

## 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 #: 0226	NQF Project: <a href="#">Population Health: Prevention Project</a>
(for Endorsement Maintenance Review)	
Original Endorsement Date: <a href="#">Nov 15, 2007</a> Most Recent Endorsement Date: <a href="#">Nov 15, 2007</a>	
BRIEF MEASURE INFORMATION	
De.1 Measure Title: <a href="#">Influenza Immunization in the ESRD Population (Facility Level)</a>	
Co.1.1 Measure Steward: <a href="#">Kidney Care Quality Alliance</a>	
De.2 Brief Description of Measure: <a href="#">Percentage of end stage renal disease (ESRD) patients aged 6 months and older receiving hemodialysis or peritoneal dialysis during the time from October 1 (or when the influenza vaccine became available) to March 31 who either received, were offered and declined, or were determined to have a medical contraindication to the influenza vaccine.</a>	
2a1.1 Numerator Statement: <a href="#">Number of patients from the denominator who:</a>	
1. <a href="#">received an influenza vaccination* (documented by the provider or reported receipt from another provider by the patient);</a>	
OR	
2. <a href="#">were assessed and offered an influenza vaccination but declined;</a>	
OR	
3. <a href="#">were assessed and determined to have a medical contraindication(s) of anaphylactic hypersensitivity to eggs or other component(s) of the vaccine, history of Guillain-Barre Syndrome within 6 weeks after a previous influenza vaccination, and/or bone marrow transplant within the past 6 months (&lt;6 months prior to encounters between October 1 and March 31).</a>	
*Only inactivated vaccine should be used in the ESRD population.	
2a1.4 Denominator Statement: <a href="#">All ESRD patients aged 6 months and older receiving hemodialysis and/or peritoneal dialysis during the time from October 1 (or when the influenza vaccine became available) to March 31.</a>	
2a1.8 Denominator Exclusions: <a href="#">None.</a>	
1.1 Measure Type: <a href="#">Process</a>	
2a1. 25-26 Data Source: <a href="#">Administrative claims, Electronic Clinical Data : Electronic Health Record, Paper Records</a>	
2a1.33 Level of Analysis: <a href="#">Facility</a>	
1.2-1.4 Is this measure paired with another measure? <a href="#">No</a>	
De.3 If included in a composite, please identify the composite measure (title and NQF number if endorsed): <a href="#">Not in a composite or paired.</a>	

STAFF NOTES <i>(issues or questions regarding any criteria)</i>
Comments on Conditions for Consideration:
Is the measure untested? Yes <input type="checkbox"/> No <input type="checkbox"/> 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, Renal

De.5 Cross Cutting Areas (Check all the areas that apply): Access, Care Coordination, Disparities, Patient and Family Engagement, Safety : Complications, Safety : Medication Safety

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):

In 2008, the adjusted incident rate of end-stage renal disease (ESRD) cases in the United States was 350.8 per million population, and the adjusted rate of prevalent cases rose 1.9 percent to 1,699 per million population. This rate is nearly 20 percent greater than that seen in 2000, and the annual rate of increase has remained between 1.9 and 2.3 percent since 2003. Total Medicare costs rose nearly 11 percent in 2008—up from a 7 percent rise the previous year—to \$454 billion. ESRD costs rose 13.2 percent to \$26.8 billion, and accounted for 5.9 percent of the Medicare budget.(1)

Infectious disease is the second leading cause of death among ESRD patients, and pulmonary infectious mortality is ten-fold higher in the ESRD population than in the general population.(2,3) Especially among the aged (4) and those with increased comorbidity,(5) influenza vaccination decreases the likelihood of hospitalization and mortality and reduces healthcare costs.(5–8) A goal of the "Healthy People 2010" was to immunize 90% of the elderly and other high-risk individuals against influenza.(9,10) Yet despite this and well-established recommendations for annual vaccination in patients with ESRD,(11) less than 63 percent of all ESRD patients received the influenza vaccination in 2008.(1) (NOTE: The goal for influenza immunization of the elderly and other high-risk individuals for "Healthy People 2020" is unchanged from the 2010 goal at 90%.[12])

These findings strongly support existing clinical practice guidelines and the underlying construct of the KCQA influenza immunization measure—i.e., to reduce the frequency of infectious complications and improve patient survival, all ESRD patients should be immunized annually against influenza, absent a documented medical contraindication. In particular, we note that the original KCQA measure specifications were modified in response to the harmonization recommendations of the NQF Influenza and Pneumococcal Immunizations Steering Committee. We maintain, however, that a separate measure addressing influenza immunization status specifically in ESRD patients is necessary, given the substantially poorer outcomes observed with infection in this vulnerable population and the need for the specifications to reflect that only inactivated virus should be used in this population.

1a.4 Citations for Evidence of High Impact cited in 1a.3: 1. U.S. Renal Dialysis System, USRDS 2010 Annual Data Report: Atlas of Chronic Kidney Disease and End-Stage Renal Disease in the United States. 2010.

2. Gilbertson D, Unruh M, McBean A, Kausz A, Snyder J, Collins A. Influenza vaccine delivery and effectiveness in end-stage renal disease. *Kidney Int.* 2003;63(2):738-43.

3. Sarnak M and Jaber B. Pulmonary infectious mortality among patients with end-stage renal disease. *Chest*. 2001;120:1883–1887.
4. Gross P, Hermogenes A, Sacks H, et al. The efficacy of influenza vaccine in elderly persons. A meta-analysis and review of the literature. *Ann Intern Med*. 1995;123:518–27.
5. Nichol K, Baken L, Nelson A. Relation between influenza vaccination and outpatient visits, hospitalization, and mortality in elderly persons with chronic lung disease. *Ann Intern Med*. 1999;130:397–403.
6. Nichol K, Margolis K, Wuorenma J, et al. The efficacy and cost effectiveness of vaccination against influenza among elderly persons living in the community. *NEJM*. 1994;331:778–84.
7. Nichol K, Wuorenma J, Von Sternberg T. Benefits of influenza vaccination for low-, intermediate-, and high-risk senior citizens. *Arch Intern Med*. 1998;158:1769–76.
8. Foster D, Talsma A, Furumoto-Dawson A, et al. Influenza vaccine effectiveness in preventing hospitalization for pneumonia in the elderly. *Am J Epidemiol*. 1992;136:296–307.
9. U.S. Department of Health and Human Services: Healthy People 2010 (2nd ed). Washington, DC, U.S. Government Printing Office, 2000.
10. Influenza and pneumococcal vaccination levels among persons aged >65 years—United States, 1999. *MMWR Morb Mortal Wkly Rep*. 2001;50:532–7.
11. Prevention and control of influenza: Recommendations of the Advisory Committee on Immunization Practices (ACIP). Centers for Disease Control and Prevention. *MMWR Recomm Rep*. 1998;47:1–26.

**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:**

The measure will promote adherence to existing clinical practice guidelines on influenza immunization in the ESRD population and will consequently reduce patient complication, hospitalization, and mortality rates.

**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.]**

KCOA tested its ESRD measures through a prospective cohort study on a nationally drawn sample of 53 dialysis facilities containing a mix of for-profit and not-for-profit providers; hospital-affiliated and freestanding facilities within large, small, and independent dialysis organizations; urban, suburban, and rural settings; and facilities both with and without electronic health records (EHRs). Approximately 25 patients per facility were sought, resulting in a final sample size of 1,115 patients. Both facility and patient samples were structured to be generally representative of the national industry profile as identified by the United States Renal Data Systems (USRDS) 2007 Annual Data Report. Because of the measure's intended use via CROWNWeb, facility records were used as the data source, and standardized, paper-based data collection sheets constructed from the endorsed specifications were employed during data collection.

(NOTE: At the time NQF made its standardized influenza immunization specifications available for comment in May 2008, KCOA voiced its general agreement with the recommended modifications. However, recognizing that the American Society of Pediatric Nephrology had not yet reached a conclusion regarding immunization in individuals aged 6 months through 17 years, KCOA expressed reservations about immediately including these patients in the pilot study. For this reason, as well as the significant constraints on research involving children, we did not test the measure in the pediatric population. We believe, however, that the lack of testing in this population is not a barrier to measure implementation because Date of Birth is not a data element requiring collection per se and is also a standard field within CROWNWeb.)

Influenza immunization data were provided for 1,104 of the 1,115 patients (99%) included in the study sample. The immunization

status of the study population at the conclusion of the study was as follows:

- Patients vaccinated = 958
- Patients who were assessed but declined the vaccine = 120
- Patients who were assessed and determined to have a medical contraindication to the vaccine = 5
- Unvaccinated patients for whom no explanatory information was provided = 21 (Note: These patients were counted as unimmunized when calculating measure performance scores.)
- Patients with no vaccination information provided = 11 (Note: These patients were counted as unimmunized when calculating measure performance scores.)

Performance Rate =  

$$([ \text{Patients vaccinated} ] + [ \text{Patients who declined vaccine} ] + [ \text{Patients with medical contraindication} ]) / ( \text{Total ESRD patients} ) = ( 958 + 120 + 5 ) / 1,115 = 97.1\%$$

Despite the high overall performance rate, the performance for each individual facility in the pilot ranged from 78% to 100%.

Conclusions: Findings from the KCQA pilot test indicate that contrary to current clinical practice guidelines and recommendations, there is considerable performance variation in influenza immunization practices among dialysis facilities. The results identify an important and actionable gap in performance.

Citations for Data on Performance Gap:

Kidney Care Quality Alliance. KCQA Performance Measures Pilot Testing Results: Report to the National Quality Forum. February 2010.

**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]

KCQA tested its ESRD measures through a prospective cohort study on a nationally drawn sample of 53 dialysis facilities containing a mix of for-profit and not-for-profit providers; hospital-affiliated and freestanding facilities within large, small, and independent dialysis organizations; urban, suburban, and rural settings; and facilities both with and without electronic health records (EHRs). Approximately 25 patients per facility were sought, resulting in a final sample size of 1,115 patients. Both facility and patient samples were structured to be generally representative of the national industry profile as identified by the United States Renal Data Systems (USRDS) 2007 Annual Data Report.

**1b.4 Summary of Data on Disparities by Population Group:** [*For Maintenance* – Descriptive statistics for performance results for this measure by population group]

KCQA tested its ESRD measures through a prospective cohort study on a nationally drawn sample of 53 dialysis facilities. Approximately 25 patients per facility were sought, resulting in a final sample size of 1,115 patients. Both facility and patient samples were structured to be generally representative of the national industry profile as identified by the USRDS 2007 Annual Data Report. As minimal patient data were sought to protect confidentiality and the collection of race/ethnicity information was not necessary to test the measure's data elements for reliability and validity, an examination of the data for disparities trends was not conducted. However, the most recent USRDS data indicate that while rates of reported influenza vaccinations in ESRD patients continue to improve, reaching 62.4 percent overall in 2008, they remain significantly lower in children (31.5 percent) than in adults. Observed vaccination rates in adults was 51.5, 60.4, 66.6, and 70.9 percent, respectively, for ESRD patients aged 20-44, 45-64, 65-74, and 75 and older. In 2008, rates in white, Native American, Asian, and Hispanic patients ranged between 61.0-64.5 percent, while the rate for African Americans was slightly lower, at 58.9 percent. By modality, influenza vaccination rates are highest in hemodialysis patients, at 67 percent, compared to 61.8 and 46.1 percent in peritoneal dialysis and transplant patients.(1)

Citations for Data on Disparities:

U.S. Renal Dialysis System, USRDS 2010 Annual Data Report: Atlas of Chronic Kidney Disease and End-Stage Renal Disease in the United States. 2010.

**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*]

KCOA tested its ESRD measures through a prospective cohort study on a nationally drawn sample of 53 dialysis facilities containing a mix of for-profit and not-for-profit providers; hospital-affiliated and freestanding facilities within large, small, and independent dialysis organizations; urban, suburban, and rural settings; and facilities both with and without electronic health records (EHRs). Approximately 25 patients per facility were sought, resulting in a final sample size of 1,115 patients. Both facility and patient samples were structured to be generally representative of the national industry profile as identified by the United States Renal Data Systems (USRDS) 2007 Annual Data Report.

**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 <input type="checkbox"/>
L	M-H	M	Yes <input type="checkbox"/> IF additional research unlikely to change conclusion that benefits to patients outweigh harms: otherwise No <input type="checkbox"/>
M-H	L	M-H	Yes <input type="checkbox"/> IF potential benefits to patients clearly outweigh potential harms: otherwise No <input type="checkbox"/>
L-M-H	L-M-H	L	No <input type="checkbox"/>

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*):

**ANTECEDENTS:**

Influenza immunization has been shown to decrease the likelihood of hospitalization, morbidity, and mortality among ESRD patients >> **PROCESS:** Assessment of the proportion of a provider's ESRD patient population that has been immunized against influenza >> Identification of patients who have not been immunized >> Immunization of all previously unimmunized ESRD patients absent a medical contraindication >> **OUTCOME:** Increased overall influenza immunization rates in the ESRD population >> Reduced complications, hospitalizations, and overall morbidity and mortality in ESRD patients.

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

Clinical Practice Guideline, Systematic review of body of evidence (other than within guideline development)

**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*):

Central Topic: Promotion of routine annual influenza immunization in ESRD patients.

Population: ESRD patients aged 6 months and older in the United States.

Outcomes Addressed: Reduced morbidity and mortality in the ESRD population secondary to increased influenza immunization rates, as consistent with current clinical practice guidelines and recommendations.

Differences Between Measure Focus and Measure Target Population: None.

As noted in the most recent guidelines released by the Center for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP) and the American Academy of Pediatrics, routine annual influenza vaccination is recommended for

all persons aged 6 months and older, and is particularly important for individuals at increased risk for severe complications from influenza—including patients with ESRD. The body of evidence upon which these guidelines and this measure are based indicate that infectious disease is the second leading cause of death among ESRD patients and that pulmonary infectious mortality is tenfold higher in the ESRD population than in the general population.(1-5) Especially among the young,(4,5) the aged,(6-10) and those with increased comorbidity,(7-10) influenza vaccination has been demonstrated to be a safe and efficacious means of decreasing the likelihood of hospitalization and mortality and reduces healthcare costs.(7–14) A goal of the “Healthy People 2010” program was to immunize 90% of the elderly and other high-risk individuals against influenza.(15,16) Yet despite this and well-established recommendations for annual vaccination in patients with ESRD,(17) less than 63 percent of all ESRD patients received the influenza vaccination in 2008.(18) (NOTE: The goal for influenza immunization of the elderly and other high-risk individuals for “Healthy People 2020” is unchanged from the 2010 goal at 90%.[19])

These findings strongly support existing clinical practice guidelines and the underlying construct of the KCQA influenza immunization measure—i.e., to reduce the frequency of infectious complications and improve patient survival, all ESRD patients should be immunized annually against influenza, absent a documented medical contraindication.

**1c.5 Quantity of Studies in the Body of Evidence** (*Total number of studies, not articles*): The body of evidence presented in Section 1c.6 cites fourteen peer-reviewed clinical studies.

**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*): As noted in the most recent guidelines released by the Center for Disease Control and Prevention’s (CDC) Advisory Committee on Immunization Practices (ACIP) and American Academy of Pediatrics, routine annual influenza vaccination is recommended for all persons aged 6 months and older, and is particularly important for individuals at increased risk for severe complications from influenza—including patients with ESRD. The body of evidence upon which these guidelines and this measure are based indicate that infectious disease is the second leading cause of death among ESRD patients and that pulmonary infectious mortality is tenfold higher in the ESRD population than in the general population.(1-5) Especially among the young,(4,5) the aged,(6-10) and those with increased comorbidity,(7-10) influenza vaccination has been demonstrated to be a safe and efficacious means of decreasing the likelihood of hospitalization and mortality and reduces healthcare costs.(7–14) A goal of the “Healthy People 2010” program was to immunize 90% of the elderly and other high-risk individuals against influenza.(15,16) Yet despite this and well-established recommendations for annual vaccination in patients with ESRD,(17) less than 63 percent of all ESRD patients received the influenza vaccination in 2008.(18)

These findings strongly support existing clinical practice guidelines and the underlying construct of the KCQA influenza immunization measure—i.e., to reduce the frequency of infectious complications and improve patient survival, all ESRD patients should be immunized annually against influenza, absent a documented medical contraindication.

**1c.7 Consistency of Results across Studies** (*Summarize the consistency of the magnitude and direction of the effect*): The studies cited in Section 1c.6. consistently demonstrate that influenza immunization in the ESRD population decrease the likelihood of hospitalization and mortality and reduces healthcare costs.

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

Research has clearly and consistently illustrated the net benefit of routine influenza immunization of the ESRD population. The studies cited in Section 1c.6. demonstrate that influenza immunization safely and efficaciously decreases morbidity and mortality in ESRD patients and reduces healthcare costs.

**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:**

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

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

1c.13 Grade Assigned to the Body of Evidence: Not applicable. In its February 2011 meeting of the Strategic Advisory Group of Experts (SAGE) Workgroup on Influenza Vaccines and Immunization, the World Health Organization notes that the application of grading systems is not appropriate for statements about the burden of disease due to influenza. It additionally notes that existing grading systems are not always appropriate for evaluating the strength of evidence for immunization recommendations, which need to take into account factors such as herd immunity that can only be assessed in observational post-licensure studies. (1)

1c.14 Summary of Controversy/Contradictory Evidence: There are no randomized clinical trials (RCTs) comparing outcomes for immunized and unimmunized ESRD patients, as a treatment/placebo RCT in that regard would be unethical given the known risks of failure to immunize. Despite this, we have provided evidence demonstrating that influenza immunization safely and efficaciously decreases morbidity and mortality in ESRD patients and reduces healthcare costs.

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

1. Gilbertson D, Unruh M, McBean A, Kausz A, Snyder J, Collins A. Influenza vaccine delivery and effectiveness in end-stage renal disease. *Kidney Int.* 2003;63(2):738-43.
2. Sarnak M and Jaber B. Pulmonary infectious mortality among patients with end-stage renal disease. *Chest.* 2001;120:1883–1887.
3. Thompson W, Shay D, Weintraub E, et al. Influenza-associated hospitalizations in the United States. *JAMA.* 2004;292:1333–40.
4. Poehling K, Edwards K, Weinberg G, et al. The underrecognized burden of influenza in young children. *NEJM.* 2006;355:31–40.
5. Izurieta H, Thompson W, Kramarz P, et al. Influenza and the rates of hospitalization for respiratory disease among infants and young children. *NEJM.* 2000;342:232–9.
6. Gross P, Hermogenes A, Sacks H, et al. The efficacy of influenza vaccine in elderly persons. A meta-analysis and review of the literature. *Ann Intern Med.* 1995;123:518–27.
7. Nichol K, Baken L, Nelson A. Relation between influenza vaccination and outpatient visits, hospitalization, and mortality in elderly persons with chronic lung disease. *Ann Intern Med.* 1999;130:397–403.
8. Nichol K, Margolis K, Wuorenma J, et al. The efficacy and cost effectiveness of vaccination against influenza among elderly persons living in the community. *NEJM.* 1994;331:778–84.
9. Nichol K, Wuorenma J, Von Sternberg T. Benefits of influenza vaccination for low-, intermediate-, and high-risk senior citizens. *Arch Intern Med.* 1998;158:1769–76.
10. Foster D, Talsma A, Furumoto-Dawson A, et al. Influenza vaccine effectiveness in preventing hospitalization for pneumonia in the elderly. *Am J Epidemiol.* 1992;136:296–307.
11. Arguedas A, Soley C, Lindert K. Responses to 2009 H1N1 vaccine in children 3 to 17 years of age. *NEJM.* 2010;362:370–2.
12. Plennevaux E, Sheldon E, Blatter M, et al. Immune response after a single vaccination against 2009 influenza A H1N1 in USA: a preliminary report of two randomized controlled phase 2 trials. *Lancet.* 2009;375:41–8.
13. Scharpe J, Evenepoel P, Maes B, et al. Influenza vaccination is efficacious and safe in renal transplant recipients. *Am J Transplant.* 2008;8:332–7.
14. Edvardsson V, Flynn J, Deforest A, et al. Effective immunization against influenza in pediatric renal transplant recipients. *Clin Transplant.* 1996;10:556–60.

15. U.S. Department of Health and Human Services: Healthy People 2010 (2nd ed). Washington, DC, U.S. Government Printing Office, 2000.

16. Influenza and pneumococcal vaccination levels among persons aged >65 years—United States, 1999. MMWR Morb Mortal Wkly Rep. 2001;50:532–7.

17. Prevention and control of influenza: Recommendations of the Advisory Committee on Immunization Practices (ACIP). Centers for Disease Control and Prevention. MMWR Recomm Rep. 1998;47:1–26.

18. U.S. Renal Dialysis System, USRDS 2010 Annual Data Report: Atlas of Chronic Kidney Disease and End-Stage Renal Disease in the United States. 2010.

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

The following clinical recommendation statements are quoted from the referenced clinical guidelines and represent the evidence base for the measure.

The Advisory Committee on Immunization Practices (ACIP), 2010:

- Routine influenza vaccination is recommended for all persons aged ≥6 months. This represents an expansion of the previous recommendations for annual vaccination of all adults aged 19-49 years and is supported by evidence that annual influenza vaccination is a safe and effective preventive health action with potential benefit in all age groups.
- Vaccination to prevent influenza is particularly important for persons who are at increased risk for severe complications from influenza or at higher risk for influenza-related outpatient, emergency department (ED), or hospital visits. When vaccine supply is limited, vaccination efforts should focus on delivering vaccination to specific high-risk populations, including all children aged 6 months–4 years (59 months); all persons aged ≥50 years; and adults and children who have chronic pulmonary or cardiovascular, renal, hepatic, neurological, hematologic, or metabolic disorders.

The American Academy of Pediatrics (AAP), 2008-2009:

Annual influenza immunization is recommended for all children, both healthy and with conditions that increase the risk of complications from influenza, 6 months of age and older.

**1c.17 Clinical Practice Guideline Citation:** 1. Prevention and control of influenza with vaccines: Recommendations of the Advisory Committee on Immunization Practices (ACIP). Centers for Disease Control and Prevention. MMWR Recomm Rep. 2010;59(rr08):1–62.

2. American Academy of Pediatrics Committee on Infectious Diseases. Policy statement: recommendations for prevention and control of influenza in children, 2010-2011. Pediatrics. 2010;126(4):816-26.

**1c.18 National Guideline Clearinghouse or other URL:** ACIP =

<http://www.guideline.gov/content.aspx?id=23882&search=influenza+immunization>. American Academy of Pediatrics = <http://www.guideline.gov/content.aspx?id=24598#Section420>

**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:** Neither ACIP nor the American Academy of Pediatrics graded their influenza immunization recommendations. In its February 2011 meeting of the Strategic Advisory Group of Experts (SAGE) Workgroup on Influenza Vaccines and Immunization, the World Health Organization notes that the application of grading systems is not appropriate for statements about the burden of disease due to influenza. It additionally notes that existing grading systems are not always appropriate for evaluating the strength of evidence for immunization recommendations, which need

to take into account factors such as herd immunity that can only be assessed in observational post-licensure studies.

Citation:

World Health Organization. Minutes from the 2nd Meeting of the SATE Working Group on Influenza Vaccines and Immunization. February 14-15, 2011. Available at: <http://www.who.int/immunization/sage/en/>.

1c.22 If other, identify and describe the grading scale with definitions:

1c.23 Grade Assigned to the Recommendation: Not applicable. Neither ACIP nor the American Academy of Pediatrics graded their influenza immunization recommendations. (See 1c.13.)

1c.24 Rationale for Using this Guideline Over Others: The CDC's ACIP and the American Academy of Pediatrics guidelines present the most up-to-date summaries of available knowledge in the field of influenza immunization and prevention.

Based on the NQF descriptions for rating the evidence, what was the developer's assessment of the quantity, quality, and consistency of the body of evidence?

1c.25 Quantity: High 1c.26 Quality: Moderate 1c.27 Consistency: High

Was the threshold criterion, *Importance to Measure and Report*, met?

(1a & 1b must be rated moderate or high and 1c yes) Yes  No

Provide rationale based on specific subcriteria:

For a new measure if the Committee votes NO, then STOP.

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

## 2. RELIABILITY & VALIDITY - SCIENTIFIC ACCEPTABILITY OF MEASURE PROPERTIES

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

Measure testing must demonstrate adequate reliability and validity in order to be recommended for endorsement. Testing may be conducted for data elements and/or the computed measure score. Testing information and results should be entered in the appropriate field. Supplemental materials may be referenced or attached in item 2.1. See [guidance on measure testing](#).

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

S.2 If yes, provide web page URL: <http://www.kidneycarepartners.com>

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 patients from the denominator who:

1. received an influenza vaccination\* (documented by the provider or reported receipt from another provider by the patient);

OR

2. were assessed and offered an influenza vaccination but declined;

OR

3. were assessed and determined to have a medical contraindication(s) of anaphylactic hypersensitivity to eggs or other component(s) of the vaccine, history of Guillain-Barre Syndrome within 6 weeks after a previous influenza vaccination, and/or bone marrow transplant within the past 6 months (<6 months prior to encounters between October 1 and March 31).

\*Only inactivated vaccine should be used in the ESRD population.

**2a1.2 Numerator Time Window** (*The time period in which the target process, condition, event, or outcome is eligible for inclusion*): October 1 (or when the influenza vaccine became available) to March 31 of the reporting 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*): The necessary data elements are to be collected via the Centers for Medicare and Medicaid (CMS) CROWNWeb data repository when functional, as indicated by the measure's inclusion in CMS's list of Phase III ESRD Clinical Performance Measures in effect April 1, 2008.

Include in the numerator all patients from the denominator who:

1. Received an influenza vaccination\* (documented by the provider or reported receipt from another provider by the patient). CPT codes:

- 90655 (Influenza virus vaccine, split virus, preservative free, when administered to 6–35 months)
- 90656 (Influenza virus vaccine, split virus, preservative free, when administered to 3 years and older, for intramuscular use)
- 90657 (Influenza virus vaccine, split virus, when administered to 6–35 months)
- 90658 (Influenza virus vaccine, split virus, when administered to 3 years of age and older, for intramuscular use)

2. Were assessed and offered an influenza vaccination but declined. CPT II code 1030F (assessment of influenza immunization status).

3. Were assessed and were determined to have a medical contraindication(s) of anaphylactic hypersensitivity to eggs or other component(s) of the vaccine, history of Guillain-Barre Syndrome within 6 weeks after a previous influenza vaccination, and/or bone marrow transplant within the past 6 months (<6 months prior to encounters between October 1 and March 31). CPT II codes:

- 1030F (assessment of influenza immunization status)
- 4037F-1P, 4274F-1P, 4037F-2P, 4274F-2P (Influenza vaccine not received [appendage modifiers to CPT Category II codes])

\*Only inactivated vaccine should be used in the ESRD population.

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

All ESRD patients aged 6 months and older receiving hemodialysis and/or peritoneal dialysis during the time from October 1 (or when the influenza vaccine became available) to March 31.

**2a1.5 Target Population Category** (*Check all the populations for which the measure is specified and tested if any*): Adult/Elderly Care, Children's Health, Special Healthcare Needs

**2a1.6 Denominator Time Window** (*The time period in which cases are eligible for inclusion*):

October 1 (or when the influenza vaccine became available) to March 31 of the reporting 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*):

The necessary data elements are to be collected via the CMS CROWNWeb data repository when functional, as indicated by the measure's inclusion in CMS's list of Phase III ESRD Clinical Performance Measures in effect April 1, 2008.

Include in the denominator all patients within a facility who meet the following criteria during the time from October 1 (or when the influenza vaccine became available) to March 31 of the reporting year:

1. Diagnosis = ESRD (ICD-9 code 585.6; ICD-10 N18.0)

AND

2. Primary type of dialysis = hemodialysis, home hemodialysis, continuous ambulatory peritoneal dialysis (CAPD), continuous cycling peritoneal dialysis (CCPD), or nighttime intermittent peritoneal dialysis (NIPD). (CPT codes 90935, 90937, 90945, 90947, 90951-90970)

AND

3. Age = >6 months

**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):  
Not applicable.

**2a1.11 Risk Adjustment Type** (Select type. Provide specifications for risk stratification in 2a1.10 and for statistical model in 2a1.13): Other 2a1.12 If "Other," please describe: Not Applicable

**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.):

**DENOMINATOR**

Include in the denominator all patients within a facility who meet the following criteria during the time from October 1 (or when the influenza vaccine became available) to March 31 of the reporting year:

1. Diagnosis = ESRD

AND

2. Primary type of dialysis = hemodialysis, home hemodialysis, continuous ambulatory peritoneal dialysis (CAPD), continuous

cycling peritoneal dialysis (CCPD), or nighttime intermittent peritoneal dialysis (NIPD)

AND

3. Age = >6 months or older as of the first day of the most recent month of the reporting period. (Patient's age is or shall be determined by subtracting the patient's date of birth from the first day of the most recent month of the reporting period.)

NUMERATOR

Include in the numerator all patients from the denominator who meet the following criteria:

1. Patient received an influenza vaccination\* (documented by the provider or reported receipt from another provider by the patient);

OR

2. Patient was assessed and offered an influenza vaccination but declined;

OR

3. Patient was assessed and was determined to have a medical contraindication(s) of anaphylactic hypersensitivity to eggs or other component(s) of the vaccine, history of Guillain-Barre Syndrome within 6 weeks after a previous influenza vaccination, and/or bone marrow transplant within the past 6 months (<6 months prior to encounters between October 1 and March 31).

\*Only inactivated vaccine should be used in the ESRD population.

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

Attachment

[txKCOACalcAlgorithmFluFINAL.pdf](#)

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:

Administrative claims, Electronic Clinical Data : Electronic Health Record, Paper Records

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.): All data elements for the measure can be collected using the KCQA Influenza Immunization Data Collection Form (attached), which reflects the data elements to be included in CROWNWeb.

2a1.27-29 **Data Source/data Collection Instrument Reference Web Page URL or Attachment:** Attachment

[fmKCOADataFormFluFINAL.pdf](#)

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

Attachment

[txKCOADataDictionaryFluFINAL.pdf](#)

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): Dialysis 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):

KCOA tested its ESRD measures through a one-year prospective cohort study on a nationally drawn sample of 53 dialysis facilities containing a mix of for-profit and not-for-profit providers; hospital-affiliated and freestanding facilities within large, small, and independent dialysis organizations; urban, suburban, and rural settings; and facilities both with and without electronic health records (EHRs). Approximately 25 patients per facility were sought, resulting in a final sample size of 1,115 patients. All patients were included in the influenza immunization measure's denominator population. Both facility and patient samples were structured to be generally representative of the national industry profile as identified by the UUSRDS 2007 Annual Data Report. Given CMS's intent to include the measure in its Phase III Clinical Performance Measures, which involve CROWNWeb electronic transmission of data from facility medical records, facility records were used as the data source for the pilot. Because CROWNWeb was not operational at the time, standardized, paper-based data collection sheets were constructed from the endorsed specifications and were employed during data collection for the testing.

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

Following the data collection period, on-site data-integrity audits were performed at 11 of the 53 facilities (21%). Audit sites were selected to provide a cross-section of facilities reflective of the sample profile. Selection criteria included geographic location, facility type (e.g., for-profit vs. not-for-profit, urban vs. rural), and EHR use. Pertinent data were reabstracted from the patients' medical records and were compared to the information submitted by the facility throughout the pilot to assess the measure's reliability.

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

Inter-rater reliability was assessed during the on-site audits through a direct comparison of data submitted by the facilities throughout the pilot to data reabstracted by the auditor(s). (See Table 1 [Measure Performance, Submitted vs. Reabstracted Data] in the accompanying Attachment A.) Reliability was quantitatively summarized using Cohen's Kappa with confidence intervals. The resulting Kappa statistic for the Influenza Immunization in the ESRD Population measure was found to be 0.6568 with a 95% confidence interval of 0.5210-0.7926. (See Table 2 [Measure Aggregate Reliability] in Attachment A.) Based on the literature, this value indicates "substantial agreement" and excellent reproducibility for the measure. In addition to the Kappa value, the percent agreement between the auditor and facility abstractors (i.e., the reliability percentage) was calculated and was found to be excellent at 98.1%. (See Table 3 [Measure Reliability Percentage and Error Type] in Attachment A.) These two values demonstrate that the KCOA measure is reliable.

**2b. VALIDITY. Validity, Testing, including all Threats to Validity:** 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:**

Section 1c; no differences were identified. In both the body of evidence and the measure specifications, the target population is adult and pediatric ESRD patients, the central topic is the promotion of influenza immunization in ESRD patients to reduce morbidity and mortality and improve patient outcomes.

**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):

KCOA tested its ESRD measures through a one-year prospective cohort study on a nationally drawn sample of 53 dialysis facilities. Approximately 25 patients per facility were sought, resulting in a final sample size of 1,115 patients. Both facility and patient samples were structured to be generally representative of the national industry profile as identified in the USRDS 2007 Annual Data Report.

**2b2.2 Analytic Method** (Describe method of validity testing and rationale; if face validity, describe systematic assessment):

Validity refers to the degree to which a performance measure truly measures what it was intended to measure (i.e., construct validity) and the degree to which the conclusions drawn from a test would hold for other persons, places, and times (external validity).

Construct Validity:

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A test is said to have construct validity when it measures a construct (or theory) accurately. For the KCQA performance measure, the construct being tested is that the measure will accurately assess and depict a dialysis facility's influenza immunization practices. In claiming construct validity, we would thus be asserting that our pilot test confirmed that the KCQA measure does in fact effectively portray a facility's influenza immunization practices. Specifically, KCQA asserts the measures meet the following types of construct validity: face validity and content validity.

- A measure is said to have face validity when it appears to be valid—i.e., on its “face” it seems like a good translation of the construct being tested. Face validity uses common-sense rules—for example, to assess a facility's vaccination practices, a measure should quantify its vaccination rate. While face validity is the weakest means of demonstrating construct validity, its strength can be improved by making the process more systematic—for instance, by utilizing a panel of experts to confirm that the measure appears to be a proper translation of the construct.

- Content validity centers on a measure's ability to include or represent all of the content of the construct in question. Content under-representation occurs when important areas are missed, and construct-irrelevant variation occurs when irrelevant factors contaminate the measure. Determination of content validity requires agreement among experts in the field in question. Thus, while face validity can be established by one person, content validity must be determined by a panel.

The KCQA measure has both face and content validity based on the following: The measure was deemed appropriate and valid by (1) expert opinion within Kidney Care Partners (KCP) and KCQA; (2) expert opinion within the NOF ESRD TAPs, Steering Committee, and the CSAC, all of which advanced the measure to the next stage of the CDP; and (3) broad agreement as demonstrated through the NOF review and voting processes.

### External Validity:

A test is said to have external validity when results can be reliably generalized to the larger relevant population. External validity can be improved by employing appropriate methods to draw the sampling model from a population. KCQA posits that external validity has been met through the diligence with which the original sampling schema was crafted to reflect the national industry and patient vintage and access profiles. Because the sample is representative of the U.S. dialysis population, results can be generalized with confidence.

**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*):

### EXTERNAL VALIDITY

External validity of the KCQA influenza immunization measure was established through the meticulous construction of patient and facility samples, modeled to reflect the national industry and patient vintage and access profiles as per the 2007 USRDS Annual Data Report of Chronic Kidney Disease & End-Stage Renal Disease, the most current volume available at the time the sample was constructed. Because the sample is representative of the U.S. dialysis population, results can be generalized with confidence.

### Facility Sampling:

In the United States, dialysis services are provided at more than 4,800 sites (freestanding non-profit and for-profit centers, hospital-based, and government-affiliated entities—i.e., Department of Veterans Affairs or state/county/city-run). Based on the industry profile in the 2007 U.S. Renal Data System (USRDS), a recruitment list of 71 facilities that mirrored this profile was identified so as to reach a target of 60 facilities, from which we assumed additional attrition might occur during the one-year course of data collection. Department of Veterans Affairs (VA)-affiliated and other public facilities were excluded to streamline the facility recruitment process. (VA and other public facilities represent less than two percent of dialysis sites, and less than one percent of the patient population.) Based on the USRDS data, the following target facility distribution was constructed:

- 60% from for-profit large dialysis organizations (LDO),
- 15% from non-profit LDOs,
- 20% from for-profit non-LDOs, and
- 5% from non-profit non-LDOs.

Ultimately, 53 facilities participated in the pilot. The final facility sample contained a mix of both for-profit and not-for-profit providers; hospital-affiliated and freestanding facilities within large, small, and independent dialysis organizations; urban, suburban, and rural settings; and facilities both with and without electronic medical records, and was generally representative of the national industry profile. The facility distribution in the final sample was:

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- 59% from for-profit LDOs,
- 8% from non-profit LDOs,
- 21% from for-profit non-LDOs, and
- 13% from non-profit non-LDOs.

Additionally, KCP members represent approximately 85% of the community; the final sample contained facilities involved with KCP members (47 facilities; 89%) and those not (6 facilities; 11%).

### Patient Sampling:

Twenty-five patients per facility were sought, and three primary patient-related variables were identified: dialysis type (hemodialysis, peritoneal dialysis, or home hemodialysis), vintage on dialysis, and vascular access type. Per the 2007 USDRS report, approximately 94.5 percent of patients are on in-center hemodialysis, 5 percent on peritoneal dialysis, and 0.5 percent on home hemodialysis. The sample at the outset of the study was 92.6 percent in-center hemodialysis, 4.8 percent peritoneal dialysis, and 2.7 percent home hemodialysis. At the study's conclusion, the profile was 92.1 percent in-center hemodialysis 5.2 percent peritoneal dialysis, and 2.7 percent home hemodialysis. (The slight overrepresentation of home hemodialysis patients resulted from the participation of a facility caring exclusively for home-based patients. We also note that the 2007 USRDS atlas reports on data as of the end of 2005. In fact, the home hemodialysis population has been growing, and is currently estimated by kidney care community members to be 1 to 2%. Thus, the actual sample more accurately reflects the current situation. Regardless, nothing in the current literature indicated this small sampling difference from the national norm would have any impact on the pilot test results, and so the pilot proceeded with the original sample rather than exclude the facility with only home hemodialysis and/or attempt to replace it.)

With respect to vintage, patients were characterized as less than 90 days, 90 days to one year, and less than one year as appropriately reflecting the relevant populations to follow the performance specified by the vascular access measures. Again, the original sample was constructed to mirror the national distribution. Based on USRDS data, this equated to 6, 11, and 8 patients per facility, respectively as of September 1, 2008.

The initial patient sample size equated to 1,325 adult patients (25 patients/53 facilities), but was reduced to 1,295 because some facilities did not have enough patients of a given type. This number was reduced to 1,115 by the study's conclusion due to patient death, transplantation, or patient transfer out of the participating facility.

### FACE VALIDITY

The KCQA influenza immunization measure has face validity based on the following: The measure was deemed appropriate and valid by (1) expert opinion within KCP and KCQA; (2) expert opinion within the NQF ESRD TAPs, Steering Committee, and the CSAC, all of which advanced the measure (with recommended changes adopted by KCQA) to the next stage of the CDP; and (3) broad agreement as demonstrated through the NQF review and voting processes.

### CONTENT VALIDITY

The KCQA influenza immunization measure has content validity based on the following: The measure was deemed appropriate and valid by: (1) consensus of KCQA's expert panel; and (2) consensus of NQF's ESRD Technical Advisory Panels and Steering Committee.

**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.

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

Not applicable.

**2b3.3 Results** (Provide statistical results for analysis of exclusions, e.g., frequency, variability, sensitivity analyses):

Not applicable.

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

**2b4.1 Data/Sample** (Description of the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included):

Not applicable.

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

Not applicable.

**2b4.3 Testing Results** (Statistical risk model: Provide quantitative assessment of relative contribution of model risk factors; risk model performance metrics including cross-validation discrimination and calibration statistics, calibration curve and risk decile plot, and assessment of adequacy in the context of norms for risk models. Risk stratification: Provide quantitative assessment of relationship of risk factors to the outcome and differences in outcomes among the strata):

Not applicable.

**2b4.4 If outcome or resource use measure is not risk adjusted, provide rationale and analyses to justify lack of adjustment:** This measure assesses provider adherence to established clinical guidelines and recommendations. Influenza immunization has been demonstrated to reduce morbidity and mortality in the ESRD population. As all ESRD patients without a medical contraindication should be immunized against influenza, risk adjustment of this measure is inappropriate. (Note: As recommended by the NQF Influenza and Pneumococcal Immunization Steering Committee, patients with medical contraindications are included as a distinct numerator category.)

**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):

As previously described, KCOA tested its ESRD measures through a year-long prospective cohort study on a nationally drawn sample of 53 dialysis facilities containing a mix of for-profit and not-for-profit providers; hospital-affiliated and freestanding facilities within large, small, and independent dialysis organizations; urban, suburban, and rural settings; and facilities both with and without electronic health records (EHRs). Approximately 25 patients per facility were sought, resulting in a final sample size of 1,115 patients. All patients were included in the influenza immunization measure's denominator population. Both facility and patient samples were structured to be generally representative of the national industry profile as identified by the USRDS 2007 Annual Data Report. Facility records were used as the data source, given CMS's intent to include the measure in its Phase III Clinical Performance Measures, which involve CROWNWeb electronic transmission of data from facility medical records. Because CROWNWeb was not operational at the time, standardized, paper-based data collection sheets were constructed from the endorsed specifications and were employed during data collection for the testing.

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

The data elements necessary for measure calculation were collected from the 53 participating facilities on 1,104 of the 1,115 patients included in the study sample. (No data was submitted for the remaining 11 patients, who were consequently categorized as not having received the vaccine in the calculation of performance scores.) Performance rate was calculated using the following formula:

Performance Rate =  

$$\frac{[\text{Patients vaccinated}] + [\text{Patients who decline vaccine}] + [\text{Patients with medical contraindication}]}{(\text{Total ESRD patients})}$$

**2b5.3 Results** (Provide measure performance results/scores, e.g., distribution by quartile, mean, median, SD, etc.; identification of

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*statistically significant and meaningful differences in performance):*

Influenza immunization data were provided for 1,104 of the 1,115 patients (99%) included in the pilot study sample. The immunization status of the study population at the conclusion of the study was as follows:

- Patients vaccinated = 958
- Patients who were assessed but declined the vaccine = 120
- Patients who were assessed and determined to have a medical contraindication to the vaccine = 5
- Unvaccinated patients for whom no explanatory information was provided = 21 (Note: These patients were counted as unimmunized when calculating measure performance scores.)
- Patients with no vaccination information provided = 11 (Note: These patients were counted as unimmunized when calculating measure performance scores.)

The data elements collected thus permit calculation of performance for the measure as follows:

Performance Rate =

$$\frac{([\text{Patients vaccinated}] + [\text{Patients who decline vaccine}] + [\text{Patients with medical contraindication}])}{(\text{Total ESRD patients})} = \frac{(958 + 120 + 5)}{1,115} = 97.1\%$$

Despite the high overall performance rate, the performance for each individual facility in the pilot ranged from 78% to 100%.

Conclusions: These findings indicate that, contrary to current clinical practice guidelines and recommendations, there is considerable performance variation in influenza immunization practices among dialysis facilities. The results identify an important gap and meaningful differences in patient care.

**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):*

Not applicable.

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

The necessary data elements are to be collected via the CMS CROWNWeb data repository when functional.

**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):*

Not applicable.

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

**2c.1 If measure is stratified for disparities, provide stratified results** *(Scores by stratified categories/cohorts):* Data from the USRDS 2010 Annual Data Report influenza vaccination rates are lower in children with ESRD than in adults, in peritoneal dialysis patients than in hemodialysis patients, and in African Americans than in white, Native American, Asian, or Hispanic patients.<sup>(1)</sup> The measure could be reported in a stratified manner to monitor disparities.

Citation:

U.S. Renal Dialysis System, USRDS 2010 Annual Data Report: Atlas of Chronic Kidney Disease and End-Stage Renal Disease in the United States. 2010.

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

The measure could be reported in a stratified manner to monitor the disparities in influenza immunization rates by race/ethnicity, age, and renal replacement therapy modality.

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

### 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): Payment Program, 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): Public Health/ Disease Surveillance, Quality Improvement with Benchmarking (external benchmarking to multiple organizations), Quality Improvement (Internal to the specific organization)

3a. Usefulness for Public Reporting: H  M  L  I

(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.]**

As noted in the 2008 Federal Register notice, the measure is part of CMS's Phase III CPMs and as such is intended to be used by CMS for its public reporting and payment initiatives once CMS brings CROWNWeb fully online.

3a.2. Provide a rationale for why the measure performance results are meaningful, understandable, and useful for public reporting. If usefulness was demonstrated (e.g., focus group, cognitive testing), describe the data, method, and results: While measure results have not been tested for interpretability in public reporting, the KCP dialysis patient group members support the measure and concur that the availability of performance data on this measure is an important indicator of quality of care and that the measure will be readily interpreted by dialysis patients.

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): The measure is intended to be used by CMS for its public reporting and payment initiatives.

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].**

The measure is intended to be used by CMS for its public reporting and payment

initiatives, and data will be collected via the CROWNWeb data repository. The ESRD Conditions for Coverage (section B494.180 [h]) state that data collected through CROWNWeb are to be used in a national ESRD information system and in compilations relevant to performance assessment and quality improvement. Additionally, data on influenza immunization rates among ESRD patients are collected and reported annually by USRDS to promote community-wide QI.

**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:**

On-site interviews of participating facility personnel were conducted during the data integrity audits. Neither facility management nor the staff responsible for collecting and entering the necessary data elements reported any difficulty comprehending the measure concepts and or data elements, and agreed that the measure is an important indicator of quality that will be useful for quality improvement.

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), Abstracted from a record by someone other than person obtaining original information (e.g., chart abstraction for quality measure or registry)

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:

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:

Percent agreement between the auditor and facility abstractors (i.e., the reliability percentage) was assessed during the on-site audits through a direct comparison of data submitted by the facilities throughout the pilot to data reabstracted by the auditor(s). (See Table 3 [Measure Reliability Percentage and Error Type] in Attachment A.) This marker of accuracy was found to be excellent at 98.1%, indicating minimal susceptibility to inaccuracies and errors.

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):

As the reliability analyses indicated, the measure is specified in a manner that permits it to be reliably applied. Additionally, during the course of the pilot and during the on-site interviews, facility personnel did not report any difficulty with the measure concepts or data elements. All data elements are derived from only the facility records and do not require a review of the nephrologist's office records. The burden of manual data collection to collect all KCOA measures ranged from 1 to 15 minutes per patient once facilities became familiar with the data collection forms after the first quarter.

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We do not minimize this time commitment, but note that the CROWNWeb interface will reduce the burden and that batch electronic processing for dialysis organizations with integrated EHRs will significantly minimize burden. Nevertheless, for facilities relying on manual data entry into CROWNWeb from paper-based records, we recognize the measures are feasible, but do impose a burden to comply with the data needs.

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:

0039 : Flu Shots for Adults Ages 50 and Over

0040 : Flu Shot for Older Adults

0041 : Influenza Immunization

0149 : Influenza vaccination

0227 : Influenza Immunization

0432 : Influenza Vaccination of Nursing Home/ Skilled Nursing Facility Residents

0522 : Influenza Immunization Received for Current Flu Season

0680 : Percent of Nursing Home Residents Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short-Stay)

#### 5a. Harmonization

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

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

#### 5b. Competing Measure(s)

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

Not applicable.

### CONTACT INFORMATION

Co.1 Measure Steward (Intellectual Property Owner): Kidney Care Quality Alliance, 2550 M Street, NW, Washington, District Of Columbia, 20037

Co.2 Point of Contact: Lisa, McGonigal, MD, MPH, lmcgon@msn.com, 203-298-0567-

Co.3 Measure Developer if different from Measure Steward: <a href="#">Kidney Care Quality Alliance, 2550 M Street, NW, Washington, District Of Columbia, 20037</a>
Co.4 Point of Contact: <a href="#">Lisa, McGonigal, MD, MPH, lmcgon@msn.com, 203-298-0567-</a>
Co.5 Submitter: <a href="#">Lisa, McGonigal, MD, MPH, lmcgon@msn.com, 203-298-0567-, Kidney Care Quality Alliance</a>
Co.6 Additional organizations that sponsored/participated in measure development: <a href="#">Not applicable.</a>
Co.7 Public Contact: <a href="#">Lisa, McGonigal, MD, MPH, lmcgon@msn.com, 203-298-0567-, Kidney Care Quality Alliance</a>

### 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.

[KCQA Clinical Measures Work Group Members \(developed measures\):](#)

1. [William Haley, MD — Mayo Clinic](#)
2. [John Burkart, MD — GatesMcDonald Health Plus](#)
3. [Al Collins, MD — University of Minnesota](#)
4. [Charlie McAllister, MD — DaVita, Inc.](#)
5. [Jerry Yee, MD — Henry Ford Hospital](#)

[KCQA Clinical Measures Task Group Members \(approved measures\):](#)

1. [Charlie McAllister, MD—DaVita, Inc.](#)
2. [Raymond M. Hakim, MD, PhD — Fresenius Medical Care](#)
3. [Alan Kliger — Yale University](#)
4. [Ed Jones — Renal Physicians Association](#)
5. [Allen Nissenson — DaVita, Inc.](#)
6. [William Goodman — Amgen, Inc.](#)
7. [William Haley, MD — Mayo Clinic](#)
8. [Robert Provenzano — DaVita, Inc.](#)
9. [Gail Wick — American Nephrology Nurses Association](#)
10. [Rulan Parekh — American Kidney Fund](#)

[Kidney Care Quality Alliance Steering Committee Members \(oversaw testing\):](#)

1. [Raymond M. Hakim, MD, PhD \(Co-Chair\)—Fresenius Medical Care](#)
2. [Gail S. Wick, BSN, RN, CNN \(Co-Chair\)—American Nephrology Nurses Association](#)
3. [Dolph Chianchiano, JD—National Kidney Foundation](#)
4. [Richard S. Goldman, MD—Renal Physicians Association](#)
5. [Barbara Fivush, MD—American Society of Pediatric Nephrology](#)
6. [Maureen Michael, BSN, MBA—National Renal Administrators Association](#)
7. [Allen Nissenson, MD—DaVita](#)
8. [Barry M. Straube, MD—Centers for Medicare and Medicaid Services \(Liaison Member\)](#)

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: [2007](#)

Ad.4 Month and Year of most recent revision: [02, 2010](#)

Ad.5 What is your frequency for review/update of this measure? [As needed with changes or additions to the evidence base, but at minimum every three years.](#)

Ad.6 When is the next scheduled review/update for this measure? [02, 2013](#)

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Ad.7 Copyright statement: © 2010 Kidney Care Quality Alliance. All Rights Reserved.

Ad.8 Disclaimers:

Ad.9 Additional Information/Comments: <http://www.kidneycarepartners.com>

Date of Submission (MM/DD/YY): 07/11/2011