2 doses for the 2021–22 season. The interval between the 2 doses should be ≥4 weeks. Two doses are recommended even if the child turns age 9 years between receipt of dose 1 and dose 2.
 - Adults and children aged ≥9 years need only 1 dose of influenza vaccine for the 2021– 22 season.
- Pregnant Women
 - ACIP and the American College of Obstetricians and Gynecologists recommend that those who are pregnant or who might be pregnant or postpartum during the influenza season receive influenza vaccine.
 - Any licensed, recommended, and age-appropriate IIV4 or RIV4 may be used. LAIV4 should not be used during pregnancy but can be used postpartum.
 - Influenza vaccine can be administered at any time during pregnancy, before and during the influenza season.
- Older Adults
 - No preference is expressed for any one vaccine type.
 - \circ $\;$ Vaccination should not be delayed if a specific vaccine is not readily available.
 - For persons aged ≥65 years, any age-appropriate IIV4 formulation (standard dose or high dose, nonadjuvanted or adjuvanted) or RIV4 is an acceptable option.
- Immunocompromised Persons
 - Persons with immunocompromising conditions (including but not limited to persons with congenital and acquired immunodeficiency states, persons who are immunocompromised due to medications, and persons with anatomic and functional asplenia) should receive an ageappropriate IIV4 or RIV4.
 - ACIP recommends that LAIV4 not be used for these groups because of the uncertainbut biologically plausible risk for disease attributable to the live vaccine virus.
- Persons with a History of Guillain-Barré Syndrome After Influenza Vaccination
 - Persons who are not at higher risk for severe influenza complications (see Populations at Higher Risk for Medical Complications Attributable to Severe Influenza) and who are known to have experienced GBS within 6 weeks of a previous influenza vaccination generally should not be vaccinated.

- As an alternative to vaccination, providers might consider using influenza antiviral chemoprophylaxis for these persons.
- Persons with a History of Egg Allergy
 - Persons with a history of egg allergy who have experienced only urticaria (hives) after exposure to egg should receive influenza vaccine. Any licensed, recommended influenza vaccine (i.e., any IIV4, RIV4, or LAIV4) that is otherwise appropriate for the recipient's age and health status can be used.
 - Persons who report having had reactions to egg involving symptoms other than urticaria (e.g., angioedema or swelling, respiratory distress, lightheadedness, or recurrent vomiting) or who required epinephrine or another emergency medical intervention can similarly receive any licensed, recommended influenza vaccine (i.e., any IIV4, RIV4, or LAIV4) that is otherwise appropriate for their age and health status. If a vaccine other than ccIIV4 or RIV4 is used, the selected vaccine should be administered in an inpatient or outpatient medical setting (including but not necessarily limited to hospitals, clinics, health departments, and physician offices). Vaccine administration should be supervised by a health care provider who is able to recognize and manage severe allergic reactions.
- Persons with Previous Allergic Reactions to Influenza Vaccines
 - For egg-based IIV4s and LAIV4: A history of severe allergic reaction (e.g., anaphylaxis) to any influenza vaccine (i.e., any egg-based IIV, ccIIV, RIV, or LAIV of any valency) is a contraindication to future receipt of all egg-based IIV4s and LAIV4. Each individual egg-based IIV4 and LAIV4 is also contraindicated for persons who have had a severe allergic reaction (e.g., anaphylaxis) to any component of that vaccine.
 - For ccIIV4:
 - A history of a severe allergic reaction (e.g., anaphylaxis) to any egg-based IIV, RIV, or LAIV of any valency is a precaution to the use of ccIIV4. If ccIIV4 is administered in such instances, vaccination should occur in an inpatient or outpatient medical setting and should be supervised by a health care provider who is able to recognize and manage severe allergic reactions. Providers also can consider consultation with an allergist to help determine the vaccine component responsible for the allergic reaction.
 - A history of a severe allergic reaction (e.g., anaphylaxis) to any ccIIV of any valency or to any component of ccIIV4 is a contraindication to future receipt of ccIIV4.
 - For RIV4:
 - A history of a severe allergic reaction (e.g., anaphylaxis) to any egg-based IIV, ccIIV, or LAIV of any valency is a precaution to the use of RIV4. If RIV4 is administered in such instances, vaccination should occur in an inpatient or outpatient medical setting and should be supervised by a health care provider who is able to recognize and manage severe allergic reactions. Providers can also consider consulting with an allergist to help determine the vaccine component responsible for the allergic reaction.
 - A history of a severe allergic reaction (e.g., anaphylaxis) to any RIV of any valency or to any component of RIV4 is a contraindication to future receipt of RIV4.

[Response Ends]

1a.05. Provide the grade assigned to the evidence associated with the recommendation, and include the definition of the grade.

[Response Begins]

The ACIP unanimously voted during its October 2010 meeting to adopt the GRADE approach for developing evidence-based recommendations. Key factors for developing recommendations include the balance of benefits and harms, type or quality of evidence, values and preferences, and health economic analyses. The ACIP recommendation categories are:

- Category A: Recommendation that applies to all persons in an age- or risk-based group.
 - Category A recommendations will be made for all persons in an age group or for all persons in a risk-based group. The suggested phrasing for category A recommendations includes the phrases "recommend," "recommend against," "should," and "should not."
- Category B: Recommendation for individual clinical decision making. No recommendation/unresolved issue.
 - Category B recommendations will indicate that clinical decisions should be made on an individual basis; in other words, category B recommendations do not apply to all members of a group, but are used in context of clinician-patient interaction to determine if vaccination may be appropriate for that patient. Phrasing for category B recommendations includes the words "may" and "suggest against." In some instances, it is possible that the ACIP may have decided not to make a recommendation if additional information was needed.

The body of evidence is to be categorized into four types that represent a general hierarchy reflecting the confidence in the estimated effect of vaccination on health outcomes (benefits, harms):

- 1. Randomized controlled trials, or overwhelming evidence from observational studies.
- 2. Randomized controlled trials with important limitations, or exceptionally strong evidence from observational studies.
- 3. Observational studies, or randomized controlled trials with notable limitations.
- 4. Clinical experience and observations, observational studies with important limitations, or randomized controlled trials with several major limitations.

[Response Ends]

1a.06. Provide all other grades and definitions from the evidence grading system.

[Response Begins] Not applicable [Response Ends]

1a.07. Provide the grade assigned to the recommendation, with definition of the grade.

[Response Begins] Not applicable [Response Ends]

1a.08. Provide all other grades and definitions from the recommendation grading system.

[Response Begins]

Not applicable

[Response Ends]

1a.09. Detail the quantity (how many studies) and quality (the type of studies) of the evidence. [Response Begins] The ACIP cited 131 articles in their systematic review and evaluation of evidence. These articles included a range of clinical efficacy studies, observational studies, and randomized controlled trials.

[Response Ends]

1a.10. Provide the estimates of benefit, and consistency across studies.

[Response Begins]

In their systematic review, Grohskopf et al found ample evidence for decreasing vaccine effectiveness with increasing time post-vaccination within a single influenza season (2021). An examination of 14 studies that investigated waning influenza vaccine effectiveness found a significant decline in effectiveness within 180 days following vaccination for influenza A (H3N2) and influenza B, but not for influenza A(H1N1) (Grohskopf et al, 2021). Researchers also observed more pronounced waning vaccine effectiveness among older adults, as one study found that during the 2015–16 through 2018–19 seasons, vaccine effectiveness declined by approximately 8%–9% per month for all adults and approximately 10%–11% per month for those aged ≥65 years (2021).

Despite the evidence for waning vaccine effectiveness against influenza, several studies found that delaying immunization until October leads to increased hospitalizations for persons aged ≥65 years who otherwise would have been immunized in August or September. Therefore, in the ACIP's recommendations for adults of older age it is stated that "vaccination should not be delayed if a specific vaccine is not readily available" (Grohskopf et al, 2021).

Grohskopf, L. A., Alyanak, E., Ferdinands, J. M., Broder, K. R., Blanton, L. H., Keipp Talbot, H., & Fry, A. M.(2021). Prevention and control of seasonal influenza with vaccines: recommendations of the advisory committee on immunization practices, United States, 2021–22 influenza season. Morbidity and Mortality Weekly Report (MMWR), 70(5): 1-28. https://www.cdc.gov/mmwr/volumes/70/rr/pdfs/rr7005a1-H.pdf

[Response Ends]

1a.11. Indicate what, if any, harms were identified in the study.

[Response Begins]

Harms from the influenza vaccine were not identified in the systematic review.

[Response Ends]

1a.12. Identify any new studies conducted since the systematic review, and indicate whether the new studies change the conclusions from the systematic review.

[Response Begins]

This clinical practice guideline includes a systematic review of the most recent literature, citing studies through 2021. No new studies have been published that change the conclusions of the ACIP.

[Response Ends]

1a.13. If source of evidence is NOT from a clinical practice guideline, USPSTF

, or systematic review, describe the evidence on which you are basing the performance measure.

[Response Begins]

Not applicable

[Response Ends]

1a.14. Briefly synthesize the evidence that supports the measure.

[Response Begins] Not applicable [Response Ends]

1a.15. Detail the process used to identify the evidence.[Response Begins]Not applicable[Response Ends]

1a.16. Provide the citation(s) for the evidence.[Response Begins]Not applicable[Response Ends]

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

1b.01. Briefly explain the rationale for this measure.

Explain how the measure will improve the quality of care, and list the benefits or improvements in quality envisioned by use of this measure.

[Response Begins]

This process-based quality measure reports the percentage of short-stay nursing home residents who were assessed and appropriately given the seasonal influenza vaccine. Seasonal influenza vaccination is important to monitor in the nursing home population because of the substantial health threat that influenza poses to elderly populations. The Centers for Disease Control and Prevention (CDC) reports that influenza and pneumonia together have remained among the top ten most common causes of death for people aged 65 and older in the United States since 1999 (CDC, 2021). In fact, influenza alone caused 176,924 hospitalizations and 13,673 deaths among adults aged 65 and older during the 2019-2020 season (CDC, 2021). In addition to older age, influenza infection is also particularly threatening to people with comorbidities. Therefore, nursing home residents, who are older in age and likely to have comorbidities, are at high-risk for experiencing the adverse outcomes of influenza. In the short-stay nursing home population these comorbidities include impaired functional status, some cardiovascular conditions (atrial fibrillation, heart failure), and respiratory illnesses (pneumonia, asthma/COPD, respiratory failure) (Moyo et al, 2020).

Influenza vaccination is an effective preventative measure against infection, as well as hospitalization and mortality due to influenza. The CDC estimates that influenza vaccination averted 61,115 hospitalizations and 4,723 deaths in adults aged 65 years and older during the 2019-2020 influenza season (2020). This observation holds true in the nursing home population, as one recent prospective cohort study found that residents who received the influenza vaccine experienced a significant reduction in mortality compared to the unvaccinated nursing home population (Poscia et al, 2017). These researchers observed a 38% reduction (P<0.001) in the crude hazard ratio (CHR) for mortality in influenza vaccinated nursing home residents aged 65 and older as compared to their unvaccinated counterparts (Poscia et al, 2017). Furthermore, when adjusting for age, sex, number of diseases, cognitive performance, activities of daily living (ADL), and depression, influenza vaccination (CHR = 0.80; 95% CI 0.66–0.97) was associated with a statistically significant reduction in mortality for vaccinated residents compared to the unvaccinated population (Poscia et al, 2017). These findings were
further corroborated in a retrospective cohort study that evaluated the effectiveness of influenza vaccination during multiple outbreaks in long term care facilities in 2017. Ng et al determined vaccine effectiveness by estimating the ratio of the odds of testing positive for influenza among vaccinated individuals to the odds among unvaccinated individuals and then adjusted for age, gender, calendar month, and number of days from illness onset to date of sample collection (2017). The results demonstrated that vaccine effectiveness varies by the length of the post-vaccination period, with the highest vaccine effectiveness occurring between 15 and 180 days post vaccination (59.3%; p=0.01). The findings from Ng et al, as well as Poscia et al, suggest that vaccination is highly effective at reducing infection and mortality in the nursing home population.

References:

Centers for Disease Control and Prevention, National Center for Health Statistics. Underlying Cause of Death 1999-2020 on CDC WONDER Online Database, released in 2021. Data are from the Multiple Cause of Death Files, 1999-2020, as compiled from data provided by the 57 vital statistics jurisdictions through the Vital Statistics Cooperative Program. Accessed at http://wonder.cdc.gov/ucd-icd10.html

Centers for Disease Control and Prevention (CDC). (2020). Estimated influenza illnesses, medical visits, and hospitalizations averted by vaccination in the United States – 2019–2020 influenza season. https://www.cdc.gov/flu/about/burden-averted/2019-2020.htm.

Moyo, P., Zullo, A.R., McConeghy, K.W. Bosco, E., van Aalst, R., Chit, A., & Gravenstein, S. (2020). Risk factors for pneumonia and influenza hospitalizations in long-term care facility residents: a retrospective cohort study. BMC Geriatrics, 20(47). https://doi.org/10.1186/s12877-020-1457-8

Ng, Y., Nandar, K., Chua, L., Mak, T. M., Foo, K., Muhammad, I. R., Low, C., Ma, S., Ooi, S. P., Lin, R., James, L., & Lee, V. (2019). Evaluating the effectiveness of the influenza vaccine during respiratory outbreaks in Singapore's long term care facilities, 2017. Vaccine, 37(29): 3925–3931. https://doi.org/10.1016/j.vaccine.2019.03.054

Poscia, A., Collamati, A., Carfi, A., Topinkova, E., Richter, T., Denkinger, M., Pastorino, R., Landi, F., Ricciardi, W., Bernabei, R., & Onder, G. (2017). Influenza and pneumococcal vaccination in older adults living in nursing home: a survival analysis on the shelter study. European Journal of Public Health, 27(6): 1016–1020. https://doi.org/10.1093/eurpub/ckx15.

[Response Ends]

1b.02. Provide performance scores on the measure as specified (current and over time) at the specified level of analysis.

Include mean, std dev, min, max, interquartile range, and 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 (4b) under Usability and Use.

[Response Begins]

Current performance: Table 5 in the "Scientific Acceptability: Validity - Threats to Validity (Statistically Significant Differences, Multiple Data Sources, Missing Data)" section of this form describes the national facility score distribution for Percent of Residents Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short-Stay). The four-quarter facility-level mean score for this measure during the 2018-2019 influenza season (2018Q3-2019Q2) was 83.9% and the median score was 90.0%. The standard deviation was 17.4%, the score at the 10th percentile was 60.0%, and the score at the 90th percentile was 98.9%. The interquartile range for this measure was 17.4%, indicating there is room for improvement on this measure. Of the facilities with adequate sample size to report, 7.8% had perfect scores of 100%. This analysis is restricted to facilities that had at least 20 residents in the denominator, the minimum denominator threshold for public

reporting. Between 2018Q3 and 2019Q2, there were 12,907 facilities (100%) and 1,429,771 residents (99.9%) that met the denominator inclusion criteria n (Facilities): 12,907 k (Residents): 1,429,771 Mean score: 83.9% Std dev.: 17.4% 10th percentile: 60.0% 25th percentile: 60.0% 25th percentile: 78.4% 50th percentile: 90.0% 75th percentile: 95.8% 90th percentile: 95.8% 90th percentile: 98.9% Interquartile range: 17.4%. % of facilities with "perfect scores": 7.8% **Performance over Time:**

The national facility-level mean and median scores for the Percent of Residents Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short-Stay) have shown small, gradual increases over time across the distribution and indicate facilities have higher rates of short-stay residents being assessed and appropriately given the seasonal influenza vaccine. During the last maintenance cycle for this measure (2016), testing results using 2013Q3-2015Q1 MDS data indicated the mean facility QM score was 81.6% and the median facility QM score was 87.1% during the 2013-2014 influenza season. During the current NQF maintenance cycle (Spring 2022), 2018Q3-2019Q2 data were used and results indicated a mean facility QM score of 83.9% and a median facility QM score of 90.0%. Overall, the national facility-level mean and median scores have remained relatively stable with a small increase between the 2013-2014 influenza season and the 2018-2019 influenza season. The national facility-level score distributions for both influenza seasons are summarized in Table 1 below.

Influen za Season	К	Mea n scor e	Std dev.	10th percenti le	25th percenti le	50th percenti le	75th percenti le	90th percenti le	% of faciliti es with perfec t score	Interquart ile range
2013- 2014	13,91 2	81.6 %	17.5 %	57.6%	75.3%	87.1%	93.8%	97.4%	3.6%	18.5 % points
2018- 2019	12,90 7	83.9 %	17.4 %	60.0%	78.4%	90.0%	95.8%	98.9%	7.8%	17.4 % points

(Data Source: Data are drawn from all United States Nursing Homes with Medicare certified beds and a minimum of 20 short-stay residents in their denominator in each quarter.)

[Response Ends]

1b.03. If no or limited performance data on the measure as specified is reported above, 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. Include citations.

[Response Begins]

This is not applicable (data are available and described in 1b.02).

[Response Ends]

1b.04. 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.

Describe the data source including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included. Include mean, std dev, min, max, interquartile range, and scores by decile. 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 (4b) under Usability and Use.

[Response Begins]

Age

To examine whether facilities with higher percentages of residents age 85 or older have different performance scores for seasonal influenza vaccination, 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 short-stay residents who were assessed and appropriately given the seasonal influenza vaccine was stratified by age at the facility level. Residents aged 85 or older represented the highest mean (87.5%) followed by residents below the age of 85 (85.5%). 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 aged 85 years or older are more likely to be assessed and appropriately given a seasonal influenza vaccine than residents less than 85 years of age.

Race

To examine whether facilities with higher percentages of non-white residents have different performance scores for seasonal influenza vaccination, analyses were completed comparing the performance of facilities based on their percentage of white only and non-white residents. First, the percentage of short-stay residents who were assessed and appropriately given a seasonal influenza vaccine was stratified by racial identification at the facility level. Native Hawaiian or Other Pacific Islander residents represented the highest mean (89.15%), followed by Asian residents (88.37%), Multi-race residents (88.10%), White residents (87.21%), Hispanic or Latino residents (86.26%), American Indian/Alaska Native residents (83.49%), and Black or African American residents (80.61%). 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 for the measure. The results suggested that the white only population (87.21%) is more likely to be assessed and appropriately given a seasonal influenza vaccine than the non-white only population (82.62%).

Socioeconomic status

To examine whether facilities with higher percentages of Medicaid-eligible residents have different performance scores for seasonal influenza vaccination, analyses were completed comparing the performance of facilities based on their percentage of Medicaid-eligible only residents, residents who are eligible for both Medicaid and Medicare, residents who are eligible for neither Medicare nor Medicaid, and Medicare-eligible only residents. First, the percentage of short-stay residents who were assessed and appropriately given a seasonal influenza vaccine was stratified by Medicaid and Medicare eligibility at the facility level. Residents who were eligible for neither Medicare only residents who were eligible for both Medicare and (87.61%), followed by residents who were eligible for neither Medicare and Medicaid (84.54%), and residents who were eligible for Medicaid only (79.27%). Next a 2-way chi-squared test

for statistical dependence was run that assessed the association between quality measure score and Medicare/Medicaid eligibility. The results were significant (p=<.0001) indicating that that there is a statistically significant relationship between Medicare/Medicaid eligibility and QM score for this measure. The results suggested that the Medicaid-eligible only population is less likely to be assessed and appropriately given a seasonal influenza vaccine than the Medicare-eligible only population, indicating there is a relationship between socioeconomic status and influenza vaccination among short-stay residents.

SOURCE: Acumen analysis of 2018Q3-2019Q2 MDS 3.0 data

[Response Ends]

1b.05. If no or limited data on disparities from the measure as specified is reported above, 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 above.

[Response Begins]

This is not applicable.

[Response Ends]

Criteria 2: 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.

spma.01. Indicate whether there are changes to the specifications since the last updates/submission. If yes, update the specifications in the Measure Specifications section of the Measure Submission Form, and explain your reasoning for the changes below.

[Response Begins]

No

[Response Ends]

spma.02. Briefly describe any important changes to the measure specifications since the last measure update and provide a rationale.

For annual updates, please explain how the change in specifications affects the measure results. If a material change in specification is identified, data from re-testing of the measure with the new specifications is required for early maintenance review.

For example, specifications may have been updated based on suggestions from a previous NQF CDP review.

[Response Begins]

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

[Response Ends]

sp.01. Provide the measure title.

Measure titles should be concise yet convey who and what is being measured (see <u>What Good Looks Like</u>).

[Response Begins]

Percent of Residents Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short-Stay) [Response Ends]

sp.02. Provide a brief description of the measure.

Including type of score, measure focus, target population, timeframe, (e.g., Percentage of adult patients aged 18-75 years receiving one or more HbA1c tests per year).

[Response Begins]

This measure captures the percentage of short-stay nursing home residents who were assessed and appropriately given the influenza vaccine during the most recent influenza season. The influenza vaccination season (IVS) is defined as beginning on October 1, or when the vaccine first becomes available, and ends on March 31 of the following year.* This measure is based on the NQF's National Voluntary Standards for Influenza and Pneumococcal Immunizations. The measure denominator consists of short-stay residents. Short-stay residents are identified as those who have had 100 or fewer days of nursing home care.

*Note: While the IVS officially begins when the vaccine becomes available, which may be before October 1, the target period for the quality measure and references to the IVS for the denominator specification is from October 1 to March 31 of the following year. The numerator time window and references to the IVS in the numerator specifications may include residents who were assessed and offered the vaccine before October 1. This is based on how the influenza items were coded by the facility.

[Response Ends]

sp.04. Check all the clinical condition/topic areas that apply to your measure, below.

Please refrain from selecting the following answer option(s). We are in the process of phasing out these answer options and request that you instead select one of the other answer options as they apply to your measure. Please do not select:

• Surgery: General

[Response Begins] Infectious Diseases (ID): Influenza [Response Ends]

sp.05. Check all the non-condition specific measure domain areas that apply to your measure, below.

[Response Begins] Immunization Primary Prevention [Response Ends]

sp.06. Select one or more target population categories.

Select only those target populations which can be stratified in the reporting of the measure's result. Please refrain from selecting the following answer option(s). We are in the process of phasing out these answer options and request that you instead select one of the other answer options as they apply to your measure. Please do not select:

• Populations at Risk: Populations at Risk

[Response Begins]

Elderly (Age >= 65)

[Response Ends]

sp.07. Select the levels of analysis that apply to your measure.

Check ONLY the levels of analysis for which the measure is SPECIFIED and TESTED.

Please refrain from selecting the following answer option(s). We are in the process of phasing out these answer options and request that you instead select one of the other answer options as they apply to your measure. Please do not select:

- Clinician: Clinician
- Population: Population

[Response Begins] Facility

[Response Ends]

sp.08. Indicate the care settings that apply to your measure.

Check ONLY the settings for which the measure is SPECIFIED and TESTED.

[Response Begins] Post-Acute Care [Response Ends]

sp.09. 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. If no URL is available, indicate "none available".

[Response Begins]

http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/NHQIQualityMeasures.html; please see "MDS-3_0-QM-USERS MANUAL-v15.0.pdf" in the "MDS_QM_Users_Manual_V15_Effective_01-01-2022.zip" zipped folder in the Downloads section at the bottom of the page.

[Response Ends]

sp.11. Attach the data dictionary, code table, or value sets (and risk model codes and coefficients when applicable). Excel formats (.xlsx or .csv) are preferred.

Attach an excel or csv file; if this poses an issue, <u>contact staff</u>. Provide descriptors for any codes. Use one file with multiple worksheets, if needed.

[Response Begins]

No data dictionary/code table - all information provided in the submission form

sp.12. State the numerator.

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.

[Response Begins]

The numerator is the number of residents in the denominator sample who, during the numerator time window, meet any one of the following criteria:

- 1. Resident received the influenza vaccine during the most recent influenza season, either in the facility or outside the facility; or
- 2. Resident was offered and declined the influenza vaccine; or
- 3. Resident was ineligible due to medical contraindication(s).

The numerator time window coincides with the most recently-completed seasonal IVS which begins on October 1 and ends on March 31 of the following year. However, the measure selection period uses a June 30 end date to ensure residents who do not have an assessment completed until after March 31 but were vaccinated between October 1 and March 31 are captured in the sample.

[Response Ends]

sp.13. Provide details needed to calculate the numerator.

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 sp.11.

[Response Begins]

Residents whose cumulative length of stay is less than or equal to 100 days are considered short-stay residents and are counted in the measure. Residents are included in the numerator if they meet any of the following criteria on the selected MDS assessment during the numerator time window:

- 1. Resident received the influenza vaccine during the most recent influenza vaccine season, either in the facility (O0250A = [1]) or outside the facility (O0250C = [2]); or
- 2. Resident was offered and declined the influenza vaccine (O0250C = [4]); or
- 3. Resident was ineligible due to medical contraindication(s) (O0250C = [3]) (e.g., anaphylactic hypersensitivity to eggs or other components of the vaccine, history of Guillian-Barré Syndrome within 6 weeks after a previous influenza vaccination, bone marrow transplant within the past 6 months).

The assessment record selected will be the record with the latest target date that meets all of the following conditions:

- The record contains a qualifying reason for assessment (OBRA admission, quarterly, annual or significant change/correction assessment(A0310A = [01, 02, 03, 04, 05, 06]), PPS scheduled assessment (A0310B = [01]) or discharge assessment (A0310F = [10, 11]),
- 2. The target date is on or after October 1st of the most recently completed influenza season, and
- 3. The entry date is on or before March 31st of the most recently completed influenza season.

sp.14. State the denominator.

Brief, narrative description of the target population being measured.

[Response Begins]

The denominator consists of residents 180 days of age and older on the target date of the assessment who were in the facility for at least one day during the most recently completed IVS, from October 1 to March 31 of the following year. If a nursing home resident has more than one episode during this time window, only the more recent episode is included in this measure.

[Response Ends]

sp.15. Provide details needed to calculate the denominator.

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

Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format at sp.11.

[Response Begins]

Residents whose cumulative length of stay is less than or equal to 100 days are considered short-stay residents and are counted in measure. Residents are included in the denominator if they are aged 180 days or older, and were in the facility for at least one day from October 1 through March 31. Specifically, a resident is considered to have stayed in the facility for at least one day from October 1 through March 31 if the resident has an OBRA assessment (A0310A = [01, 02, 03, 04, 05, 06]) or PPS assessment (A0310B = [01]) or discharge assessment (A0310F = [10, 11]) with an assessment reference date on or after October 1 and an entry date (A1600) on or before March 31 of the following year. If a nursing home resident has more than one episode during the denominator time window, only the more recent episode is included in this QM to ensure each resident is counted once.

[Response Ends]

sp.16. Describe the denominator exclusions.

Brief narrative description of exclusions from the target population.

[Response Begins]

Residents whose age is 179 days or less on the target date of the selected influenza vaccination assessment are excluded from this measure. Nursing homes with denominator counts of less than 20 short-stay residents in the sample are excluded from public reporting for the corresponding population due to small sample size.

sp.17. Provide details needed to calculate the denominator exclusions.

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 sp.11.

[Response Begins]

Residents whose age is 179 days or less are excluded, with age calculation based on the resident's birthdate and the target date of the selected influenza vaccination assessment.

[Response Ends]

sp.18. Provide all information required to stratify the measure results, if necessary.

Include 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 in the Data Dictionary field.

[Response Begins] This measure is not stratified. [Response Ends]

sp.19. Select the risk adjustment type.

Select type. Provide specifications for risk stratification and/or risk models in the Scientific Acceptability section.

[Response Begins] No risk adjustment or risk stratification [Response Ends]

sp.20. Select the most relevant type of score.

Attachment: If available, please provide a sample report.

[Response Begins] Rate/proportion

[Response Ends]

sp.21. Select the appropriate interpretation of the measure score.

Classifies interpretation of score according to whether better quality or resource use is associated with a higher score, a lower score, a score falling within a defined interval, or a passing score

[Response Begins] Better quality = Higher score

[Response Ends]

sp.22. Diagram or describe the calculation of the measure score as an ordered sequence of steps.

Identify the target population; exclusions; cases meeting the target process, condition, event, or outcome; time period of data, aggregating data; risk adjustment; etc.

[Response Begins]

The calculation algorithm for the measure is:

Step 1: Identify the total number of short-stay residents meeting the denominator criteria.

Step 2: Identify the total number of short-stay residents who received the seasonal influenza vaccine during the current or most recently completed influenza season, either in the facility (O0250A = [1]) or outside the facility (O0250C = [2]).

Step 3: Identify the total number of short-stay residents who were offered and declined the seasonal influenza vaccine (O0250C = [4]).

Step 4: Identify the total number of short-stay residents who were ineligible due to medical contraindication(s) (O0250C = [3]).

Step 5: Aggregate Steps 2-4 [Sum the total number of short-stay residents who met any of the following criteria: who received the seasonal influenza vaccine during the current or most recently completed influenza season, either in the facility (O0250A = [1]) or outside the facility (O0250C = [2]); OR who were offered and declined the seasonal influenza vaccine (O0250C = [4]); OR who were ineligible due to medical contraindication(s) (O0250C = [3])].

Step 6: Divide the results of Step 5 by the result of Step 1.

[Response Ends]

sp.25. If measure is based on a sample, provide instructions for obtaining the sample and guidance on minimum sample size.

[Response Begins]

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.

[Response Ends]

sp.28. Select only the data sources for which the measure is specified.

[Response Begins]

Assessment Data

[Response Ends]

sp.29. Identify the specific data source or data collection instrument.

For example, provide the name of the database, clinical registry, collection instrument, etc., and describe how data are collected.

[Response Begins]

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: <u>https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/NHQIMDS30TechnicalInformation</u>

sp.30. Provide the data collection instrument.[Response Begins]Available at measure-specific web page URL identified in sp.09[Response Ends]

2ma.01. Indicate whether additional empirical reliability testing at the accountable entity level has been conducted. If yes, please provide results in the following section, Scientific Acceptability: Reliability - Testing. Include information on all testing conducted (prior testing as well as any new testing).

Please separate added or updated information from the most recent measure evaluation within each question response in the Scientific Acceptability sections. For example:

Current Submission: Updated testing information here. *Previous Submission:* Testing from the previous submission here.

[Response Begins] Yes [Response Ends]

2ma.02. Indicate whether additional empirical validity testing at the accountable entity level has been conducted. If yes, please provide results in the following section, Scientific Acceptability: Validity - Testing. Include information on all testing conducted (prior testing as well as any new testing).

Please separate added or updated information from the most recent measure evaluation within each question response in the Scientific Acceptability sections. For example:

Current Submission: Updated testing information here. Previous Submission:

Testing from the previous submission here.

[Response Begins] Yes [Response Ends]

2ma.03. For outcome, patient-reported outcome, resource use, cost, and some process measures, risk adjustment/stratification may be conducted. Did you perform a risk adjustment or stratification analysis? [Response Begins]

No

[Response Ends]

2ma.04. For maintenance measures in which risk adjustment/stratification has been performed, indicate whether additional risk adjustment testing has been conducted since the most recent maintenance

evaluation. This may include updates to the risk adjustment analysis with additional clinical, demographic, and social risk factors.

Please update the Scientific Acceptability: Validity - Other Threats to Validity section.

Note: This section must be updated even if social risk factors are not included in the risk adjustment strategy.

[Response Begins]

No additional risk adjustment analysis included

[Response Ends]

Measure testing must demonstrate adequate reliability and validity in order to be recommended for endorsement. Testing may be conducted for data elements and/or the computed measure score. Testing information and results should be entered in the appropriate fields in the Scientific Acceptability sections of the Measure Submission Form.

• Measures must be tested for all the data sources and levels of analyses that are specified. If there is more than one set of data specifications or more than one level of analysis, contact NQF staff about how to present all the testing information in one form.

• All required sections must be completed.

• For composites with outcome and resource use measures, Questions 2b.23-2b.37 (Risk Adjustment) also must be completed.

• If specified for multiple data sources/sets of specifications (e.g., claims and EHRs), Questions 2b.11-2b.13 also must be completed.

• An appendix for supplemental materials may be submitted (see Question 1 in the Additional section), but there is no guarantee it will be reviewed.

• Contact NQF staff with any questions. Check for resources at the <u>Submitting Standards webpage</u>.

• For information on the most updated guidance on how to address social risk factors variables and testing in this form refer to the release notes for the <u>2021 Measure Evaluation Criteria and Guidance</u>.

Note: The information provided in this form is intended to aid the Standing Committee and other stakeholders in understanding to what degree the testing results for this measure meet NQF's evaluation criteria for testing.

2a. Reliability testing demonstrates the measure data elements are repeatable, producing the same results a high proportion of the time when assessed in the same population in the same time period and/or that the measure score is precise. For instrument-based measures (including PRO-PMs) and composite performance measures, reliability should be demonstrated for the computed performance score.

2b1. Validity testing demonstrates that the measure data elements are correct and/or the measure score correctly reflects the quality of care provided, adequately identifying differences in quality. For instrument based measures (including PRO-PMs) and composite performance measures, validity should be demonstrated for the computed performance score.

2b2. Exclusions are supported by the clinical evidence and are of sufficient frequency to warrant inclusion in the specifications of the measure;

AND

If patient preference (e.g., informed decision-making) is a basis for exclusion, there must be evidence that the exclusion impacts performance on the measure; in such cases, the measure must be specified so that the

information about patient preference and the effect on the measure is transparent (e.g., numerator category computed separately, denominator exclusion category computed separately).

2b3. For outcome measures and other measures when indicated (e.g., resource use):

• an evidence-based risk-adjustment strategy (e.g., risk models, risk stratification) is specified; is based on patient factors (including clinical and social risk factors) that influence the measured outcome and are present at start of care; 14,15 and has demonstrated adequate discrimination and calibration

OR

• rationale/data support no risk adjustment/ stratification.

2b4. Data analysis of computed measure scores demonstrates that methods for scoring and analysis of the specified measure allow for identification of statistically significant and practically/clinically meaningful 16 differences in performance;

OR

there is evidence of overall less-than-optimal performance.

2b5. If multiple data sources/methods are specified, there is demonstration they produce comparable results.

2b6. Analyses 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.

2c. For composite performance measures, empirical analyses support the composite construction approach and demonstrate that:

2c1. the component measures fit the quality construct and add value to the overall composite while achieving the related objective of parsimony to the extent possible; and

2c2. the aggregation and weighting rules are consistent with the quality construct and rationale while achieving the related objective of simplicity to the extent possible.

(if not conducted or results not adequate, justification must be submitted and accepted)

Definitions

Reliability testing applies to both the data elements and computed measure score. Examples of reliability testing for data elements include, but are not limited to: inter-rater/abstractor or intra-rater/abstractor studies; internal consistency for multi-item scales; test-retest for survey items. Reliability testing of the measure score addresses precision of measurement (e.g., signal-to-noise).

Validity testing applies to both the data elements and computed measure score. Validity testing of data elements typically analyzes agreement with another authoritative source of the same information. Examples of validity testing of the measure score include, but are not limited to: testing hypotheses that the measures scores indicate quality of care, e.g., measure scores are different for groups known to have differences in quality assessed by another valid quality measure or method; correlation of measure scores with another valid indicator of quality for the specific topic; or relationship to conceptually related measures (e.g., scores on process measures to scores on outcome measures). Face validity of the measure score as a quality indicator may be adequate if accomplished through a systematic and transparent process, by identified experts, and explicitly addresses whether performance scores resulting from the measure as specified can be used to distinguish good from poor quality. The degree of consensus and any areas of disagreement must be provided/discussed.

Examples of evidence that an exclusion distorts measure results include, but are not limited to: frequency of occurrence, variability of exclusions across providers, and sensitivity analyses with and without the exclusion. Patient preference is not a clinical exception to eligibility and can be influenced by provider interventions. Risk factors that influence outcomes should not be specified as exclusions.

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

Please separate added or updated information from the most recent measure evaluation within each question response in the Importance to Scientific Acceptability sections. For example:

2021 Submission:

Updated testing information here.

2018 Submission:

Testing from the previous submission here.

2a. Reliability

2a.01. Select only the data sources for which the measure is tested. [Response Begins] Assessment Data [Response Ends]

2a.02. 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).

[Response Begins]

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.

[Response Ends]

2a.03. Provide the dates of the data used in testing.

Use the following format: "MM-DD-YYYY - MM-DD-YYYY"

[Response Begins]

Critical Data Element Testing (08-01-2006 - 02-28-2007)

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. It is important to note that the MDS 3.0 forms used in the RAND study are similar to the MDS 3.0 v1.17.0 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 unrelated to this measure (changes in item specifications and the addition of some new items). In particular, the influenza vaccination item has very similar item wording in the MDS 3.0 v1.17.0 and the 2008 recommended form.

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.

The authors of the RAND study also conducted an evaluation of the MDS 3.0 form in 2012 to determine whether their revisions improved reliability, validity, resident input, and clinical utility, all while decreasing collection burden. The results of this 2012 follow-up study were also used for the testing of critical data elements.

Saliba, D., & Buchanan, J. (2012). "Making the Investment Count: Revision of the Minimum Data Set for Nursing Homes, MDS 3.0." Journal of American Medical Directors Association 13(7): 602-10. https://doi.org/10.1016/j.jamda.2012.06.002.

Performance Measure Score Testing (07-01-2018 - 06-30-2019)

Since the Percent of Residents Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine is refreshed only once per 12-month period for public reporting, four quarters of MDS 3.0 data (2018Q3-2019Q2) were used to construct this measure and calculate the QM scores. This time window (2018Q3-2019Q2) covers the 2018-2019 influenza season (October 1 2018 – March 31 2019).

[Response Ends]

2a.04. Select the levels of analysis for which the measure is tested.

Testing must be provided for all the levels specified and intended for measure implementation, e.g., individual clinician, hospital, health plan.

Please refrain from selecting the following answer option(s). We are in the process of phasing out these answer options and request that you instead select one of the other answer options as they apply to your measure.

Please do not select:

- Clinician: Clinician
- Population: Population

[Response Begins]

Facility [Response Ends]

2a.05. List the measured entities 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.

[Response Begins]

Critical Data Element Testing

The RAND Development and Validation of MDS 3.0 study sample included a representative sample of forprofit 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. Approximately 63% of the 71 community facilities were for profit, 35% were not-for-profit, and 1% were government owned. Most facilities (90%) were free-standing nursing homes and 10% were hospitalbased. Over half of the sample facilities (57%) had 100-199 beds, 22% had over 200 beds, and 4% had fewer than 50. Most nursing homes (78%) were located in urban areas (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 ($n \ge 20$) to publicly report this measure between 2018Q3 and 2019Q2 (k = 12,907), unless otherwise noted.

[Response Ends]

2a.06. Identify the number and descriptive characteristics of patients included in the analysis (e.g., age, sex, race, diagnosis), separated by level of analysis and data source; if a sample was used, describe how patients were selected for inclusion in the sample.

If there is a minimum case count used for testing, that minimum must be reflected in the specifications.

[Response Begins]

Critical Data Element Testing

The RAND Development and Validation of MDS 3.0 study sample included 3,822 residents from 71 community nursing homes and 764 residents from 19 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 short-stay residents who were assessed and appropriately given the seasonal influenza vaccine. The analysis of MDS 3.0 data included all short-stay residents who met the denominator inclusion criteria for this measure in facilities with sufficient sample size ($[n \ge 20]$, [k = 12,907]) and reported this measure between 2018Q3 and 2019Q2. 1,429,771 residents met the short-stay denominator inclusion criteria in these facilities.

Table 1 describes the characteristics of the residents who were counted in the denominator for the short-stay population after applying facility sample size restrictions to 2018Q3-2019Q2 data (n =1,429,771). The majority of residents who met the denominator criteria were female (58.6%) and White (76.5%), while a smaller proportion of residents were male (41.4%) and Black or African American (11.6%). A majority of residents were eligible for Medicare only (60.2%). Approximately 31% of residents were over the age of 85 and 30.5% were between the ages of 75-84. The most frequently reported diagnoses were Hypertension (75.4%), Diabetes Mellitus (34.7%), and Depression (33.2%). Other common diagnoses reported for more than a quarter of residents were Anemia (28.7%), Asthma, Chronic Obstructive Pulmonary Disease (COPD), or Chronic Lung Disease (25.5%), and heart failure (25.3%). Table 1 also outlines the characteristics of the

residents who were counted in the numerator for the short-stay population. Compared to the denominator, the numerator had a slightly higher share of females, Medicare only residents, residents over the age of 85, residents with hypertension, heart failure, depression, and arthritis.

*	Short-Stay Denominat or	*	*	Short- Stay Numerat or	*	*	Percentage Ratio (% Numerator /% Denominat or)
Resident Characteristics	Frequency (n)	Total Observatio ns (N)	Percenta ge (%)	Frequenc y (n)	Total Observatio ns (N)	Percenta ge (%)	*
Sex	*	*	*	*	*	*	*
Female	837,345	1,429,771	58.6%	726,407	1,231,425	59.0%	1.01
Male	592,426	1,429,771	41.4%	505,018	1,231,425	41.0%	0.99
Race/Ethnicity	*	*	*	*	*	*	*
White Only	1,093,942	1,429,771	76.5%	953,968	1,231,425	77.5%	1.01
Black or African Ameri can Only	166,507	1,429,771	11.6%	134,217	1,231,425	10.9%	0.94
Hispanic or Latino Only	72,588	1,429,771	5.1%	62,616	1,231,425	5.1%	1.00
Asian Only	27,409	1,429,771	1.9%	24,222	1,231,425	2.0%	1.03
American Indian/Alaska Native Only	5,493	1,429,771	0.4%	4,586	1,231,425	0.4%	0.97
Native Hawaiian or Other Pacific Islander Only	5,530	1,429,771	0.4%	4,930	1,231,425	0.4%	1.04
Multi-race	5,818	1,429,771	0.4%	5,125	1,231,425	0.4%	1.02
Medicare- Medicaid Eligibility	*	*	*	*	*	*	*
Medicaid & Medicare	282,398	1,429,771	19.8%	238,727	1,231,425	19.4%	0.98
Medicaid Only	101,793	1,429,771	7.1%	80,693	1,231,425	6.6%	0.92
Medicare Only	860,253	1,429,771	60.2%	753,693	1,231,425	61.2%	1.02

Table 1. Characteristics of Short-Stay Residents Included in Analyses, NQF #0680 (2018Q3-2019Q2)

*	Short-Stay Denominat or	*	*	Short- Stay Numerat or	*	*	Percentage Ratio (% Numerator /% Denominat or)
Neither Medicaid nor Medicare	185,327	1,429,771	13.0%	158,312	1,231,425	12.9%	0.99
Age	*	*	*	*	*	*	*
<65	228,085	1,429,771	16.0%	186,345	1,231,425	15.1%	0.95
65-74	322,289	1,429,771	22.5%	276,851	1,231,425	22.5%	1.00
75-84	435,585	1,429,771	30.5%	379,713	1,231,425	30.8%	1.01
85+	443,812	1,429,771	31.0%	388,516	1,231,425	31.6%	1.02
Diagnoses*	*	*	*	*	*	*	*
Arthritis	42,394	185,011	22.9%	36,358	154,099	23.6%	1.03
Osteoporosis	13,768	185,015	7.4%	11,970	154,102	7.8%	1.04
Hip Fracture	25,823	384,233	6.7%	22,693	325,165	7.0%	1.04
Other Fracture	39,807	384,228	10.4%	34,804	325,160	10.7%	1.03
Depression	127,444	384,220	33.2%	109,595	325,153	33.7%	1.02
Stroke	36,833	384,231	9.6%	31,031	325,163	9.5%	1.00
Alzheimer's Disease	21,914	384,231	5.7%	18,317	325,165	5.6%	0.99
Non- Alzheimer's Dementia	87,419	384,233	22.8%	73,153	325,166	22.5%	0.99
Malnutrition or at risk for malnutrition	72,599	1,429,035	5.1%	62,059	1,230,822	5.0%	0.99
Cancer	25,974	184,962	14.0%	21,274	154,058	13.8%	0.98
Anemia	110,380	384,183	28.7%	94,660	325,124	29.1%	1.01
Heart Failure	97,028	384,225	25.3%	83,450	325,159	25.7%	1.02
Hypertension	289,536	384,200	75.4%	247,359	325,138	76.1%	1.01
Diabetes Mellitus	495,547	1,429,039	34.7%	428,091	1,230,825	34.8%	1.00
Anxiety Disorder	278,079	1,429,015	19.5%	240,694	1,230,801	19.6%	1.00

*	Short-Stay Denominat or	*	*	Short- Stay Numerat or	*	*	Percentage Ratio (% Numerator /% Denominat or)
Asthma, Chronic Obstructive Pulmonary Disease, or Chronic Lung Disease	98,329	384,837	25.6%	83,918	325,685	25.8%	1.01

* Diagnoses are collected from MDS Section I active diagnoses checkbox items (I0100 – I6500).

* Cells are intentionally left blank.

[Response Ends]

2a.07. 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.

[Response Begins]

Data for Critical Data Elements

RAND reliability analysis of data elements used the same sample as described in Sections 2a.05 and 2a.06 (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 2a.02, 2a.03, and 2a.05.

[Response Ends]

2a.08. List 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.

[Response Begins]

Resident-level social risk factor variables related to influenza vaccination 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 2a.06.

[Response Ends]

Note: If accuracy/correctness (validity) of data elements was empirically tested, separate reliability testing of data elements is not required – in 2a.07 check patient or encounter-level data; in 2a.08 enter "see validity testing section of data elements"; and enter "N/A" for 2a.09 and 2a.10.

2a.09. Select the level of reliability testing conducted.

Choose one or both levels.

[Response Begins]

Patient or Encounter-Level (e.g., inter-abstractor reliability; data element reliability must address ALL critical data elements)

Accountable Entity Level (e.g., signal-to-noise analysis)

[Response Ends]

2a.10. For each level of reliability testing 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.

[Response Begins]

Critical Data Element Reliability

1. The national test of MDS 3.0 items examined the agreement between assessors (reliability). Inter-rater reliability measures the extent to which two data collectors achieve the same results when assessing the same resident within the same time frame. Two types of reliability were tested: gold-standard nurse to gold-standard nurse, and gold-standard nurse to facility-nurse. 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. The gold-standard to gold-standard comparisons provided information on instrument performance with highly trained nurses using research protocols. The gold-standard to facility-nurse comparisons measured item performance in a more operational environment in which one assessor had ongoing facility responsibilities. Residents participating in the test were selected to capture a representative sample of short- and long-stay residents. Kappa statistics 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. A rating of 0.70 is considered substantial agreement.

Landis, JR, Koch, GG. The measurement of observer agreement for categorical data. *Biometrics33*(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 <u>https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-</u> <u>Instruments/NursingHomeQualityInits/downloads/MDS30FinalReport.pdf.</u>

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 (ensuring at least 20 residents could be used in each randomly selected half of a facility's residents). Data from the 2018-2019 flu season were used to calculate the 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 receiving an influenza vaccination 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 influenza vaccination measure is a binomial random variable, conditional on the provider's true value that comes from a beta distribution. Data from the 2018-2019 flu season 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:

$$\sigma_{provider-to-provider}^{2} = \frac{\alpha\beta}{(\alpha+\beta+1)(\alpha+\beta)^{2}}$$

Sigma squared provider to provider variance equals alpha times beta over open paren alpha plus beta plus 1 close paren open paren alpha plus beta close paren squared

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:

$$\sigma_{provider-specific-error}^2 = \frac{p(1-p)}{n}$$

Sigma squared provider-specific error equals p open paren 1 minus p close paren over n, where p equals each facility's QM score and n equals the number of residents in each facility

The reliability score for each facility was then calculated using the following formula:

$$reliability = \frac{\sigma_{provider-to-provider}^{2}}{\sigma_{provider-to-provider}^{2} + \sigma_{provider-specific-error}^{2}}$$

Reliability equals sigma squared provider to provider variance over sigma squared provider to provider variance plus sigma squared 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.

[Response Ends]

2a.11. For each level of reliability testing checked above, what were the statistical results from reliability testing?

For example, provide the percent agreement and kappa for the critical data elements, or distribution of reliability statistics from a signal-to-noise analysis. For score-level reliability testing, when using a signal-to-noise analysis, more than just one overall statistic should be reported (i.e., to demonstrate variation in reliability across providers). If a particular method yields only one statistic, this should be explained. In addition, reporting of results stratified by sample size is preferred (pg. 18, <u>NQF Measure Evaluation Criteria</u>).

[Response Begins]

Critical Data Element Reliability

In their testing of the MDS 3.0, RAND observed that the kappa for gold-standard to gold-standard assessments of the influenza vaccination received in this facility item was 0.989; and the kappa for gold-standard nurse assessment to facility nurse assessment of the influenza vaccination received in this facility item was 0.941. The kappa for gold-standard to gold-standard assessments of if no influenza vaccination was received then why item was 0.976; and the kappa for gold-standard nurse assessment to facility nurse assessment of if no influenza vaccination was received then why item was 0.976; and the kappa for gold-standard nurse assessment to facility nurse assessment of if no influenza vaccination was received then why item was 0.815. Kappa is a statistical measure of inter-rater agreement for qualitative data, ranging from 0.0 to 1.0. A rating of 0.989 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

- Split-half reliability analysis: The split-half correlation for this measure in the short-stay population was positive, and the relationship was strong (r = 0.91, ICC(2,1) = 0.91, p < .01), suggesting there is considerable evidence of internal reliability.
- 2. Signal-to-noise analysis: The average signal-to-noise reliability score for this quality measure using facility scores based on data from the 2018-2019 flu season was observed to be 0.94. The distribution of signal-to-noise reliability scores for the influenza vaccination measure can be found in Table 2 below. These results suggest that the measure is very reliable in separating facility characteristics from variability within a facility.

Table 2. Distribution of Signal-to-Noise Reliability Sco	res, NQF #0680 (2018Q3-2019Q2)
--	--------------------------------

Measure	Average Score	Score Percentile	*	*
*	*	25th	50th	75th
NQF #0680 (Short-Stay)	0.94	0.91	0.96	0.99

* Indicates the table cell left intentionally blank

[Response Ends]

2a.12. Interpret the results, in terms of how they demonstrate reliability.

(In other words, what do the results mean and what are the norms for the test conducted?)

[Response Begins]

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 influenza vaccination item has very similar item wording in the latest MDS 3.0 form and the 2008 recommended form.

Performance Measure Score Reliability

These analyses demonstrate that the influenza vaccination measure shows considerable evidence of internal reliability in the short-stay population. The average signal-to-noise ratio across all providers in the short-stay population was 0.94, meaning 94% of the variance in scores for this measure were explained by inter-facility variation. These results suggest that the measure is very reliable in separating provider characteristics from variability within provider in the short-stay population.

[Response Ends]

2b. Validity

2b.01. Select the level of validity testing that was conducted.

[Response Begins]

Patient or Encounter-Level (data element validity must address ALL critical data elements)

Accountable Entity Level (e.g. hospitals, clinicians)

Empirical validity testing

[Response Ends]

2b.02. 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.

[Response Begins]

Critical Data Element Validity

1. 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

1. Convergent validity: The Percent of Residents Assessed and Appropriately Given the Seasonal Influenza Vaccine (NQF #0680) measure should be related to other measures that are theoretically similar or based on related concepts. To test this relationship, convergent validity was estimated using correlation coefficients between NQF #0680 and three groups of measures: vaccination measures, Five-Star ratings, other quality measures based on clinician recommendation or relevant literature. Related vaccination measures, such as Percent of Residents Assessed and Appropriately Given the Pneumococcal Vaccine (Short-Stay) and The Percent of Residents Assessed and Appropriately Given the Seasonal Influenza Vaccine (Long-Stay), were examined with the hypothesis that a facility's percentile ranking (compared to all facilities reporting the measure) should be consistent among related vaccination measures will be higher than the correlations with all other measures because the vaccination measures similar processes. Facility Five-Star ratings were also examined with the hypothesis that a facility's percentile ranking (compared to all facilities reporting the measure) should be somewhat consistent among those facility Five-Star ratings. Facility Five-Star

Ratings, such as overall facility five-star ratings, quality ratings, staffing ratings, registered nurse staffing ratings, and survey ratings, were examined for this purpose. Additionally, other MDS quality measures that were identified as having associations with NQF #0680 in recent literature or by clinician recommendation 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. Quality Measures, such as Percent of Residents Who Newly Received an Antipsychotic Medication (Short-Stay), Percent of Residents Who Have/Had a Catheter Inserted and Left in Their Bladder (Long-Stay), Percent of Residents Who Were Physically Restrained (Long-Stay), Healthcare Associated Infections (Short-Stay), Discharge to Community – Post Acute Care (PAC) Skilled Nursing Facility (SNF) Quality Reporting Program (QRP), and Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury (Short-Stay) were examined for this purpose. Public reporting data was used to calculate the correlations between NQF #0680 (Percent of Residents Assessed and Appropriately Given the Seasonal Influenza Vaccine) and facility Five-Star ratings, as well as the other related quality measures.

[Response Ends]

2b.03. Provide the statistical results from validity testing.

Examples may include correlations or t-test results.

[Response Begins]

Critical Data Elements

The kappa for gold-standard nurse assessment to facility nurse assessment of the influenza vaccination received in this facility item was 0.941. The kappa for gold-standard nurse assessment to facility nurse assessment of if no influenza vaccination was received then why item was 0.815.

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

 Convergent Validity: The analysis found low but statistically significant positive correlations between Percent of Residents Assessed and Appropriately Given the Seasonal Influenza Vaccine (NQF #0680) and overall facility five-star ratings, quality ratings, staffing ratings, registered nurse staffing ratings, and survey ratings. The coefficient estimates and associated p-values are summarized in Table 3 below. All correlations are statistically significant and in the expected direction, suggesting lowmoderate convergent validity.

Facility Five-Star Rating	Spearman Correlation	P-Value
Overall facility ratings	0.299	<.0001
Quality ratings	0.236	<.0001
Staffing ratings	0.157	<.0001
Registered nurse staffing ratings	0.110	<.0001

Table 3. Correlations between NQF #0680 and Facility Five-Star Ratings (2018Q3-2019Q2)

Facility Five-Star Rating	Spearman Correlation	P-Value
Survey ratings	0.258	<.0001
MDS Quality Measure	*	*
Percent of Residents Who Newly Received an Antipsychotic Medication (Short-Stay)	-0.135	<.0001
Percent of Residents Assessed and Appropriately Given the Influenza Vaccine (Long-Stay)	0.586	<.0001
Percent of Residents Assessed and Appropriately Given the Pneumococcal Vaccine (Short-Stay)*	0.728	<.0001
Percent of Residents Who Have/Had a Catheter Inserted and Left in Their Bladder (Long-Stay)*	-0.094	<.0001
Percent of Residents Who Were Physically Restrained (Long-Stay)*	-0.055	<.0001
Healthcare Associated Infections (Short-Stay)(Risk Adjusted)**	-0.091	<.0001
Discharge to Community (Risk Adjusted)***	0.200	<.0001
Changes in Skin Integrity****	-0.063	<.0001

* 2019 Public Reporting Data; ** FY2019 HAI Data*** 2018-2019 DTC Data; **** SNF Quality Reporting Program Provider Data Nov2021

* Indicates the table cell left intentionally blank

[Response Ends]

2b.04. Provide 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?)

[Response Begins]

Performance Measure Score Validity

The measure's correlations with facility five-star ratings and other related quality measures are all statistically significant and in the expected direction, demonstrating low-moderate convergent validity. This measure has low but statistically significant positive correlations with Overall Facility Five-Star Ratings, Quality Ratings, Staffing Ratings, Registered Nurse Staffing Ratings, and Survey Ratings. This measure has a positive and statistically significant correlation with Percent of Residents Assessed and Appropriately Given the Pneumococcal Vaccine (Short-Stay). The correlations between this measure and both the pneumococcal vaccination measure and long-stay influenza vaccination measures are in the expected direction and moderate in magnitude, suggesting moderate convergent validity. These moderate correlations are consistent with our expectation that the correlations between NQF #0680 and the related vaccination measures would be higher because they are measuring similar processes. Although these correlations are moderate, they are likely not very high due to differences in the vaccination schedules for the pneumococcal and influenza vaccines. Furthermore, the population differences between the short-stay and long-stay influenza vaccination measures are likely to lead to a moderate correlation. The short-stay influenza vaccination measure also has negative and statistically significant correlations with Percent of Residents Who Newly Received an Antipsychotic Medication (Short-Stay), Percent of Residents Who Have/Had a Catheter Inserted and Left in Their Bladder (Long-Stay), Percent of Residents Who Were Physically Restrained (Long-Stay), Healthcare Associated

Infections (Short-Stay), Discharge to Community – Post Acute Care (PAC) Skilled Nursing Facility (SNF) Quality Reporting Program (QRP), and Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury (Short-Stay). The correlations between these quality measures and the short-stay influenza vaccination measure were modest, which is expected since different outcomes are being measured. These modest correlations are also likely due to population differences caused by different denominator definitions for each of these measures. While most of these correlation coefficients are modest in magnitude, they are all statistically significant and in the expected direction, which further establishes convergent validity.

[Response Ends]

2b.05. 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 in Importance to Measure and Report: Gap in Care/Disparities.

[Response Begins]

- 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 to measure performance gaps and meaningful differences. 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.
- 2. In order to identify meaningful differences in facility performance on NQF #0680, the current variability in the facility-level quality measure scores was explored (see 2b.06).

[Response Ends]

2b.06. Describe the statistical results from testing the ability to identify statistically significant and/or clinically/practically meaningful differences in performance measure scores across measured entities.

Examples may include 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.

[Response Begins]

 Confidence interval analysis: Table 4 shows the proportion of facilities that scored significantly higher or lower than the national facility-level mean. Data from 2018Q3-2019Q2 was combined to produce Table 4, as this range of data provides an opportunity to capture low performing and high performing facilities. 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.

Table 4. Proportion of Facilities with Scores Significantly Different from the National Facility-Level Mean,NQF #0680 (2018Q3-2019Q2)

Mean QM Score	Number of facilities	Number of facilities with 95% confidence interval lower than national mean (%)	*	Number of facilities with 95% confidence interval higher than national mean (%)	*	Total number of facilities with scores significantly different from mean (%)	*
*	*	Ν	%	Ν	%	Ν	%
83.90%	12,907	2,563	19.9%	5,203	40.3%	7,766	60.2%

* Indicates the table cell left intentionally blank

For one year of data in the short-stay population, 60.2% of facilities had a score that was statistically significantly different from the national mean with 95% confidence, suggesting a large performance gap and room for quality improvement. Approximately 20% of facilities had scores that were statistically significantly lower than the national mean, and 40.3% of facilities had scores that were statistically significantly higher than the national mean with 95% confidence.

 Table 5 describes the current variability in the quality measure scores of facilities nationally in the 2018-2019 flu season (2018Q3-2019Q2). The mean facility-level score for this quality measure was 83.9%, with a median score of 90.0%. The interquartile range for this measure was 17.4 percentage points. Among facilities who were eligible to publicly report this measure, 7.8% (k = 1,007) had perfect scores of 100%.

Populati on	К	Mea n scor e	Std dev.	10th percent ile	25th percent ile	50th percent ile	75th percent ile	90th percent ile	% of faciliti es with perfec t score	Interquart ile range
Short- Stay	12,9 07	83.9 %	17.4 %	60.0%	78.4%	90.0%	95.8%	98.9%	7.8%	17.4%

Table 5. National Facility-Level Score Distribution, NQF #0680 (2018Q3-2019Q2)

[Response Ends]

2b.07. Provide 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.

In other words, what do the results mean in terms of statistical and meaningful differences?

[Response Begins]

The confidence interval analysis for this measure indicates that there are meaningful differences in facilitylevel scores for this measure, as 60.2% of facilities had a mean score for which the 95% confidence intervals did not overlap with the national mean. Overall, 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 1.5 times higher than the 10th percentile. Moreover, the quality measure scores vary sufficiently from the national mean so that there are meaningful differences to differentiate the best and worst performers for this measure.

[Response Ends]

2b.08. Describe the method of testing conducted to identify the extent and distribution of missing data (or non-response) and demonstrate that performance results are not biased due to systematic missing data (or differences between responders and non-responders). Include how the specified handling of missing data minimizes bias.

Describe the steps—do not just name a method; what statistical analysis was used.

[Response Begins]

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 2b.09.

[Response Ends]

2b.09. Provide the overall frequency of missing data, the distribution of missing data across providers, and the results from testing related to missing data.

For example, provide results of sensitivity analysis of the effect of various rules for missing data/non-response. If no empirical sensitivity analysis was conducted, identify the approaches for handling missing data that were considered and benefits and drawbacks of each).

[Response Begins]

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:

1. Resident's age on target date of selected target assessment is 179 days or less.

Only 134 episodes in the 2018-2019 (2018Q3-2019Q2) short-stay resident sample were excluded from the denominator for this measure due to the resident's age on the target date of the selected target assessment being 179 days or less, which accounts for 0.009% of the total episodes.

[Response Ends]

2b.10. Provide 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.

In other words, 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 was conducted, justify the selected approach for missing data.

[Response Begins]

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.

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 eCQMs). It does not apply to measures that use more than one source of data in one set of specification for 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.

2b.11. Indicate whether there is more than one set of specifications for this measure.

[Response Begins]

No, there is only one set of specifications for this measure

[Response Ends]

2b.12. 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. Indicate what statistical analysis was used.

[Response Begins] [Response Ends]

2b.13. Provide the statistical results from testing comparability of performance scores for the same entities when using different data sources/specifications.

Examples may include correlation, and/or rank order.

[Response Begins] [Response Ends]

2b.14. Provide your interpretation of the results in terms of the differences in performance measure scores for the same entities across the different data sources/specifications.

In other words, what do the results mean and what are the norms for the test conducted.

[Response Begins] [Response Ends]

2b.15. Indicate whether the measure uses exclusions.[Response Begins]Yes, the measure uses exclusions.[Response Ends]

2b.16. Describe the method of testing exclusions and what was tested.

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?

[Response Begins]

Please see Section **2b.08**. "Missing data analysis and minimizing bias for analysis of this measure's exclusions," which are only for missing data on the applicable influenza vaccination items.

[Response Ends]

2b.17. Provide 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.

[Response Begins]

Please see Section **2b.09**. "Missing data analysis and minimizing bias for analysis of this measure's exclusions," which are only for missing data on the applicable influenza vaccination items.

[Response Ends]

2b.18. Provide your interpretation of the results, in terms of demonstrating that exclusions are needed to prevent unfair distortion of performance results.

In other words, 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.

[Response Begins]

Please see Section **2b.10**. "Missing data analysis and minimizing bias for analysis of this measure's exclusions," which are only for missing data on the applicable influenza vaccination items.

[Response Ends]

2b.19. Check all methods used to address risk factors.

[Response Begins] No risk adjustment or stratification [Response Ends]

2b.20. If using statistical risk models, provide detailed risk model specifications, including the risk model method, risk factors, risk factor data sources, coefficients, equations, codes with descriptors, and definitions.

[Response Begins]

[Response Ends]

2b.21. If an outcome or resource use measure is not risk-adjusted or stratified, provide rationale and analyses to demonstrate that controlling for differences in patient characteristics (i.e., case mix) is not needed to achieve fair comparisons across measured entities.

[Response Begins]

The measure is not risk adjusted through a statistical model nor through stratification. Neither relevant clinical nor social risk factors were tested statistically because the Percent of Residents Assessed and Appropriately Given the Seasonal Influenza Vaccine is a process measure. The target population of a process measure is defined to include all patients for whom the process measure is appropriate.

[Response Ends]

2b.22. Select all applicable resources and methods used to develop the conceptual model of how social risk impacts this outcome.

[Response Begins] [Response Ends]

2b.23. Describe the conceptual and statistical methods and criteria used to test and select patient-level risk factors (e.g., clinical factors, social risk factors) used in the statistical risk model or for stratification by risk.

Please be sure to address the following: potential factors identified in the literature and/or expert panel; regression analysis; statistical significance of p<0.10 or other statistical tests; correlation of x or higher. Patient factors should be present at the start of care, if applicable. Also discuss any "ordering" of risk factor inclusion; note whether social risk factors are added after all clinical factors. Discuss any considerations regarding data sources (e.g., availability, specificity).

[Response Begins] [Response Ends]

2b.24. Detail the statistical results of the analyses used to test and select risk factors for inclusion in or exclusion from the risk model/stratification.

[Response Begins] [Response Ends]

2b.25. Describe the analyses and interpretation resulting in the decision to select or not select social risk factors.

Examples may include prevalence of the factor across measured entities, availability of the data source, empirical association with the outcome, contribution of unique variation in the outcome, or assessment of between-unit effects and within-unit effects. Also describe the impact of adjusting for risk (or making no adjustment) on providers at high or low extremes of risk.

[Response Begins] [Response Ends]

2b.26. 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 control for differences in patient

characteristics (i.e., case mix) below. If stratified ONLY, enter "N/A" for questions about the statistical risk model discrimination and calibration statistics.

Validation testing should be conducted in a data set that is separate from the one used to develop the model.

[Response Begins] [Response Ends]

2b.27. Provide risk model discrimination statistics. *For example, provide c-statistics or R-squared values.*

[Response Begins] [Response Ends]

2b.28. Provide the statistical risk model calibration statistics (e.g., Hosmer-Lemeshow statistic).
[Response Begins]
This is not applicable, as this measure is not risk-adjusted.
[Response Ends]

2b.29. Provide the risk decile plots or calibration curves used in calibrating the statistical risk model. *The preferred file format is .png, but most image formats are acceptable.*

[Response Begins] [Response Ends]

2b.30. Provide the results of the risk stratification analysis. [Response Begins] [Response Ends]

2b.31. Provide your interpretation of the results, in terms of demonstrating adequacy of controlling for differences in patient characteristics (i.e., case mix).

In other words, what do the results mean and what are the norms for the test conducted?

[Response Begins] [Response Ends]

2b.32. Describe any additional testing conducted to justify the risk adjustment approach used in specifying the measure.

Not required but would provide additional support of adequacy of the risk model, e.g., testing of risk model in another data set; sensitivity analysis for missing data; other methods that were assessed.

[Response Begins] [Response Ends]

Criterion 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.

3.01. Check all methods below that are used to generate the data elements needed to compute the measure score.

[Response Begins]

Generated or collected by and used by healthcare personnel during the provision of care (e.g., blood pressure, lab value, diagnosis, depression score)

[Response Ends]

3.02. Detail to what extent the specified data elements are available electronically in defined fields.

In other words, indicate whether data elements that are needed to compute the performance measure score are in defined, computer-readable fields.

[Response Begins]

ALL data elements are in defined fields in electronic clinical data (e.g., clinical registry, nursing home MDS, home health OASIS)

[Response Ends]

3.03. 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 data elements not from electronic sources.

[Response Begins]

This is not applicable; all data elements used to calculate the measure are in defined fields in electronic clinical data.

[Response Ends]

3.04. Describe any efforts to develop an eCQM.

[Response Begins]

There are no current efforts to develop this measure as an eCQM.

[Response Ends]

3.06. 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.

[Response Begins]

The general data collection method for the MDS 3.0 is currently in operational use and mandatory for all Medicare/Medicaid certified nursing facilities.

[Response Ends]

Consider implications for both individuals providing data (patients, service recipients, respondents) and those whose performance is being measured.

3.07. Detail 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),

Attach the fee schedule here, if applicable.

[Response Begins]

This is not applicable.

[Response Ends]

Criterion 4: Use and Usability

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 highquality, efficient healthcare for individuals or populations.

Extent to which intended audiences (e.g., consumers, purchasers, providers, policy makers) can understand the results of the measure and are likely to find them useful for decision making.

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 demonstrating performance improvement.

4a. Use

4a.01. Check all current uses. For each current use checked, please provide:

Name of program and sponsor

URL

Purpose

Geographic area and number and percentage of accountable entities and patients included

Level of measurement and setting

[Response Begins]

Public Reporting

[Public Reporting Please Explain]

Public Reporting:

- Program and sponsor: Care Compare and Provider Data Catalog/Centers for Medicare and Medicaid Services (CMS)
- URL:
 - Care Compare: https://www.medicare.gov/care-compare/
 - Provider Data Catalog: https://data.cms.gov/provider-data/
- Purpose: Consumer information
- Geographic area and number and percentage of accountable entities and patients included: All United States Nursing Homes with Medicare-eligible short-stay residents. Between 2018Q3 and 2019Q2 there were 12,907 eligible facilities and 1,429,900 residents with target assessments, and all 12,907 facilities (100%) had sufficient sample size (20 or more short-stay residents included in the denominator) to report on this measure, and 1,429,771 residents (99.9%) 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 Nursing Home Quality Initiative (NHQI) through Care Compare and Provider Data Catalog.

Quality Improvement with Benchmarking (external benchmarking to multiple organizations)

[Quality Improvement with Benchmarking (external benchmarking to multiple organizations) Please Explain]

Quality Improvement with Benchmarking (external benchmarking to multiple organizations):

- Program and sponsor: Certification and Survey Provider Enhanced Reports (CASPER)/Centers for Medicare and Medicaid Services
- URL: https://www.qtso.com/providernh.html
- 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 short-stay residents regardless of denominator sample size. Between 2018Q3 and 2019Q2 there were 12,907 eligible facilities and 1,429,900 residents with target assessments.

Quality Improvement (Internal to the specific organization)

[Quality Improvement (Internal to the specific organization) Please Explain]

Quality Improvement (internal to the specific organization):

- Program and sponsor: Certification and Survey Provider Enhanced Reports (CASPER)/Centers for Medicare and Medicaid Services
- URL: https://www.qtso.com/providernh.html
- 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 short-stay residents regardless of denominator sample size. Between 2018Q3 and 2019Q2 there were 12,907 eligible facilities and 1,429,900 residents with target assessments.

[Response Ends]

4a.02. Check all planned uses.

[Response Begins]

Public reporting

Quality Improvement with Benchmarking (external benchmarking to multiple organizations)

Quality Improvement (internal to the specific organization)

[Response Ends]

4a.03. If not currently publicly reported OR used in at least one other accountability application (e.g., payment program, certification, licensing), explain why the measure is not in use.

For example, do policies or actions of the developer/steward or accountable entities restrict access to performance results or block implementation?

[Response Begins]

This section is not applicable. The QM is current publicly reported for nursing homes and planned to be publicly reported for IRFs and LTCHs.

[Response Ends]

4a.04. If not currently publicly reported OR used in at least one other accountability application, provide a credible plan for implementation within the expected timeframes: used in any accountability application within 3 years, and publicly reported within 6 years of initial endorsement.

A 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.

[Response Begins]

This section is not applicable.

[Response Ends]

4a.05. Describe how performance results, data, and assistance with interpretation have been provided to those being measured or other users during development or implementation.

Detail 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.

[Response Begins]

- This quality measure (NQF 0680, Percent of Residents Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short-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 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 (<u>https://www.medicare.gov/care-compare/?providerType=NursingHome</u>) or the Provider Data Catalog (<u>https://data.cms.gov/provider-data/</u>). 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.
- Further, providers have an opportunity to review their performance prior to public reporting on the Care 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. 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://gtso.cms.gov/system/files/qtso/cspr_sec11_mds_prvdr_0.pdf

[Response Ends]

4a.06. Describe the process for providing measure results, including when/how often results were provided, what data were provided, what educational/explanatory efforts were made, etc.

[Response Begins]

- 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 a Help Line, which is accessible by telephone and email, to answer provider questions about the NHQI quality measures and reporting requirements.

[Response Ends]

4a.07. Summarize the feedback on measure performance and implementation from the measured entities and others. Describe how feedback was obtained.

[Response Begins]

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).

[Response Ends]

4a.08. Summarize the feedback obtained from those being measured.

[Response Begins]

Upon review of all inquiries submitted to the quality measure support inbox between 10/2019 and 02/2022, those being measured raised no concerns regarding the performance and implementation of NQF 0680.

[Response Ends]

4a.09. Summarize the feedback obtained from other users.

[Response Begins]

Upon review of all inquiries submitted to the quality measure support inbox between 10/2019 and 02/2022, other users raised no concerns regarding the performance and implementation of NQF 0680.

4a.10. Describe how the feedback described has been considered when developing or revising the measure specifications or implementation, including whether the measure was modified and why or why not.

[Response Begins] This is not applicable.

[Response Ends]

4b. Usability

4b.01. You may refer to data provided in Importance to Measure and Report: Gap in Care/Disparities, 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, provide an explanation. 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.

[Response Begins]

- Progress (trends in performance results, number and percentage of people receiving high-quality healthcare):
- Overall, the national facility-level mean and median scores for the Percent of Residents Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short-Stay) have shown a small increase between the 2013-2014 influenza season (2013Q3-2014Q2) and the 2018-2019 influenza season (2018Q3-2019Q2) across the score distribution. The mean score for this measure was 81.6% during the 2013-2014 season and the median score was 87.1%. During the 2018-2019 season, the mean and median were 83.9% and 90.0%, respectively.

Geographic area and number and percentages of accountable entities and patients included:

All United States Nursing Homes with Medicare-eligible short-stay residents. Between 2018Q3 and 2019Q2 there were 12,907 eligible facilities and 1,429,900 residents with target assessments, and all 12,907 facilities (100%) had sufficient sample size (20 or more short-stay residents included in the denominator) to report on this measure, and 1,429,771 residents (99.9%) were included in the calculation of this measure.

[Response Ends]

4b.02. Explain any unexpected findings (positive or negative) during implementation of this measure, including unintended impacts on patients.

[Response Begins]

There were no unexpected findings during the testing process for NQF 0680.

[Response Ends]

4b.03. Explain any unexpected benefits realized from implementation of this measure.

[Response Begins]

This is not applicable; there are no unexpected benefits from the implementation of NQF 0680.

[Response Ends]

Criterion 5: Related and 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.

If you are updating a maintenance measure submission for the first time in MIMS, please note that the previous related and competing data appearing in question 5.03 may need to be entered in to 5.01 and 5.02, if the measures are NQF endorsed. Please review and update questions 5.01, 5.02, and 5.03 accordingly.

5.01. Search and select all NQF-endorsed related measures (conceptually, either same measure focus or target population).

(Can search and select measures.)

[Response Begins]

1659: Influenza Immunization

[Response Ends]

5.02. Search and select all NQF-endorsed competing measures (conceptually, the measures have both the same measure focus or target population).

(Can search and select measures.)

[Response Begins]

[Response Ends]

5.03. If there are related or competing measures to this measure, but they are not NQF-endorsed, please indicate the measure title and steward.

[Response Begins]

There are no related or competing measures that are not NQF-endorsed.

[Response Ends]

5.04. If this measure conceptually addresses EITHER the same measure focus OR the same target population as NQF-endorsed measure(s), indicate whether the measure specifications are harmonized to the extent possible.

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[Response Begins]
No
[Response Ends]
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5.05. If the measure specifications are not completely harmonized, identify the differences, rationale, and impact on interpretability and data collection burden.

[Response Begins]

 NQF 1659 targets a different population in multiple settings and does not include those assessed but not given the vaccine. NQF 1659 also has a broader numerator that includes inpatients age six months and older who were screened for influenza vaccine status and were vaccinated prior to discharge if indicated.

5.06. Describe why this measure is superior to competing measures (e.g., a more valid or efficient way to measure quality). Alternatively, justify endorsing an additional measure.

Provide analyses when possible.

[Response Begins]

This is not applicable, as there are no competing measures.

[Response Ends]