This form contains the information submitted by measure developers/stewards, organized according to NQF’s measure evaluation criteria and process. The evaluation criteria, evaluation guidance documents, and a blank online submission form are available on the submitting standards web page.

<table>
<thead>
<tr>
<th>NQF #: 0682</th>
<th>NQF Project: Ad Hoc Reviews-Expansion of Settings</th>
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</thead>
<tbody>
<tr>
<td>(for Endorsement Maintenance Review)</td>
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<tr>
<td><strong>Original Endorsement Date:</strong> Mar 03, 2011  <strong>Most Recent Endorsement Date:</strong> Mar 03, 2011  <strong>Last Updated Date:</strong> March 05, 2012</td>
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### BRIEF MEASURE INFORMATION

**De.1 Measure Title:** Percent of Residents or Patients Assessed and Appropriately Given the Pneumococcal Vaccine (Short-Stay)

**Co.1.1 Measure Steward:** Centers for Medicare & Medicaid Services

**De.2 Brief Description of Measure:** The measure reports the percentage of short stay nursing home residents or IRF or LTCH patients who were assessed and appropriately given the pneumococcal vaccine during the 12-month reporting period. This measure is based on data from Minimum Data Set (MDS) 3.0 assessments of nursing home residents, the Inpatient Rehabilitation Facilities Patient Assessment Instrument (IRF-PAI) for IRF patients, and the Long Term Care Hospital (LTCH) Continuity Assessment Record and Evaluation (CARE) Data Set for long-term care hospital patients, using items that have been harmonized across the three assessment instruments. Short-stay nursing home residents are those residents who are discharged within the first 100 days of their nursing home stay.

The NQF standard specifications were harmonized to achieve a uniform approach to measurement across settings and populations, addressing who is included in or excluded from the target denominator population, who is included in the numerator population, and the time windows. In 2008, the NQF steering committee met to identify voluntary consensus measures for influenza and pneumococcal vaccination that were harmonized across healthcare settings. The steering committee recognized that “in the interest of standardization and minimizing burden for those implementing and using measures, measure harmonization is an important consideration in evaluating and recommending measures for endorsement.” The committee supported the use of measure IM-017—which reports the percent of nursing home/Skilled Nursing Facility residents whose pneumococcal polysaccharide vaccine (PPV) status is up to date during the 12-month reporting period - as the basis for a harmonized measure across settings (National Quality Forum, 2008b). The NQF standardized specifications differ from the currently reported measure in several ways. Note that for some residents or patients, a single vaccination during their lifetime is sufficient and the vaccination would be considered up to date; for others (those who are immunocompromised or older than age 65, but the first vaccine was administered more than 5 years before when the resident was younger than 65), a second dose would be needed to qualify as vaccination up to date. Although the guidelines recommend a second dose in these circumstances, the NQF Committee believed that adding that requirement would make measurement too complex for the amount of benefit gained. Also, given the importance of revaccination among older adults, focusing on up-to-date status, rather than on ever having received the vaccine, is critically important. This focus on up-to-date rather than ever having received a vaccination is supported by the NQF steering committee in their discussion of the national voluntary consensus standards for this measure (National Quality Forum, 2008a).

This measure will include only residents or patients aged 5 years and older in the denominator. In their 2008 review of voluntary consensus standards for influenza and pneumococcal vaccination the NQF steering committee recommended limiting the use of measure IM-017 which reports the percent of nursing home/Skilled Nursing Facility residents whose PPV status is up to date, to residents age 5 and older. They state in their recommendation, “the specifications for high-risk groups begin at age 5, because the schedule for children ages 2-5 is different and complicated.” (National Quality Forum, 2008b) The Advisory Committee on Immunization Practices (ACIP) provides age specific guidelines for pneumococcal immunization for both children and adults. These guidelines vary based on age and risk level and should be followed accordingly. Up-to-date vaccination status is defined as a...
**Numerator Statement:** The following numerator components will be computed and reported separately: (1) **up-to-date vaccine status; (2) ineligible to receive vaccine due to medical contraindications; or (3) offered and declined vaccine. Measure numerator specifications for the three provider type assessment tools are listed below:

**MDS 3.0 assessment:** Residents are counted if they are short-stay, defined as residents whose length of stay is less than or equal to 100 days. Residents aged 5 years and older are counted if they meet any of the following criteria on the most recent MDS 3.0 assessment, which may be an OBRA assessment (A0310A=01,02,03,04,05,06), PPS assessment(A0310B = 01, 02, 03, 04, 05, 06), or discharge assessment(A0310F = 10, 11), during the 12-month reporting period. The following numerator components will be computed and reported separately:

1. **Up-to-date vaccine status (O0300A=1)**
2. **Ineligible due to medical contraindications (O0300B=1)**
3. **Offered and declined vaccine (O0300B=2)**

**LTCH CARE Data Set:** Patients aged 5 years and older are counted if they meet any of the following criteria on the most recent LTCH CARE Data Set assessment during the 12-month reporting period. The following numerator components will be computed and reported separately:

1. **Up-to-date vaccine status (O0300A=1)**
2. **Ineligible due to medical contraindications (O0300B=1)**
3. **Offered and declined vaccine (O0300B=2)**

**IRF-PAI assessment:** Patients aged 5 years and older are counted if they meet any of the following criteria on the IRF-PAI assessment during the 12-month reporting period. The following numerator components will be computed and reported separately, in the *IRF-PAI tool:

1. **Up-to-date vaccine status**
2. **Ineligible due to medical contraindications**
3. **Offered and declined vaccine**

*Note that the components of the IRF-PAI have not yet been assigned item numbers but will be assigned item numbers to match the MDS 3.0 and LTCH CARE Data Set.

**"Up-to-date" vaccination status is defined as a resident or patient who has been vaccinated in accordance with the current CDC vaccination guidelines for pneumococcal disease for his/her age and health status. The current CDC vaccination guidelines for resident or patient who has been vaccinated in accordance with the current CDC vaccination guidelines for pneumococcal disease for his/her age and health status. The current CDC vaccination guidelines for adults are available at http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5934a3.htm. The current CDC vaccination guidelines for infants and children are available at http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5911a1.htm?s_cid=rr5911a1_e.**


**Centers for Disease Control and Prevention (2010). Updated recommendations for prevention of invasive pneumococcal disease among adults using the 23-valent pneumococcal polysaccharide vaccine (PPSV23). MMWR 2010. 59(34), 1102-1106. Available from: [http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5934a3.htm](http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5934a3.htm)**

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adults are available at http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5934a3.htm. The current CDC vaccination guidelines for infants and children are available at http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5911a1.htm?s_cid=rr5911a1_e.

2a1.4 Denominator Statement: The denominator consists of all residents or patients aged 5 years and older in the pneumococcal vaccination sample (defined in Denominator Details section) with an assessment within the 12-month period. Specifications for the three provider type assessment tools are listed below:

MDS 3.0: Short-stay residents aged 5 years and older in the pneumococcal vaccination sample with an MDS 3.0 assessment (which may be an OBRA, PPS, or discharge assessment) within the 12-month period.

LTCH CARE Data Set: Patients aged 5 years and older in the pneumococcal vaccination sample with a LTCH CARE Data Set assessment (which may be an admission or discharge assessment) within the 12-month period.

IRF-PAI: Patients aged 5 years and older in the pneumococcal vaccination sample with an IRF-PAI assessment (which may be an admission or discharge assessment) within the 12-month period.

2a1.8 Denominator Exclusions: Residents or patients younger than 5 years old will be excluded from the denominator. Facilities with denominator counts of less than 20 in the sample will be excluded from public reporting owing to small sample size.

1.1 Measure Type: Process

2a1. 25-26 Data Source: Electronic Clinical Data

2a1.33 Level of Analysis: Facility, Population : National

1.2-1.4 Is this measure paired with another measure? No

De.3 If included in a composite, please identify the composite measure (title and NQF number if endorsed): This is not applicable

STAFF NOTES (issues or questions regarding any criteria)

Comments on Conditions for Consideration:

Is the measure untested? Yes□ No□ If untested, explain how it meets criteria for consideration for time-limited endorsement:

1a. Specific national health goal/priority identified by DHHS or NPP addressed by the measure (check De.5):

5. Similar/related endorsed or submitted measures (check 5.1):

Other Criteria:

Staff Reviewer Name(s):

1. IMPACT, OPPORTUNITY, EVIDENCE - IMPORTANCE TO MEASURE AND REPORT

Importance to Measure and Report is a threshold criterion that must be met in order to recommend a measure for endorsement. All three subcriteria must be met to pass this criterion. See guidance on evidence. Measures must be judged to be important to measure and report in order to be evaluated against the remaining criteria. (evaluation criteria)

1a. High Impact: □ H □ M □ L □ I □
(The measure directly addresses a specific national health goal/priority identified by DHHS or NPP, or some other high impact aspect of healthcare.)

De.4 Subject/Topic Areas (Check all the areas that apply): Prevention : Immunization
De.5 Cross Cutting Areas (Check all the areas that apply): Population Health

1a.1 Demonstrated High Impact Aspect of Healthcare: Affects large numbers, Severity of illness, Frequently performed procedure, A leading cause of morbidity/mortality, Patient/societal consequences of poor quality

See Guidance for Definitions of Rating Scale: H=High; M=Moderate; L=Low; I=Insufficient; NA=Not Applicable
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1a.2 If “Other,” please describe:

1a.3 Summary of Evidence of High Impact (Provide epidemiologic or resource use data):
According to the Centers for Disease Control and Prevention (CDC), pneumococcal disease kills more people in the United States each year than all other vaccine-preventable diseases combined (CDC, 2009). In 2006, all possible pneumonia diagnoses (including viral, bacterial and unspecified organisms) killed 55,477 people in the United States (NCHS, 2009) and was responsible for approximately 589,000 hospital discharges in males and 643,000 hospital discharges in females (NCHS 2006). Among the 2006 discharges, individuals age 65 or older and had the highest rate at 189 per 10,000 (NCHS, 2006). For patients in long-term care facilities, pneumonia is the leading cause of morbidity and mortality and is the leading cause of transfer to acute-care hospitals (Furman et al., 2004). Older people and those with chronic health conditions are at high risk for pneumococcal disease. Pneumonia is of even greater concern for post-surgery patients: CDC reports that pneumonia is the third-most-frequent healthcare-acquired infection (HAI) among post-surgical patients, with a prevalence of 15%; and among cases in which the cause of death was an HAI, pneumonia is the most frequent HAI (38%) (CDC, 2009). Given that many patients in post-acute care (PAC) settings are post-surgery, vaccinations of post-acute care residents can prevent or lower the risk of residents becoming seriously ill. Stroke patients are also at higher risk of pneumonia as a complication; pneumonia is one of the most common adverse events and the second most common cause of acute-hospital readmission (Hung et al., 2005).

The pneumococcal vaccine protects against the bacterial strain of pneumonia caused by Streptococcus pneumoniae (S. pneumoniae). Specific data related to S. pneumoniae in nursing facilities, LTCHs and IRFs is currently unknown. Generally speaking, S. pneumoniae accounted for 5,000 deaths among persons of all ages in 2009 (CDC 2010). The estimated overall annual incidence of S. pneumoniae in the United States is 15-30 cases per 100,000 population, with the rate being higher in persons aged 65 or older (about 50-83 cases per 100,000 population) (CDC 1997). The use of the PPSV23 vaccine among adults aged 65 or older and those adults aged 19-64 years with underlying medical conditions is recommended, as they are at greater risk for serious pneumococcal infection (CDC 2010).

Hospitalization rates for pneumonia-related stays for the elderly population have been increasing over the past 15 years; among those 85 or older, at least 1 in 20 people were hospitalized each year because of pneumonia (Fry et al., 2005). In 2005, Medicare paid an average of $6,342 per hospital discharge for pneumonia-related short-stay hospitalizations; the average length of stay was 6.1 days. The number of Medicare-reimbursed discharges related to pneumococcal infection for the same year was 670,000 (Health Care Financing Review, 2007).

Healthy People 2010 (Objective 14-29f) and Healthy People 2020 (Objective IID-13.3) set a goal of 90% of adults vaccinated against pneumococcal disease in long-term care facilities and nursing homes by 2010 and 2020, respectively (Health People, 2010, Healthy People, 2020). However, estimated pneumococcal vaccination coverage remains below 50% among high-risk groups (NHIS, 2006). In 2006, 66 percent of persons in long-term care facilities and nursing homes certified by the Centers for Medicare and Medicaid Services (CMS) reported having up-to-date pneumococcal vaccinations (Healthy People 2020). CMS currently uses MDS 2.0 data to publicly report a pneumococcal vaccination quality measure (QM) for nursing facility residents. In an analysis of quality measures using MDS data from the 2006 Q1 for a random 10% facility sample, the University of Colorado found that this measure had a significant amount of variability across facilities. The quality measure varied from 15.6% at the 10th percentile to 98.1% at the 90th percentile. In addition, 8.0% of facilities had 100% vaccination (Brega et al., 2008). The first quarter (Q1) 2007 statewide averages for the PAC population ranged from 48.8% to 91.8%, with a 73.7% national average (Colorado Foundation for Medical Care, 2007). See attached Table 1: Measure Variability Across Facilities.

Although the majority of measure-specific data and quality measurement information regarding pneumococcal vaccination among the elderly has been conducted using the MDS 2.0 in a nursing home setting, and nursing homes, LTCHs, and IRFs are not entirely identical, there is overlap in these populations and risk factors. A 2009 report prepared by RTI International explored the demographic and clinical factors in all three provider populations and found similarities in age, race, and diagnosis. In regard to age, in 2006, 80% of LTCH patients were 65 or older, and 91% of both IRFs and skilled nursing facility residents were 65 or older. Comparing race, in 2006, LTCH populations were 76% white, IRFs populations were 82% white, and nursing facility populations were 89% white. When comparing the All Patient Refined—Diagnosis Related Groups (APR-DRG) illness severity index, LTCHs had significantly higher numbers of level 3 or 4 patients (74%) compared with nursing facilities (39%) and IRFs (33%) (Gage et al., 2009).

See Guidance for Definitions of Rating Scale: H=High; M=Moderate; L=Low; I=Insufficient; NA=Not Applicable
The study also found that the location of a post-acute care referral is often made based on nonclinical factors such as geographic availability and hospital affiliations. The study found "a greater likelihood of using a PAC provider setting if the hospital had subprovider (a hospital-based rehabilitation unit or skilled nursing facility is considered a subprovider) or a co-located PAC provider of that type (facilities classified as co-located if two or more independently owned providers were physically located within 250 yards of each other)." For example, if a provider had a co-located inpatient rehabilitation facility, the provider had 2.265 times the odds (p<.0001) of referring to an inpatient rehabilitation facility, compared to if they did not have a co-located IRF. Chances of referral were also higher for co-located LTCHs and nursing homes (Gage et al., 2009). Given the impact of the geographic proximity of PAC facilities on the type of PAC patients use (MedPAC, 2011; Gage et al., 2009), it is important to note that availability of LTCH and IRF beds varies widely across the country. There are multiple states with no LTCHs, according to the 2009 Medicare Provider of Service file (MedPAC, 2011 ch. 10; Gage et al., 2009). Although IRFs are more common than LTCHs, several states have limited number of IRF beds (e.g., Maryland with 0.19 beds per 1,000 beneficiaries).

The similarities between the facilities and the potential overlap in patients, along with nonclinical factors that affect where a patient is treated, all suggest that research regarding nursing home residents and the use of the MDS assessment have applicability to the use of the LTCH CARE Data Set and the IRF-PAI.

1a.4 Citations for Evidence of High Impact cited in 1a.3:


1b. Opportunity for Improvement: H □ M □ L □ I □
(There is a demonstrated performance gap - variability or overall less than optimal performance)

1b.1 Briefly explain the benefits (improvements in quality) envisioned by use of this measure:
This measure is intended to encourage nursing homes, LTCHs, and IRFs to focus on this important aspect of clinical care by assessing residents/patients on the status of their pneumococcal vaccine immunization and to provide immunization as deemed clinically appropriate.

1b.2 Summary of Data Demonstrating Performance Gap (Variation or overall less than optimal performance across providers):

[For Maintenance – Description statistics for performance results for this measure - distribution of scores for measured entities by quartile/decile, mean, median, SD, min, max, etc.]

A study of the implementation of a pneumococcal vaccination standing order on an inpatient hospital serving geriatric patients found that after implementing the order, the vaccination rate increased from 0% to 15.4%, and vaccination opportunity rate increased from 8% to 59.1% (Eckrode et al., 2007). This indicates that there is a wide range of performance among facilities that are measuring vaccination rates and those that are not.

In an analysis of quality measures using MDS 2.0 data from 2006 Q1 for a random 10% facility sample (presented below), the University of Colorado found that this measure had a significant amount of variability across facilities. The quality measure varied from 15.6% at the 10th percentile to 98.1% at the 90th percentile. In addition, 8.0% of facilities had 100% vaccination (Brega et al., 2008). See attached Table 1: Measure Variability Across Facilities.

1b.3 Citations for Data on Performance Gap: [For Maintenance – Description of the data or sample for measure results reported in 1b.2 including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included]


1b.4 Summary of Data on Disparities by Population Group: [For Maintenance – Descriptive statistics for performance results
A study that examined racial disparities in receipt and documentation of pneumococcal vaccinations among nursing home residents concluded that racial disparities exist in vaccination coverage among U.S. nursing home residents (Li & Mukamel, 2010). The incidence of pneumococcal infection in black adults is three to five times as high as that of white adults (Smith et al., 2007), but pneumococcal vaccination rates are lower for black nursing home residents than for white residents—31% of black residents compared with 24% of white residents age 65 years or older had never received pneumococcal vaccination. Blacks also had a higher likelihood of unknown vaccination status than whites in Medicaid-only nursing facilities and lower odds of unknown vaccination status in government-owned nursing facilities. The racial difference in pneumococcal vaccination exists predominantly in certain nursing facility types (Marsteller et al., 2008).

Within nursing homes specifically, racial segregation between facilities has been shown to be a major factor in racial disparities in this population, primarily for African Americans. In 2000, a study drawing on national MDS and Online Survey, Certification, and Reporting (OSCAR) data found that two-thirds of all black residents were living in just 10% of all facilities (Smith et al., 2007). A 2002 survey of a stratified sample of 39 nursing homes and 181 residential care/assisted living facilities in four states had similar findings (Howard et al., 2002). Facilities serving African Americans have demonstrated a lower level of quality care than those serving whites, with lower staff-to-resident ratios and higher deficiency ratings (Grabowski, 2004). Minority groups in general, and African Americans in particular, also have more limited access to nursing home care than whites (National Center for Health Statistics [NCHS], 1997; Marsteller et al., 2008).

According to the 2011 MedPAC report examining Medicare beneficiaries’ use of LTCHs in 2009, LTCHs have a slight overrepresentation of minority patients, particularly African American patients, compared to the Medicare population as a whole. Across all Medicare beneficiaries in 2009, 17% were minorities (10% African American, 3% Hispanic, and 4% other). In the same year, LTCHs consisted of approximately 26% minority patients (19% African American, 4% Hispanic, and 4% other) (MedPAC, 2011, ch. 10). Minority rates in IRFs ranged depending on the payer from 15% to 20% minority. Between May and June 2010 approximately 10-13% of IRF patients were African American and 5-7% were Hispanic, suggesting a slightly higher than average percentage of Hispanic patients in IRFs (MedPAC, 2011, ch. 9).

1b.5 Citations for Data on Disparities Cited in 1b.4: [For Maintenance – Description of the data or sample for measure results reported in 1b.4 including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included]


See Guidance for Definitions of Rating Scale: H=High; M=Moderate; L=Low; I=Insufficient; NA=Not Applicable


1c. Evidence (Measure focus is a health outcome OR meets the criteria for quantity, quality, consistency of the body of evidence.)

Is the measure focus a health outcome? Yes ☐ No ☐ If not a health outcome, rate the body of evidence.

<table>
<thead>
<tr>
<th>Quantity</th>
<th>Quality</th>
<th>Consistency</th>
<th>Does the measure pass subcriterion1c?</th>
</tr>
</thead>
<tbody>
<tr>
<td>M-H</td>
<td>M-H</td>
<td>M-H</td>
<td>Yes ☐ IF additional research unlikely to change conclusion that benefits to patients outweigh harms: otherwise No ☐</td>
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<tr>
<td>L</td>
<td>M-H</td>
<td>M</td>
<td>Yes ☐ IF potential benefits to patients clearly outweigh potential harms: otherwise No ☐</td>
</tr>
<tr>
<td>M-H</td>
<td>L-M-H</td>
<td>L-M-H</td>
<td>No ☐</td>
</tr>
</tbody>
</table>

Health outcome – rationale supports relationship to at least one healthcare structure, process, intervention, or service

Does the measure pass subcriterion1c?

Yes ☐ IF rationale supports relationship

1c.1 Structure-Process-Outcome Relationship (Briefly state the measure focus, e.g., health outcome, intermediate clinical outcome, process, structure; then identify the appropriate links, e.g., structure-process-health outcome; process-health outcome; intermediate clinical outcome-health outcome):

In 2004, the seventh-most common cause of death for persons age 65 or older in the United States was pneumonia and influenza (Gorina et al., 2008). Influenza and pneumonia continue to be a leading cause of death, and they were reported by CMS in 2011 to be the fifth-leading cause of death among individuals age 65 or older (CMS, 2011). Additionally, pneumonia is among the top 20 most common Medicare Severity Long term Care Diagnosis Related Groups (MS-LTC-DRG) (MedPAC, 2011). Death related to pneumonia affects the elderly at a higher rate, especially for persons aged 85 or older (Thompson et al., 2003; CDC, 2011). Almost 60,000 deaths in 2004 were caused by influenza and pneumonia, and more than 85% of those were among the elderly (Gorina et al., 2008). CMS reports that there are currently more than 40,000 cases of invasive pneumococcal disease in the United States and approximately one third of these are in individuals age 65 or older (CMS, 2011). Also, over half of the more than 5,000 annual deaths from invasive pneumococcal diseases occurred in individuals age 65 or older (CMS, 2011). Frail elderly are especially at risk for contracting pneumonia as a complication of another infection or medical condition, particularly stroke or previous or recent surgery or a condition requiring surgery or a ventilator—all of which are conditions for which patients may spend some of their recovery time in an IRF or LTCH (Hung et al., 2005; CDC, 2011; Fagon et al., 1993). In 2004, there were approximately 123,000 deaths with influenza and pneumonia mentioned on the death certificate as a secondary cause of death (Gorina et al., 2008).

1c.2-3 Type of Evidence (Check all that apply):

Other, Selected individual studies (rather than entire body of evidence)

Based on CDC guidelines. Note: USPSTF does not publish its own guidelines, but instead supports the CDC ACIP recommendations.

1c.4 Directness of Evidence to the Specified Measure (State the central topic, population, and outcomes addressed in the body of evidence and identify any differences from the measure focus and measure target population):

The evidence available addresses the vaccination, disease, and death rates, for pneumococcal vaccine amongst the U.S. population. Specifically, it addresses vaccination amongst nursing home residents and provides evidence of the similarities between nursing facilities, LTCHs, and IRFs. As the evidence suggests, immunization of post-acute care residents or patients against pneumococcal infections is an important mechanism for reducing serious illness and mortality in all at-risk patients, regardless of setting.

In addition to protecting vaccinated individuals, research suggests that vaccination programs using the pneumococcal conjugate vaccine can contribute to development of a herd immunity amongst the elderly, protecting even those who cannot get vaccinated.
According to the 2010 update to the ACIP recommendations for prevention of invasive pneumococcal disease, pneumococcal vaccinations have reduced pneumococcal infection among unvaccinated persons, including those aged greater than 65. In 2000 the CDC introduced the infant-7 valent pneumococcal vaccine immunization program. By 2007 the overall incidence rate of invasive pneumococcal disease among person ages 65 and older had decreased by 37% (CDC 2010). Additional indirect effects are expected to occur when the PCV13 immunization (Given to youths age <18) program, initiated in 2010, is fully implemented, although the magnitude of these effects is difficult to predict (CDC 2010). It is important to note that herd immunity is only relevant in the context of the pneumococcal conjugate vaccine.

The evidence available directly relates to the proposed measures by addressing pneumococcal vaccine and outcomes of pneumococcal vaccination in the population both for the vaccinated individual and in the context of herd immunity. The empirical evidence specifically addresses this in the nursing home setting and provides support for the harmonization of this measure across the three post acute settings.


1c.5 Quantity of Studies in the Body of Evidence (Total number of studies, not articles): Left blank, as instructed by NQF during the guidance call held on Thursday, September 22, 2011

1c.6 Quality of Body of Evidence (Summarize the certainty or confidence in the estimates of benefits and harms to patients across studies in the body of evidence resulting from study factors. Please address: a) study design/flaws; b) directness/indirectness of the evidence to this measure (e.g., interventions, comparisons, outcomes assessed, population included in the evidence); and c) imprecision/wide confidence intervals due to few patients or events): Left blank, as instructed by NQF during the guidance call held on Thursday, September 22, 2011

1c.7 Consistency of Results across Studies (Summarize the consistency of the magnitude and direction of the effect): Left blank, as instructed by NQF during the guidance call held on Thursday, September 22, 2011

1c.8 Net Benefit (Provide estimates of effect for benefit/outcome; identify harms addressed and estimates of effect; and net benefit - benefit over harms): Left blank, as instructed by NQF during the guidance call held on Thursday, September 22, 2011

1c.9 Grading of Strength/Quality of the Body of Evidence. Has the body of evidence been graded? No

1c.10 If body of evidence graded, identify the entity that graded the evidence including balance of representation and any disclosures regarding bias: This is not applicable, see 1c.9

1c.11 System Used for Grading the Body of Evidence: Other

1c.12 If other, identify and describe the grading scale with definitions: This is not applicable, see 1c.9

1c.13 Grade Assigned to the Body of Evidence: This is not applicable, see 1c.9

1c.14 Summary of Controversy/Contradictory Evidence: No contradictory evidence has been identified.

The pneumococcal vaccine is well tolerated, although recipients do report varying levels of adverse events (Musher, 2010). Although the adverse events are relatively minor, it is important to consider their potential impact on therapy, length of stay, and resource utilization.

According to the package insert for PNEUMOVAX 23, the pneumococcal vaccination administered to individuals ages 65 and older, seniors experience systemic adverse event reactions 21.7% of the time after their first vaccination and 33% of the time after re-vaccination. The most common adverse events experienced in clinical trials were local reactions at injection site including soreness,
erythema, warmth, swelling and induration, and fevers greater than or equal to 102°F. A 1997 to 1998 study of 1008 participants found a 35% frequency of systemic adverse events (tiredness, muscle aches, chills) among 50-65 year olds after their first vaccination and a 22% frequency of systemic adverse events in individuals ages 65 plus after first vaccination. After re-vaccination both age groups had systemic adverse event rates of 35%. In terms of more serious events, severe pain was reported by 2% of vaccination subjects and 6% of re-vaccination subjects. Amongst subjects age 65 and older, severe site reactions were reported 4% of the time after first vaccine and 17% of the time after a secondary vaccine. No deaths occurred during the 14-day follow up period after each vaccination (Musher 2010). Despite these side effects, the CDC does recommend vaccination for all adults ages 65 and older as well as all residents of nursing homes and long term care facilities (CDC April 2011).

1c.15 Citations for Evidence other than Guidelines (Guidelines addressed below):


1c.16 Quote verbatim, the specific guideline recommendation (Including guideline # and/or page #):
The U.S. Centers for Disease Control recommends pneumococcal vaccinations for all residents of nursing homes and patients in other long term care facilities.


1c.17 Clinical Practice Guideline Citation: The U.S. Centers for Disease Control recommends pneumococcal vaccinations for all residents of nursing homes and patients in other long term care facilities.


1c.19 Grading of Strength of Guideline Recommendation. Has the recommendation been graded? No

1c.20 If guideline recommendation graded, identify the entity that graded the evidence including balance of representation and any disclosures regarding bias:

1c.21 System Used for Grading the Strength of Guideline Recommendation: Other

1c.22 If other, identify and describe the grading scale with definitions: This is not applicable, see 1c.21.

1c.23 Grade Assigned to the Recommendation: This is not applicable, see 1c.21.

1c.24 Rationale for Using this Guideline Over Others: This is not applicable, see 1c.21.

Based on the NQF descriptions for rating the evidence, what was the developer’s assessment of the quantity, quality, and consistency of the body of evidence?
1c.25 Quantity: High  1c.26 Quality: High  1c.27 Consistency: High

Was the threshold criterion, Importance to Measure and Report, met? (1a & 1b must be rated moderate or high and 1c yes) Yes☑ No□

Provide rationale based on specific subcriteria:

For a new measure if the Committee votes NO, then STOP.
For a measure undergoing endorsement maintenance, if the Committee votes NO because of 1b. (no opportunity for improvement), it may be considered for continued endorsement and all criteria need to be evaluated.

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2. RELIABILITY & VALIDITY - SCIENTIFIC ACCEPTABILITY OF MEASURE PROPERTIES

Extent to which the measure, as specified, produces consistent (reliable) and credible (valid) results about the quality of care when implemented. (evaluation criteria)

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 field. Supplemental materials may be referenced or attached in item 2.1. See guidance on measure testing.

S.1 Measure Web Page (In the future, NQF will require measure stewards to provide a URL link to a web page where current detailed specifications can be obtained). Do you have a web page where current detailed specifications for this measure can be obtained? Yes

S.2 If yes, provide web page URL: Web site structure and url details currently in progress, specifications to be determined by CMS.

2a. RELIABILITY. Precise Specifications and Reliability Testing: H□ M☑ L□ I□

2a1. Precise Measure Specifications. (The measure specifications precise and unambiguous.)

2a1.1 Numerator Statement (Brief, narrative description of the measure focus or what is being measured about the target population, e.g., cases from the target population with the target process, condition, event, or outcome):
The following numerator components will be computed and reported separately: (1) **up-to-date vaccine status; (2) ineligible to receive vaccine due to medical contraindications; or (3) offered and declined vaccine. Measure numerator specifications for the three provider type assessment tools are listed below:
MDS 3.0 assessment: Residents are counted if they are short-stay, defined as residents whose length of stay is less than or equal to 100 days. Residents aged 5 years and older are counted if they meet any of the following criteria on the most recent MDS 3.0 assessment, which may be an OBRA assessment (A0310A=01,02,03,04,05,06), PPS assessment(A0310B = 01, 02, 03, 04, 05, 06), or discharge assessment(A0310F = 10, 11), during the 12-month reporting period. The following numerator components will be computed and reported separately:
1. **Up-to-date vaccine status (O0300A=1)
2. Ineligible due to medical contraindications (O0300B=1)
3. Offered and declined vaccine (O0300B=2)

LTCH CARE Data Set: Patients aged 5 years and older are counted if they meet any of the following criteria on the most recent LTCH CARE Data Set assessment during the 12-month reporting period. The following numerator components will be computed and reported separately:
1. **Up-to-date vaccine status (O0300A=1)
2. Ineligible due to medical contraindications (O0300B=1)
3. Offered and declined vaccine (O0300B=2)

IRF-PAI assessment: Patients aged 5 years and older are counted if they meet any of the following criteria on the IRF-PAI assessment during the 12-month reporting period. The following numerator components will be computed and reported separately, in the *IRF-PAI tool:
1. **Up-to-date vaccine status
2. Ineligible due to medical contraindications
3. Offered and declined vaccine

*Note that the components of the IRF-PAI have not yet been assigned item numbers but will be assigned item numbers to match the MDS 3.0 and LTCH CARE Data Set.

**"Up–to-date" vaccination status is defined as a resident or patient who has been vaccinated in accordance with the current CDC vaccination guidelines for pneumococcal disease for his/her age and health status. The current CDC vaccination guidelines for adults are available at [http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5934a3.htm](http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5934a3.htm). The current CDC vaccination guidelines for infants and children are available at [http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5911a1.htm?s_cid=rr5911a1_e](http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5911a1.htm?s_cid=rr5911a1_e).

2a1.2 **Numerator Time Window** *(The time period in which the target process, condition, event, or outcome is eligible for inclusion)*: This time window is the selected 12-month reporting period.

2a1.3 **Numerator Details** *(All information required to identify and calculate the cases from the target population with the target process, condition, event, or outcome such as definitions, codes with descriptors, and/or specific data collection items/responses)*: Specifications for the three provider type assessment tools are listed below:

MDS 3.0: Residents are counted if they are short-stay, defined as residents whose length of stay is less than or equal to 100 days. Short-stay residents aged 5 years and older are counted if they meet any of the following criteria on the most recent MDS 3.0 assessment, an OBRA assessment(A0310A=01,02,03,04,05,06), PPS assessment (A0310B = 01, 02, 03, 04, 05, 06), or discharge assessment(A0310F=10,11) during the 12-month reporting period: (1) have an up-to-date** pneumococcal vaccine status (item O0300A=1); or (2) were offered and declined the vaccine (item O0300B=2); or (3) were ineligible due to medical contraindication(s) (i.e., anaphylactic hypersensitivity to components of the vaccine; bone marrow transplant within the past 12 months; or receiving a course of chemotherapy within the past two weeks) (item O0300B=1).

LTCH CARE Data Set: Patients aged 5 years and older are counted if they meet any of the following criteria on the LTCH CARE Data Set assessment during the 12-month reporting period: (1) have an up-to-date pneumococcal vaccine status** (item O0300A=1); or (2) were offered and declined the vaccine (item O0300B=2); or (3) were ineligible due to medical contraindication(s) (i.e., anaphylactic hypersensitivity to components of the vaccine; bone marrow transplant within the past 12 months; or receiving a course of chemotherapy within the past two weeks) (item O0300B=1).

IRF-PAI: Patients aged 5 years and older are counted if they meet any of the following criteria on the most recent IRF-PAI
assessment during the 12-month reporting period: (1) have an up-to-date pneumococcal vaccine status* ** or (2) were offered and declined the vaccine*; or (3) were ineligible due to medical contraindication(s)* (i.e., anaphylactic hypersensitivity to components of the vaccine; bone marrow transplant within the past 12 months; or receiving a course of chemotherapy within the past two weeks). *Note that the components of the IRF-PAI have not yet been assigned item numbers but will be assigned item numbers to match the MDS 3.0 and LTCH CARE Data Set **“Up–to-date” vaccination status is defined as a resident or patient who has been vaccinated in accordance with the current CDC vaccination guidelines for pneumococcal disease for his/her age and health status. The current CDC vaccination guidelines for adults are available at http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5934a3.htm. The current CDC vaccination guidelines for infants and children are available at http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5911a1.htm?s_cid=rr5911a1_e.

2a1.4 Denominator Statement (Brief, narrative description of the target population being measured):
The denominator consists of all residents or patients aged 5 years and older in the pneumococcal vaccination sample (defined in Denominator Details section) with an assessment within the 12-month period.

Specifications for the three provider type assessment tools are listed below:

MDS 3.0: Short-stay residents aged 5 years and older in the pneumococcal vaccination sample with an MDS 3.0 assessment (which may be an OBRA, PPS, or discharge assessment) within the 12-month period.

LTCH CARE Data Set: Patients aged 5 years and older in the pneumococcal vaccination sample with a LTCH CARE Data Set assessment (which may be an admission or discharge assessment) within the 12-month period.

IRF-PAI: Patients aged 5 years and older in the pneumococcal vaccination sample with an IRF-PAI assessment (which may be an admission or discharge assessment) within the 12-month period.

2a1.5 Target Population Category (Check all the populations for which the measure is specified and tested if any): Adult/Elderly Care, Populations at Risk

2a1.6 Denominator Time Window (The time period in which cases are eligible for inclusion): This time window is the selected 12-month reporting period.

2a1.7 Denominator Details (All information required to identify and calculate the target population/denominator such as definitions, codes with descriptors, and/or specific data collection items/responses):
All residents or patients aged 5 years and older who have an assessment during the 12-month period. Specifications for the three provider type assessment tools are listed below:

MDS 3.0: Short-stay residents are defined as residents whose length of stay is less than or equal to 100 days. The short-stay pneumococcal vaccination sample includes residents aged 5 years and older with a target assessment who have (1) a PPS MDS 3.0 assessment (item A0310B=01,02,03,04,05,06) with assessment reference date (item A2300) during the 12-month target period; or (2) an OBRA assessment (A0310A=01,02,03,04,05,06) or (3) a discharge MDS 3.0 assessment (item A0310F=10,11) with discharge date (item A2000) during the 12-month target period.

*According to the MDS 3.0 manual, the target period refers to the span of time that defines the quality measure’s reporting period (e.g. a calendar quarter). In any target period, there will likely be multiple assessments.

LTCH CARE Data Set: The pneumococcal vaccination sample includes patients aged 5 years and older who have (1) a CARE Data assessment with assessment reference date (A0210) during the 12-month target period or (2) a discharge assessment (A0250=10) with discharge date (A0270) during the 12-month target period.

IRF-PAI: The pneumococcal vaccination sample includes patients aged 5 years and older who have (1) an IRF-PAI assessment with assessment reference date (item 13) during the 12-month target period or (2) a discharge assessment with discharge date (item 40) during the 12-month target period.

2a1.8 Denominator Exclusions (Brief narrative description of exclusions from the target population):
Residents or patients younger than 5 years old will be excluded from the denominator. Facilities with denominator counts of less than 20 in the sample will be excluded from public reporting owing to small sample size.

2a1.9 Denominator Exclusion Details (All information required to identify and calculate exclusions from the denominator such as definitions, codes with descriptors, and/or specific data collection items/responses):
Residents or patients younger than 5 years old will be excluded from the denominator.

2a1.10 Stratification Details/Variables (All information required to stratify the measure results including the stratification variables, codes with descriptors, definitions, and/or specific data collection items/responses):
Specifications for the three provider type assessment tools are listed below:

MDS 3.0: Based on the descriptions of the long-stay and short-stay populations above, there are inherent differences in facilities’ responsibility for assessing and/or providing vaccines for these distinct populations. For the short-stay population, facilities have less time to assess and/or provide the vaccine than for the long-stay population. As a result, nursing facilities’ vaccination rates for post-acute care populations should not be compared with rates for long-term care populations. Separating them recognizes these differences in vaccination rates.

LTCH CARE Data Set: Patients in LTCHs have an average length of stay of 26.2 days. Because this is shorter than the maximum 100-day length of stay for short-stay residents as defined in the nursing home measure, it is appropriate to include all patients with assessments in the 12-month evaluation period, without stratifying by length-of-stay.

IRF-PAI: Patients in IRFs have an average length of stay of 13.1 days. Because this is shorter than the maximum 100-day length of stay for short-stay residents as defined in the nursing home measures, it is appropriate to include all patients with assessments in the 12-month evaluation period, without stratifying by length-of-stay.

2a1.11 Risk Adjustment Type (Select type. Provide specifications for risk stratification in 2a1.10 and for statistical model in 2a1.13): No risk adjustment or risk stratification 2a1.12 If "Other," please describe:

2a1.13 Statistical Risk Model and Variables (Name the statistical method - e.g., logistic regression and list all the risk factor variables. Note - risk model development should be addressed in 2b4.):
This is not applicable

2a1.14-16 Detailed Risk Model Available at Web page URL (or attachment). Include coefficients, equations, codes with descriptors, definitions, and/or specific data collection items/responses. Attach documents only if they are not available on a webpage and keep attached file to 5 MB or less. NQF strongly prefers you make documents available at a Web page URL. Please supply login/password if needed:

2a1.17-18. Type of Score: Rate/proportion

2a1.19 Interpretation of Score (Classifies interpretation of score according to whether better quality is associated with a higher score, a lower score, a score falling within a defined interval, or a passing score): Better quality = Higher score

2a1.20 Calculation Algorithm/Measure Logic (Describe the calculation of the measure score as an ordered sequence of steps including identifying the target population; exclusions; cases meeting the target process, condition, event, or outcome; aggregating data; risk adjustment; etc.):
For each facility, the number of residents or patients meeting the numerator criteria and the number meeting the denominator criteria are counted. The following numerator components will be computed and reported separately: (1) up-to-date** vaccination status; (2) ineligible due to medical contraindications; and (3) offered and declined.
Specifications for the three provider type assessment tools are listed below:
**MDS 3.0**: the number of short-stay residents meeting the numerator criteria and the number of residents meeting the denominator criteria are counted. The following numerator components will be computed and reported separately:
1. Up-to-date** vaccine status (O0300A=1)
2. Ineligible due to medical contraindications (O0300B=1)
3. Offered and declined (O0300B=2)

**LTCH CARE Data Set**: The number of patients meeting the numerator criteria and the number of patients meeting the denominator criteria are counted. The following numerator components will be computed and reported separately:
1. Up-to-date** vaccine status (O0300A=1)
2. Ineligible due to medical contraindications (O0300B=1)
3. Offered and declined (O0300B=2)

**IRF-PAI**: The number of patients meeting the numerator criteria and the number of patients meeting the denominator criteria are counted. The following numerator components will be computed and reported separately:
1. Up-to-date** vaccine status *
2. Ineligible due to medical contraindications *
3. Offered and declined *
*Note that the components of the IRF-PAI have not yet been assigned item numbers but will be assigned item numbers to match the MDS 3.0 and LTCH CARE Data Set.

**"Up–to-date" vaccination status is defined as a resident or patient who has been vaccinated in accordance with the current CDC vaccination guidelines for pneumococcal disease for his/her age and health status. The current CDC vaccination guidelines for adults are available at [http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5934a3.htm](http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5934a3.htm). The current CDC vaccination guidelines for infants and children are available at [http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5911a1.htm?s_cid=rr5911a1_e](http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5911a1.htm?s_cid=rr5911a1_e).**
2a1.34-35 Care Setting *(Check all the settings for which the measure is specified and tested)*: Other; Long Term Care Hospitals, Post Acute/Long Term Care Facility: Nursing Home/Skilled Nursing Facility, Post Acute/Long Term Care Facility: Rehabilitation

2a2. Reliability Testing. *(Reliability testing was conducted with appropriate method, scope, and adequate demonstration of reliability.)*

2a2.1 Data/Sample *(Description of the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included)*:

Major tests of the reliability of the pneumococcal measure have been conducted. First, the MDS 2.0 measure items and the existing quality measures were tested in the Data Assessment and Verification (DAVE 2) project conducted by Abt Associates (2007). This project used a nationwide sample of randomly selected nursing homes, using MDS assessments for the period April 1 to December 31, 2006 (Abt Associates, 2007). During this project, 173 two-stage reviews were performed.

Second, the University of Colorado used national facility-level quality measure data: data from 2003 Quarter 3 (Q3) through 2006 Q3 came from the Quality Improvement and Evaluation System (QIES) MDS Express Reports on the CMS intranet and OSCAR data related to facility characteristics (e.g., state, resident census, number of beds, staffing), and certification survey results from QIES Workbench (Brega et al., 2008). A 10% random sample of all Medicare-certified nursing facilities was also downloaded from MDS assessment records. Analyses were based on complete MDS data from January 2005 through March 2006, nearly complete data for April 2006, and partial data for May and June 2006.

Third, testing of the reliability of MDS 3.0 data items underlying the pneumococcal immunization measure and a comparison with the MDS 2.0 quality measure items were conducted by RAND as part of the MDS 3.0 development process (Saliba and Buchanan, 2008).

Since items in the IRF-PAI for the IRFs and LTCH CARE Data Set for the LTCHs are identical to the MDS 3.0 items, results of the reliability assessment of MDS 3.0 data items for the pneumococcal quality measure are applicable to inform the use of these items for the IRF and LTCH settings.

2a2.2 Analytic Method *(Describe method of reliability testing & rationale)*:

The national test of MDS 3.0 items examined the agreement between assessors (reliability), user satisfaction and feedback on changes, and time to complete the assessment. The network of Quality Improvement Organizations (QIOs) was employed to identify gold-standard (research) nurses and recruit community nursing homes to participate in the national evaluation, including a representative sample of for-profit and not-for-profit facilities and hospital-based and freestanding facilities. The gold-standard nurses were trained in the MDS 3.0 instrument, and they, in turn, trained a facility nurse from each participating nursing home in their home states. Residents participating in the test were selected to capture a representative sample of short- and long-stay residents.

The DAVE 2 Project used a two-stage cluster sample design to examine MDS reporting. A trained nurse reviewer selected a current resident with a recent assessment performed by the nursing home within the last 14 days. In Stage 1 of this review, the nurse reviewer conducted a blind reassessment of the resident using standard MDS assessment and coding procedures (examination of the medical record; observation of the resident; interview of staff, resident, and family; and use of coding criteria). In Stage 2 of this assessment, the DAVE 2 nurse reviewer’s assessment was compared with the corresponding nursing facility assessment, and each discrepancy was reconciled, with the nursing facility assessor and the nurse reviewer agreeing on the appropriate response. In addition to data entering the facility MDS code, the DAVE 2 code, and the reconciled code into the MDS-QC data entry software, the DAVE 2 nurse reviewer entered a "reason code" to attribute the cause of the discrepancy, per MDS item reviewed, to an established list of reasons.

2a2.3 Testing Results *(Reliability statistics, assessment of adequacy in the context of norms for the test conducted)*:

According to the University of Colorado findings, the pneumococcal immunization measure for short-stay residents received ratings of "guarded" for the dimensions of validity and reliability. Moderate Two-Stage discrepancy rates were obtained for the vaccination QI/QMs. The rate was 13.4% for pneumococcal. The Retrospective Medical Record Reviews rate was lower, and the difference reached standard significance for the pneumococcal measure. More detailed analysis of QI/QM discrepancies indicates that facilities under-code QI/QMs when recording them on the MDS, much more often than they over-code them.
Two-Stage Resource Utilization Group, Version III (RUG-III) group discrepancies on SNF PPS assessments were found to be quite high, with a rate of 22.1%. This RUG-III group rate is a bit higher than the 15% rate found in the original DAVE project. A somewhat higher rate may be expected for DAVE 2 because reviews during this project were conducted on-site using independent resident assessment and reconciliation with facility staff, whereas the original DAVE reviews were conducted offsite with access only to a partial medical record mailed by the facility.

The national pilot test of the MDS 3.0 items conducted by Saliba and Buchanan showed good reliability. The kappa statistic for gold-standard nurse to gold-standard nurse agreement was 0.979 (n=349) for pneumococcal vaccine given, and the kappa for gold-standard nurse to facility nurse agreement was 0.952 (n=900) (Saliba and Buchanan, 2008).

Studies have not been conducted on the reliability of the pneumococcal measure items in the LTCH or IRF setting. However, because the populations and risk factors in these settings are similar, and decisions about which setting a patient is referred to are often made based on geography and provider relationships, it is reasonable to apply the reliability testing from the nursing home setting to LTCHs and IRFs. Although, in some instances, the populations across provider settings are not identical and minor differences in reliability may exist, the nursing home measure can be meaningfully applied in LTCHs and IRFs.


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<th>2b. VALIDITY. Validity, Testing, including all Threats to Validity:</th>
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2b1.1 Describe how the measure specifications (measure focus, target population, and exclusions) are consistent with the evidence cited in support of the measure focus (criterion 1c) and identify any differences from the evidence:
The measure specifications for this measure are based on the specifications of NQF #0682, Percent of Residents Assessed and Appropriately Given the Pneumococcal Vaccine (Short Stay), which was originally based on NQF #0433, Pneumococcal Vaccination of Nursing Home/Skilled Nursing Facility Residents. Three major studies have demonstrated the validity and reliability of this MDS 3.0 items used for this measure in nursing home settings. Studies have not been conducted on the reliability of the influenza measure items from the LTCH CARE Data Set or the IRF-PAI. Because the populations in which these tools are used and risk factors in these settings are similar and decisions about which setting a patient is referred to are often made based on geography and provider relationships, it is reasonable to apply the reliability testing from the MDS to the LTCH CARE Data Set and the IRF-PAI.

2b2. Validity Testing. (Validity testing was conducted with appropriate method, scope, and adequate demonstration of validity.)

2b2.1 Data/Sample (Description of the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included):
The MDS 2.0 and MDS 3.0 vaccination items were tested by the DAVE 2 Project, which used a nationwide sample of randomly selected nursing facilities using MDS assessments for the period April 1 to December 31, 2006. The sample size (number of reviews) was 164 for the pneumococcal vaccination QI/QM.

2b2.2 Analytic Method (Describe method of validity testing and rationale; if face validity, describe systematic assessment):
The national test of MDS 3.0 items examined the agreement between assessors (reliability); the validity of new cognitive, depression, and behavior items; the response rates for interview items; user satisfaction and feedback on changes; and time to complete the assessment. The network of QIOs was employed to identify gold-standard (research) nurses and recruit community nursing facilities to participate in the national evaluation, including a representative sample of for-profit and not-for-profit facilities and hospital-based and freestanding facilities. The gold-standard nurses were trained in the MDS 3.0 instrument, and they, in turn, trained a facility nurse from each participating nursing home in their home states. Residents participating in the test were selected to capture a representative sample of short- and long-stay residents.
The DAVE 2 Project used a two-stage cluster sample design to examine MDS reporting. A trained nurse reviewer selected a current resident with a recent assessment performed by the nursing home within the last 14 days. In Stage 1 of this review, the nurse reviewer conducted a blind reassessment of the resident using standard MDS assessment and coding procedures (examination of the medical record; observation of the resident; interview of staff, resident, and family; and use of coding criteria). In Stage 2 of this assessment, the DAVE 2 nurse reviewer’s assessment was compared with the corresponding nursing facility assessment, and each discrepancy was reconciled, with the nursing facility assessor and the nurse reviewer agreeing on the appropriate response. In addition to data entering the facility MDS code, the DAVE 2 code, and the reconciled code into the MDS-QC data entry software, the DAVE 2 nurse reviewer entered a "reason code" to attribute the cause of the discrepancy, per MDS item reviewed, to an established list of reasons.

2b2.3 Testing Results (Statistical results, assessment of adequacy in the context of norms for the test conducted; if face validity, describe results of systematic assessment):
According to the University of Colorado findings, the pneumococcal immunization measure for short-stay residents received ratings of "guarded" for the dimensions of validity and reliability. Moderate Two-Stage discrepancy rates were obtained for the vaccination QI/QMs. The rate was 13.4% for pneumococcal. The Retrospective Medical Record Reviews rate was lower, and the difference reached standard significance for the pneumococcal measure. More detailed analysis of QI/QM discrepancies indicates that facilities under-code QI/QMs much more often than they over-code them.

Two-Stage RUG-III group discrepancies on skilled nursing facility (SNF) PPS assessments were found to be quite high, with a rate of 22.1%. This RUG-III group rate is a bit higher than the 15% rate found in the original DAVE project. A somewhat higher rate may be expected for DAVE 2 because reviews during this project were conducted onsite using independent resident assessment and reconciliation with facility staff, whereas the original DAVE reviews were conducted offsite with access only to a partial medical record mailed by the facility.

Studies have not been conducted on the validity of this measure using the LTCH CARE Data Set or IRF-PAI. Because the populations that use these tools and risk factors in these settings are similar and decisions about which setting a patient is referred to are often made based on geography and provider relationships, it is reasonable to apply the validity testing from the MDS 3.0 setting to LTCH CARE Data Set and IRF-PAI. Although the populations are not identical and minor differences in validity may exist, the nursing home measures can be meaningfully utilized in LTCHs and IRFs.


POTENTIAL THREATS TO VALIDITY. (All potential threats to validity were appropriately tested with adequate results.)

2b3. Measure Exclusions. (Exclusions were supported by the clinical evidence in 1c or appropriately tested with results demonstrating the need to specify them.)

2b3.1 Data/Sample for analysis of exclusions (Description of the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included):
All residents and patients for whom complete data exist are included. For nursing homes, all short-stay residents for whom complete data exist are included.

2b3.2 Analytic Method (Describe type of analysis and rationale for examining exclusions, including exclusion related to patient preference):
This is not applicable

2b3.3 Results (Provide statistical results for analysis of exclusions, e.g., frequency, variability, sensitivity analyses):
This is not applicable

2b4. Risk Adjustment Strategy. (For outcome measures, adjustment for differences in case mix (severity) across measured
entities was appropriately tested with adequate results.)

2b4.1 Data/Sample (Description of the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included):
This is not applicable

2b4.2 Analytic Method (Describe methods and rationale for development and testing of risk model or risk stratification including selection of factors/variables):
This is not applicable

2b4.3 Testing Results (Statistical risk model: Provide quantitative assessment of relative contribution of model risk factors; risk model performance metrics including cross-validation discrimination and calibration statistics, calibration curve and risk decile plot, and assessment of adequacy in the context of norms for risk models. Risk stratification: Provide quantitative assessment of relationship of risk factors to the outcome and differences in outcomes among the strata):
This is not applicable

2b4.4 If outcome or resource use measure is not risk adjusted, provide rationale and analyses to justify lack of adjustment: The proposed measure is a process measure, and it is not risk adjusted.

2b5. Identification of Meaningful Differences in Performance. (The performance measure scores were appropriately analyzed and discriminated meaningful differences in quality.)

2b5.1 Data/Sample (Describe the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included):
The testing did not include the updated specifications, which increase the number of residents who might be counted in the numerator and denominator. We indicated that the measures were tested because this change does not affect the underlying items and their reliability, nor the reportability or usability of the quality measure. In addition, it is unlikely that variability across facilities would be accounted for based on whether individuals who refused to be vaccinated or had medical contraindications to vaccination are included in the numerator and denominator. The data sample is from MDS 2.0 data from 2006 Q1.

2b5.2 Analytic Method (Describe methods and rationale to identify statistically significant and practically/meaningfully differences in performance):
Because the computed scores are not estimates, but include all residents who meet the measure criteria, in terms of discriminating performance, the computed scores can be used to make valid comparisons.

2b5.3 Results (Provide measure performance results/scores, e.g., distribution by quartile, mean, median, SD, etc.; identification of statistically significant and meaningfully differences in performance):
In its analysis of quality measures using MDS 2.0 data from 2006 Q1, the University of Colorado found that this measure could be reported for 76% of facilities and had a reasonable amount of variability across facilities in the rates of pneumococcal immunization. The quality measure varied from 15.6% at the 10th percentile to 98.1% at the 90th percentile (Brega et al., 2008).

See attached Table 1: Measure Variability Across Facilities.

Studies have not been conducted on meaningful differences within this measure using the LTCH CARE Data Set or IRF-PAI tools. Because the populations that use these tools and risk factors in these settings are similar, and decisions about which setting a patient is referred to is often made based on geography and provider relationships, it is reasonable to apply the validity testing from the MDS 2.0 to LTCH CARE Data Set and IRF-PAI. Although the populations are not identical and some differences may exist, the nursing home measures can be meaningfully utilized in LTCHs and IRFs.


2b6. Comparability of Multiple Data Sources/Methods. (If specified for more than one data source, the various approaches result in comparable scores.)

2b6.1 Data/Sample (Describe the data or sample including number of measured entities; number of patients; dates of data; if a
sample, characteristics of the entities included):
This is not applicable

2b6.2 Analytic Method (Describe methods and rationale for testing comparability of scores produced by the different data sources specified in the measure):
This is not applicable

2b6.3 Testing Results (Provide statistical results, e.g., correlation statistics, comparison of rankings; assessment of adequacy in the context of norms for the test conducted):
This is not applicable

2c. Disparities in Care: H □ M □ L □ I □ NA □ (If applicable, the measure specifications allow identification of disparities.)

2c.1 If measure is stratified for disparities, provide stratified results (Scores by stratified categories/cohorts): This is not applicable

2c.2 If disparities have been reported/identified (e.g., in 1b), but measure is not specified to detect disparities, please explain:
This is not applicable.
Although MDS 3.0 collects data on the resident’s race and other characteristics, there are currently no plans to stratify the measure. As noted in the NQF’s Report on Voluntary Consensus Standards for Influenza and Pneumococcal Immunizations, a comprehensive measure can be stratified to allow examination of a particular patient group of interest (e.g., diagnosis of chronic obstructive pulmonary disease) without creating multiple versions of the same measure (NQF, 2008b). However, the ultimate goal is to vaccinate all recommended populations, including the elderly and patient and/or residents in post-acute care facilities, which is what this measure is intended to capture.


2.1-2.3 Supplemental Testing Methodology Information:
Attachment Response_to_NQF_Review_0682.doc

Steering Committee: Overall, was the criterion, Scientific Acceptability of Measure Properties, met? (Reliability and Validity must be rated moderate or high) Yes □ No □
Provide rationale based on specific subcriteria:
If the Committee votes No, STOP

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

C.1 Intended Purpose/Use (Check all the purposes and/or uses for which the measure is intended): Public Reporting, Quality Improvement (Internal to the specific organization), Quality Improvement with Benchmarking (external benchmarking to multiple organizations)

3.1 Current Use (Check all that apply; for any that are checked, provide the specific program information in the following questions): Public Reporting, Quality Improvement with Benchmarking (external benchmarking to multiple organizations), Quality Improvement (Internal to the specific organization)

3a. Usefulness for Public Reporting: H □ M □ L □ I □
For current use of the pneumococcal immunization quality measure, please see Nursing Home Compare at
http://www.medicare.gov/NHCompare/

Currently, results of the LTCH CARE Data Set and the IRF-PAI are not publicly reported. However, in the future these results will be reported in a model similar to the Nursing Home Compare model. Data will be reported separately for each setting.

3a.2. Provide a rationale for why the measure performance results are meaningful, understandable, and useful for public reporting. If usefulness was demonstrated (e.g., focus group, cognitive testing), describe the data, method, and results: While a study examining the relevance and use of pneumococcal vaccination information has not been conducted, according to a study comparing influenza vaccination rates reported on the Nursing Home Compare database with the vaccination rate of community-dwelling elderly as reported to the CDC during the 2005-2006, 2006-2007, and 2007-2008 influenza seasons, the increase in influenza vaccination rates in nursing homes over the three years was no greater than that among community-dwelling elderly. The study concluded there is a lack of clear evidence that public reporting improves vaccination rates in nursing homes.

However, a study of consumers’ ability to accurately interpret the quality information given for all the measures reported by Nursing Home Compare suggests that consumers find publicly reported information useable and useful. Data came from 4,754 family members of nursing home residents and found that 31% of these consumers used the Internet in choosing a nursing home, and 12% recalled using Nursing Home Compare. This study also found that, in general, the comprehension index scores were high, indicating good understanding. Although the influenza measure was not specifically included in the analysis, the study showed that, overall, data for the measures posted on Nursing Home Compare are understood by consumers. Because this short-stay seasonal influenza vaccination quality measure is an expansion of the current measure in use for nursing homes, we anticipate that the proposed measure will also be understood by patients and family members in LTCHs and IRFs.

An examination MDS data from approximately 1.8 million post-acute care short-stays greater than 14 days, provided at 8,137 nursing homes, compared quality measures before and after the Nursing Home Compare public reporting requirements went into effect in 2002. The study found the three post-acute care measures used at the launch of Nursing Home Compare improved. Some of that improvement was an increase in patients choosing high quality facilities, suggesting that consumers chose higher-quality nursing homes based on the available information. A study that looked a MDS data from 1999 –2005 from 8,137 nursing homes, covering over 9 million post-acute care stays, found that most post-acute quality measures included in Nursing Home Compare were better in the three years following its launch as compared with before.

Lastly, analysis of a 2007 survey nationally distributed to nursing home administrators that asked about their response to publication of quality measures on Nursing Home Compare found that the nursing home perceives the Nursing Home Compare report card influences key constituencies with their likelihood of committing resources to improve. A substantial proportion of nursing homes believe the Nursing Home Compare report card influences key constituencies, making facilities with lower reported QM scores three times more likely to make certain investments than high-quality facilities in competitive markets.

Currently, results of the LTCH CARE Data Set and the IRF-PAI are not publicly reported. However, in the future these results may be reported in a model similar to the Nursing Home Compare model. Studies have not been conducted on the interpretability of LTCH CARE Data Set or the IRF-PAI or other measures for LTCHs and IRFs. Although the populations are not identical, the populations and risk factors in LTCHs, IRFs, and nursing homes are very similar. Therefore it is reasonable to believe that
interpretabiliy will be transferable across these three post-acute settings.

In 2005, a technical expert panel addressing quality measure development in LTCHs supported the use of the CARE tool (precursor to LTCH CARE Data Set) to measure quality in LTCHs and encouraged CMS to “be mindful of measures that are already being used in other short term care settings and when feasible and appropriate, to replicate those measures to the long term care hospital quality measurement set.” (MedPAC, 2011, ch.10) A similar technical expert panel addressing the development of quality measures for IRFs supported the use of IRF-PAI for IRFs quality data collection and encouraged that “CMS select measures that apply to other settings that provide rehabilitation.” (MedPAC, 2011, ch.9).


Werner R, Stuart E, Polsky D. Public Reporting Drove Quality Gains At Nursing Homes. Health Aff September 2010 vol. 29 no. 9 1706-1713.


3.2 Use for other Accountability Functions (payment, certification, accreditation). If used in a public accountability program, provide name of program(s), locations, Web page URL(s): This is not applicable

3b. Usefulness for Quality Improvement: H M L I
(The measure is meaningful, understandable and useful for quality improvement.)

3b.1. Use in QI. If used in quality improvement program, provide name of program(s), locations, Web page URL(s):
[For Maintenance – If not used for QI, indicate the reasons and describe progress toward using performance results for improvement].

3b.2. Provide rationale for why the measure performance results are meaningful, understandable, and useful for quality improvement. If usefulness was demonstrated (e.g., QI initiative), describe the data, method and results:

Overall, to what extent was the criterion, Usability, met? H M L I Provide rationale based on specific subcriteria:

4. FEASIBILITY

Extent to which the required data are readily available, retrievable without undue burden, and can be implemented for performance measurement. (evaluation criteria)

4a. Data Generated as a Byproduct of Care Processes: H M L I

4a.1-2 How are the data elements needed to compute measure scores generated? (Check all that apply).
Data used in the measure are:
generated by and used by healthcare personnel during the provision of care, e.g., blood pressure, lab value, medical condition

4b. Electronic Sources: H M L I

4b.1 Are the data elements needed for the measure as specified available electronically (Elements that are needed to compute measure scores are in defined, computer-readable fields): ALL data elements are in a combination of electronic sources

4b.2 If ALL data elements are not from electronic sources, specify a credible, near-term path to electronic capture, OR provide a rationale for using other than electronic sources:

4c. Susceptibility to Inaccuracies, Errors, or Unintended Consequences: H M L I

4c.1 Identify susceptibility to inaccuracies, errors, or unintended consequences of the measurement identified during testing and/or operational use and strategies to prevent, minimize, or detect. If audited, provide results:
The analysis previously reported indicates that the data elements for the current measure have some inaccuracies that result in inconsistencies on identifying a particular case, or in the inclusion or exclusion of a given case. However, it is uncertain whether these data accuracy problems are more prevalent in the current post-acute care measure than the chronic care measure, and thus whether the reliability is stronger for the chronic care measure than for the acute-care measure. In its empirical review of the quality measures, the University of Colorado found that length of stay has an impact on the rates for the vaccination measures (Brega et al., 2007). Residents with short stays are less likely to be vaccinated than residents with longer stays, which can be problematic for those facilities serving primarily a short-stay population.
The average length of stay for patients in LTCHs in 2009 was 26.4 days (MedPAC, 2011, ch 10). In IRFs, the average length of stay in 2009 was 13.1 days (MedPAC, 2011, ch 9 and ch 10). Because the average length of stay in each of these facilities is well under the 100-day maximum for short-stay nursing home residents, it is reasonable to utilize a short-stay measure to evaluate their performance.

Abt Associates’ DAVE 2 Project found that 13% of the time the current pneumococcal immunization items (based on MDS 2.0) were assessed differently by different assessors (Abt Associates, 2007). Part of that may be because definitions for the currently reported measure are misunderstood, or the assessors leave items blank that should have been completed. The changes made to the MDS 3.0 regarding the vaccine measures were minor, however; these changes improved the clarity of the items. MDS 3.0 contains most of the necessary items to parallel the MDS 2.0 measure that is currently reported. More detailed analysis of QI/QM discrepancies indicates that facilities under-code QI/QMs much more often than they over-code them (Saliba and Buchanan, 2008).

Also, because the items for the pneumococcal vaccine quality measure in the LTCH CARE Data Set and IRF-PAI are new, it is possible that there will be challenges with implementation, interpretation, reliability, or validity. However, given the similarities between the populations across all three settings in which the tools are used, we do not anticipate that many of these issues will arise.


See Guidance for Definitions of Rating Scale: H=High; M=Moderate; L=Low; I=Insufficient; NA=Not Applicable

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4d. Data Collection Strategy/Implementation:  H M L I

A.2 Please check if either of the following apply (regarding proprietary measures):

4d.1 Describe what you have learned/modified as a result of testing and/or operational use of the measure regarding data collection, availability of data, missing data, timing and frequency of data collection, sampling, patient confidentiality, time and cost of data collection, other feasibility/implementation issues (e.g., fees for use of proprietary measures):

For nursing homes, the data collection method is already in operational use and there are no issues with these areas. For IRFs, the data will be collected by adding an additional item to the IRF-PAI, an assessment instrument already in place. Additional time and resources will be needed for implementing the LTCH CARE Data Set; however, given its similarity to the MDS 3.0, we do not anticipate any major challenges with implementation.

Data are collected as part of an existing process of care with no additional cost for nursing homes, inpatient rehabilitation facilities and long-term care hospitals.

Overall, to what extent was the criterion, Feasibility, met? H M L I

Provide rationale based on specific subcriteria:

OVERALL SUITABILITY FOR ENDORSEMENT

Does the measure meet all the NQF criteria for endorsement? Yes No

Rationale:

If the Committee votes No, STOP.
If the Committee votes Yes, the final recommendation is contingent on comparison to related and competing measures.

5. COMPARISON TO 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 before a final recommendation is made.

5.1 If there are related measures (either same measure focus or target population) or competing measures (both the same measure focus and same target population), list the NQF # and title of all related and/or competing measures:

0433: Pneumococcal Vaccination of Nursing Home/ Skilled Nursing Facility Residents

5a. Harmonization

5a.1 If this measure has EITHER the same measure focus OR the same target population as NQF-endorsed measure(s): Are the measure specifications completely harmonized? Yes

5a.2 If the measure specifications are not completely harmonized, identify the differences, rationale, and impact on interpretability and data collection burden:

5b. Competing Measure(s)

5b.1 If this measure has both the same measure focus and the same target population as NQF-endorsed measure(s): Describe why this measure is superior to competing measures (e.g., a more valid or efficient way to measure quality); OR provide a rationale for the additive value of endorsing an additional measure. (Provide analyses when possible):

The current measure for Nursing Homes is expanded to additional post-acute care settings (LTCHs and IRFs) and associated addition in the data source (MDS 3.0 will remain the data source of nursing homes, IRF-PAI will be data source for IRFs, and the LTCH CARE Data Set will be data source for LTCHs). The proposed measure is harmonized to the NQF Voluntary Consensus Standards for Influenza and Pneumococcal Immunizations.
No current measure exists for LTCHs and IRFs, so this measure adds distinctive value.

### CONTACT INFORMATION

Co.1 Measure Steward (Intellectual Property Owner): Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland, 21244

Co.2 Point of Contact: Eddie, Garcia, mmsnqf@hsag.com, 410-786-6738-9

Co.3 Measure Developer if different from Measure Steward: Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland, 21244

Co.4 Point of Contact: Cheryl, Wiseman, Cheryl.Wiseman2@CMS.hhs.gov, 410-768-6738-5

Co.5 Submitter: Karen, Reilly, kreilly@rti.org, 410-786-6738-5, Centers for Medicare & Medicaid Services

Co.6 Additional organizations that sponsored/participated in measure development:

Co.7 Public Contact: Cheryl, Weiseman, MS, MPH, cheryl.wiseman2@cms.hhs.gov, 410-786-1775-, Centers for Medicare & Medicaid Services

### ADDITIONAL INFORMATION

Workgroup/Expert Panel involved in measure development

Ad.1 Provide a list of sponsoring organizations and workgroup/panel members’ names and organizations. Describe the members’ role in measure development.

See attached Table 2: Nursing Home Quality Measures Technical Expert Panel (January 2009), showing a list of workgroup or panel member names and organizations. This technical expert panel (TEP) on nursing homes met during 2 days in January 2009 to review an environmental scan of the current quality measures and to make recommendations regarding the transition from MDS 2.0 to MDS 3.0.

See attached Table 3: Inpatient Rehabilitation Facilities and Long-Term Care Hospitals Quality Measures Technical Expert Panel (July 2011) for list of workgroup or panel member names and organizations. A TEP on LTCHs met on July 7, 2011 to review proposed LTCH quality measures and provide feedback on the specifications, as well as to provide input on the feasibility of the measures, any unintended consequences, and suggestions for improving the measures. A TEP on IRF met on July 6, 2011 to review proposed IRF quality measures and provide feedback on the specifications, as well as to provide input on the feasibility of the measures, any unintended consequences, and suggestions for improving the measures.

Ad.2 If adapted, provide title of original measure, NQF # if endorsed, and measure steward. Briefly describe the reasons for adapting the original measure and any work with the original measure steward: The proposed measure expands NQF-endorsed nursing home measure NQF # 0682, Percent of Residents Assessed and Appropriately Given the Pneumococcal Vaccine (measure steward: CMS), to two post-acute care settings (LTCHs and IRFs). The measure is harmonized across three settings and to the NQF voluntary consensus standards for influenza and pneumococcal immunizations, with the goal to achieve a uniform approach to measurement and reporting across the three post-acute care settings and populations. This expansion is supported by the evidence from the CDC ACIP guidelines for the prevention of invasive pneumococcal diseases among adults using the 23-valent pneumococcal polysaccharide vaccine (PPSV23), available at: http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5934a3.htm, and the NQF voluntary consensus standards for influenza and pneumococcal immunizations, available at: http://www.qualityforum.org/Publications/2008/12/National_Voluntary_Consensus_Standards_for_Influenza_and_Pneumococcal_Immunizations.aspx

Measure Developer/Steward Updates and Ongoing Maintenance

Ad.3 Year the measure was first released: 2010

Ad.4 Month and Year of most recent revision: 12, 2009

Ad.5 What is your frequency for review/update of this measure? Every 3 years

Ad.6 When is the next scheduled review/update for this measure?
Ad.7 Copyright statement:
Ad.8 Disclaimers:
Ad.9 Additional Information/Comments: Please see attachment CMS Memo to NQF 682.doc
Date of Submission (MM/DD/YY): 04/08/2010