NATIONAL QUALITY FORUM

Measure Submission and Evaluation Worksheet 5.0

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.

NQF #: 0525   **NQF Project:** Population Health: Prevention Project
(for Endorsement Maintenance Review) **Original Endorsement Date:** Mar 31, 2009   **Most Recent Endorsement Date:** Mar 31, 2009

BRIEF MEASURE INFORMATION
De.1 Measure Title: Pneumococcal Polysaccharide Vaccine (PPV) Ever Received (Home Health)
Co.1.1 Measure Steward: Centers for Medicare and Medicaid Services, Office of Clinical Standards and Quality, Quality Measurement and Health Assessment Group
De.2 Brief Description of Measure: Percentage of home health episodes of care during which patients were determined to have ever received Pneumococcal Polysaccharide Vaccine (PPV).
2a1.1 Numerator Statement: Number of home health episodes of care during which patients were determined to have ever received Pneumococcal Polysaccharide Vaccine (PPV).
2a1.4 Denominator Statement: Number of home health episodes of care ending during the reporting period, other than those covered by generic or measure-specific exclusions.
2a1.8 Denominator Exclusions: Episodes which ended in patient death. Episodes in which the patient does not meet the CDC age/condition guidelines for PPV vaccine.
1.1 Measure Type: Process **2a1. 25-26 Data Source:** Electronic Clinical Data **2a1.33 Level of Analysis:** Facility **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*): N/A

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
De.5 Cross Cutting Areas *(Check all the areas that apply)*:   Population Health

1a.1 Demonstrated High Impact Aspect of Healthcare: Affects large numbers, A leading cause of morbidity/mortality

1a.2 If "Other," please describe:

1a.3 Summary of Evidence of High Impact *(Provide epidemiologic or resource use data)*:
CDC data from 2006 show that 5000 Americans die each year from invasive pneumococcal disease (IPD: bacteremia, pneumonia with bacteremia and meningitis) and half are older adults (1) with a case fatality rate of 40% for those 85 years and older (2). The pneumococcal vaccine (PPV) consists of 23 antigens and covers 85-90% of the serotypes of pneumococcus indicating its coverage against the disease. The vaccine provides 5 years of immunity in healthy adults (2) and should be considered 23 different vaccines in one administration.

One third of older adults report having not been vaccinated with PPV to prevent IPD according to 2009 data from the Behavioral Risk Factor Surveillance Survey, thus there is potential for improvement (3).

The CDC updated its recommendations for PPV administration in September 2010 to include additional patient groups (i.e. those people with asthma and smokers) and maintained its recommendation that all persons age 65 and older are vaccinated (1). The list of groups for whom PPV is recommended is available from the CDC (1).

1a.4 Citations for Evidence of High Impact cited in 1a.3:   Reference List
(1)   Centers for Disease Control and Prevention. Updated recommendations for prevention of invasive pneumococcal disease among adults using the 23-valent pneumococcal polysaccharide vaccine(PPSV23). MMWR Morb Mortal Wkly Rep 2010; 59(34):1102-1106.
(2)   Bader MS. Immunization for the elderly. Am J Med Sci 2007; 334(6):481-486.
(3)   Centers for Disease Control and Prevention. Behavioral Risk Factor Surveillance Survey Immunization Data. 2010. Atlanta, GA, Centers for Disease Control and Prevention. Ref Type: Report

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:
Pneumococcal vaccination is associated with significant reductions in the overall pneumonia rate, in the risk of hospitalization for pneumonia, and in the risk of death due to pneumonia among vaccinated subjects. Thus, the CDC recommends PPV for Americans age 65 and older and those with selected chronic conditions. This measure meets the National Priorities Partnership (NPP) goal of providing preventive services recommended by the U.S. Preventive Services Task Force and utilizes the NQF endorsed harmonized, standard measure specifications for PPV.

1b.2 Summary of Data Demonstrating Performance Gap *(Variation or overall less than optimal performance across providers)*:
[*For Maintenance* – *Descriptive statistics for performance results for this measure - distribution of scores for measured entities by quartile/decile, mean, median, SD, min, max, etc.*]
Agency Avg: 60%
Std Dev: 25%
Skew: -0.58
Min: 0%
10th: 22%
25th: 44%
50th: 64%
75th: 78%

90th: 89%
Max: 100%

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*]
OASIS-C data from Medicare certified agencies with at least 10 quality episodes to which the measure applies, collected between 1/1/2010 and 9/30/2010. 89% of agencies (9,033) met the ten episode threshold for this measure. The measure applied to 97% of all quality episodes (2.79 million out of 2.89 million). As less than 12 months of data were available for testing, we relaxed the public reporting constraint of 20 episodes per agency in 12 months to 10 episodes per agency in 9 months.

1b.4 Summary of Data on Disparities by Population Group: [*For Maintenance* –*Descriptive statistics for performance results for this measure by population group*]
Observed Rate by Patient Race
White   63%
Black   50%
Hispanic 47%
Other   59%

Observed Rate by Patient Age
<65   49%
65-75   59%
75-85   63%
85+   64%

Observed Rate by Patient Gender
Male   59%
Female 61%

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*]
OASIS-C data from Medicare certified agencies with at least 10 quality episodes to which the measure applies, collected between 1/1/2010 and 9/30/2010. 89% of agencies (9,033) met the ten episode threshold for this measure. The measure applied to 97% of all quality episodes (2.79 million out of 2.89 million). As less than 12 months of data were available for testing, we relaxed the public reporting constraint of 20 episodes per agency in 12 months to 10 episodes per agency in 9 months.

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.

Quantity: H☐ M☐ L☐ I☐   Quality: H☐ M☐ L☐ I☐   Consistency: H☐ M☐ L☐ I☐

Quantity	Quality	Consistency	Does the measure pass subcriterion1c?
M-H	M-H	M-H	Yes☐
L	M-H	M	Yes☐ IF additional research unlikely to change conclusion that benefits to patients outweigh harms: otherwise No☐
M-H	L	M-H	Yes☐ IF potential benefits to patients clearly outweigh potential harms: otherwise No☐
L-M-H	L-M-H	L	No ☐

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*)**:**

Invasive pneumococcal disease is a well-known cause of morbidity and mortality, especially among older persons and those with asthma or smokers, among other conditions. Pneumococcal vaccination is associated with significant reductions in the overall pneumonia rate, in the risk of hospitalization for pneumonia, and in the risk of death due to pneumonia among vaccinated subjects. Thus, the CDC recommends PPV for Americans age 65 and older and those with selected chronic conditions.

1c.2-3 Type of Evidence *(Check all that apply)*:
Cohort study, Observational study, Evidence-based guideline, Randomized controlled trial, Systematic synthesis of research, Meta-analysis

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)*:
According to the Sept 2010 CDC "Updated Recommendations for Prevention of Invasive Pneumococcal Disease Among Adults Using the 23-Valent Pneumococcal Polysaccharide Vaccine (PPSV23)"(1), most evaluations of PPSV23 efficacy and effectiveness are consistent with protection against invasive pneumococcal disease (IPD) among the general population of older persons. Observational studies have suggested effectiveness estimates ranging from approximately 50% to 80% for prevention of IPD among immunocompetent older adults and adults with various underlying illnesses, supporting the recommendations for using PPSV23 to prevent IPD (2). A recent meta-analysis of 15 randomized controlled trials (RCTs) and seven nonrandomized observational studies of PPSV23 efficacy and effectiveness suggested an overall efficacy of 74% against IPD (CI = 56%--85%), based on pooled results of 10 of the RCTs (3). Analysis of the results from the seven observational studies yielded a pooled vaccine effectiveness estimate of 52% (CI = 39%--63%).

1c.5 Quantity of Studies in the Body of Evidence *(Total number of studies, not articles)*: This submission is based on a previously submitted form which did not require this information.

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)*: This submission is based on a previously submitted form which did not require this information.

1c.7 Consistency of Results across Studies *(Summarize the consistency of the magnitude and direction of the effect)*: This submission is based on a previously submitted form which did not require this information.

1c.8 Net Benefit *(Provide estimates of effect for benefit/outcome; identify harms addressed and estimates of effect; and net benefit - benefit over harms)*:
This submission is based on a previously submitted form which did not require this information.

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 submission is based on a previously submitted form which did not require this information.

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

1c.12 If other, identify and describe the grading scale with definitions: This submission is based on a previously submitted form which did not require this information.

1c.13 Grade Assigned to the Body of Evidence: Fair

1c.14 Summary of Controversy/Contradictory Evidence: The research evidence for effectiveness of PPV is mixed. According to the Sept 2010 CDC "Updated Recommendations for Prevention of Invasive Pneumococcal Disease Among Adults Using the 23-Valent Pneumococcal Polysaccharide Vaccine (PPSV23)", analysis of the results from seven observational studies (3) yielded a pooled vaccine effectiveness estimate of 52% (CI = 39%--63%). In contrast, a recent meta-analysis that included six RCTs

estimated the combined PPSV23 efficacy against pneumococcal bacteremia at only 10%, with a very wide CI (CI = -77%--54%) (4). The large difference in findings from these two meta-analyses might be related to inclusion of different trials.

1c.15 Citations for Evidence other than Guidelines*(Guidelines addressed below)*:
(1) Centers for Disease Control and Prevention. Updated recommendations for prevention of invasive pneumococcal disease among adults using the 23-valent pneumococcal polysaccharide vaccine(PPSV23). MMWR Morb Mortal Wkly Rep 2010; 59(34):1102-1106.
2)World Health Organization. 23-valent pneumococcal polysaccharide vaccine. WHO position paper. Wkly Epidemiol Rec 2008;83:373--84.
3) Moberley SA, Holden J, Tatham DP, Andrews RM. Vaccines for preventing pneumococcal infection in adults. Cochrane Database Syst Rev 2008;(1):CD000422.
4) Huss A, Scott P, Stuck AE, Trotter C, Egger M. Efficacy of pneumococcal vaccination in adults: a meta-analysis. CMAJ 2009;180:48--58.:1-6.

1c.16 Quote verbatim, <u>the specific guideline recommendation</u> *(Including guideline # and/or page #)*:
Sept 2010 recommendations from the Advisory Committee (ACIP)for administration of 23-valent pneumococcal polysaccharide vaccine (PPSV23) among adults aged =19 years.

- PPSV23 should be administered to adults aged 19--64 years with chronic or immunosuppressing medical conditions, including those who have asthma.

- Adults aged 19--64 years who smoke cigarettes should receive PPSV23 and smoking cessation guidance.

- Routine PPSV23 use is no longer recommended for Alaska Natives or American Indians aged <65 years unless they have medical indications for PPSV23. However, in certain situations, public health authorities may recommend PPSV23 for Alaska Natives and American Indians aged 50--64 years who are living in areas where the risk for invasive pneumococcal disease is increased.

- All persons should be vaccinated with PPSV23 at age 65 years. Those who received PPSV23 before age 65 years for any indication should receive another dose of the vaccine at age 65 years or later if at least 5 years have passed since their previous dose. Those who receive PPSV23 at or after age 65 years should receive only a single dose.

- ACIP does not recommend routine revaccination for most persons for whom PPSV23 is indicated. A second dose of PPSV23 is recommended 5 years after the first dose for persons aged 19--64 years with functional or anatomic asplenia and for persons with immunocompromising conditions. ACIP does not recommend multiple revaccinations because of uncertainty regarding clinical benefit and safety.

1c.17 Clinical Practice Guideline Citation: Advisory Committee (ACIP)recommendations for administration of 23-valent pneumococcal polysaccharide vaccine (PPSV23) among adults aged =19 years.

1c.18 National Guideline Clearinghouse or other URL: http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5934a3.htm#tab

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 submission is based on a previously submitted form which did not require this information.

1c.23 Grade Assigned to the Recommendation: Moderate

1c.24 Rationale for Using this Guideline Over Others: The CDC´s ACIP guidelines were used in the development of NQF´s Pneumococcal Immunization Standard Measure Specifications.

Based on the NQF descriptions for rating the evidence, what was the <u>developer's assessment</u> of the quantity, quality, and consistency of the body of evidence?
1c.25 Quantity: Moderate   **1c.26** Quality: Moderate **1c.27** Consistency: Moderate

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.

2. RELIABILITY & VALIDITY - SCIENTIFIC ACCEPTABILITY OF MEASURE PROPERTIES

Extent to which the measure, <u>as specified</u>, produces consistent (reliable) and credible (valid) results about the quality of care when implemented. (<u>evaluation criteria</u>)
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 <u>this</u> measure can be obtained? Yes

S.2 If yes, provide web page URL: http://www.cms.gov/HomeHealthQualityInits/Downloads/HHQITechnicalDocOfMeasures.pdf

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)*:
Number of home health episodes of care during which patients were determined to have ever received Pneumococcal Polysaccharide Vaccine (PPV).

2a1.2 Numerator Time Window *(The time period in which the target process, condition, event, or outcome is eligible for inclusion)*:
CMS systems report data on episodes that end within a rolling 12 month period, updated quarterly.

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)*:
Measure specifications follow National Voluntary Consensus Standards for
Influenza and Pneumococcal Immunizations, Final Deliverable to CMS under
Contract # HHSM-500-2006-00027I – Task Order 0008: Adult Immunizations, published September 15, 2008
Numerator is based on responses to items in the OASIS-C data set as follows:

Number of home health patient episodes of care where at end of episode:
-         (M1050) PPV Rec'd = 1 (yes) OR
-       (M1055) PPV not Rec'd = 1 (Rec'd in past)

2a1.4 Denominator Statement *(Brief, narrative description of the target population being measured)*:
Number of home health episodes of care ending during the reporting period, other than those covered by generic or measure-specific exclusions.

2a1.5 Target Population Category *(Check all the populations for which the measure is specified and tested if any)*:

2a1.6 Denominator Time Window *(The time period in which cases are eligible for inclusion)*:
CMS systems report data on episodes that end within a rolling 12 month period, updated quarterly.

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)*:
Number of home health patient episodes of care, defined as:
A start/resumption of care assessment ((M0100) Reason for Assessment = 1 (Start of care) or 3 (Resumption of care)) paired with a corresponding discharge/transfer assessment ((M0100) Reason for Assessment = 6 (Transfer to inpatient facility – not discharged), 7 (Transfer to inpatient facility – discharged), 8 (Death at home), or 9 (Discharge from agency)), other than those covered by denominator exclusions.

2a1.8 Denominator Exclusions *(Brief narrative description of exclusions from the target population)*:
Episodes which ended in patient death. Episodes in which the patient does not meet the CDC age/condition guidelines for PPV vaccine.

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)*:
Measure-specific exclusions:
Number of home health patient episodes of care where at end of episode:
- (M0100) Reason for Assessment = 8 (death at home)
PLUS
Number of home health patient episodes of care where at end of episode:
- (M0100) Reason for Assessment = 6 or 7 (transfer to inpatient) or 9 (discharge) AND:
  (M1055) PPV not Rec'd = 4 (not indicated, patient does not meet age/condition guidelines)

Generic Exclusions: Medicare-certified home health agencies are currently required to collect and submit OASIS data only for adult (aged 18 and over) non-maternity Medicare and Medicaid patients who are receiving skilled home health care. Therefore, maternity patients, patients less than 18 years of age, non-Medicare/Medicaid patients, and patients who are not receiving skilled home services are all excluded from the measure calculation. However, the OASIS items and related measures could potentially be used for other adult patients receiving services in a community setting, ideally with further testing. The publicly-reported data on CMS' Home Health Compare web site also repress cells with fewer than 20 observations, and reports for home health agencies in operation less than six months.

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)*:
N/A

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.)*:
N/A

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.)*:
Calculation Algorithm contained in Technical Specifications available at:
www.cms.gov/HomeHealthQualityInits/Downloads/HHQITechnicalDocOfMeasures.pdf

2a1.21-23 Calculation Algorithm/Measure Logic Diagram URL or attachment:

2a1.24 Sampling (Survey) Methodology. If measure is based on a sample (or survey), provide instructions for obtaining the sample, conducting the survey and guidance on minimum sample size (response rate):
N/A - completion of OASIS-C assessments is mandated by CMS and all completed assessments are used to calculate measure.

2a1.25 Data Source *(Check all the sources for which the measure is specified and tested)*. If other, please describe:
 Electronic Clinical Data

2a1.26 Data Source/Data Collection Instrument (*Identify the specific data source/data collection instrument, e.g. name of database, clinical registry, collection instrument, etc.*): OASIS-C data set collected by Home Health Agency clinicians and submitted electronically to state data repositories.

2a1.27-29 Data Source/data Collection Instrument Reference Web Page URL or Attachment: URL
https://www.cms.gov/HomeHealthQualityInits/Downloads/HHQIOASISCAllTimePoint.pdf

2a1.30-32 Data Dictionary/Code Table Web Page URL or Attachment:
URL
https://www.cms.gov/OASIS/Downloads/oasisp200.zip

2a1.33 Level of Analysis (*Check the levels of analysis for which the measure is specified and tested)*: Facility

2a1.34-35 Care Setting *(Check all the settings for which the measure is specified and tested)*: Home Health

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)*:
All agencies with at least 20 quality episodes beginning and ending between 1/1/2010 and 12/31/2010 were included in the reliability analysis, because only information for agencies with at least 20 episodes is publicly reported. Of these, 8,992 agencies met the threshold for the measure PPV Ever Received. For the national analysis, a beta-binomial distribution was fitted using all agencies. For the HHR (hospital referral region) analysis described below, separate beta-binomials were fitted for each of 306 HHRs, using only those agencies in the HHR. It is worth noting, that even the agencies that are in HRRs with only a small number of agencies have high reliability scores, because these small HRR agencies tend to service many episodes relative to the rest of the country.

2a2.2 Analytic Method *(Describe method of reliability testing & rationale)*:
Based on guidance received from NQF in April 2011, we conducted additional reliability analysis of this measure using the beta-binomial method described in "The Reliability of Provider Profiling: A Tutorial" by John L. Adams. The beta-binomial method was developed for provider level measures reported as rates, and it allows one to calculate an agency level "reliability score," interpreted as the percent of variance due to the difference in measure score among providers. Thus, a reliability score of .80 signifies that

80% of the variance is due to differences among providers, and 20% of the variance is due to measurement error or sampling uncertainty. A high reliability score implies that performance on a measure is unlikely to be due to measurement error or insufficient sample size, but rather due to true differences between the agency and other agencies. Each agency receives an agency specific reliability score which depends on both agency size, agency performance on the measure, and measure variance for the relevant comparison group of agencies.

In addition to calculating reliability scores at the national level, we also calculated agency reliability scores at the level of hospital referral regions (HRRs), because the HRR grouping more adequately captures the types of comparisons health care consumers are likely to make. HRRs are region designations determined in the Dartmouth Atlas of Health Care study, and they represent regional health care markets for tertiary medical care that generally requires the service of a major referral center. They are aggregated hospital service areas (HSAs) and thus aggregated local health care markets. The HRRs are used to determine categories of sufficient size to make comparisons while still capturing the local set of HHA choices available to a beneficiary.

2a2.3 Testing Results *(Reliability statistics, assessment of adequacy in the context of norms for the test conducted)*:
Distribution of Within National Reliability Scores
Mean   0.978
Min   0.845
10th   0.940
25th   0.971
50th   0.988
75th   0.995
90th   0.998
Max   1.00

The distribution of national reliability scores (percent of variance due to the difference in measure score among providers at the national level) shows that at least 75% of agencies have a reliability score greater than 0.971, implying that their performance can likely be distinguished from other agencies (i.e., performance on this measure is unlikely to be due to measurement error or insufficient sample size, but is instead due to true differences between the agency and other agencies as it substantially exceeds within agency variation).

Distribution of Within HHR Reliability Scores
Mean   0.964
Min   0.072
10th   0.914
25th   0.958
50th   0.982
75th   0.992
90th   0.997
Max   1.00

The distribution of HRR reliability scores (percent of variance due to the difference in measure score among providers at the HRR level) for this measure also shows that at least 75% of agencies have a reliability score greater than 0.958, suggesting that between agency variation substantially exceeds within agency variation.

2b. VALIDITY. Validity, Testing, <u>including all Threats to Validity</u>:   H☐ M☐ L☐ I☐

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:**

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)*:
OASIS-C quality episodes from 1/1/2010 – 9/30/2010 for all beneficiaries at Medicare Certified agencies. A 20% sample (about 500,000 episodes), chosen at random, was used to identify patient characteristics correlated to outcomes. A different 20% sample

was used to validate the predictive models.

2b2.2 Analytic Method *(Describe method of validity testing and rationale; if face validity, describe systematic assessment)*:
Two measures that could potentially be clinically related to this measure were selected from measures that are currently calculated as part of the Outcome-based Quality Improvement and Potentially Avoidable Event home health reports. They were Acute Care Hospitalization and Improvement in Dyspnea. For each of these measures, preliminary prediction models using most of the Agency Patient-Related Characteristic Report variables except race were developed. Improvement in the outcome Acute Care Hospitalization, would be expected to be associated with "PPV Ever Received," because Invasive pneumococcal disease is a well-known cause of morbidity and mortality, especially among older persons, smokers and those with asthma or other chronic conditions. Improvement in Dyspnea would be expected to be associated with "PPV Ever Received," because those likely to have dyspnea interfering with activity (the OASIS item used to calculate the measure) are also those at higher risk for invasive pneumococcal disease—older people and those with selected chronic diseases associated with dyspnea (asthma, smokers).
A bivariate relationship (95% confidence interval using logistic regression) and the relationship between the TLE PBQI measure and the preliminary risk adjusted target outcome measure (95% confidence interval using logistic regression) were computed. Predictive validity analysis was conducted at the individual quality episode level. Odds ratios for both a bivariate relationship between the process and outcome and for the multivariate relationship between the process, patient risk-factors, and the outcome were reported.

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)*:
The predictive validity analysis demonstrated the expected positive relationship with "Improvement in Dyspnea" and the predicted negative relationship with "Acute Care Hospitalization".

Improvement in Dyspnea v. PPV Ever Received - 95% CI (Odds Ratio)
Bivariate Relationship - 95% CI (Odds Ratio): 1.060 – 1.096
Risk Adjusted Outcome: 1.065 – 1.103
Expected Relationship? Yes

Acute Care Hospitalization v. PPV Ever Received - 95% CI (Odds Ratio)
Bivariate Relationship 95% CI (Odds Ratio): 0.862 - 0.883
Risk Adjusted Outcome: 0.808 – 0.830
Expected Relationship? Yes

The bivariate relationship results report the odds ratio calculated by including an indicator for "PPV Ever Received" as the only control variable in a logistic regression with each outcome (e.g. "Improvement in Dyspnea") as the dependent variable. The Improvement in Dyspnea 95% confidence interval [1.060 – 1.096] suggests that patients who have ever received the PPV have between 1.060 and 1.096 times the odds of improving in dyspnea than those who do not receive the assessment, significant at the p<0.05 level. In lay terms, a patient receiving the PPV is more likely to improve in dyspnea than a patient who has never received the PPV.
Similarly, The "Acute Care Hospitalization" 95% confidence interval [0.862 - 0.883] suggests that patients who have ever received the PPV have between 0.862 - 0.883 times the odds of experiencing an acute care hospitalization than those who do not receive the assessment, significant at the p<0.05 level. In lay terms, a patient receiving the PPV is less likely to be hospitalized than a patient who has never received the PPV.

To account for the possibility that the receiving a PPV is correlated with underlying patient characteristics, we also calculated a multivariate "risk adjusted" odds ratio. This odds ratio was calculated by including both the indicator for "PPV Ever Received" and a set of risk factors based on patient characteristics in a logistic regression with each outcome as the dependent variable. The risk adjusted Improvement in Dyspnea 95% confidence interval [1.065 – 1.103] suggests that after controlling for patient characteristics, patients who received the PPV had between 1.065 – 1.103 times the odds of experiencing an acute care hospitalization than those otherwise similar patients who did not receive the PPV, significant at the p<0.05 level. Thus, risk adjustment slightly attenuated the relationship between PPV Ever Received and Improvement in Dyspnea, but the distinction between those who did and have never received the PPV was still significant. Conversely, risk adjustment slightly strengthened the relationship between PPV Ever Received and Acute Care Hospitalization.

The risk adjusted results are different from the bivariate results because differences in patient characteristics for those patients who received the PPV versus those patients who have not are controlled for in the risk adjusted results. For example, if agencies are routinely less likely to provide a PPV to patients who are acutely ill with a respiratory disorder, who are in turn unlikely to improve in dyspnea, that association would show up as an odds ratio of greater than one in the bivariate analysis. However, it would not affect the risk adjusted odds ratio. We chose to report both the bivariate and the risk adjusted odds ratios in part because risk adjustment models were still under development when this testing was conducted in November 2010.

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 quality episodes (2.89 million) from 1/1/2010 to 9/30/2010.
- 2.02 million episodes ending in discharge not to an inpatient facility;
- 855,705 episodes ending in transfer to an inpatient facility;
- 17,879 episodes ending in patient death at home.

2b3.2 Analytic Method (*Describe type of analysis and rationale for examining exclusions, including exclusion related to patient preference*):
Frequency of exclusions by type.

2b3.3 Results (*Provide statistical results for analysis of exclusions, e.g., frequency, variability, sensitivity analyses*):
The exclusions are supported by sufficient frequency of occurrence so that results would be distorted without the exclusions:
% of quality episodes excluded: 3%
# total of quality episodes excluded: 78,013
# excluded due to condition/diagnosis (patient does not meet PPV age/condition guidelines):   78,013
Additionally, 17,879 episodes ended in patient death at home.

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*):
NA - process measure

2b4.2 Analytic Method (*Describe methods and rationale for development and testing of risk model or risk stratification including selection of factors/variables*):
NA - process measure

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*):
NA - process measure

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

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*):
OASIS-C data from Medicare certified agencies with at least 10 quality episodes to which the measure applies. 89% of agencies 9,033 met the ten episode threshold for this measure. The measure applied to 97% of all quality episodes (2.79 million out of 2.89

million).

2b5.2 Analytic Method *(Describe methods and rationale to identify statistically significant and practically/meaningfully differences in performance)*:
Difference in performance between 90th percentile agency and 10th percentile agency was calculated and reviewed by Technical Expert Panel to identify magnitude of difference that might be considered meaningful.

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)*:
 Agency Avg: 60%
Std Dev: 25%
Skew: -0.58
Min: 0%
10th: 22%
25th: 44%
50th: 64%
75th: 78%
90th: 89%
Max: 100%
Meaningful Difference: 90th - 10th Percentile- 67%
Meaningful Difference: 75th - 25th Percentile - 34%

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)*:
N/A - Single data source, OASIS C

2b6.2 Analytic Method *(Describe methods and rationale for testing comparability of scores produced by the different data sources specified in the measure)*:
N/A - Single data source, OASIS C

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)*:
N/A - Single data source, OASIS C

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 measure is not currently stratified, as it is based on the National Voluntary Consensus Standards for Influenza and Pneumococcal Immunizations which are not stratified. Evidence of disparities in care exist, however. A review of the recent literature indicates there is evidence of disparities in care. There are fewer blacks and Hispanics with PPV vaccination rates among older people: 63% of whites; 42% of blacks and 44% of Hispanics (1). Explanations for disparities include patient factors (lack of awareness of the need for PPV, fear of side effects among minority older people) and provider factors (lack of awareness of recommendations, failure to recommend the vaccine, under-estimation of safety and effectiveness, failure to institute standing orders for vaccine administration)(2).

References:
1) Singleton JA, Santibanez TA, Wortley PM. Influenza and pneumococcal vaccination of adults aged > or = 65: racial/ethnic differences. Am J Prev Med 2005; 29(5):412-420.
(2) Flowers L. Racial and ethnic disparities in influenza and pneumococcal immunization rates among Medicare beneficiaries. Issue Brief (Public Policy Inst (Am Assoc Retired Pers)) 2007;(IB83):1-6

2c.2 If disparities have been reported/identified (e.g., in 1b), but measure is not specified to detect disparities, please explain:

Our analysis of measure scores did indicate care disparities for PPV.
Observed Rate by Patient Race
White: 63%   Black: 50%   Hispanic: 47%   Other: 59%

Observed Rate by Patient Age
<65: 49%   65-75: 59%   75-85: 63%   85+: 64%

Observed Rate by Patient Gender
Male: 59%   Female: 61%

This is a harmonized measure based on national standards and used in a number of care settings across HHS. We anticipate a need for follow-up with the standards group regarding whether there is sufficient evidence of health care disparities to indicate a potential need for stratification by race and ethnicity.

2.1-2.3 Supplemental Testing Methodology Information:

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

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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 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)*:

3a. Usefulness for Public Reporting: H ☐ M ☐ L ☐ I ☐
(*The measure is meaningful, understandable and useful for public reporting.*)

3a.1. Use in Public Reporting - disclosure of performance results to the public at large *(If used in a public reporting program, provide name of program(s), locations, Web page URL(s)).* If not publicly reported in a national or community program, state the reason AND plans to achieve public reporting, potential reporting programs or commitments, and timeline, e.g., within 3 years of endorsement: [*For Maintenance – If not publicly reported, describe progress made toward achieving disclosure of performance results to the public at large and expected date for public reporting; provide rationale why continued endorsement should be considered.*]
Medicare Home Health Compare
http://www.medicare.gov/HomeHealthCompare/search.aspx

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:

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): Home Health Quality Initiatives
https://www.cms.gov/HomeHealthQualityInits/01_Overview.asp#TopOfPage

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,
Coded by someone other than person obtaining original information (e.g., DRG, ICD-9 codes on claims)

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)*: Yes

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:
Inaccuracies may result either due to confusion/lack of training on the part of the clinician completing the OASIS or intentionally, to manipulate scores on quality measures. CMS has created and disseminated manuals and training materials to maximize accurate reporting of this data. Data accuracy could be audited through a review of claims related to immunizations.

All home health agencies serving adult, non-maternity Medicare and/or Medicaid patients must submit their OASIS assessment data to their respective state OASIS repository in a standard format. The repository software passes each incoming OASIS assessment record through an extensive set of quality edits. These include internal range and logic checks that assure that assessment items include only allowable values and that they are consistent with each other. When there are significant errors in an assessment, it is not accepted by the repository and the erroneous data are not available to be included in any published quality information. Data accuracy is also supported by the state survey process. Surveyors use OASIS to characterize each agency's caseload and to select sample patients to be interviewed. They also review and assess the accuracy of the agency's OASIS assessments. In addition, CMS payment contractors assess the accuracy of a sample of the OASIS assessments as part of their medical review processes. We are unable to provide results of these audit activities as we do not currently have access to the findings of the CMS surveyors, the data repository or CMS contractors regarding OASIS data accuracy.

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)*:

No issues regarding availability of data, missing data, timing or frequency of data collection, patient confidentiality, time or cost of data collection, feasibility or implementation have become apparent since OASIS-C was implemented 1/1/2010.

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:

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?

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)*:
N/A - PPV Ever Received measures the rate of PPV immunization in a different target population - home health patients.

CONTACT INFORMATION

Co.1 Measure Steward (Intellectual Property Owner): Centers for Medicare and Medicaid Services, Office of Clinical Standards and Quality, Quality Measurement and Health Assessment Group, 7500 Security Blvd, Baltimore, Maryland, 20014

Co.2 Point of Contact: Edward Q., Garcia III, MHS, Health Policy Analyst, MMSNQF@hsag.com, 410-786-6738-

Co.3 Measure Developer if different from Measure Steward: Acumen LLC, 500 Airport Blvd, Suite 365, Burlingame, California, 94010

Co.4 Point of Contact: Keziah, Cook, PhD, kcook@acumenllc.com, 650-558-8882-247

Co.5 Submitter: Deborah, Deitz, RN, BSN, Deborah_deitz@abtassoc.com, 617-520-3039-, Abt Associates Inc

Co.6 Additional organizations that sponsored/participated in measure development:
Abt Associates, Inc.
Case Western Reserve University
University of Colorado at Denver, Division of Health Care Policy and Research

Co.7 Public Contact: Robin, Dowell, robin.dowell@cms.hhs.gov, 410-786-0060-, Centers for Medicare and Medicaid Services, Office of Clinical Standards and Quality, Quality Measurement and Health Assessment Group

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.
In December 2010, a Technical Expert Panel (TEP) was convened to review the analysis conducted on the home health measures that received NQF time limited endorsement (including PPV Ever Received). The TEP was comprised of individuals selected by CMS for their expertise and perspectives related to the panel objectives, from a pool of individuals who were nominated in response to the September 2010 Call for TEP notice.

2010 HH TLE Measure Review TEP Members:
Mary Carr RN, MPH - Associate Director for Regulatory Affairs, National Association of Home Care and Hospice
Rick Fortinsky, PhD- Professor of Medicine, Physicians Health Services Endowed Chair in Geriatrics and Gerontology, UConn Center for Health Services Research
Barbara Gage, PhD - Deputy Director of Aging, Disability, and Long-term Care, Post-Acute Care Research Lead, Research Triangle Institute
Margherita Labson, R.N., Executive Director for the Home Care Program at The Joint Commission
Steve Landers MD, MPH - Director, Center for Home Care and Community Rehabilitation, Cleveland Clinic
Bruce Leff, MD – Associate Director, Elder House Call Program,
Barbara McCann, MSW - Chief Industry Officer, Interim HealthCare
Jennifer S. Mensik PhD, RN, NEA-BC, FACHE - Director, Clinical Practices and Research, Banner Health, Arizona and Western Regions
Dana Mukamel, Professor, Department of Medicine, Division of General Internal Medicine & Primary Care, University of California, Irvine & Senior Fellow, Health Policy Research Institute, Irvine, California
Robert J. Rosati Ph.D - Vice President, Clinical Informatics, Visiting Nurse Service of New York, Center for Home Care Policy and Research
Judy Sangl Sc.D. – Health Scientist Administrator, Agency for Healthcare Research and Quality (AHRQ), Center for Patient Safety and Quality Improvement (CQuIPS), Rockville, MD

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: PPV Ever Received

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: 01, 2010
Ad.5 What is your frequency for review/update of this measure? Annual
Ad.6 When is the next scheduled review/update for this measure? 06, 2012

Ad.7 Copyright statement:

Ad.8 Disclaimers:

Ad.9 Additional Information/Comments:

Date of Submission (*MM/DD/YY*): 07/13/2011