# 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 <u>submitting standards web page</u>.

## NQF #: 0431 NQF Project: Population Health: Prevention Project

(for Endorsement Maintenance Review)

Original Endorsement Date: Jul 31, 2008 Most Recent Endorsement Date: Jul 31, 2008

# **BRIEF MEASURE INFORMATION**

De.1 Measure Title: INFLUENZA VACCINATION COVERAGE AMONG HEALTHCARE PERSONNEL

Co.1.1 Measure Steward: Centers for Disease Control and Prevention

De.2 Brief Description of Measure: Percentage of healthcare personnel (HCP) who receive the influenza vaccination.

**2a1.1 Numerator Statement:** HCP in the denominator population who during the time from October 1 (or when the vaccine became available) through March 31 of the following year:

(a) received an influenza vaccination administered at the healthcare facility, or reported in writing (paper or electronic) or provided documentation that influenza vaccination was received elsewhere; or

(b) were determined to have a medical contraindication/condition of severe allergic reaction to eggs or to other component(s) of the vaccine, or history of Guillain-Barré Syndrome within 6 weeks after a previous influenza vaccination; or

(c) declined influenza vaccination; or

(d) persons with unknown vaccination status or who do not otherwise meet any of the definitions of the above-mentioned numerator categories.

Numerators are to be calculated separately for each of the above groups.

**2a1.4 Denominator Statement:** Number of HCP who are working in the healthcare facility for at least 30 working days between October 1 and March 31 of the following year, regardless of clinical responsibility or patient contact.

Denominators are to be calculated separately for:

(a) Employees: all persons who receive a direct paycheck from the reporting facility (i.e., on the facility's payroll).

(b) Licensed independent practitioners: include physicians (MD, DO), advanced practice nurses, and physician assistants only who are affiliated with the reporting facility who do not receive a direct paycheck from the reporting facility.

(c) Adult students/trainees and volunteers: include all adult students/trainees and volunteers who do not receive a direct paycheck from the reporting facility.

2a1.8 Denominator Exclusions: None.

1.1 Measure Type: Process

2a1. 25-26 Data Source: Electronic Clinical Data, Management Data, Paper Records, Patient Reported Data/Survey 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*): 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 <u>endorsed</u> or submitted measures (*check 5.1*):

Other Criteria:

Staff Reviewer Name(s):

# 1. IMPACT, OPPORTUITY, 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 <u>guidance on evidence</u>.

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

(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): Infectious Diseases, Infectious Diseases : Respiratory, Prevention, Prevention : Immunization

De.5 Cross Cutting Areas (Check all the areas that apply): Population Health, Safety : Healthcare Associated Infections

1a.1 Demonstrated High Impact Aspect of Healthcare: Affects large numbers, Patient/societal consequences of poor quality

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

1a.3 Summary of Evidence of High Impact (*Provide epidemiologic or resource use data*):

From 1976-2007, influenza virus infections caused an average of 23,607 influenza-related deaths with a wide yearly range of 3,349 to 48,614 deaths over 31 influenza seasons; approximately 90% of these deaths occurred among persons aged 65 and older.(1) Healthcare personnel (HCP) can serve as vectors for influenza transmission because they are at risk for both acquiring influenza from patients and transmitting it to patients and HCP often come to work when ill.(2) One early report of HCP influenza infections during the 2009 H1N1 influenza pandemic estimated 50% of infected HCP had contracted the influenza virus from patients or coworkers in the healthcare setting.(3) Influenza virus infection is common among HCP: one study suggested that nearly one-quarter of HCP were infected during influenza season, but few of these recalled having influenza.(4) Therefore, all HCP are recommended to receive the seasonal influenza vaccine annually to protect themselves and their patients.(5)

Nosocomial influenza outbreaks in healthcare facilities result in longer stays and greater mortality for patients (6-9) and missed work for HCP.(2,9) Higher influenza vaccination coverage among HCP is associated with reductions in nosocomial influenza among hospitalized patients (8,10) and nursing home residents.(11-13) Influenza vaccination of HCP is also associated with decreased all-cause mortality among nursing home residents.(11-14)

1a.4 Citations for Evidence of High Impact cited in 1a.3: 1. Thompson MG, Shay DK, Zhou H, et al. Estimates of deaths associated with seasonal influenza – United States, 1976-2007. MMWR Morb Mortal Wkly Rep. 2010; 59(33):1057-1062.
2. Wilde JA, McMillan JA, Serwint J, et al. Effectiveness of influenza vaccine in healthcare professionals: a randomized trial. JAMA 1999; 281: 908–913.

3. Harriman K, Rosenberg J, Robinson S, et al. Novel influenza A (H1N1) virus infections among health-care personnel – United States, April-May 2009. MMWR Morb Mortal Wkly Rep. 2009; 58(23): 641-645.

4. Elder AG, O'Donnell B, McCruden EA, et al. Incidence and recall of influenza in a cohort of Glasgow health-care workers during the 1993-4 epidemic: results of serum testing and questionnaire. BMJ. 1996; 313:1241-1242.

5. Fiore AE, Uyeki TM, Broder K, et al. Prevention and control of influenza with vaccines: Recommendations of the Advisory Committee on Immunization Practices (ACIP), 2010. MMWR Recomm Rep. 2010; 59(08): 1-62.

6. Cunney RJ, Bialachowski A, Thornley D, Smaill FM, Pennie RA. An outbreak of influenza A in a neonatal intensive care unit. Infect Control Hosp Epidemiol. 2000; 21:449-454.

7. Bridges CB, Kuehnert MJ, Hall CB. Transmission of influenza: implications for control in health care settings. Clin Infect Dis 2003;

37: 1094–1101.

8. Weinstock DM, Eagan J, Malak SA, et al. Control of influenza A on a bone marrow transplant unit. Infect Control Hosp Epidemiol. 2000; 21:730-732.

9. Sartor C, Zandotti C, Romain F, et al. Disruption of services in an internal medicine unit due to a nosocomial influenza outbreak. Infect Control Hosp Epidemiol 2002; 23:615–619.

10. Salgado CD, Giannetta ET, Hayden FG, Farr BM. Preventing nosocomial influenza by improving the vaccine acceptance rate of clinicians. Infect Control Hosp Epidemiol 2004; 25:923–928.

11. Hayward AC, Harling R, Wetten S, et al. Effectiveness of an influenza vaccine programme for care home staff to prevent death, morbidity, and health service use among residents: cluster randomised controlled trial. BMJ 2006; 333: 1241-1246.

12. Potter J, Stott DJ, Roberts MA, et al. Influenza vaccination of healthcare workers in long-term-care hospitals reduces the mortality of elderly patients. J Infect Dis. 1997; 175:1-6.

13. Lemaitre M, Meret T, Rothan-Tondeur M, et al. Effect of influenza vaccination of nursing home staff on mortality of residents: a cluster-randomized trial. J Am Geriatr Soc. 2009; 57:1580-1586.

14. Carman WF, Elder AG, Wallace LA, et al. Effects of influenza vaccination of health-care workers on mortality of elderly people in long-term care: a randomised controlled trial. Lancet 2000; 355:93–97.

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:

Use of this measure to monitor influenza vaccination among HCP is envisioned to result in increased influenza vaccination uptake among HCP, because improvements in tracking and reporting HCP influenza vaccination status will allow healthcare institutions to better identify and target unvaccinated HCP. Increased influenza vaccination coverage among HCP is expected to result in reduced morbidity and mortality related to influenza virus infection among patients, as described above in Section 1a.3.

**1b.2 Summary of Data Demonstrating Performance Gap (Variation or overall less than optimal performance across providers):** [*For Maintenance* – Descriptive statistics for performance results <u>for this measure</u> - distribution of scores for measured entities by quartile/decile, mean, median, SD, min, max, etc.]

Ámong employees, the median influenza vaccination coverage rate among healthcare institutions participating in the field test was 63% (quartile 1: 44%, quartile 3: 79%).

Among credentialed non-employees, the median influenza vaccination coverage rate was 46% (quartile 1: 8%, quartile 3: 90%). Among other non-employees, the median influenza vaccination coverage rate was 51% (quartile 1: 29%, quartile 3: 92%).

Reported influenza vaccination coverage rates vary noticeably by denominator group. In addition, all three estimates are substantially lower than the Healthy People 2020 goal of 90% influenza vaccination coverage among HCP, demonstrating substantial room for improvements.

1b.3 Citations for Data on Performance Gap: [For <u>Maintenance</u> – 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] The measurement testing was conducted from October 2010 to March 2011 among 234 healthcare institutions from four jurisdictions, including 78 acute care hospitals, 59 long-term care facilities, 16 ambulatory surgical centers, 43 dialysis clinics, and 38 physician practices. This represents a 74% response rate from our initially recruited sample of 318 healthcare institutions (92 acute care hospitals, 89 long-term care facilities, 30 ambulatory surgical centers, 51 dialysis clinics, and 56 physician practices). Demographic and policy characteristics of participating institutions are further described in Section 2b5.1.

**1b.4 Summary of Data on Disparities by Population Group:** [*For <u>Maintenance</u> – Descriptive statistics for performance results for this measure by population group*] Not applicable.

1b.5 Citations for Data on Disparities Cited in 1b.4: [For <u>Maintenance</u> – 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]

Not applicable.

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

| NOF #0431 INFLUEN7 | A VACCINATION COVERAG | F AMONG HEALTHCAR | RE PERSONNEL |
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|                    |                       |                   |              |

1c.8 Net Benefit (Provide estimates of effect for benefit/outcome; identify harms addressed and estimates of effect; and net benefit - benefit over harms):

Harms to patients are unlikely because the measure pertains to vaccinating healthcare personnel (as opposed to vaccinating patients).

1c.9 Grading of Strength/Quality of the Body of Evidence. Has the body of evidence been graded? Yes

1c.10 If body of evidence graded, identify the entity that graded the evidence including balance of representation and any disclosures regarding bias: The Advisory Committee on Immunization Practices (ACIP) of the federal Centers for Disease Control and Prevention (CDC) has reviewed the evidence. Because the ACIP is a federal advisory committee, stipulations of the Federal Advisory Committee Act (FACA) are followed that includes issues of representation and conflict of interest.

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

1c.12 If other, identify and describe the grading scale with definitions: Expert consensus. CDC's Advisory Committee on Immunization Practices (ACIP) provides recommendations for the prevention and control of influenza at least annually. The ACIP Influenza Work Group meets every 2–4 weeks throughout the year to discuss newly published studies, review current guidelines, and consider revisions to the recommendations. Published, peer-reviewed studies are the primary source of data used by ACIP in making recommendations for the prevention and control of influenza, but unpublished data that are relevant to issues under discussion also are considered. Among studies discussed or cited, those of greatest scientific quality are the most influential. The ACIP did not use a formal grading scale for evaluating the evidence. However, the ACIP has recently adopted the GRADE method for reviewing evidence and developing recommendations, and future ACIP recommendations will include use of the GRADE system [ref: Ahmed F, Temte J, Campos-Outcalt D, Schunemann HJ. Methods for developing evidence-based recommendations by the Advisory Committee on Immunization Practices (ACIP) of the U.S. Centers for Disease Control and Prevention (CDC). Vaccine 2011;29:9171-9176].

1c.13 Grade Assigned to the Body of Evidence: The ACIP has not assigned a formal grade to the body of evidence. The ACIP recommended influenza vaccination of healthcare personnel based on expert consensus regarding the evidence.

1c.14 **Summary of Controversy/Contradictory Evidence:** Some have asserted that results of the four randomized trials are not conclusive because the primary outcome of mortality used in these studies was nonspecific and was not laboratory-confirmed influenza. However, the remarkable consistency of the findings on reduced mortality among long-term care residents across these four studies provide evidence of the beneficial effect of vaccinating healthcare personnel.

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

 Hayward AC, Harling R, Wetten S, et al. Effectiveness of an influenza vaccine programme for care home staff to prevent death, morbidity, and health service use among residents: cluster randomised controlled trial. BMJ 2006; 333: 1241-1246.
 Potter J, Stott DJ, Roberts MA, et al. Influenza vaccination of healthcare workers in long-term-care hospitals reduces the mortality of elderly patients. J Infect Dis. 1997; 175:1-6.

3. Lemaitre M, Meret T, Rothan-Tondeur M, et al. Effect of influenza vaccination of nursing home staff on mortality of residents: a cluster-randomized trial. J Am Geriatr Soc. 2009; 57:1580-1586.

4. Carman WF, Elder AG, Wallace LA, et al. Effects of influenza vaccination of health-care workers on mortality of elderly people in long-term care: a randomised controlled trial. Lancet 2000; 355:93–97.

5. Talbot TR, Babcock H, Caplan AL, et al. Revised SHEA position paper: influenza vaccination of healthcare personnel. Infection Control and Hospital Epidemiology 2010; 31:987-995.

1c.16 Quote verbatim, the specific quideline recommendation (Including guideline # and/or page #):

"All HCP and persons in training for health-care professions should be vaccinated annually against influenza. Persons working in health-care settings who should be vaccinated include physicians, nurses, and other workers in both hospital and outpatient-care settings, medical emergency-response workers (e.g., paramedics and emergency medical technicians), employees of nursing home and long-term-care facilities who have contact with patients or residents, and students in these professions who will have contact with patients." (From page 36 of the Advisory Committee on Immunization Practices' recommendations for influenza vaccination, cited in Section 1c.17 below.)

1c.17 Clinical Practice Guideline Citation: Fiore AE, Uyeki TM, Broder K, et al. Prevention and control of influenza with vaccines: Recommendations of the Advisory Committee on Immunization Practices (ACIP), 2010. MMWR Recomm Rep. 2010; 59(08): 1-62.

1c.18 National Guideline Clearinghouse or other URL: http://www.guideline.gov/content.aspx?id=8697&search=immunization

1c.19 Grading of Strength of Guideline Recommendation. Has the recommendation been graded? Yes

1c.20 If guideline recommendation graded, identify the entity that graded the evidence including balance of representation and any disclosures regarding bias: Advisory Committee on Immunization Practices (ACIP) of the federal Centers for Disease Control and Prevention (CDC). Because the ACIP is a federal advisory committee, stipulations of the Federal Advisory Committee Act (FACA) are followed that includes issues of representation and conflict of interest.

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

1c.22 If other, identify and describe the grading scale with definitions: The ACIP has recently adopted the GRADE system, and ACIP recommendations will be labelled as category A or category B (rather than labelling ACIP recommendations as strong or weak). Category A recommendations will be made for vaccination of all persons in an age- or risk-factor-based group. Category B recommendations will be made for individual clinical decision making; category B recommendations do not apply to all members of an age- or risk-based group, but in the context of a clinician-patient interaction, vaccination may be found to be appropriate for a person. The ACIP recommendations.

1c.23 Grade Assigned to the Recommendation: The ACIP and other organizations including but not limited to the Society for Healthcare Epidemiology of America, the Infectious Diseases Society of America, the Association of Professionals in Infection Control and Epidemiology, the American Academy of Pediatrics, strongly recommend influenza vaccination of HCP. The ACIP recommendation for influenza vaccination of HCP translates to a category A recommendation.

1c.24 Rationale for Using this Guideline Over Others: The Advisory Committee on Immunization Practices (ACIP), established in 1964 by the Surgeon General of the U.S. Public Health Service, provides national recommendations on use of vaccines and related agents for control of vaccine-preventable diseases in the U.S. For recommendations on childhood and adult immunization, the USPSTF refers readers to the ACIP recommendations. The ACIP is nationally recognized as the premier source for vaccination recommendations, and nearly all organizations recommending influenza vaccination for HCP cite the recommendations of the ACIP.

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: High 1c.26 Quality: Moderate1c.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.

# 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. (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 <u>guidance on measure testing</u>.

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? No

S.2 If yes, provide web page URL:

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

**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):

HCP in the denominator population who during the time from October 1 (or when the vaccine became available) through March 31 of the following year:

(a) received an influenza vaccination administered at the healthcare facility, or reported in writing (paper or electronic) or provided documentation that influenza vaccination was received elsewhere; or

(b) were determined to have a medical contraindication/condition of severe allergic reaction to eggs or to other component(s) of the vaccine, or history of Guillain-Barré Syndrome within 6 weeks after a previous influenza vaccination; or

(c) declined influenza vaccination; or

(d) persons with unknown vaccination status or who do not otherwise meet any of the definitions of the above-mentioned numerator categories.

Numerators are to be calculated separately for each of the above groups.

2a1.2 Numerator Time Window (*The time period in which the target process, condition, event, or outcome is eligible for inclusion*): HCP are eligible for inclusion in the numerator from October 1 (or the time influenza vaccine becomes available, whichever is sooner) to March 31 of the following year.

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: 1. Persons who declined vaccination because of conditions other than those specified in the 2nd numerator category above should be categorized as declined vaccination.

2. Persons who declined vaccination and did not provide any other information should be categorized as declined vaccination.

3. Persons who did not receive vaccination because of religious exemptions should be categorized as declined vaccination.

4. Persons who deferred vaccination all season should be categorized as declined vaccination.

5. The numerator categories are mutually exclusive. The sum of the four numerator categories should be equal to the denominator.

2a1.4 **Denominator Statement** (Brief, narrative description of the target population being measured):

Number of HCP who are working in the healthcare facility for at least 30 working days between October 1 and March 31 of the following year, regardless of clinical responsibility or patient contact.

Denominators are to be calculated separately for:

(a) Employees: all persons who receive a direct paycheck from the reporting facility (i.e., on the facility's payroll).

(b) Licensed independent practitioners: include physicians (MD, DO), advanced practice nurses, and physician assistants only who are affiliated with the reporting facility who do not receive a direct paycheck from the reporting facility.

(c) Adult students/trainees and volunteers: include all adult students/trainees and volunteers who do not receive a direct paycheck from the reporting facility.

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

2a1.6 Denominator Time Window (*The time period in which cases are eligible for inclusion*): HCP are eligible for inclusion in the denominator from October 1 to March 31 of the following year.

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):

1. Include all HCP in each of the three denominator categories who have worked at the facility between October 1 and March 31 for at least 30 working days. This includes persons who joined after October 1 or who left before March 31, or who were on extended

leave during part of the reporting period. Working for any number of hours in a day should be counted as a working day. 2. Include both full-time and part-time persons. If a person works in two or more facilities, each facility should include the person in their denominator. 3. Count persons as individuals rather than full-time equivalents. 4. Licensed practitioners who receive a direct paycheck from the reporting facility, or who are owners of the reporting facility, should be counted as employees. 5. The denominator categories are mutually exclusive. The numerator data are to be reported separately for each of the three denominator categories. 2a1.8 Denominator Exclusions (Brief narrative description of exclusions from the target population): None. 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): Not applicable. 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 ): The measure should be calculated separately for each denominator group of healthcare personnel: employees; licensed independent practitioners; and adult students/trainees and volunteers. Definitions for these groups are as follows: (a) Employees: all persons who receive a direct paycheck from the reporting facility (i.e., on the facility's payroll). (b) Licensed independent practitioners; include physicians (MD, DO), advanced practice nurses, and physician assistants only who are affiliated with the reporting facility and do not receive a direct paycheck from the reporting facility. (c) Adult students/trainees and volunteers: include all adult students/trainees and volunteers who do not receive a direct paycheck from the reporting facility. 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.): 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.):

Among each of the three denominator groups, the measure may be calculated by dividing the number of HCP in the first numerator category (i.e., received an influenza vaccination) by the number of HCP in that denominator group, and multiplying by 100 to produce a vaccination rate expressed as a percentage of all HCP in the denominator group. Rates of medical contraindications, declinations, and unknown vaccination status can be calculated similarly using the second, third, and fourth numerator categories,

respectively.

As noted above, numerator categories should not be summed; each numerator status should be calculated and reported separately.

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

Attachment HCP\_Logic.docx

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): Not applicable.

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

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.*): Data sources for required data elements include management/personnel data, medical or occupational health records, vaccination record documents, HCP self-reporting in writing (paper or electronic) that vaccination was received elsewhere, HCP providing documentation of receipt of vaccine elsewhere, verbal or written declination by HCP, and verbal or written documentation of medical contraindications.

2a1.27-29 Data Source/data Collection Instrument Reference Web Page URL or Attachment: Attachment HCP\_Flu\_Instrument\_NQF.ppt

2a1.30-32 Data Dictionary/Code Table Web Page URL or Attachment: Attachment HCP Flu Data Dictionary.docx

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): Ambulatory Care : Ambulatory Surgery Center (ASC), Ambulatory Care : Clinic/Urgent Care, Ambulatory Care : Clinician Office, Dialysis Facility, Hospital/Acute Care Facility, Post Acute/Long Term Care Facility : Nursing Home/Skilled Nursing Facility

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):

Overview of study entities: 318 healthcare institutions were recruited for measure testing in California, New Mexico, New York City, and Pennsylvania; 234 (74%) responded to the three quantitative surveys fielded in November 2010, January 2011, and April 2011. Characteristics of participating healthcare institutions are described in detail in Section 2b5.1. From the 234 respondents participating in the pilot project, 93 institutions were randomly selected in California, New Mexico, and New York City to undergo reliability testing as described below (the reliability testing and case study instruments were piloted in Pennsylvania). Of these 93 institutions, 82 also completed case studies to assess comprehension of the measure specifications for both numerator and denominator elements. The 93 institutions participating in the reliability testing included 26 acute care hospitals, 19 long-term care facilities, 16 dialysis clinics, 13 ambulatory surgery centers, and 19 physician practices. The 82 institutions completing case studies included 24 acute care hospitals, 18 long-term care facilities, 14 dialysis clinics, 12 ambulatory surgery centers, and 14 physician practices.

2a2.2 Analytic Method (Describe method of reliability testing & rationale): Inter-rater reliability was assessed via record review; both electronic and paper records were reviewed, depending on what type of

data sources were used by the healthcare institution. Project staff from pilot jurisdictions A, B, and C reviewed individual-level records from 93 randomly selected facilities to assess agreement with how the facility staff categorized the numerator and denominator information. For each facility, project staff were instructed to select 60 records using systematic sampling or simple random sampling (20 employees, 20 credentialed non-employees, 20 other non-employees). At smaller institutions or those not having HCP in all three groups, the total number of records assessed may have been fewer than 60. Site visits were conducted by project staff in Jurisdictions A and B, whereas facilities were asked to mail or fax records to the project staff in Jurisdiction C.

We also assessed institutional comprehension of the measure definitions using 'case studies' in order to confirm that our measure specifications were clearly understood by institutions participating in the pilot, and that implementation of the measure specifications would produce comparable results at different types of healthcare institutions. Each institution received a series of 23 brief vignettes, describing a different situation or type of HCP that might be encountered during the vaccination measurement process. Institutions were asked to select the appropriate denominator or numerator group in which to classify the healthcare worker described in the scenario.

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

For numerator data, inter-rater agreement was 88% in Jurisdiction A (kappa: 0.82), 94% in Jurisdiction B (kappa: 0.89), and 80% in Jurisdiction C (kappa: 0.66). Most of the disagreements for all three jurisdictions resulted from healthcare institutions reporting verbal declinations in the "declined vaccination" numerator rather than categorizing these declinations as unknown numerator status in accordance with the project protocol, which originally specified that vaccine declinations required written documentation.

For denominator data, inter-rater agreement was 97% in Jurisdiction A (kappa: 0.95), 99% in Jurisdiction B (kappa: 0.96), and 68% in Jurisdiction C (kappa: 0.55). For both numerator and denominator, agreement was generally lower among facilities from Jurisdiction C because Jurisdiction C was unable to conduct on-site validation visits and therefore was not always able to review complete documentation for numerator or denominator data. See Appendix A for full results.

(It should be noted that denominator data assessed for inter-rater reliability was based on records for HCP who were included by the healthcare institution staff in their denominator reports. Assessment of groups of HCP who may have been excluded from the denominator was conducted through our quantitative surveys; results are described below in Section 4c.1. Modifications to the initial measure based on results of this assessment are described in Section 4d.1.)

Case studies:

Most numerator and denominator elements were correctly identified by the majority of respondents at all types of healthcare institutions. Problematic denominator elements included poor understanding of how to classify physician-owners of healthcare facilities who work part-time and physicians who were credentialed by a facility but had not admitted patients in the past 12 months. Problematic numerator elements mostly related to confusion about how to report persistent deferrals of vaccination and verbal declinations (i.e. declinations without documentation) for non-medical reasons. Minor modifications were made to numerator and denominator codes to clarify these issues. See Appendix B for full results.

#### 2b. VALIDITY. Validity, Testing, including all Threats to Validity: H M L

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 focus and target population for the measure that received time-limited endorsement from the NQF was designed to be fully consistent with the ACIP recommendations for healthcare personnel influenza vaccination. However, the field test of the measure revealed that the denominator population for non-employees needed to be restricted to physicians, advanced practices nurses, physician assistants, students/trainees, and volunteers in order for the measure to be valid and reliable (see sections 4c and 4d).

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):

Convergent validity was assessed using survey questions asked of all pilot participants (n=234). Face validity was assessed using a modified Delphi technique via a panel of nine experts.

**2b2.2 Analytic Method** (*Describe method of validity testing and rationale; if face validity, describe systematic assessment)*: Convergent validity was assessed because it was felt to be the strongest type of measure validity that could be tested given that there is no 'gold standard' for validation of HCP vaccination (unlike patient vaccination, not every HCP will have a medical record or chart to audit). We examined the association between the number of evidence-based strategies used by a healthcare institution to promote influenza vaccination and the institution's reported vaccination rate among each denominator group of HCP. We expected that vaccination rates would be positively correlated with an increasing number of strategies that have been found previously to be associated with higher influenza vaccination coverage among HCP.

Face validity was assessed via a Delphi panel conducted in June 2011. The panel comprised 9 experts in influenza vaccination measurement and quality improvement, recruited from multiple institutions and organizations. Experts were suggested by project staff at CDC and in the pilot jurisdictions as well as nominated by members of the pilot project Steering Committee. Experts rated the elements of the proposed measure on a scale of 1 to 9 prior to a telephone conference call (Round 1 ratings), and their ratings were aggregated and distributed to the group, with areas of disagreement noted. The experts were convened for a one-hour moderated telephone conference, focusing on elements of the Round 1 ratings where consensus on validity was lacking. Finally, experts received a revised set of measure elements and once again rated the validity of these elements individually after the conference call (Round 2 ratings). Experts were considered to have reached consensus on an element when no more than two panelists rated the element outside the three-point grouping containing the median rating.

One of the objectives of the face validity exercise was to assess how to improve the measure specifications to address the reporting issues that were identified through quantitative surveys of participating institutions, case studies, and inter-rater reliability assessment. The revised set of measure elements presented to the panel for the second round of ratings included modifications based on the panel 's moderated discussion as well as those based on issues identified in other data collection efforts described in this submission. Results of the second round of ratings are presented in Section 2b2.3 below.

**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):

For convergent validity, significance testing using a one-way ANOVA produced the following results: the association between employee vaccination rates and number of strategies used was borderline significant at p=0.05. The association between credentialed non-employee vaccination rates and number of strategies used was significant at p=0.02. The association between other non-employee vaccination rates and number of strategies used was significant at p=0.01. Thus, the measure demonstrated convergent validity.

For our analysis of face validity, our Delphi panel of nine experts reached the strongest consensus on the validity of the following definitions for denominator groups: credentialed non-employees defined as non-employee physicians, advanced practice nurses, and physician assistants working at the institution for 30 or more days between October 1 and March 31 of the following year, and other non-employees defined as students and volunteers working at the institution for 30 or more days between October 1 and March 31 of the following year. (There was also consensus on the validity of defining "other non-employees" as all non-employee HCP who were required by the institution to receive a periodic PPD test for tuberculosis. However, we did not recommend use of that definition in the revised measure due to the likelihood of variable testing requirements among institutions in different states, which would reduce comparability of results.) The panel reached consensus on the validity of the following numerator groups: receiving influenza vaccination at the institution, documented receipt of influenza vaccination outside the institution, documented receipt of a medical contraindication to vaccination, and documented declination of vaccine for non-medical reasons including religious exemptions.

See Appendix C for full results.

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): Not applicable – no exclusions.

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

Not applicable – no exclusions.

2b3.3 **Results** (*Provide statistical results for analysis of exclusions, e.g., frequency, variability, sensitivity analyses*): Not applicable – no exclusions.

**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): Not applicable – no risk adjustment needed.

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

Not applicable - no risk adjustment needed.

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. <u>Risk stratification</u>: Provide quantitative assessment of relationship of risk factors to the outcome and differences in outcomes among the strata): Not applicable – no risk adjustment needed.

2b4.4 If outcome or resource use measure is not risk adjusted, provide rationale and analyses to justify lack of adjustment: Risk adjustment is not appropriate for the proposed measure. By virtue of their work environment, all HCP are potentially at risk for contracting influenza and transmitting the influenza virus to patients. The ACIP recommends that all HCP receive annual seasonal influenza vaccination.

**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 measurement testing was conducted from October 2010 to March 2011 among 234 healthcare institutions from four jurisdictions, including 78 acute care hospitals, 59 long-term care facilities, 16 ambulatory surgical centers, 43 dialysis clinics, and 38 physician practices. This sample represents a 74% response rate from our initially recruited sample of 318 healthcare institutions (92 acute care hospitals, 89 long-term care facilities, 30 ambulatory surgical centers, 51 dialysis clinics, and 56 physician practices).

Participants represented a diversity of types of healthcare institutions, with different policies and levels of experience related to providing vaccination and measuring influenza vaccination among HCP. Overall, approximately 20% of facilities were public facilities, with remainder evenly divided between private for-profit and not-for-profit ownership. Slightly over half were located in urban areas, with the remainder evenly divided between suburban and rural locations. Nearly 90% of participating facilities had offered influenza vaccine to HCP for at least 5 years. About 30% of facilities had no experience measuring HCP influenza vaccination, but another 40% had been measuring HCP vaccination for at least 5 years. See Appendix D for full results by facility type.

**2b5.2 Analytic Method** (*Describe methods and rationale to identify statistically significant and practically/meaningfully differences in performance*):

Meaningful differences in performance across facilities can be assessed by categorizing facilities as above average, average, and below average based on quartiles of achievement, as follows:

- a) above average performance: vaccination rate in the top quartile
- b) average performance: vaccination rate in the 2nd and 3rd quartile
- c) below average performance: vaccination rate in the bottom quartile.

Performance can also be evaluated for each denominator category.

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*): Among employees, the median influenza vaccination coverage rate was 63% (guartile 1: 44%, guartile 3: 79%).

Among credentialed non-employees, the median influenza vaccination coverage rate was 46% (quartile 1: 8%, quartile 3: 90%).

Among other non-employees, the median influenza vaccination coverage rate was 51% (quartile 1: 29%, quartile 3: 92%).

**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):

All healthcare institutions participating in the measure testing process (n=234) were asked to report what type or types of data sources were used to gather reporting information for each numerator and denominator measure element in all three groups of healthcare personnel.

**2b6.2 Analytic Method** (Describe methods and rationale for testing comparability of scores produced by the different data sources specified in the measure):

For each denominator element in each of the three healthcare personnel denominator groups, median vaccination rates were calculated among healthcare institutions gathering data from different types of data sources; management data, and paper occupational health records were the most commonly used data sources. For each numerator element in each of the three healthcare personnel denominator groups, median vaccination rates (or contraindication rates, or declination rates, as appropriate) were calculated among healthcare institutions gathering data from different types of data sources; paper occupational health records, electronic occupational health records, and self-report were the most commonly used data sources. (Vaccination rates were calculated using the sum of reported vaccinations received both at and outside of the healthcare facility.) Data distributions based on quartiles, as described in section 2b5.2, were examined to determine whether reported performance was significantly different based on the type of data source used.

**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*):

In general, although reported median vaccination rates (or contraindication or declination rates) varied by data source used for some measure elements, testing results demonstrate the distribution of reported data was similar among all types of data sources (i.e. first and third quartiles were similar for each data source used to report that measure element). For example, the median reported vaccination rate among healthcare institutions using paper occupational records as a data source for employees vaccinated at the institution was 65%, versus a median of 58% reported by those using self-reported data, and 60% reported by those using electronic clinical data. The ranges described by the first and third quartile for each source are similar: 45% to 78% for paper records, 43% to 78% for self-reported data, and 45% to 74% for electronic clinical data. Our results suggest that all types of data for which the proposed measure is specified will produce comparable measurements, with facility performance falling into the same performance category regardless of data source used.

The only data element for which results varied by data source used was the reported vaccination rate at institutions using selfreported data to determine vaccination status of credentialed non-employees vaccinated at the healthcare institution. Reported vaccination coverage in this group was 3% with an interquartile range of 0% to 100%. By contrast, reported vaccination coverage among credentialed non-employees at facilities using electronic clinical data was 38% with an interquartile range of 8% to 75%. Therefore, facilities using self-reported data would be classified at a lower performance level (below average) than facilities using electronic clinical data (average). Vaccination coverage estimates at facilities using self-reported to determine vaccination status of other non-employees vaccinated at the healthcare institution were also notably lower than for other data sources; however, interquartile ranges for all three data sources were so wide that the classification of performance level by quartile as described in Section 2b5.2 would not differ. (See Appendix E for full results.)

The likely source of the observed variation in reporting rates was the lack of specificity in the original definitions of both nonemployee categories, which resulted in a large proportion of pilot institutions being unable to fully report vaccination (i.e. numerator)

data for both non-employee denominator categories. We believe that the modifications to the proposed measure will substantially mitigate observed difficulties with reporting data on these group and as a result, all numerator elements reported using different data sources will be similar across denominator groups. (Difficulties reporting data for credentialed and other non-employees and resulting modifications to the proposed measure are described more fully in Section 4..1 below.) 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): Among employees, the median influenza vaccination coverage rate was 63% (quartile 1: 44%, quartile 3: 79%). Among credentialed non-employees, the median influenza vaccination coverage rate was 46% (quartile 1: 8%, quartile 3: 90%). Among other non-employees, the median influenza vaccination coverage rate was 51% (quartile 1: 29%, quartile 3: 92%). 2c.2 If disparities have been reported/identified (e.g., in 1b), but measure is not specified to detect disparities, please explain: Not applicable. 2.1-2.3 Supplemental Testing Methodology Information: Attachment Appendix Tables-634491732254840966.docx 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 Health/Disease Surveillance, 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): Not in use 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. The proposed measure is not currently in use for public reporting. However, the Centers for Medicare and Medicaid Services (CMS) recently published a proposed rule for CMS' Hospital Inpatient Quality Reporting (IQR) Program, stating that the measure as endorsed by the National Quality Forum would be incorporated in hospital reporting requirements for FY2015 with data reporting beginning in 2013 (the CMS Final Rule, CMS-1518-F, was published on August 1, 2011:

https://www.cms.gov/AcuteInpatientPPS/FR2012/itemdetail.asp?filterType=none&filterByDID=-

99&sortByDID=1&sortOrder=ascending&itemID=CMS1250103&intNumPerPage=10. The relevant text begins on page 591). As part of the Hospital IQR Program, CMS publishes institutional-level data on reported measures at HospitalCompare.hhs.gov, a

publicly available Internet resource for assessing quality of care at hospitals nationally.

In addition, the CMS has published a Proposed Rule on July 18, 2011 (CMS-1525-P) in the Federal Register that includes reporting of healthcare personnel influenza vaccination for ambulatory surgical centers.

3a.2. Provide a rationale for why the measure performance results are meaningful, understandable, and useful for public reporting. <u>If usefulness was demonstrated</u> (e.g., focus group, cognitive testing), describe the data, method, and results: The CMS Final Rule published on August 1, 2011, which includes public comments as well as responses to the public comments, support the usefulness of the measure for public reporting.

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): As noted in Section 3a.1, it is expected that upon endorsement, the proposed measure would be incorporated into CMS' QI program for acute care hospitals, known as the Hospital Inpatient Quality Reporting (IQR) Program, with reporting beginning in 2013. In addition, the Joint Commission has expressed interest in using the NQF-endorsed measure of HCP influenza vaccination as part of its revised standard IC.02.04.01 – Influenza Vaccination for Licensed Independent Practitioners and Staff. These revised standards have undergone a field review and would likely be implemented in late 2012 or in 2013.

**3b. Usefulness for Quality Improvement:** H M L I 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 <u>Maintenance</u> – If not used for QI, indicate the reasons and describe progress toward using performance results for improvement*].

The Joint Commission standard on influenza vaccination for licensed independent practitioners and staff (revised standard IC.02.04.01) stipulates measurement and improvement of vaccination rates. It is anticipated that institutions would use the measure for quality improvement and reporting purposes because of Joint Commission standard and the CMS Rules.

**3b.2.** Provide rationale for why the measure performance results are meaningful, understandable, and useful for quality improvement. If usefulness was demonstrated (*e.g.*, *Ql initiative*), describe the data, method and results: Hospitals, and to a lesser extent other types of institutions, have been measuring healthcare personnel influenza vaccination rates for quality improvement purposes, but these measurements are not done in a standardized manner. The proposed standardized measure will allow institutions to benchmark their performance, and therefore help in educating and motivating their staff for increasing influenza vaccination rates.

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

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*): Some data elements are in 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: Because the measure is for healthcare personnel (as opposed to patients), it would be difficult to capture all data from electronic sources (e.g., verbal declination, verbal statement of medical contraindication). However, such verbal statements could be entered into electronic databases.

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

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: We assessed the susceptibility of our measure to inaccurate or erroneous results by examining potential threats to validity such as differences in data collection practices and systematic missing or mis-reported data. Results related to differences in data collection practices are described above in Section 2b6.3 and in Appendix E.

One potential area of low-validity data in this measure is reported medical contraindications to influenza vaccination. True medical contraindications are extremely rare (<1% of the population): only persons who have previously experienced severe allergic reactions to influenza vaccination or vaccine components including eggs and persons who have a history of Guillain-Barré Syndrome within 6 weeks following vaccination are advised not to receive influenza vaccine. However, surveys of facilities participating in the measure testing process indicated that a substantial proportion of participants granted medical contraindications for other conditions including moderate to severe illness at the time of vaccination (47%), pregnancy (28%), and age of 50 years or older (13%). In addition, 29% of facilities did not report granting contraindications for allergic/hypersensitivity reactions and half did not consider a history of GBS following vaccination to be a contraindication to vaccination. As a result, although the median reported rate of medical contraindications was 0%-1% in all settings tested, the 95th percentile of contraindication rates was 6%-20% at different facility types. Inter-rater data presented in Section 2a.3. indicate that a notable proportion of medical contraindication B, and 4/9 in Jurisdiction C). A precise definition of medical contraindications has been included in the revised measure specifications. At institutions reporting contraindication rates greater than 3%, reports of medical contraindication is necessary.

A potential threat to validity for the original measure that received time-limited NQF endorsement is the systematic absence of data on certain types of healthcare personnel. We analyzed the proportion of participating facilities that were able to report different numerator and denominator elements for all three HCP groups using chi-squares. Overall, more than 90% of healthcare facilities participating in the measurement testing process were able to report denominator data for all three HCP groups, and more than two-thirds were able to report numerator data for all three HCP groups. Acute care hospitals were more likely than other types of facilities to be unable to report denominator data for credentialed non-employees and other non-employees, as were larger healthcare institutions (as measured by number of employees). Similar relationships were found between ability to report all numerator elements among employees, credentialed non-employees, and other non-employees. However, when facility size was taken into account, there was no statistically significant difference in the ability of hospitals vs. other types of healthcare facilities to report any measure elements. These results suggest that healthcare institutions with a larger number of HCP working there may have a more difficult time reporting vaccination data for all HCP. In order to mitigate differences in reporting ability among institutions of different sizes, we modified measure specifications to include a more limited number of non-employee healthcare personnel, as described in Section 4d.1 below.

# 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*): Based on the results of our measure testing, the following modifications were made to the original measure specifications:

First, the specifications for the "credentialed non-employees" denominator category were revised to include only non-employee physicians, non-employee advanced practice nurses, and non-employee physician assistants. (The name of the category was also changed to "licensed independent practitioners" to reflect this modification.) The rationale for this change was that these three groups were the most common groups credentialed by reporting institutions, so limiting reporting to these three groups will make results more comparable across healthcare institutions. Over 80% of institutions require non-employee physicians to undergo periodic credentialing, over 50% require nurse practitioners and advanced practice nurses to be credentialed, and nearly half (45%)

require physician assistants to be credentialed. By contrast, less than one-quarter of institutions (23%) credential therapists such as occupational or respiratory therapists, and less than one-fifth (16%) credential technicians. In addition, 21% of institutions (including 37% of acute care hospitals) reported that time to collect data on credentialed non-employees at their institution was a major barrier to reporting HCP vaccination rates (using the original measure specifications), and 24% of institutions (including 39% of acute care hospitals) reported that determining the vaccination status of credentialed non-employees was a major barrier to reporting HCP vaccination rates. It was felt that reducing the size of this denominator category and making the category definition more specific would reduce these institutional barriers to reporting.

Second, the specifications for the "other non-employees" denominator category were revised to include only students and volunteers. (The name of the category was also changed to "adult students/trainees and volunteers" to reflect this modification.) The rationale for this change was that students and volunteers are groups that would be consistently defined across different types of facilities and are more likely to be tracked than other types of non-credentialed non-employees. Among healthcare institutions reporting HCP of each type working there, only 15% of facilities could not or did not consider tracking volunteers, compared to 22% who did not track personnel hired through a contact agency, 35% who did not track construction workers, and 44% who did not track vendors. Although 29% of institutions reported not tracking students, it was felt that students present a high risk of nosocomial influenza transmission due to frequent and prolonged contact with patients, and should be included. Students and volunteers were also the two categories of non-credentialed non-employees upon which our Delphi panel of experts reached consensus regarding the validity of measuring vaccination rates. In addition, similarly to credentialed non-employees, a substantial proportion of other non-employees (27%) were major barriers to reporting. It was felt that a smaller and more tightly defined denominator group would increase the feasibility of measuring vaccination among other non-employees in addition to producing more comparable results across institutions.

Third, the denominator statement was revised to include healthcare personnel working at least 30 days in the facility, rather than at least one day. The rationale for this change was substantial concern from the pilot project's Steering Committee regarding the feasibility for healthcare institutions of determining the vaccination status of healthcare personnel present at the facility for only one day. Our Delphi panel of experts reached greater consensus on the validity of denominator data reported on credentialed non-employees and other non-employees working for 30 or more days than reporting for those working 7 or more days, or 1 or more days. (Agreement on validity of employees did not vary by time period, likely because nearly all employees would be working at the institution for 30 or more days).

Finally, an additional category was added to the numerator statement to capture "unknown" vaccination status. The rationale for this change was, given the difficulties in tracking non-employee personnel reported by participating healthcare institutions, the number of personnel with unknown status would be more likely to be valid if reported by the healthcare institution rather than calculated by determining the difference between the sum of the reported numerator categories and the sum of the reported denominator categories. In addition, highlighting personnel with unknown vaccination status as a separate numerator category will provide facilities with actionable data and allow them to assess improvements in ability to track HCP influenza vaccination from year to year.

With these modifications, the proposed measure provides a comprehensive view of influenza vaccination rates among HCP that can feasibly be measured by a variety of types of healthcare institutions of different sizes. Such a measure will produce valid and reliable results and can provide the basis for expansion of measurement to vaccination rates in other HCP groups in the future.

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  |
| If the Committee votes No, STOP.<br>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: 0432 : Influenza 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 <u>NQF-endorsed measure(s)</u>: Are the measure specifications completely harmonized? No

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

An additional category was added to the numerator statement to explicitly capture "unknown" vaccination status. See Section 4d.1 for rationale.

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*): Not applicable.

# CONTACT INFORMATION

Co.1 Measure Steward (Intellectual Property Owner): Centers for Disease Control and Prevention, 1600 Clifton Road NE, Mail Stop A-19, Atlanta, Georgia, 30333

Co.2 Point of Contact: Faruque, Ahmed, PhD, fahmed@cdc.gov, 404-639-8827-

Co.3 Measure Developer if different from Measure Steward: Centers for Disease Control and Prevention, 1600 Clifton Road NE, Mail Stop A-19, Atlanta, Georgia, 30333

Co.4 Point of Contact: Faruque, Ahmed, PhD, fahmed@cdc.gov, 404-639-8827-

Co.5 Submitter: Faruque, Ahmed, PhD, fahmed@cdc.gov, 404-639-8827-, Centers for Disease Control and Prevention

Co.6 Additional organizations that sponsored/participated in measure development: See Ad.1 below.

Co.7 Public Contact: Faruque, Ahmed, PhD, fahmed@cdc.gov, 404-639-8827-, Centers for Disease Control and Prevention

# 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.

Development of the final proposed measure described above was guided by the input of staff from the jurisdictions that assisted in implementation of the pilot-testing process: the California Department of Public Health, the New Mexico Department of Health, the New York City Department of Health and Mental Hygiene, and the University of Pittsburgh Medical Center.

Prior to the measure testing process, we also established a Steering Committee to guide our pilot testing and to inform the specifications of the final proposed measure. In addition to staff from the pilot jurisdictions, the Committee consisted of the following members: Ms. Kristie Baus (Centers for Medicare and Medicaid Services); Dr. Barbara Braun (Joint Commission); Ms. Jayne Hart Chambers (Federation of American Hospitals); Dr. John Cooper (Centers for Medicare and Medicaid Services); Dr. Stanley Grogg

(American Osteopathic Association); Dr. Charles Helms (University of Iowa Hospitals and Clinics); Ms. Nancy Hughes (American Nurses Association); Dr. Jeffrey Kelman (Centers for Medicare and Medicaid Services); Ms. Nancy Kupka (Joint Commission); Ms. Linda Kusek (Joint Commission); Dr. Mark Montoney (Vanguard Health Services); Ms. Sharon Sprenger (Joint Commission); Dr. Tom Talbot (Vanderbilt University); and Dr. Litjen Tan (American Medical Association).

The Delphi panel of experts who assessed the face validity of the measure consisted of Ms. Kristie Baus (Centers for Medicare and Medicaid Services); Ms. Sharon Sprenger (Joint Commission); Dr. Tom Talbot (Vanderbilt University); Dr. Dale Bratzler (Oklahoma Foundation for Medical Quality); Ms. Kristen Ehresmann (Minnesota Department of Health); Dr. Trish Perl (Johns Hopkins School of Medicine & Bloomberg School of Hygiene); Dr. Mark Russi (Yale-New Haven Hospital); Dr. Ed Septimus (HCA Healthcare System); and Dr. Richard Zimmerman (University of Pittsburgh School of Medicine).

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: Not applicable.

Measure Developer/Steward Updates and Ongoing Maintenance

Ad.3 Year the measure was first released: 2008

Ad.4 Month and Year of most recent revision: 07, 2011

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

Ad.6 When is the next scheduled review/update for this measure? 07, 2013

Ad.7 Copyright statement: Not applicable (government entity)

Ad.8 Disclaimers: The measure specifications and supporting documentation are those of the authors and do not necessarily represent the views of the Centers for Disease Control and Prevention.

Ad.9 Additional Information/Comments: We would like to clarify the following in response to comments from the NQF Population Health Prevention Endorsement Maintenance Steering Committee members on September 13, 2011:

1) Please include outsourced and contract workers (i.e. food and custodial services) to the denominator population. The measure as currently specified does not capture these personnel.

Response: We elected not to include contract workers in the denominator of the measure because the results of our pilot testing suggested that data on these personnel would be incomplete and therefore of limited validity. For example, we found that:

• 27% of pilot facilities reported their ability to determine the vaccination status of other non-employees as a major barrier to using the measure

• 28% of pilot facilities do not currently collect data on other non-employees vaccinated at the facility, and 45% do not collect data on other non-employees vaccinated outside the facility.

• 23% of facilities felt that the denominator data they reported for other non-employees was "not at all" accurate.

• When asked about specific personnel groups, 27% of facilities reported they could not or did not track vaccination among contracted custodial workers, and 45% reported having no such workers at the facility.

In our assessment of face validity, our Delphi panel of experts did not achieve consensus on inclusion of contracted custodial workers or contracted cafeteria workers. In each case, although 5 panel members believed that inclusion of these groups could produce valid data, 3 panel members felt that including these groups would not produce valid data. We elected to include in the revised measure only those non-employee groups that produced strong consensus of face validity among our panel, as these results were corroborated by our quantitative survey data.

Finally, we found that "other non-employees" (which included contract workers as well as students, volunteers, construction workers, medical vendors, etc.) comprised only 2% of the reported workforce at all pilot facilities (ranging up to 10% of HCP in pilot hospitals). Therefore, the exclusion of this category of HCP results in a more valid measure without substantially reducing the comprehensiveness of the measure. However, if NQF feels that it is important to include these personnel in spite of the potential for producing data of lower validity, these groups could be included with the third denominator category, as follows: "Adult students/trainees, volunteers, and contracted food service and custodial workers".

2) Please explain the purpose of numerator category "d" (persons with unknown vaccination status or who do not otherwise meet any of the definitions of the above-mentioned numerator categories) under 2a1.1.

- o Is this the group that fails the measure?
- o Please explain the necessity of category d.

Response: This group would be considered to be unvaccinated when vaccination rates are computed. The purpose of numerator category "d" is twofold. First, given the reported difficulties in tracking the numerator status of non-employee healthcare personnel, we felt that asking facilities to report the number of HCP with unknown status would result in greater transparency and would serve to alert reporting facilities if the reported numerator categories do not sum to the reported denominator number. Secondly, highlighting personnel with unknown vaccination status as a separate numerator category provides facilities with actionable data to assess improvements in ability to track HCP influenza vaccination, declination, and contraindication rates from year to year.

However, if NQF feels strongly that this category is inconsistent with the harmonized NQF influenza vaccination measure, we are happy to delete it and use only numerator categories a, b, and c, as described in Section 2a.1.1.

3) The Steering Committee recommends that the data be stratified to reveal any potential disparities and equity concerns within workforce and patient populations.

Response: CDC appreciates the recommendations of the Steering Committee and will provide stratified data that may be used to monitor potential disparities or inequities in vaccination during the next endorsement maintenance cycle. Because the address and zip codes of the reporting facilities will be available, we should be able to report influenza vaccination rates of healthcare personnel in facilities located in disadvantaged areas compared to those in more affluent areas.

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