

**End Stage Renal Disease (ESRD)
Quality Measure Development and Maintenance
Preventive Care Clinical Technical Expert Panel Draft Summary Report
Prepared by: Arbor Research Collaborative for Health and The University of Michigan Kidney
Epidemiology and Cost Center
Conducted April 16-17, 2013 in Baltimore, MD
Sent to CMS on June 28, 2013**

Contract No. 500-2008-000221, Task Order No. HHSM-500-T0001

Table of Contents

Technical Expert Panel Summary	4
Technical Expert Panel Objectives.....	4
Technical Expert Panel Meeting	4
1. Introduction.....	7
2. Influenza Vaccination Among Dialysis Patients.....	7
2.1 Background and Scientific Importance.....	7
2.2 Existing Measure	9
2.3 New Measure Development.....	10
2.3.1 Numerator Definition	10
2.3.2 Denominator Definition.....	11
2.3.4 Data Collection and Measure Feasibility	12
2.3.5 Usability	15
2.4 Proposed Measures.....	15
3. Pneumococcal Vaccination Among Dialysis Patients	16
3.1 Background and Scientific Importance.....	16
3.2 Existing Measure	18
3.3 New Measure Development.....	19
3.3.1 Numerator Definition	19
3.3.2 Denominator Definition.....	20
3.3.3 Data Collection and Measure Feasibility	20
3.3.4 Usability	24
3.4 Proposed Measures.....	24
4. Hepatitis B Vaccination and Testing Among Dialysis Patients.....	25
4.1 Background and Scientific Importance.....	25
4.2 Existing Measure	27
4.3 New Measure Development.....	28
4.3.1 Numerator and Denominator Definitions	28
4.3.2 Data Collection and Measure Feasibility	28
4.3.3 Usability	31
4.4 Proposed Measures.....	31
5. Influenza and Hepatitis B Vaccination Among Healthcare Personnel.....	31

5.1 Background and Scientific Importance.....	31
5.2 Existing Measures.....	33
5.2.1 Influenza	33
5.3 New Measure Development.....	34
5.3.1 Numerator Definition	34
5.3.2 Denominator Definition.....	34
5.3.3 Data Collection and Measure Feasibility	34
5.3.4 Usability	35
5.4 Proposed Measures.....	35
5.4.1 Influenza	35
5.4.2 Hepatitis B	35
6. Conclusion	36
7. References	37

Technical Expert Panel Summary

The Centers for Medicare & Medicaid Services (CMS) has contracted with Arbor Research Collaborative for Health (Arbor Research) and the University of Michigan Kidney Epidemiology and Cost Center (UM-KECC) to develop End-Stage Renal Disease (ESRD) Quality Measures (QMs) for the following four measure areas:

- Mineral and Bone Disorder
- Hemodialysis Adequacy
- Preventive Care (Pneumococcal, Hepatitis B, and Influenza Vaccinations)
- Dialysis Adequacy for Pediatric Patients (Peritoneal Dialysis Adequacy [PD])

The purpose of the project is to develop measurements that can be used to provide quality care to Medicare beneficiaries.

Technical Expert Panel Objectives

The objectives of these ESRD C-TEPs were described in the charter that was approved by the C-TEPs. The C-TEPs were charged with providing expertise and input to Arbor Research on the development and implementation of measures that will be used to assess and improve the quality of care for Americans with ESRD. The C-TEPs were to provide guidance and assist in the development and specification of new quality measures in specific clinical areas. In addition, the C-TEP members were to consider potential measures using the framework of CMS and the National Quality Forum (NQF). The four evaluation criteria are: [importance](#), [scientific acceptability](#), [feasibility](#), and [usability](#).

Technical Expert Panel Meeting

The Preventive Care, Mineral and Bone Disorder, and Hemodialysis Adequacy TEP met in Baltimore, MD on April 16-17, 2013. The Pediatric Peritoneal Dialysis Adequacy TEP met via conference call on April 11 and April 17, 2013.

The TEPs were comprised of individuals with the following areas of expertise and perspectives:

- Topic Knowledge: ESRD
- Performance Measurement
- Quality Improvement
- Consumer Perspective
- Purchaser Perspective
- Health Care Disparities

The following individuals participated in this TEP:

Name	Title	Organization	Measure Area	Disclosures
Constance Anderson, BSN MBA	Vice President of Clinical Operations	Northwest Kidney Centers	Preventive Care	None
Kevin Chan, MD, MSC	Senior Director of Clinical Outcomes Research and Medical Analytics	Fresenius Medical Care North America	Preventive Care	Employee, Fresenius Medical Care
Alfred Cheung, MD	Professor of Medicine, Division of Nephrology	University of Utah	Preventive Care	Past consultant: Allergan, Ascension Health Ventures, Baxter, CTI Clinical Trial and Consulting, Davita, Hemosphere, Shire; Current consultant: Sorbent Therapeutics; Past and present lecturer: various non-profit organizations, including NKF and ASN; Committee membership: ASN, NKF; Steering committee for multicenter trial: Baxter, CorMedix; Past DSMB for multicenter trial: PharmaNet; Contributing author: Up-to-date; Present funding for research projects: Veterans Affairs; Present advisory board: Amgen; Present council member: International Society of Nephrology; NIH: present funding for various research projects; present DSMB; DOPPS: ASN representative on executive committee

Name	Title	Organization	Measure Area	Disclosures
David Gilbertson	Executive Director of Epidemiology and Biostatistics	United States Renal Data System (USRDS)	Preventive Care	None
Raymond Hakim, MD, PhD	Attending Physician/Nephrologist	Vanderbilt University	Preventive Care	None
Celeste Castillo Lee*	Senior Project Manager, Office of the Provost	University of Michigan	Preventive Care	None
Paul Martin, MD, FRCP, FRCPI	Chief, Division of Hepatology	University of Miami Miller School of Medicine	Preventive Care	None
Alicia Neu, MD	Professor, Pediatric Nephrology	John Hopkins Medicine	Preventive Care	Grant/Research support from Amgen, Abbott, Genzyme, Sanofi Pasteur, Merck; Consultant, GlaxoSmithKlein
David Van Wyck, MD	Vice President, Clinical Services	DaVita	Preventive Care	Stockholder & employee, DaVita Healthcare Partners

* Not present for in-person meeting, but participated in pre and post-TEP discussion.

1. Introduction

Despite improvements in infection control practices and dialysis techniques, infectious disease remains a major cause of morbidity and mortality among patients on long-term hemodialysis and peritoneal dialysis [USRDS 2012]. Patients with ESRD are at increased risk for various infections due to greater blood access exposure and greater impaired cell-mediated and humoral immunity [Janus 2008]. The same immunodeficiencies that limit immune response to disease typically also lead to lower seroconversion rates when vaccinated, lower peak antibody titers, and more rapid decline of antibody levels compared to healthy individuals [Janus 2008; Johnson 1992]. Although guidelines published by the Centers for Disease Control and Prevention (CDC) are well-established, vaccination coverage, particularly for influenza and pneumococcus, still falls below recommended levels and outbreaks of HBV in dialysis units remain a concern [Edey 2010; Kallen 2010]. Thus, implementation of quality measures could further improve vaccination and screening rates among ESRD patients thereby enhancing longevity while reducing morbidity for ESRD patients.

Accordingly, the Preventive Care TEP was convened to make recommendations regarding the development of quality measures for preventive care among dialysis patients as well as healthcare personnel (HCP) that would reflect consideration of the scientific literature, current clinical practice guidelines, and relevant pre-existing quality measures. Specifically, the TEP was charged to consider measures for the following areas:

- 1) Influenza vaccination among dialysis patients
- 2) Pneumococcal vaccination among dialysis patients
- 3) Hepatitis B vaccination and testing among dialysis patients
- 4) Influenza vaccination among healthcare personnel
- 5) Hepatitis B vaccination and testing among healthcare personnel

This report summarizes discussions of the in-person CMS ESRD Technical Expert Panel (TEP) meeting held in Baltimore, MD, April 16-17. Following the in-person meeting, further discussion was requested for the following areas:

- 1) Influenza vaccination among dialysis patients
- 2) Pneumococcal vaccination among dialysis patients
- 3) Influenza vaccination among healthcare personnel

All communications occurring subsequent to the in-person meeting are included in the addendum to this report.

2. Influenza Vaccination Among Dialysis Patients

2.1 Background and Scientific Importance

The TEP evaluated relevant published literature and clinical practice guidelines as a means of assessing the magnitude and significance of the health problem in addition to the impact influenza vaccination has on achieving desired health outcomes. According to the CDC, seasonal influenza is associated with approximately 36,000 deaths and 226,000 hospitalizations annually [CDC 2010a]. While overall rates of influenza infection are highest among children, rates of serious illness and mortality are highest among adults aged 65 years or older and children aged two years or younger as well as among immunocompromised patients, which include ESRD patients [CDC 2010a]. It was noted that while the presence of randomized clinical trials cited in the literature is limited, observational research in several care settings has shown lower rates of mortality and hospitalization among patients receiving the influenza vaccine compared to unvaccinated patients.

Recent studies on influenza vaccination among dialysis patients were highlighted for particular consideration by the TEP. Bond et al. (2012) conducted a survey-based study of dialysis facilities across three ESRD Networks to examine the association of influenza vaccination with all-cause mortality for the 2005-2006 influenza season. Of the 34,502 patients included, 80.3% received the influenza vaccine during the October-December 2005 measurement period. The authors found that, for the January-December 2006 follow-up period, vaccinated patients had a nearly 30% lower odds of mortality compared to unvaccinated patients (OR=0.71; 95% CI=0.65-0.77) [Bond 2012]. Using Medicare claims data, Gilbertson et al. (2003) measured vaccination between September-December and identified mortality and hospitalization outcomes between January-April of the following year for the 1997-1998 and 1998-1999 influenza seasons. Vaccination rates were less than 50% for both seasons. However, consistent with Bond et al., the authors reported a significant ($p<0.05$) decrease in odds of all-cause mortality, with odds ratios of 0.75 (1998) and 0.77 (1999) for hemodialysis patients and 0.70 (1998) and 0.83 (1999) for peritoneal dialysis patients. Modestly lower odds of all-cause hospitalization for vaccinated patients were also found [Gilbertson 2003]. A consistent effect of vaccination on outcomes was observed in analyses stratified by age group, comorbidity, as well as race. In addition, in preliminary work, Messina et al applied facility-level analysis of Medicare claims data to show a significantly lower risk of all-cause mortality in the year following vaccination in facilities having higher influenza vaccination rates [Messina 2010]. Compared to facilities where more than 77% of patients were vaccinated, facilities having less than 52% of patients vaccinated had a 19% higher risk of mortality ($p<0.05$) after adjusting for facility characteristics. Finally, analyses of Medicare claims data prepared by Arbor Research/UM- KECC for the TEP showed a stable association between influenza vaccination and decreased odds of all-cause mortality over time (ORs ranged 0.68-0.74 [$p<0.05$] for the 2006-2007 through 2010-2011 influenza seasons).

In addition to evidence from the literature, the TEP was also presented with a summary of the clinical practice guidelines published by the CDC recommending universal vaccination among dialysis patients [CDC 2010a]. These guidelines state:

- Annual influenza vaccinations should be administered to all persons aged 6 months or older
- Trivalent inactivated influenza vaccine should be used for high-risk conditions (including ESRD patients)
- Vaccination efforts should begin as soon as vaccine is available and continue through the influenza season

It was noted that the Healthy People 2010 and 2020 vaccination goals of 90% [Healthy People 2020] should be considered in concert with the CDC guidelines recommending universal vaccination, and that, despite these efforts, vaccination rates have historically been lower. As mentioned above, Gilbertson et al. reported rates ranging between 40-50% for the 1997-1998 and 1998-1999 influenza seasons [Gilbertson 2003]. More recently, trends from the annual Dialysis Facility Reports based on Medicare claims data showed the average influenza vaccination rate has climbed from approximately 62% in 2006 to 69% in 2011. Facility-level rates similarly suggest a performance gap, with a median vaccination rate of 72% reported for 2011. It was emphasized that the rates presented by Gilbertson et al. as well as those from the Dialysis Facility Reports were obtained using Medicare claims data, which tend to underreport vaccination rates due to patients receiving influenza vaccination in settings that may not produce a Medicare claim. This is further suggested by the paper by Bond et al., which used survey data and reported a vaccination rate of 80.3% among dialysis patients for the 2005-2006 influenza season [Bond 2012]. Though significantly higher than the rates observed using Medicare claims data, it was noted that this still falls short of the 90% Healthy People 2010 goal. The TEP concluded that there was sufficient evidence to suggest that influenza vaccination among dialysis patients is important and significantly associated with desired health outcomes. It was additionally determined that there is adequate evidence of a performance gap that could be actionably reduced through the implementation of a quality measure.

2.2 Existing Measure

In considering a new measure for influenza vaccination among dialysis patients, the TEP closely reviewed a pre-existing measure developed specifically for ESRD patients by the Kidney Care Quality Alliance (KCQA) and endorsed by the National Quality Foundation (NQF) on November 15, 2007 with an update on February 6, 2013 (NQF #0226). The key characteristics of the KCQA measure are presented in Table 1.

Initial concerns expressed by the TEP were related to the treatment of deceased patients. Measure specifications indicate that the denominator includes patients who die during the measurement period only if they were vaccinated, otherwise they are excluded. It was noted that such an approach was limited as it would exclude patients who are not vaccinated and subsequently die from influenza-related causes. It was suggested that this exclusion might yield more favorable measure scores for facilities but it does not serve the best interests of improving care for dialysis patients. It was agreed that even among the sickest patients, vaccination should be recommended. There was strong consensus among the TEP that an influenza vaccination measure should include patients who die during the influenza season regardless of vaccination status and that this was an important reason to proceed with discussion of a new or modified measure.

Table 1. Key components of the KCQA quality measure for influenza vaccination among ESRD patients.

Description	Percentage of ESRD patients being dialyzed from Oct 1 (or when the influenza vaccine became available) through Mar 31 who either received, were offered and declined, or were determined to have a medical contraindication to the influenza vaccine.
Denominator	All ESRD patients aged ≥ 6 months receiving HD or PD from Oct 1 (or when the influenza vaccine became available) to Mar 31.
Numerator	Number of patients from the denominator who (to be calculated and reported separately): <ol style="list-style-type: none">1) received an influenza vaccination* (documented by the provider or reported receipt from another provider by the patient) [*Only TIV should be used in the ESRD population]2) were assessed and offered an influenza vaccination but declined3) 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-Barré Syndrome within 6 weeks after a previous influenza vaccination, bone marrow transplant within the past 6 months (less than 6 months prior to encounters between Oct 1 and Mar 31)
Exclusions	The following are excluded from the denominator: <ul style="list-style-type: none">▪ Patients who died between Oct 1 – Mar 31 and were not vaccinated▪ Patients who received less than 7 treatments per month at the facility

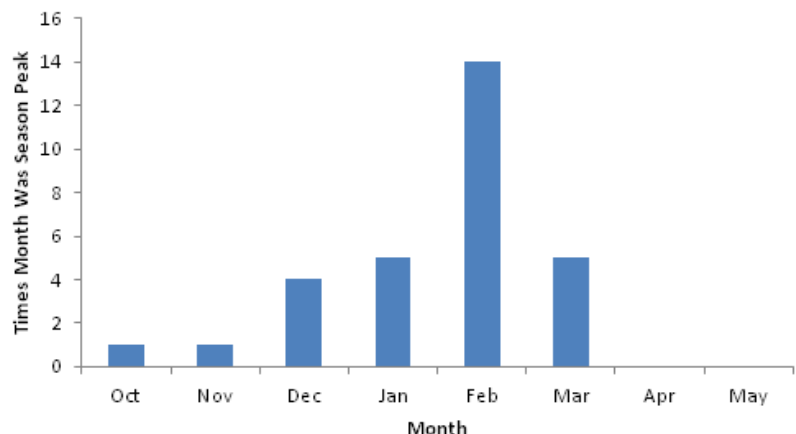
2.3 New Measure Development

2.3.1 Numerator Definition

Central to the TEP's discussion of the measure numerator was the definition of the vaccination measurement period. The CDC guidelines recommend vaccination efforts begin as soon as vaccine becomes available [CDC 2010a]. A review of vaccine distribution times indicated vaccine has been made available as early as the end of August in two of the last three seasons [<http://www.cdc.gov/flu/professionals/vaccination/vaccinesupply.htm>]. Though the language of the KCQA measure assigns the start of the measurement period as "Oct 1 (or when the influenza vaccine became available)," the TEP agreed it would be logistically more feasible and clearer to facilities if the measure had a fixed, constant measurement period that fully encompassed the time period when the influenza vaccine is made available for patients. Since the influenza vaccine can be available as early as August, it was agreed the measurement period should begin August 1 to be most inclusive and not risk incentivizing withholding vaccine (by starting the measurement period on October 1, for example). In considering the August 1 start date, it was noted that immune response to the influenza vaccine can be low in ESRD patients and questioned whether immunity could wane prior to peak influenza season among patients vaccinated too early. The question was posed whether to encourage revaccination or administering a higher dose of vaccine in certain patients. The TEP acknowledged that although this topic would certainly benefit from further scientific inquiry, there were currently no guidelines addressing this issue, so it was decided to exclude language related to revaccination or vaccine dose from the proposed measure specifications.

The TEP then considered the most appropriate end date for the vaccination measurement period. It was noted that if the purpose of the measure is to accurately capture the total number of patients receiving the vaccine in a season, a more inclusive time period might be appropriate. It was emphasized, however, that a measure is an indicator of quality and should serve to incentivize practices that improve quality. A review of CDC data indicated that the majority of influenza outbreaks since 1982-1983 peaked between January-March (Figure 1). This means the majority of influenza-related hospitalizations and deaths occur in the latter half of the influenza season. It was suggested that incentivizing early vaccination (prior to the peak influenza outbreaks) would serve to protect patients and ensure adequate immunity in advance of peak influenza activity, and thus it might be appropriate to consider a time period ending December 31, rather than keeping the KCQA end date of March 31. Although there was general consensus among TEP members regarding the value of this approach, some TEP members cautioned that an end date of December 31 would provide no incentive to continue vaccination in the second half of the season and incident dialysis patients during that period could be missed. It was noted that preliminary analyses of Medicare claims data conducted by Arbor Research/UM-KECC showed that >97% of vaccinations among dialysis patients between September and March of the following year occurred by December 31 (2006-2007 through 2010-2011 influenza seasons). Ultimately, it was decided to develop two separate measures: one that would end on December 31 to incentivize early vaccination, and another that would end on March 31 to further incentivize vaccination (or evaluation of vaccination status) of patients who enter a facility during the latter half of the influenza season.

Figure 1. Peak month of influenza activity: 1982-1983 through 2011-2012 [<http://www.cdc.gov/flu/about/season/flu-season.htm>].



The final consideration among TEP members regarding the numerator calculation involved what type of calculation should be performed for various patient groups. The KCQA measure uses a three-part numerator, separately calculating patients who received, declined, or were contraindicated for the vaccine. Initially, the TEP considered only including patients in the numerator calculation who received the vaccine since, for example, the fraction of patients who were medically contraindicated for vaccination were expected to account for a small percentage of all patients and expected to be relatively stable across facilities. It was questioned as to how meaningful it is to explicitly capture these groups separately. It was noted, however, that in 2008 NQF recommended standard measure specifications for the purpose of harmonizing influenza and pneumococcal vaccination measures, and that these specifications included the three-part numerator incorporated in the KCQA measure [NQF 2008]. In order to meet NQF's recommendations for harmonized immunization measures, the TEP agreed to retain the three-part numerator.

2.3.2 Denominator Definition

A key aspect of determining the criteria for the measure denominator involved defining the population at risk. Considering the seasonal nature of influenza and the recommendations for universal vaccination, identifying the population at risk would be closely tied to when the time at risk begins. Though the numerator was defined as starting in August, due to the early availability of vaccine, TEP members agreed that an August start date for the denominator would be less appropriate. The influenza season typically does not begin until October, and thus this serves to help define which patients are at risk for influenza-related morbidity and mortality. Since it was previously decided that the measure should not explicitly exclude deceased patient regardless of vaccination status, it was noted that a denominator beginning in August would capture patients who died between August-September, perhaps before being vaccinated. However, these deaths would likely not be attributable to influenza-related causes, so penalizing a facility under these circumstances would not necessarily serve to promote improved quality of care. A point prevalent denominator of patients alive and on dialysis as of December 31 was alternatively suggested, but TEP members agreed this would miss patients who died earlier, possibly from influenza-related causes. Ultimately the TEP decided to align the denominator with the influenza season. The denominator of the first measure would include patients treated at a facility for at least 30 days from October 1-December 31, and the second measure would include patients treated at a facility for at least 30 days from October 1-March 31.

The TEP noted the measures should include all patients aged six months or older, in concordance with the CDC guidelines, and they agreed the measure should allow for the inclusion of patients who were at a facility for part of the measurement period. With regards to this latter aspect, the TEP considered an appropriate means of

assigning patients to facilities. The KCQA measure excludes patients who receive fewer than seven treatments per month at the facility of interest. A concern was raised as to how well this approach would work for peritoneal dialysis or home hemodialysis patients. It was noted that these patients come into clinics much less frequently and that perhaps facility assignment based on length of time rather than number of treatments would be more appropriate. The TEP decided that two weeks cumulative treatment was a reasonable amount of time for a facility to evaluate a patient's vaccination status and vaccinate a patient if previously not vaccinated. Furthermore, this time frame could be uniformly applied to not only in-center hemodialysis patients but also to a facility's peritoneal dialysis and home hemodialysis patients. Counting all patients who were in a facility for a total of at least two weeks during the specified time period would sufficiently assign patients to a facility and still be able to capture those patients who subsequently died. Patients who transfer and are thus treated at multiple facilities during the measurement period would be assigned to more than one facility accordingly. The TEP agreed that this was appropriate as each facility should be responsible for either administering the vaccine or verifying vaccination status. During final deliberations, however, the two week period was changed to 30 days in an effort to harmonize TEP recommendations for the influenza and pneumococcal vaccination measures.

2.3.4 Data Collection and Measure Feasibility

The TEP was charged with evaluating CROWNWeb as a potential data source for the preventive care measures under consideration. Before discussing the creation of any new data elements, the TEP reviewed current collection methods as well as preliminary data. CROWNWeb serves as a national source for data from dialysis facilities and currently includes data elements related to vaccination. Facility-wide data collection began in May 2012, with data through December 2012 available for review by the TEP. It was emphasized that these data have not gone through formal data validation or reliability testing, so results should be interpreted cautiously. Of additional concern specifically to the Preventive Care TEP was the discovery of a technical problem related to the batch submission of vaccination data. The percent of facilities reporting monthly vaccination data ranged from 23-50% for the months May-November (compared to 86-97% for other clinical data). Because only 5% of facilities had reported vaccination data for December, these data were excluded from all analyses presented by Arbor Research/UM-KECC.

The data elements currently used to capture influenza vaccination information in CROWNWeb were developed to be compatible with the KCQA measure. A screenshot of the vaccination data entry screen with influenza elements highlighted is presented in Figure 2.

Figure 2. Screenshot of CROWNWeb vaccination data entry tab, highlighting elements for influenza vaccination.

The screenshot shows the 'Vaccination' tab in the CROWNWeb system. A red box highlights the 'Influenza Vaccination' section, which contains the following fields:

- Influenza Vaccination Not Received:** A checkbox.
- Influenza Vaccination Date:** A date field showing '06/2011'.
- Site Received Influenza Vaccination:** A dropdown menu showing 'Received Outside Facility'.
- Reason No Influenza Vaccination:** A dropdown menu.
- Influenza Exclusion Reason:** A dropdown menu.

Other sections visible in the form include:

- Pneumococcal Vaccination:** Includes a 'Not Received' checkbox, a 'Year' field (showing '2011'), and a 'Reason No Pneumococcal Vaccination' dropdown.
- Hepatitis B Vaccination:** Includes 'Initial 1', 'Initial 2', and 'Initial 3' date fields, all showing dates in 2011.
- Hepatitis B Booster:** Includes 'Booster Date 1' through 'Booster Date 4' date fields, all showing dates in 2011.
- Hepatitis B Test Type (HBsAg):** A dropdown menu showing 'HBsAg (Hepatitis B surface antigen)'.
- Anti-HBs (mIU/ml):** A text field with a date field below it.
- Hepatitis C Screen Test:** A dropdown menu showing 'Recombinant Immunoblot Assay'.

A description of the data entry logic is provided below:

Influenza Vaccination Not Received:

- ☐ No → Influenza Vaccination Date: [MM/YYYY]
 Site Received Influenza Vaccination:
 - ☐ Received at Facility
 - ☐ Received Outside Facility
- ☐ Yes → Reason No Influenza Vaccination:
 - ☐ Medical Reason
 - ☐ Personal Reason
- Influenza Exclusion Reason:
 - [If Medical] → ☐ Allergic ☐ Adverse Reaction ☐ Other Medical
 - [If Personal] → ☐ Cultural ☐ Personal Choice

Test calculations of facility-level influenza vaccination rates using data from September-November 2012 were presented (Table 2). Results were provided for mean rates of vaccination (73.6%), refusal (9.6%), and medical contraindication (5.9%). In reviewing the data, several important points were raised. First, it became apparent that the only way patients would be excluded from the three-part numerator was if they were vaccinated in a

month outside of the measurement period. There are no data elements available to capture the vaccine not being administered for reasons other than refusal or medical contraindication, for example if the vaccine had not been offered. Another key observation was that the mean rate for medical contraindication appeared quite high (5.9%). Stratified results showed that only 0.3% were reporting allergy or adverse reaction whereas 5.7% were indicating 'Other Medical Reason'. Further investigation revealed that CROWNWeb administrators were instructing facilities to select 'Other Medical Reason' if the vaccine was not administered for any reason other than those already provided explicitly in CROWNWeb [personal communication]. The TEP noted this could result in significant misclassification, as facilities could be selecting 'Other Medical Reason' under circumstances when this would not be appropriate, for example if the vaccine were not offered or if the patient had previously received it. Finally, it was suggested that the data elements in their current form are potentially confusing. Because data do not carry over from month to month, it was unclear if facilities were entering data specific to the month or if data reflected the patient's broader history. The presence of historical vaccination dates (pre-2012) consistently entered throughout the months in 2012 for certain patients indicated some facilities were submitting data reflecting the patient's most recent history of influenza vaccination in prior years rather than in the current year. The presence of a vaccination date in one month followed by medical contraindication in subsequent months indicated other facilities were interpreting the questions on a month to month basis. For the reasons noted above, the TEP agreed that the CROWNWeb data collection elements would benefit from revision.

Table 2. Facility-level influenza vaccination rates, September-November 2012 (CROWNWeb)*†

<i>Measure</i>	<i># of facilities</i>	<i>Mean</i>	<i>Std Dev</i>	<i>5th Pctl</i>	<i>50th Pctl</i>	<i>95th Pctl</i>
% Vaccinated, Refused, or Contraindicated (Sep-Nov 2012)	665	90.9	15.2	60.0	96.7	100.0
% Vaccinated in Sep-Nov 2012	665	73.6	24.9	8.9	81.6	100.0
% Refused	665	9.6	15.8	0.0	5.0	36.2
% Medical Contraindication	665	5.9	16.7	0.0	0.0	29.2
% Allergy or Adverse Reaction	665	0.3	1.2	0.0	0.0	2.3
% Other Medical Reason	665	5.7	16.7	0.0	0.0	28.6
% Vaccinated Outside of Sep-Nov 2012	665	9.1	15.2	0.0	3.3	40.0

*Analyses based on data from CROWNWeb among facilities reporting for the entire period Sep 1 through Nov 30 2012. Facilities with <5 patients were excluded.

†Among all patients > 6 months of age, alive and on dialysis at the facility with records for all three months.

The proposed revised data elements are provided below:

Influenza Vaccination Received *This Month*:

- ☐ No → Reason No Influenza Vaccination:
- ☐ Already vaccinated this flu season
 - ☐ Medical Reason: Allergic or Adverse Reaction
 - ☐ Other Medical Reason
 - ☐ Declined
 - ☐ Other Reason
- ☐ Yes → Influenza Vaccination Date: [MM/YYYY]
Where Influenza Vaccination Received:

- ☐ Documented At Facility
- ☐ Documented Outside Facility
- ☐ Patient Self-Reported Outside Facility

The TEP agreed that the proposed revisions to the data elements currently implemented in CROWNWeb were minimal and would represent little to no additional burden on facilities. The purpose of the revisions was to clarify data collection instructions and reduce the opportunity for misclassification during data entry. The TEP also discussed the possibility that two separate measures could impact the burden on facilities. However, it was noted that the data elements used in calculating both measures were identical, so no additional effort from the facilities would be required. The TEP concluded that the two proposed measures for influenza vaccination among dialysis patients would meet the NQF criterion for feasibility.

2.3.5 Usability

In considering measure usability, the TEP agreed that, as the proposed measures were currently specified, the results would be meaningful, understandable, and useful for public reporting, given accurate data collection.

2.4 Proposed Measures

The influenza vaccination measures recommended by the Preventive Care TEP are presented in Tables 3 and 4. Note that the TEP continued to discuss these measures after the TEP meeting, and a summary of those discussions are included in the addendum.

Table 3. Timely Influenza Vaccination (ESRD Patients).

Denominator	The following patients are included in the denominator: <ul style="list-style-type: none"> 1) Alive and aged ≥ 6 months on Oct 1, and 2) On chronic dialysis ≥ 30 days in a facility at any point between Oct 1 and Dec 31 (in-center or home dialysis)
Numerator	Number of patients from the denominator who (to be calculated and reported separately): <ul style="list-style-type: none"> 1) received an influenza vaccination between Aug 1 and Dec 31 (documented by the dialysis provider, documented off-site vaccination, or patient self-report) [*Only inactivated vaccine should be used in the ESRD population] 2) were offered an influenza vaccination but declined 3) were determined to have a medical contraindication

Table 4. Full-Season Influenza Vaccination (ESRD Patients).

Denominator	The following patients are included in the denominator: <ul style="list-style-type: none"> 1) Alive and aged ≥ 6 months on Oct 1, and 2) On chronic dialysis ≥ 30 days in a facility at any point between Oct 1 and Mar 31 (in-center or home dialysis)
Numerator	Number of patients from the denominator who (to be calculated and reported separately): <ul style="list-style-type: none"> 1) received an influenza vaccination between Aug 1 and Mar 31 (documented by the dialysis provider, documented off-site vaccination,

- or patient self-report) [*Only inactivated vaccine should be used in the ESRD population]
- 2) were offered an influenza vaccination but declined
 - 3) were determined to have a medical contraindication
-

3. Pneumococcal Vaccination Among Dialysis Patients

3.1 Background and Scientific Importance

The TEP began its consideration of measures related to pneumococcal vaccination among dialysis patients by reviewing relevant published literature and clinical practice guidelines as it had for influenza. According to the CDC, *Streptococcus pneumoniae* (pneumococcus) remains a leading cause of serious illness in the United States, resulting in approximately 4,000 deaths per year, primarily among adults [CDC 2012]. In the general population, incidence rates are highest among those age 65 years or older (36.4 per 100,000), however rates among high-risk and immunocompromised groups (which includes ESRD patients) can be more than 20 times higher [CDC 2012]. Similar to influenza, the presence of randomized clinical trials cited in the literature has been limited. However, observational research has demonstrated lower rates of mortality and hospitalization among patients receiving the pneumococcal vaccine compared to unvaccinated patients.

Recent studies on pneumococcal vaccination among dialysis patients were reviewed in detail by the TEP. The Bond et al. (2012) survey-based study described earlier examined the association of pneumococcal vaccination with all-cause mortality in addition to its analysis of influenza vaccination. Results indicated that 45.3% of the 34,502 surveyed patients had ever received the pneumococcal vaccine as of December 2005. Further, for the January-December 2006 follow-up period, vaccinated patients had nearly 25% lower odds of mortality compared to unvaccinated patients (OR=0.76; 95% CI=0.70-0.82) [Bond 2012]. Using Medicare claims data, Gilbertson et al. (2011) measured vaccination between November 2003-October 2005 and identified mortality and hospitalization outcomes between November 2005-May 2006. This more limited measurement period produced a vaccination rate of 21%. Pneumococcal vaccination was found to be associated with a lower hazard ratio for overall mortality (HR=0.94; 95% CI=0.90-0.98), cardiac death (HR=0.91; 95% CI=0.85-0.97), and hospitalization for bacteremia/viremia/septicemia (HR=0.95; 95% CI=0.91-1.00) [Gilbertson 2011]. Some TEP members stressed that the evidence presented was limited to evaluating the 23-valent pneumococcal polysaccharide vaccine (PPSV23), and that no studies have been performed examining the association of the 13-valent pneumococcal conjugate vaccine (PCV13) with health outcomes in this patient population. It was countered that the PCV13 vaccine was only available very recently, and therefore not enough time had elapsed to allow for many studies to be conducted and published. It was emphasized, however, that the vaccination recommendation is a Category A recommendation, and studies cited in the guidelines indicate that >50% of invasive pneumococcal infection is caused by serotypes included in the PCV13 vaccine. The question was therefore raised and left open for future discussion as to whether a measure for PCV13 would meet NQF's criteria for scientific importance.

Following a review of the literature, the TEP was presented with a summary of the clinical practice guidelines published by the CDC recommending pneumococcal vaccination among adult dialysis patients [CDC 2012]. These guidelines state:

- Routine use of 13-valent pneumococcal conjugate vaccine (PCV13) is recommended for adults aged ≥19 years with immunocompromising conditions [includes chronic renal failure].

- PCV13 should be administered to eligible adults in addition to the 23-valent pneumococcal polysaccharide vaccine (PPSV23).
- Among immunocompromised pneumococcal vaccine-naïve persons:
 - Adults aged ≥ 19 years should receive a dose of PCV13 first, followed by a dose of PPSV23 ≥ 8 weeks later.
 - A second PPSV23 dose is recommended 5 years after the first PPSV23 dose for persons aged 19-64 years.
 - Those who received PPSV23 before age 65 years for any indication should receive another dose of the vaccine at age 65 years or later if ≥ 5 years have elapsed since their previous PPSV23 dose.
- Among immunocompromised persons who were previously vaccinated with PPSV23:
 - Adults aged ≥ 19 years who previously have received ≥ 1 doses of PPSV23 should be given a PCV13 dose ≥ 1 year after the last PPSV23 dose was received.
 - For those who require additional doses of PPSV23, the first such dose should be given no sooner than 8 weeks after PCV13 and ≥ 5 years after the most recent dose of PPSV23.

A brief summary of the more complex pediatric recommendations was also provided [CDC 2010b]. The TEP discussed the nature of the CDC guidelines and the recommendation of a five-year booster for PPSV23. It was questioned whether more frequent boosters might be more appropriate given the indication in the literature that rates of immunity wane over time [Fuchshuber 1996; Linnemann 1986; Robinson 2004; Rytel 1986]. Some TEP members raised concerns about the possibility of causing harm by over-vaccinating patients if the complete vaccination history is unknown, as is sometimes the case in the dialysis facility setting. It was countered that a study in HIV patients showed limited to no safety concerns related to receiving multiple doses of PCV13 six months apart [Glesby 2013]. Others indicated there are concerns, however, regarding decreased immune response if PCV13 is administered within less than one year of PPSV23 [CDC 2012]. Additional questions were raised regarding why antibody testing is not included as part of the CDC recommendations given known problems with poorer initial immune response as well as waning immunity among ESRD patients. Limitations related to the feasibility of implementing such testing were discussed. Because both vaccines are multivalent, individual antibody tests would be needed for each serotype included in the vaccine. In addition, it is unclear what action should be recommended if a patient has adequate seroresponse to some but not all of the strains included in a vaccine. Ultimately, there was consensus that the TEP's role was not to develop or revise clinical guidelines, but rather to propose quality measures based on the strength of existing evidence and guidelines. It was agreed that further discussion of measure development should be in the context of the guidelines as they are currently written but the TEP did recommend that additional efforts be put forth by the CDC and/or CMS to investigate whether there may be further benefits for dialysis patients (and presumably other immunocompromised patients) by more frequent repeat pneumococcal vaccination.

As with influenza, it was noted that the Healthy People 2010 and 2020 vaccination goals should be considered along with the CDC guidelines. Among non-institutionalized high-risk adults aged 18-64 years, the vaccination goal is 60% [Healthy People 2020]. For adults aged 65 years or older, it is 90% [Healthy People 2020]. Rates cited in the literature, however, have been lower. As described above, Gilbertson et al. reported a rate of 21% for the two-year period November 2003-October 2005 using Medicare claims data [Gilbertson 2011]. Adopting a more expanded measurement period, Bond et al. found a vaccination rate of 45.3% among patients reporting if they ever had received the vaccine as of December 2005 [Bond 2012]. More recent trends of pneumococcal vaccination using Medicare claims data for the period 2006-2011 were prepared by Arbor Research/UM-KECC and presented to the TEP. There was an overall increasing trend among annual rates ranging from 11.6% in 2006 to 16.4% in 2011. Multi-year analyses showed higher coverage. Over a three-year period (2009-2011) the vaccination rate was 46.0%, and over a five-year period (2007-2011) it was 64.0%. Considering the guidelines recommend vaccination upon diagnosis with a high-risk condition, including ESRD, Arbor Research/UM-KECC

also performed a sub-analysis of incident dialysis patients. Annual rates among this population were slightly higher, ranging from 17.6-26.6% during the period 2006-2011, however not as high as might be expected among presumably largely vaccine-naïve patients. Facility-level rates supported the evidence for a performance gap, with median annual vaccination rates of 11.6-16.0% reported for the period 2006-2011. The TEP agreed that the evidence in the literature combined with the CDC guidelines suggested that pneumococcal vaccination among dialysis patients is an important process that is significantly associated with improved health outcomes. Though there was consensus that it is difficult to accurately assess vaccination status using data sources such as Medicare claims, it was also concluded that there is likely sufficient evidence of a performance gap. A majority of the TEP agreed that such a performance gap could be appropriately addressed by the development and implementation of a quality measure. Some TEP members disagreed, however, voicing concerns over the lack of scientific evidence to support an association between vaccination and improved health outcomes, particularly for PCV13, as well as the likelihood of feasibility issues related to collecting sufficient data to distinguish, time, track, and manage two different pneumococcal vaccines with two different but interconnected sets of administration guidelines. Several TEP members acknowledged that feasibility challenges would likely be an issue, but that it was important to consider measures in this area as a means of promoting quality care for patients. It was again emphasized that pneumococcal vaccination in this patient population is a Category A recommendation, so even though it might be difficult for providers to track vaccination history among their patients, they have a responsibility to do so to ensure proper care. Ultimately, the TEP decided to continue discussion of pneumococcal vaccination measure development.

3.2 Existing Measure

In considering new measures related to pneumococcal vaccination among dialysis patients, the TEP closely reviewed several pre-existing measures. Among these, a measure developed for long-stay nursing home facility residents by the Centers for Medicare and Medicaid Services (CMS) and endorsed by the NQF on March 3, 2011 with an update on August 21, 2012 (NQF #0683) received the most attention. The key characteristics of the CMS measure are presented in Table 5. Initial reactions to this measure were generally positive with the primary limitation related to the fact that it only addressed PPSV23, whereas guidelines for dialysis patients now include the PCV13 vaccine. It was agreed that discussion should proceed for determining 1) if it would be possible to properly adapt the CMS measure to the dialysis population and 2) how the new requirement for administering PCV13 in addition to PPSV23 could best be addressed in a quality measure.

Table 5. Key components of the CMS quality measure for pneumococcal vaccination among long-stay nursing home residents.

Description	Percent of long-stay nursing home residents assessed and appropriately given the pneumococcal vaccine.
	This measure reports the percent of long-stay residents whose pneumococcal polysaccharide vaccine (PPV) status is up to date.
Denominator	All long-stay residents during the 12-month reporting period. <ul style="list-style-type: none"> ▪ Long-stay residents are defined as residents whose length of stay is greater than 100 days. ▪ Facilities with <30 residents in the sample are excluded from public reporting.
Numerator	Number of patients from the denominator who (to be calculated separately): <ol style="list-style-type: none"> 1) have up-to-date vaccine status or received the vaccine during the reporting

- period
 - 2) were ineligible due to medical contraindications
 - 3) were offered the pneumococcal vaccine but declined
-

3.3 New Measure Development

3.3.1 Numerator Definition

A key aspect of the TEP's discussion of a measure numerator involved striking a balance between reflecting CDC guidelines, which are complex and could require the use of numerous conditional statements, and creating a simple measure that could be feasibly and meaningfully implemented. There was general appreciation for the simplicity of the CMS measure, which was designed for the long-stay nursing home population. This measure places the burden of determining which patients need the vaccine on the facility and omits any attempt to capture that level of detail from the measure calculation. It was expressed that though this measure was developed explicitly for the PPSV23 vaccine, the language is general enough where it could be more broadly applied to PCV13 as well. Many TEP members agreed that it could be beneficial to define a measure that addressed both PPSV23 and PCV13.

Accordingly, the following measure description was proposed:

- All patients ≥ 2 months of age should have evidence of having received a pneumococcal vaccination in the last 5 years.

The age requirement of two months is a reflection of CDC guidelines indicating the age at which patients can begin receiving the PCV13 vaccine [CDC 2012]. The use of five years as a measure of a patient's up-to-date status is rooted in the five-year booster recommendation for PPSV23. It was noted that this is a one-time five-year booster, however, not that patients are recommended to receive PPSV23 every five years. Additionally, the PCV13 recommendation is for a single lifetime dose for patients >71 months (or ≥ 5 years) of age [CDC 2012]. Thus, it would be possible for a patient to be up-to-date and not have received a pneumococcal vaccination within the past five years. It was suggested, therefore, that the language referring to five years be removed and rather that the measure assess whether a pneumococcal vaccine was ever received. Some favored this revision as it would be more aligned with the existing CMS measure. Other TEP members expressed concerns that this could represent an oversimplification, and the measure would no longer be adequately assessing how well facilities are following the CDC guidelines. The language would also not necessarily encourage facilities to ensure patients are receiving both PPSV23 and PCV13. There was consensus that it would be important to develop one or more measures to incentivize both types of vaccine.

Resulting from the above discussion, two alternative measure descriptions were proposed:

- Adults who are eligible for the pneumococcal vaccine should be vaccinated with PCV13 during the next pneumococcal vaccination opportunity.
- Adults on dialysis who previously have received at least 1 dose of PPSV23 should be given a PCV13 dose at least 1 year after the last PPSV23 dose.

These measures were drafted to more specifically target the PCV13 vaccine as well as reflect the CDC guidelines as closely as possible. The feasibility of collecting accurate and complete data on patient vaccination histories was discussed. It was suggested that this would be a challenge, particularly in light of missing information regarding patient vaccination prior to entry at the dialysis facility. Patients often come to the dialysis facility from the hospital setting, where it was noted there are also recommendations for pneumococcal vaccination.

Unfortunately, patients are frequently unclear on which vaccination they received, and timely transfer of hospital records does not always occur. Apart from feasibility, there were separate concerns that measures such as those listed above could incentivize providing PCV13 vaccination earlier than is recommended following the PPSV23 vaccine. It was stressed that a measure should adequately allow for the one year lag between PPSV23 and PCV13, because immunogenicity is reduced if PCV13 is given in rapid succession to PPSV23 [CDC 2012]. This led to the development of the following measure description:

- All patients should receive PCV13 (or written evidence thereof) within 1 year of starting chronic dialysis.

It was suggested that this alternative wording could help address the challenge of incident patients with unknown vaccination status. Some TEP members raised concerns that this measure would not incentivize evaluation of vaccination status among patients on dialysis less than one year. It was further expressed that failing to ensure coverage for these patients would not represent quality care. The possibility of developing a measure specifically for incident patients was briefly discussed. Because this would suffer from the same feasibility challenges described above related to obtaining complete and accurate vaccination history data prior to entry at the dialysis facility, it was agreed that an incident patient measure should not be explored further.

The final consensus was to move forward with two separate measures, one targeting PPSV23 that would be closely aligned with the existing CMS measure (patients with up-to-date status) and the other specific to PCV13 that would measure patients who had ever received the PCV13 vaccine. Additionally, it was decided that both measures should incorporate a three-part numerator, calculating separately patients who received, refused, or were contraindicated for the respective vaccine, in agreement with NQF's recommended specifications for harmonized immunization measures [NQF 2008].

3.3.2 Denominator Definition

Due to the different vaccination schedules recommended for PPSV23 and PCV13, it was noted that each measure should have slightly different denominator specifications. Accordingly, it was suggested that the PPSV23 measure exclude patients less than two years of age. It was additionally proposed that the PCV13 measure exclude patients less than five years of age. Though patients can begin receiving the PCV13 vaccine as early as two months, the dosing recommendations are more complicated for patients under five years, with variable dosing schedules based on age and previous vaccination with the seven-valent conjugated pneumococcal vaccine [CDC 2010b]. In order to develop a comprehensive specification that would cover the broadest range of patients in a single measure, the five-year age limit was recommended. It was also suggested that the PCV13 measure exclude patients who had received PPSV23 within the last year to address the concerns related to incentivizing premature vaccination raised in prior discussions.

As was a key factor for the influenza measures, the issue of facility assignment was also discussed in relation to pneumococcal vaccination. Because all types of dialysis are to be included (in-center hemodialysis, home hemodialysis, and peritoneal dialysis), the TEP agreed that assignment should be a function of number of days rather than number of treatments for the reasons mentioned during the influenza discussions. It was again suggested that 30 days should be used as this is the duration typically used internally by facilities when assuming the role of primary provider over a patient. Following further debate between 14 and 30 days, there was consensus that 30 days would be most appropriate after considering feasibility of implementation and harmonization with other facility practices. It was agreed that this time period should also be applied to the influenza measures previously discussed.

3.3.3 Data Collection and Measure Feasibility

Feasibility and meaningful data collection were central to the TEP's deliberations regarding measure development for pneumococcal vaccination, particularly given the complex nature of the CDC guidelines. It was

noted that determining up-to-date vaccination status would require knowing potentially a long history of vaccination for each patient. It was argued that this would be very difficult to achieve as it would be dependent on a facility's ability to obtain vaccination records from other providers (for example, hospitals, pediatrician offices, etc). As this is often a challenge and patients frequently are unsure of the details of their own vaccination history, questions were raised regarding how a facility should manage patients where such information is missing. Because vaccination coverage in high-risk groups is expected to be low, it was suggested that patients with unknown status be treated as vaccine-naïve, or unvaccinated. Further, if patients only know they received a pneumococcal vaccine, it was deemed acceptable to assume the vaccine was PPSV23, due to the very recent nature of the PCV13 recommendation, however such an assumption will be less stable over time. Though there was general consensus that obtaining and maintaining vaccination history data over a five-year period or longer would present a challenge, the majority of the TEP agreed that it would be both feasible and sufficiently meaningful from a quality of care perspective to proceed with recommending one or more measures for pneumococcal vaccination.

In order to assess logistics, it was important for the TEP to evaluate CROWNWeb as a potential data source for the pneumococcal vaccination measures being proposed. As was done for influenza, the TEP examined current data collection elements as well as preliminary data. The TEP was reminded that CROWNWeb data have not been formally validated or subjected to reliability testing. The issue of missing data and incomplete facility reporting was also revisited to urge caution when interpreting preliminary results.

The data elements currently used to collect information for pneumococcal vaccination in CROWNWeb were developed in tandem with the influenza elements and thus closely resemble those fields. A screenshot of the vaccination data entry screen with pneumococcal elements highlighted is presented in Figure 3.

A description of the data entry logic is provided below:

Pneumococcal Vaccination Not Received:

- ☐ No → Pneumococcal Vaccination Date: [YYYY]
- ☐ Yes → Reason No Pneumococcal Vaccination:
 - ☐ Medical Reason
 - ☐ Personal Reason
- Pneumococcal Exclusion Reason:
 - [If Medical] → ☐ Allergic ☐ Adverse Reaction ☐ Other Medical
 - [If Personal] → ☐ Cultural ☐ Personal Choice

Figure 3. Screenshot of CROWNWeb vaccination data entry tab, highlighting elements for pneumococcal vaccination.

Vaccination

Influenza Vaccination Not Received ☐

Influenza Vaccination Date 06/2011

Site Received Influenza Vaccination Received Outside Facility

Reason No Influenza Vaccination

Influenza Exclusion Reason

Pneumococcal Vaccination Not Received ☐

Pneumococcal Vaccination Year 2011

Reason No Pneumococcal Vaccination

Pneumococcal Exclusion Reason

Hepatitis B Vaccination Not Received ☐

Hepatitis B Vaccination Initial 1 06/15/2011

Hepatitis B Vaccination Initial 2 06/16/2011

Hepatitis B Vaccination Initial 3 06/17/2011

Hepatitis B Vaccination Initial 4 06/18/2011

Reason No Hepatitis B Vaccination

Hepatitis B Exclusion Reason

Hepatitis B Booster Date 1 06/15/2011

Hepatitis B Booster Date 2 06/16/2011

Hepatitis B Booster Date 3 06/17/2011

Hepatitis B Booster Date 4 06/18/2011

Hepatitis B Test Type (HBsAg) HBsAg (Hepatitis B surface antigen)

Other Hepatitis B Test Type

Anti-HBs (mIU/ml)

Hepatitis C Screen Test Recombinant Immunoblot Assay

Other Hepatitis C Screen Test

Preliminary analyses of facility-level pneumococcal vaccination rates using data from May-November 2012 were developed by Arbor Research/UM-KECC and presented to the TEP (Table 6). Vaccination within the last five years was calculated as a proxy for up-to-date status for the purpose of this analysis. Results were provided for mean percents of vaccination within the last five years (50.6%), refusal (14.4%), and medical contraindication (29.8%). Separately, results were also provided for mean percent of vaccination in 2012 (15.2%). It was discussed that these data elements suffered from similar limitations as those observed for the influenza analyses. If the vaccination is not administered for any reason other than patient refusal or medical contraindication, this would not be captured. The previously discovered practice of facilities using 'Other Medical Reason' under these circumstances was even more pronounced for pneumococcal vaccination, where the mean facility percent of this category was 29.8%, accounting for nearly all of the medical contraindication exclusions. It was hypothesized that this field is being selected when the patient is, in fact, up-to-date, because the frequency of true medical contraindication was expected to be close to 0%. Finally, it was suggested that the data elements would benefit from greater clarity in general. For example, it was recommended that information on PPSV23 and PCV13 be collected separately. It was also proposed that the site where the vaccine was administered be collected for pneumococcal vaccination as it is for influenza. It was noted that this is particularly important among pediatric patients who may be more likely to receive the vaccine from a pediatrician and for incident patients who may have received the vaccine at a hospital prior to entry to the dialysis facility. At the conclusion of this discussion there was strong consensus among TEP members that the CROWNWeb data collection elements should be revised.

Table 6. Facility-level pneumococcal vaccination rates, May-November 2012 (CROWNWeb)*†

<i>Measure</i>	<i># of facilities</i>	<i>Mean</i>	<i>Std Dev</i>	<i>5th Pctl</i>	<i>50th Pctl</i>	<i>95th Pctl</i>
% Vaccinated, Refused, or Contraindicated (<i>Vaccinated in last 5 years</i>)	3725	97.0	5.9	85.2	100.0	100.0
% Vaccinated Ever	3725	53.7	30.2	0.0	59.1	96.5
% Vaccinated in Last 5 Years	3725	50.6	28.9	0.0	55.6	92.0
% Vaccinated in 2012	3725	15.2	15.5	0.0	10.9	47.6
% Refused	3725	14.4	22.7	0.0	5.9	71.4
% Medical Contraindication	3725	29.8	32.2	0.0	17.9	95.9
% Allergy or Adverse Reaction	3725	0.1	0.5	0.0	0.0	0.0
% Other Medical Reason	3725	29.8	32.2	0.0	17.8	95.9

*Analyses based on data from CROWNWeb among facilities reporting anytime during the period May 1 through Nov 30 2012. Facilities with <5 patients were excluded.

†Among all patients regardless of duration on dialysis, duration at the facility, and vital status on Nov 30.

The proposed revised data elements are provided below:

PPSV23 Pneumococcal Vaccination Received:

- ☐ No → Reason No PPSV23 Vaccination:
- ☐ Medical Reason: Allergic or Adverse Reaction
 - ☐ Other Medical Reason
 - ☐ Declined
 - ☐ Other Reason
- ☐ Yes → Most Recent PPSV23 Vaccination Date: [MM/YYYY]
Where PPSV23 Vaccination Received:
- ☐ Documented At Facility
 - ☐ Documented Outside Facility
- ☐ Unknown

PCV13 Pneumococcal Vaccination Received:

- ☐ No → Reason No PCV13 Vaccination:
- ☐ Medical Reason: Allergic or Adverse Reaction
 - ☐ Other Medical Reason
 - ☐ Declined
 - ☐ Other Reason
- ☐ Yes → Most Recent PCV13 Vaccination Date: [MM/YYYY]
Where PCV13 Vaccination Received:
- ☐ Documented At Facility
 - ☐ Documented Outside Facility

The TEP concluded that the revised data elements designed to be implemented in CROWNWeb would involve slightly greater burden to the facilities than those currently in use. It was agreed, however, that the current elements did not produce data of meaningful or usable quality and that the modest increase in burden related to the revised elements could be outweighed by the value of the information obtained. Here again, however, the issue was raised regarding the challenges that would undoubtedly be faced by requiring dialysis facilities to track lifetime vaccination status for not one, but two pneumococcal vaccines. It was noted that while the completion of the data elements in itself may not represent undue burden, the resultant data may be so inaccurate or incomplete, due to the burden of acquisition, as to render them meaningless for measure calculation. Other TEP members countered that providers have a responsibility to their patients and to follow the clinical practice guidelines and that measures afford the opportunity to incentivize and promote quality care. Ultimately, the TEP concluded that the ability of the two proposed measures to meet the NQF criterion for feasibility was in question, but the majority agreed that it was still important to make the recommendations in the interest of promoting quality care as well as educating CMS and NQF about the significance and difficulty of accurately documenting pneumococcal immunization status among ESRD patients.

3.3.4 Usability

As with the influenza measures, the TEP agreed that, given accurate and consistent data collection, the proposed pneumococcal vaccination measures should provide results that would be meaningful, understandable, and useful for public reporting.

3.4 Proposed Measures

The pneumococcal vaccination measures recommended by the Preventive Care TEP are presented in Tables 7 and 8. Note that the TEP continued to discuss these measures after the TEP meeting, and a summary of those discussions are included in the addendum.

Table 7. Modified Existing NQF Pneumococcal Vaccination Measure (PPSV23).

Denominator	The following patients are included in the denominator: 1) Aged ≥2 years at the start of the reporting period 2) On chronic dialysis ≥30 days in a facility at any point during the 12-month reporting period (in-center or home dialysis)
Numerator	Number of patients from the denominator who (to be calculated and reported separately): 1) have up-to-date PPSV23 vaccine status or received the vaccine during the 12-month reporting period 2) were offered PPSV23 vaccination but declined 3) were determined to have a medical contraindication

Table 8. Pneumococcal Vaccination Measure (PCV13).

Denominator	The following patients are included in the denominator: 1) Aged ≥5 years at the start of the reporting period 2) On chronic dialysis ≥30 days in a facility at any point during the 12-month reporting period (in-center or home dialysis) The following patients are excluded from the denominator: 1) Patients who received PPSV23 vaccination within 12 months prior to the start of the reporting period
-------------	--

Numerator	Number of patients from the denominator who (to be calculated and reported separately): <ol style="list-style-type: none"> 1) ever received the PCV13 vaccination (documented by the dialysis provider or documented off-site vaccination) 2) were offered PCV13 vaccination but declined 3) were determined to have a medical contraindication
-----------	--

4. Hepatitis B Vaccination and Testing Among Dialysis Patients

4.1 Background and Scientific Importance

The TEP opened its discussion of measures for hepatitis B vaccination and testing in dialysis patients by considering the importance of the health problem as well as current clinical practice guidelines. Hepatitis B virus is highly infectious. An untreated percutaneous exposure to an infected source carries a risk of seroconversion of up to 30% [Edey 2010]. In contrast, the risks for hepatitis C virus (HCV) and human immunodeficiency virus (HIV) are 1.8% and 0.31%, respectively [Edey 2010]. In addition to being at increased risk for hepatitis B infection, it has been demonstrated that hemodialysis patients are more likely to become chronic carriers than the general population [Ribot 1979]. Studies have shown that screening and vaccination, along with other facility practices, have been effective at lowering transmission within dialysis units. This is evidenced by a decrease in hepatitis B incidence among chronic hemodialysis from 6.2% in 1974 [Snydman 1977] to 1.0% in 1980 [Alter 1983] and to 0.05% in 2001 [Tokars 2004]. It was noted that no national surveillance data for hepatitis B incidence and prevalence rates among dialysis patients have been published since the 2001 CDC study [Tokars 2004].

Following the discussion of the literature, the TEP was provided with a detailed summary of the clinical practice guidelines published by the CDC recommending hepatitis B vaccination and serological testing among dialysis patients [CDC 2001]. It was noted that these recommendations had been fully adopted by CMS as part of Medicare's Conditions for Coverage for End Stage Renal Disease Facilities [Medicare and Medicaid Programs 2008]. An overview of the specific CDC guidelines is provided below:

- HBV vaccination is recommended for all susceptible chronic HD and PD patients.
 - Patients with a history of HBV vaccination who have surface antibody (anti-HBs) levels <10 mIU/mL when they begin dialysis should be revaccinated with a complete primary series.
- Anti-HBs testing should be performed 1-2 months after the last dose of the vaccine series.
 - Patients with anti-HBs <10 mIU/mL after the primary vaccine series should be revaccinated with an additional 3 doses and retested for anti-HBs 1-2 months later.
 - No additional doses of vaccine are warranted for those who do not respond to the second series.
 - Patients who do not respond to revaccination should be tested monthly for surface antigen (HBsAg).
- The need for booster doses should be assessed by annual anti-HBs testing.
- If anti-HBs declines to <10 mIU/mL, administer a booster dose and continue to retest annually for surface antibody.
 - Retesting immediately for surface antibody after the booster dose is not necessary.
- The HBV serologic status of all patients should be known before admission to the hemodialysis unit. This includes HBsAg, anti-HBs, and total core antibody (anti-HBc).

- If a patient's HBV serologic status is not known at the time of admission, testing should be completed within 7 days of being admitted to the dialysis unit.

Consistent with findings for influenza and pneumococcal vaccination, reports of rates for hepatitis B vaccination and testing among dialysis patients have been lower than recommended clinical targets. A review of the most recent published data available, based on a 2001 survey-based surveillance study conducted by the CDC, indicated 59.8% of dialysis patients had ever received at least three doses of hepatitis B vaccine and only 39.6% had anti-HBs levels ≥ 10 mIU/ml [Tokars 2004]. This study also found that 78.8% of facilities were performing monthly HBsAg testing of susceptible patients. It was noted that this study was conducted the same year the CDC guidelines were published (2001), so the lower hepatitis B vaccination rates measured by Tokars et al do not necessarily reflect facility non-compliance. Rather, these rates describe facility practice and patient prevalence immediately preceding implementation of the updated guidelines.

More recent trends of hepatitis B vaccination and anti-HBs testing using Medicare claims data for the period 2006-2011 were prepared by Arbor Research/UM-KECC and presented to the TEP. The percent of patients receiving at least one dose of hepatitis B vaccine during the measurement year increased from 27.2% in 2006 to 29.8% in 2009, then declined to 26.4% in 2011. A similar pattern was observed for patients receiving at least three doses, ranging from 8.2% in 2006 to 9.5% in 2011 with a peak of 10.8% in 2009. As with pneumococcal vaccination, multi-year analyses showed higher coverage. Over a five-year period (2007-2011) the percent of patients receiving at least one dose was 41.1%, and for patients receiving at least 3 doses it was 21.9%. A slightly different pattern was observed for anti-HBs testing. The percent of patients receiving at least one anti-HBs test during the measurement year increased from 80.5% in 2006 to 86.8% in 2007, then declined to 81.4% in 2011. Because the guidelines specifically recommend testing and vaccination upon entry to a dialysis facility, Arbor Research/UM-KECC performed a sub-analysis of incident dialysis patients. Annual rates for at least one dose of vaccine among this population were slightly higher with an increasing trend from 30.3% to 39.0% during the period 2006-2011. Testing rates, however, showed a steady decline during the same time period from 91.3-80.0% for HBsAg tests and from 85.2-73.2% for anti-HBs tests. It was noted that hepatitis B testing is covered under the ESRD PPS bundle whereas vaccination is not [Federal Register 2010]. It was suggested that the recent decline in claims-based reporting of HBsAg testing in 2011 may be an artifact of reduced submission of claims for testing due to lack of financial incentive rather than a true decline in practice. Following presentation of these results, there was broad consensus that analyses using Medicare claims for hepatitis B vaccination and testing should be interpreted cautiously and should perhaps not be used to inform the TEP's assessment of the presence of a performance gap.

Some TEP members questioned the need for a measure, arguing that the inclusion of the CDC guidelines in Medicare's Conditions for Coverage was sufficient and likely provided greater incentive for compliance than a quality measure could. It was suggested that the development of one or more quality measures could simplify and/or enhance enforcement of the Conditions for Coverage and thus should be considered. It was countered that this is not the purpose of quality measures and enforcement of the Conditions for Coverage should be left to the State surveyors. Further, the absence of recent published data showing deficiencies in vaccination or testing rates combined with a presumed very low incidence of hepatitis B virus among dialysis patients suggested that the implementation of quality measures would not incite actionable modifications in practice. Other TEP members disagreed, stressing that the absence of recent data was not evidence of absence of a problem. Some concerns were raised about the growing immigrant populations that come to the US from regions with relatively high HBV prevalence. A rise in background HBV prevalence could cascade to the dialysis population, leading to an increased risk of seroconversion if proper prevention practices are not in place. In response, it was argued that seroconversion can occur due to events beyond the dialysis facility's control. However, a quality measure would not distinguish between events resulting from poor facility practice and events stemming from unrelated causes, so measuring seroconversion would not serve as a pure indicator of

quality. Ultimately, there was unanimous agreement that the absence of recent data on hepatitis B vaccination and testing rates as well as absence of recent data on HBV incidence and prevalence among dialysis patients is a major problem. Though evidence of a performance gap may currently be insufficient to support the development of one or more quality measures, it was decided to pursue discussion of recommendations for collecting updated data so that this topic could be reexamined in the future.

4.2 Existing Measure

There are presently no NQF-endorsed measures related to hepatitis B vaccination or testing in any patient population. However, the TEP did briefly review one unendorsed pre-existing physician-level measure for hepatitis B vaccination among hepatitis C positive patients developed jointly by the American Gastroenterological Association Institute and the Physician Consortium for Performance Improvement. The key characteristics of this measure are presented in Table 9. In light of the absence of pre-existing measures, a number of proposed measure descriptions were also developed and discussed by the TEP (Table 10). However, because the TEP concluded there was insufficient recent data to support the need for developing one or more measures related to hepatitis B vaccination and testing among dialysis patients, it was decided to devote more time to discussing data collection needs rather than refining the proposed measure descriptions.

Table 9. Key components of the pre-existing quality measure for hepatitis B vaccination among hepatitis C positive patients developed by the American Gastroenterological Association Institute and the Physician Consortium for Performance Improvement.

Description	Percentage of patients aged 18 years and older with a diagnosis of hepatitis C who have received at least one injection of hepatitis B vaccine, or who have documented immunity to hepatitis B.
Denominator	All patients aged 18 years and older with a diagnosis of hepatitis C. Excludes patients with: <ul style="list-style-type: none">Documentation of a medical or patient reason for not administering at least one injection of hepatitis B vaccination.
Numerator	Patients who have received at least one injection of hepatitis B vaccine, or who have documented immunity to hepatitis B.

Table 10. Hepatitis B vaccination and testing measure descriptions proposed and discussed by the Preventive Care TEP.

Hepatitis B screening among incident dialysis patients	Facility percentage of patients who received testing for hepatitis B surface antigen (HBsAg), hepatitis B surface antibody (anti-HBs), and hepatitis B core antibody (anti-HBc) within 30 days before initiating chronic dialysis or within 7 days after initiating chronic dialysis.
Hepatitis B vaccination among incident dialysis patients	Yearly average of the percentage of susceptible patients who received ≥3 doses of hepatitis B vaccine within 9 months of chronic dialysis initiation. *Susceptible is defined as testing negative for all three tests: HBsAg, anti-HBs (<10mIU/ml), total anti-HBc within 30 days of initiating chronic dialysis.
Routine hepatitis B surface	Among facility chronic dialysis patients whose most recent hepatitis B

antibody (anti-HBs) screening	surface antibody (anti-HBs) test in the prior year was $\geq 10\text{mIU/ml}$ or who received a booster dose of the hepatitis B vaccine in the prior year, the facility percentage who were tested at least once for hepatitis B surface antibody (anti-HBs) during the current measurement year.
Hepatitis B vaccination boosters	Among the facility's chronic dialysis patients whose most recent hepatitis B surface antibody (anti-HBs) test in the prior year was $\geq 10\text{mIU/ml}$ or who received a booster dose of the hepatitis B vaccine in the prior year, the facility percentage who received ≥ 1 dose of hepatitis B vaccine within 30 days of a hepatitis B surface antibody (anti-HBs) test of $< 10\text{mIU/ml}$ during the current measurement year.
Hepatitis B seroconversion	Among chronic dialysis facility patients who were being treated by the facility as of January 1 of the current measurement year and who were negative for their most recent hepatitis B surface antigen (HBsAg) test in the prior year, the facility percentage who ever tested positive for hepatitis B surface antigen (HBsAg) during the current measurement year.

4.3 New Measure Development

4.3.1 Numerator and Denominator Definitions

Due to the TEP's decision to focus on data collection recommendations rather than measure specification development, numerator and denominator definitions were not addressed.

4.3.2 Data Collection and Measure Feasibility

Given the absence of recent published data reporting on HBV incidence and prevalence as well as vaccination and testing rates among dialysis patients, a central topic of discussion for the TEP involved evaluating data collection, particularly in CROWNWeb. The data elements currently used to capture information for hepatitis B vaccination in CROWNWeb were designed in parallel to those developed for influenza and pneumococcal vaccination, though they also allow for up to four vaccination dates to account for the multi-dose series. Data elements are also in place for recording booster vaccine doses, routine anti-HBs test dates and results, and additional testing such as HBsAg or anti-HBc. A screenshot of the vaccination data entry screen with hepatitis B elements highlighted is presented in Figure 4.

A description of the data entry logic is provided below:

Hepatitis B Vaccination Not Received:

- ☐ No → Hepatitis B Vaccination Initial 1: [MM/DD/YYYY]
Hepatitis B Vaccination Initial 2: [MM/DD/YYYY]
Hepatitis B Vaccination Initial 3: [MM/DD/YYYY]
Hepatitis B Vaccination Initial 4: [MM/DD/YYYY]

- ☐ Yes → Reason No Hepatitis B Vaccination:
 - ☐ Medical Reason
 - ☐ Personal Reason

- Hepatitis B Exclusion Reason:

[If Medical] → ☐ Allergic ☐ Adverse Reaction ☐ Other Medical
[If Personal] → ☐ Cultural ☐ Personal Choice

Hepatitis B Booster Information:

Hepatitis B Booster Date 1: [MM/DD/YYYY]

Hepatitis B Booster Date 2: [MM/DD/YYYY]

Hepatitis B Booster Date 3: [MM/DD/YYYY]

Hepatitis B Booster Date 4: [MM/DD/YYYY]

Hepatitis B Testing Information:

Hepatitis B Test Type (HBsAg): [**flagged for removal*]

- ☐ HBsAg
- ☐ Anti-HBc
- ☐ Anti-HBs
- ☐ IgM Anti-HBc
- ☐ Other → Other Hepatitis B Test Type: [*free text*]

Hepatitis B Test Date: [MM/DD/YYYY] [**flagged for removal*]

Anti-HBs (mIU/ml): _____ [*free text*]

Anti-HBs (mIU/ml) Date: _____ [MM/DD/YYYY]

Figure 4. Screenshot of CROWNWeb vaccination data entry tab, highlighting elements for hepatitis B vaccination and testing.

Vaccination

Influenza Vaccination Not Received ☐

Influenza Vaccination Date 06/2011

Site Received Influenza Vaccination Received Outside Facility

Reason No Influenza Vaccination

Influenza Exclusion Reason

Pneumococcal Vaccination Not Received ☐

Pneumococcal Vaccination Year 2011

Reason No Pneumococcal Vaccination

Pneumococcal Exclusion Reason

Hepatitis B Vaccination

Hepatitis B Vaccination Not Received ☐

Hepatitis B Vaccination Initial 1 06/15/2011

Hepatitis B Vaccination Initial 2 06/16/2011

Hepatitis B Vaccination Initial 3 06/17/2011

Hepatitis B Vaccination Initial 4 06/18/2011

Reason No Hepatitis B Vaccination

Hepatitis B Exclusion Reason

Hepatitis B Booster Date 1 06/15/2011

Hepatitis B Booster Date 2 06/16/2011

Hepatitis B Booster Date 3 06/17/2011

Hepatitis B Booster Date 4 06/18/2011

Hepatitis B Test Type (HBsAg) HBsAg (Hepatitis B surface antigen)

Other Hepatitis B Test Type

Anti-HBs (mIU/ml)

mm/dd/yyyy

Hepatitis C Screen Test Recombinant Immunoblot Assay

Other Hepatitis C Screen Test

Limited preliminary analyses of facility-level hepatitis B vaccination and testing rates using CROWNWeb data from May-November 2012 were developed by Arbor Research/UM-KECC and presented to the TEP. The mean percent of patients ever receiving at least one dose of hepatitis B vaccine was 66.5%, and it was 25.0% for ever receiving at least three doses (Table 11). Additional results were provided for mean percents of patients receiving at least one dose of vaccine in 2012 (32.9%), vaccine refusal (9.8%), and medical contraindication (21.2%). Separately, mean percents of ever receiving a test for anti-HBs (54.2%) and receiving a test for anti-HBs in 2012 (48.8%) were also reported (Table 12).

Table 11. Facility-level hepatitis B vaccination rates, May-November 2012 (CROWNWeb)*[†]

<i>Measure</i>	<i># of Facilities</i>	<i>Mean</i>	<i>Std Dev</i>	<i>5th Pctl</i>	<i>50th Pctl</i>	<i>95th Pctl</i>
% Vaccinated (≥1 Dose Ever)	3725	66.5	28.8	0.0	76.7	97.4
% Vaccinated (≥3 Doses Ever)	3725	25.0	29.3	0.0	7.7	77.6
% Vaccinated (≥1 Dose in 2012)	3725	32.9	18.3	0.0	33.3	62.5
% Refused	3725	9.8	20.6	0.0	2.0	51.3
% Medical Contraindication	3725	21.2	25.7	0.0	11.1	83.8
% Allergy or Adverse Reaction	3725	0.2	1.2	0.0	0.0	0.9
% Other Medical Reason	3725	21.0	25.7	0.0	10.9	83.8

*Analyses based on data from CROWNWeb among facilities reporting anytime during the period May 1 through Nov 30 2012. Facilities with <5 patients were excluded.

[†]Among all patients regardless of duration on dialysis, duration at the facility, and vital status on Nov 30.

Table 12. Facility-level hepatitis B surface antibody (anti-HBs) testing rates, May-November 2012 (CROWNWeb)*[†]

<i>Measure</i>	<i># of Facilities</i>	<i>Mean</i>	<i>Std Dev</i>	<i>5th Pctl</i>	<i>50th Pctl</i>	<i>95th Pctl</i>
% anti-HBs (Ever) [§]	3725	54.2	43.8	0.0	75.7	100.0
% anti-HBs (2012) [§]	3725	48.8	42.4	0.0	57.1	100.0
% Missing anti-HBs Data	3725	45.8	43.8	0.0	24.3	100.0
% >1 anti-HBs Test [†]	3725	4.2	13.2	0.0	0.0	32.2
% anti-HBs Numeric ^{§†}	2876	91.2	22.4	33.3	100.0	100.0
% Numeric (≥10 mIU/ml) ^{§‡}	2796	87.0	23.3	39.0	100.0	100.0

*Analyses based on data from CROWNWeb among facilities reporting anytime during the period May 1 through Nov 30 2012. Among all patients regardless of duration on dialysis, duration at the facility, and vital status on Nov 30.

[§]Uses the most recent anti-HBs test as determined by the test date.

[†]As determined by anti-HBs test date.

[‡]Denominator includes only facilities with at least one anti-HBs test.

[‡]Denominator includes only facilities with at least one numeric anti-HBs test.

Review of these results in concert with the data collection screenshot led many TEP members to conclude the data elements would benefit from substantial revision. The TEP identified a series of limitations. With respect to vaccination data entry, it is unclear if the “initial” hepatitis B vaccination dates refer to the first ever series (for example, as a child), or the first series as a dialysis patient. For booster dates, it is unclear if this refers to booster doses following a full multi-dose series or if it refers to any dose following the first dose of a series. The lack of data carry-over from month to month complicates this issue, as facilities are required to reenter all of these dates each time, resulting in a number of data quality concerns. With respect to testing, it was noted that designation of anti-HBs test result as a free-text field was highly problematic, as that could potentially produce a

substantial amount of unusable data. Concern was also expressed over the other testing fields being flagged for removal. This would result in no data collection for tests such as HBsAg and anti-HBc, which are routine for certain patients and important for determining infection status [CDC 2001]. It was suggested, however, that if these data were to continue being collected in CROWNWeb, the data elements would need to be revised to allow for multiple tests per month as well as include places to enter test results. It was emphasized that it would be insufficient to collect only the fact that a test was performed, rather the result is just as if not more important.

The TEP concluded that the data elements as they are currently constructed would not be usable for any potential measure. There was also concern that the data elements did not fully align with the vaccination and testing requirements outlined in the Conditions for Coverage. It was suggested that revising the data elements to capture all the data needed to evaluate compliance with the Conditions for Coverage would place undue burden on the facilities, especially given that facilities are already assessed for compliance by State surveyors. Others countered that the surveys are infrequent and do not produce a consistent, nationally representative source of data for reviewing vaccination and testing rates. Ultimately, though the increased burden on facilities was acknowledged, it was agreed that hepatitis B data elements should continue to be collected but in substantially revised form. Rather than recommend specific data elements, as with influenza and pneumococcal vaccination, the TEP decided to recommend that the new data elements for hepatitis B be redesigned to better reflect the requirements indicated in the CDC guidelines and Conditions for Coverage.

4.3.3 Usability

There was broad consensus that it would be difficult to achieve accurate and consistent data collection. Some TEP members questioned whether it would be possible to ever develop measures that could produce results that would be meaningful, understandable, and useful for public reporting. Others argued that it was still important to try despite the obvious challenges. The TEP ultimately agreed this topic would benefit from reexamination once more recent data are available.

4.4 Proposed Measures

The TEP unanimously agreed not to propose any measures related to hepatitis B vaccination or testing among dialysis patients. Rather, the TEP made formal recommendations related to improved data collection and reevaluation of this issue pending availability of recent and reliable data. These recommendations are presented below.

1. Hepatitis B data should be collected in a way that would be meaningful, interpretable, and consistent with the requirements in Medicare's Conditions for Coverage.
2. Measure development should be re-evaluated after sufficient data have been collected and analyzed.

5. Influenza and Hepatitis B Vaccination Among Healthcare Personnel

5.1 Background and Scientific Importance

The TEP began its deliberation of measures for vaccination among healthcare personnel (HCP) by reviewing recent published data as well as current clinical practice guidelines. Due to the absence of clinical practice guidelines or scientific evidence supporting special consideration for pneumococcal vaccination among HCP, only measures for influenza and hepatitis B vaccination were evaluated by the TEP. Because HCP may have frequent contact with infectious patients or infective patient material, they are at higher risk for exposure and possible spread of vaccine-preventable diseases. It was noted that prevention of illness through comprehensive personnel vaccination programs is more cost-effective than case management or outbreak control. A recent

study was described that showed influenza vaccination reduced infection among HCP by 88% and decreased HCP work absence due to respiratory illness by 28% [Talbot 2005]. With respect to the impact of HCP vaccination on patient outcomes, two studies in geriatric long-term care facilities were discussed. Both studies reported significantly lower patient all-cause mortality at sites where HCP were routinely vaccinated compared to sites where routine vaccination was not offered (10% vs 17% mortality, and 14% vs 22% mortality) [Carman 2000; Potter 1997]. A meta-analysis of studies examining the effect of influenza vaccination among HCP who work with geriatric patients was also described. Results indicated that, across all included studies, patients had a 32% lower risk of dying when HCP were vaccinated (OR=0.68; 95% CI: 0.55-0.84) [Thomas 2010].

Following discussion of the literature, the TEP was presented with a summary of the clinical practice guidelines published by the CDC recommending universal influenza and hepatitis B vaccination among HCP. The influenza vaccination guidelines state [CDC 2011]:

- Annual influenza vaccinations should be administered to all healthcare personnel.
- Live attenuated vaccine (LAIV) can be used for healthcare personnel in any setting, except those who care for severely immunocompromised hospitalized persons who require care in a protective environment.
- Vaccination efforts should begin as soon as vaccine is available and continue through the influenza season.

The hepatitis B vaccination guidelines state [CDC 2001]:

- Hepatitis B vaccinations should be administered to all healthcare personnel.
- Surface antibody (anti-HBs) testing should be performed 1-2 months after the last dose of the vaccine series.
 - Healthcare personnel with anti-HBs <10 mIU/ml after the primary vaccine series should be revaccinated with an additional three doses and retested for anti-HBs 1-2 months later.
 - No additional doses of vaccine are warranted for those who do not respond to the second vaccine series.
 - Healthcare personnel who do not respond to revaccination should be tested for surface antigen (HBsAg).
- For healthcare personnel who respond to the vaccine, booster doses are not necessary, and periodic serologic testing to monitor anti-HBs is not recommended.
- Routine testing of healthcare personnel is not recommended except when required to document response to hepatitis B vaccination.

It was noted that the Healthy People 2010 and 2020 vaccination goals are 90% for both influenza and hepatitis B vaccination among HCP [Healthy People 2020]. Current data for influenza vaccination rates among HCP specifically in dialysis facilities were unavailable. However, a recent analysis of the CMS Minimum Data Set (MDS) reported a vaccination rate of 45.5% among HCP in nursing homes for the 2008-2009 influenza season [Healthy People 2020]. Results from the 2009 National Health Interview Survey indicated hepatitis B vaccination rates were 64.3% among HCP [Healthy People 2020], however a 2001 survey-based study conducted by the CDC reported a vaccination rate of 88.7% in dialysis facilities [Tokars 2004]. The TEP concluded that there was sufficient evidence supporting the importance of influenza vaccination among HCP and that it was significantly associated with improved patient outcomes. Though published data demonstrating a performance gap were limited, some TEP members cited anecdotal reports of inadequate influenza vaccination among HCP in dialysis facilities. It was suggested that the strength of evidence supporting further discussion of hepatitis B vaccination among HCP was less clear. Though it was agreed that vaccination was important, the question was raised regarding the degree to which vaccinating HCP against hepatitis B virus protects patients from infection. There

was consensus that the primary reason for vaccination is to protect HCP in case of accidental exposure from an infected patient. There are currently insufficient data to support the assertion that vaccinating HCP protects patients. Moreover, there are insufficient data to suggest a performance gap. Facilities are required to vaccinate all staff against hepatitis B virus as indicated in the Conditions for Coverage, and there are no data to suggest this is not occurring. Further, the lack of existing measures in other care settings suggests this is not an issue that has required measures to incentivize practice. The TEP unanimously agreed not to recommend developing a measure for hepatitis B vaccination among HCP in the dialysis facility setting.

5.2 Existing Measures

5.2.1 Influenza

There is currently one pre-existing measure for influenza vaccination among HCP in multiple care settings which was developed by the CDC and endorsed by the NQF on July 31, 2008 with an update on May 2, 2012 (NQF #0431). The key characteristics of the CDC measure are presented in Table 13. This measure consists of a three-part denominator, calculating the percentage of HCP receiving the influenza vaccine separately for employees, licensed independent practitioners, and adult students/volunteers. As with the KCQA influenza measure, the numerator includes those who receive, decline, and are medically contraindicated for the vaccine. However, the CDC numerator also includes a fourth category for HCP with unknown status. The vaccination measurement period is also consistent with the KCQA measure, capturing vaccinations between October 1 and March 31 of the following year. Initial reactions to this measure were positive with only a few minor changes suggested in order to better harmonize this measure with the proposed patient influenza vaccination measures discussed previously. It was agreed that discussion should proceed for determining 1) if the vaccination measurement period should be expanded to start earlier than October, 2) if the fourth component of the numerator (unknown status) should be dropped, and 3) if the inclusion of students and volunteers in the denominator was appropriate and feasible.

Table 13. Key components of the CDC quality measure for influenza vaccination among healthcare personnel.

Description	Percentage of healthcare personnel (HCP) who receive the influenza vaccination.
Denominator	<p>Number of HCP who are working in the healthcare facility for ≥ 30 working days between Oct 1 and Mar 31 of the following year, regardless of clinical responsibility or patient contact. To be calculated separately for:</p> <ol style="list-style-type: none"> 1) Employees: all persons who receive a direct paycheck from the reporting facility 2) 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 3) Adult students/trainees and volunteers: include all adult students/trainees and volunteers who do not receive a direct paycheck from the reporting facility
Numerator	<p>HCP in the denominator population who during the time from Oct 1 (or when the vaccine became available) through Mar 31 of the following year (to be calculated separately):</p> <ol style="list-style-type: none"> 1) Received an influenza vaccination administered at the healthcare facility, or reported in writing or provided documentation that influenza vaccination was received elsewhere 2) Were determined to have a medical contraindication 3) Declined influenza vaccination 4) Persons with unknown vaccination status or who do not otherwise meet any of the definitions of the above-mentioned numerator categories

5.3 New Measure Development

5.3.1 Numerator Definition

In order to harmonize the HCP measure with the recommended patient measures previously discussed, the TEP agreed the vaccination measurement period should begin August 1 instead of October 1. Subsequent discussion focused on the end date as TEP members considered whether a December 31 end date would be more appropriate than March 31. As with the patient measures, the central issue was whether to incentivize early vaccination or encourage vaccination throughout the entire season, which is important in cases when early vaccination is missed. The possibility of two measures in parallel to the patient measures was raised but quickly dismissed by the TEP as unnecessary for the HCP population. Ultimately it was decided to retain the March 31 end date for the vaccination measurement period as this would be the most inclusive with regard to HCP vaccination.

In further evaluating the existing CDC measure, the TEP considered the four-part numerator and whether it would benefit from any modification. A question was raised regarding whether to allow for self-reported vaccination as was accepted for the patient measures. Whereas it might be difficult to enforce among patients, it was agreed that HCP should be required to produce documentation that they received the vaccine outside the facility and that this requirement should be incorporated into the measure language. The TEP also discussed the fourth component of the CDC numerator, which includes HCP of unknown vaccination status. It was expressed that this component was confusing and that HCP of unknown status should be considered unvaccinated and not included in the numerator. It was agreed that the proposed HCP measure should only incorporate the three-part numerator as seen before, calculating separately HCP who received, refused, or were contraindicated for the influenza vaccine, to be consistent with the TEP's proposed patient influenza vaccination measures and in agreement with NQF's specifications for harmonized immunization measures [NQF 2008].

5.3.2 Denominator Definition

In general, the TEP was supportive of the denominator as specified in the existing CDC measure. There was broad agreement with the time period of October 1 through March 31 as well as the 30 working day requirement. There was further support for the separate calculation of denominator components based on different types of HCP. A concern was raised about the inclusion of adult students/trainees and volunteers. It was noted that it would be quite difficult for facilities to track how many days HCP in this group had worked at a facility. Their presence can be sporadic and inconsistent, and many may not work a total of 30 days during the influenza season. For feasibility reasons, it was decided that this group should be excluded, and the denominator should be restricted to employees and licensed independent practitioners.

5.3.3 Data Collection and Measure Feasibility

Data for influenza vaccination among HCP are currently not captured in CROWNWeb, so no existing data elements were available for review. The TEP agreed that, if CMS supported the recommendation to incorporate HCP influenza vaccination data collection in CROWNWeb, it would be possible to define data elements that would result in limited additional burden to facilities and produce meaningful data for use in a quality measure. An example of data elements that could be used for the proposed measure are provided below:

Influenza Vaccination Received Between Aug 1, XXXX and Mar 31, XXXX:

- ☐ No → Reason No Influenza Vaccination:
 - ☐ Medical Reason: Allergic or Adverse Reaction
 - ☐ Other Medical Reason
 - ☐ Declined

☐ Other Reason

☐ Yes → Influenza Vaccination Date: [MM/YYYY]

Where Influenza Vaccination Received:

☐ Documented At Facility

☐ Documented Outside Facility

5.3.4 Usability

There was consensus that, given the addition of data elements to CROWNWeb as well as accurate and consistent data collection, the proposed HCP influenza vaccination measure should provide results that would be meaningful, understandable, and useful for public reporting.

5.4 Proposed Measures

5.4.1 Influenza

The influenza vaccination measure proposed by the Preventive Care TEP is presented in Table 14. Note that the TEP continued to discuss this measure after the TEP meeting, and a summary of those discussions are included in the addendum.

Table 14. Modified Existing NQF HCP Influenza Vaccination Measure.

Denominator	Number of HCP who are working in the healthcare facility for ≥30 working days between Oct 1 and Mar 31 of the following year, regardless of clinical responsibility or patient contact. To be calculated and reported separately for: <ol style="list-style-type: none">1) Employees: all persons who receive a direct paycheck from the reporting facility2) 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
Numerator	HCP who during the time from Aug 1 (or when the vaccine became available) through Mar 31 of the following year (to be calculated and reported separately): <ol style="list-style-type: none">1) received an influenza vaccination administered at the healthcare facility, or reported in writing or provided documentation that influenza vaccination was received elsewhere2) were offered an influenza vaccination but declined3) were determined to have a medical contraindication

5.4.2 Hepatitis B

The TEP unanimously agreed not to propose any measures related to hepatitis B vaccination among HCP in the dialysis care setting for the following reasons:

1. The process of vaccinating HCP against hepatitis B virus is more about protecting HCP than patients.
2. HBV vaccination among HCP is already required as part of Conditions for Coverage.
3. There are insufficient data to determine whether a performance gap exists.

6. Conclusion

The Preventive Care TEP discussed the development of quality measures in the areas of influenza, pneumococcal, and hepatitis B vaccination and testing among dialysis patients and healthcare personnel. After careful consideration of the scientific evidence, the TEP made the following recommendations:

- Two patient measures for influenza vaccination with different measurement periods, reflecting two separate incentives 1) early vaccination to ensure immunity prior to peak influenza season, and 2) vigilant vaccination of patients new to a facility during the second half of the influenza season.
- Revised data collection in CROWNWeb for pneumococcal vaccination. Data elements should be as follows:
 - Influenza Vaccination Received *This Month*:
 - ☐ No → Reason No Influenza Vaccination:
 - ☐ Already vaccinated this flu season
 - ☐ Medical Reason: Allergic or Adverse Reaction
 - ☐ Other Medical Reason
 - ☐ Declined
 - ☐ Other Reason
 - ☐ Yes → Influenza Vaccination Date: [MM/YYYY]
Where Influenza Vaccination Received:
 - ☐ Documented At Facility
 - ☐ Documented Outside Facility
 - ☐ Patient Self-Reported Outside Facility
- Two patient measures for pneumococcal vaccination 1) up-to-date vaccination status for PPSV23, and 2) lifetime vaccination status of PCV13.
- Revised data collection in CROWNWeb for pneumococcal vaccination. Data elements should be as follows:
 - PPSV23 Pneumococcal Vaccination Received:
 - ☐ No → Reason No PPSV23 Vaccination:
 - ☐ Medical Reason: Allergic or Adverse Reaction
 - ☐ Other Medical Reason
 - ☐ Declined
 - ☐ Other Reason
 - ☐ Yes → *Most Recent* PPSV23 Vaccination Date: [MM/YYYY]
Where PPSV23 Vaccination Received:
 - ☐ Documented At Facility
 - ☐ Documented Outside Facility
 - ☐ Unknown
 - PCV13 Pneumococcal Vaccination Received:
 - ☐ No → Reason No PCV13 Vaccination:

- ☐ Medical Reason: Allergic or Adverse Reaction
- ☐ Other Medical Reason
- ☐ Declined
- ☐ Other Reason

☐ Yes → Most Recent PCV13 Vaccination Date: [MM/YYYY]

Where PCV13 Vaccination Received:

- ☐ Documented At Facility
- ☐ Documented Outside Facility

- No measure but improved data collection in CROWNWeb for hepatitis B vaccination and testing among patients to enable future discussion of quality measures in this area. Data elements should be constructed to reflect requirements in Medicare's Conditions for Coverage for End Stage Renal Disease Facilities.
- One measure for influenza vaccination among healthcare personnel modeled after the NQF-endorsed measure developed by the CDC with modifications to the vaccination measurement period and denominator specifications.
- Data collection in CROWNWeb for influenza vaccination among healthcare personnel. Data elements should be as follows:

Influenza Vaccination Received Between Aug 1, XXXX and Mar 31, XXXX:

☐ No → Reason No Influenza Vaccination:

- ☐ Medical Reason: Allergic or Adverse Reaction
- ☐ Other Medical Reason
- ☐ Declined
- ☐ Other Reason

☐ Yes → Influenza Vaccination Date: [MM/YYYY]

Where Influenza Vaccination Received:

- ☐ Documented At Facility
- ☐ Documented Outside Facility

- No measure for hepatitis B vaccination among healthcare personnel.

Note that the TEP continued to discuss these measures after the TEP meeting, and a summary of those discussions are included in the addendum.

7. References

Alter MJ, Favero MS, Petersen NJ, Doto IL, Leger RT, Maynard JE. National surveillance of dialysis-associated hepatitis and other diseases: 1976 and 1980. *Dial Transplant*. 1983;12:860-5.

Bond TC, Spaulding AC, Krisher J, et al. Mortality of dialysis patients according to influenza and pneumococcal vaccination status. *Am J Kidney Dis*. 2012;60:959-65.

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 randomized controlled trial. *Lancet*. 200;355(9198):93-7.

Centers for Disease Control and Prevention (CDC). Recommendations for Preventing Transmission of Infections Among Chronic Hemodialysis Patients. *MMWR* 2001;50(RR-5):1-43.

Centers for Disease Control and Prevention (CDC). Prevention and Control of Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR* 2010a;59(RR-8):1-62.

Centers for Disease Control and Prevention (CDC). Prevention of Pneumococcal Disease Among Infants and Children — Use of 13-Valent Pneumococcal Conjugate Vaccine and 23-Valent Pneumococcal Polysaccharide Vaccine: Recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR* 2010b;59(RR-11):1-18.

Centers for Disease Control and Prevention (CDC). Immunization of Health-Care Personnel: Recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR* 2011;60(RR-7):1-45.

Centers for Disease Control and Prevention (CDC). Use of 13-Valent Pneumococcal Conjugate Vaccine and 23-Valent Pneumococcal Polysaccharide Vaccine for Adults with Immunocompromising Conditions: Recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR* 2012;61(40):816-9.

Centers for Disease Control and Prevention (CDC). Seasonal Influenza Vaccine & Total Doses Distributed. *CDC.gov*. Retrieved 05/13/2013 from <http://www.cdc.gov/flu/professionals/vaccination/vaccinesupply.htm>.

Edey M, Barraclough K, Johnson DW. Review article: Hepatitis B and dialysis. *Nephrology*. 2010;15:137-45.

Final Rule: Medicare Program End-Stage Renal Disease Prospective Payment, H. Centers for Medicare & Medicaid Services, Editor. Federal Register, 2010.

Gilbertson DT, Unruh M, McBean AM, et al. Influenza vaccine delivery and effectiveness in end-stage renal disease. *Kidney Int*. 2003;63:738-43.

Gilbertson DT, Guo H, Arneson TJ, et al. The association of pneumococcal vaccination with hospitalization and mortality in hemodialysis patients. *Nephrol Dial Transplant*. 2011;26:2934-9.

Glesby M, Brinson C, Greenberg R, et al. Immunogenicity and safety of 13-valent pneumococcal conjugate vaccine in HIV⁺ adults with prior 23-valent pneumococcal polysaccharide vaccination. Poster presented at the 20th Conference on Retroviruses and Opportunistic Infections 2013. Abstract retrieved from <http://www.retroconference.org/2013b/Abstracts/45746.htm>. Accessed 05/13/2013.

Fuchshuber A, Kühnemund O, Keuth B, et al. Pneumococcal vaccine in children and young adults with chronic renal disease. *Nephrol Dial Transplant*. 1996;11:468-73.

Janus N, Vacher L-V, Karie S, et al. Vaccination and chronic kidney disease. *Nephrol Dial Transplant*. 2008;23:800-7.

Johnson D, Fleming S. The use of vaccines in renal failure. *Clin Pharmacokinet*. 1992;22(6):434-46.

Kallen AJ, Arduino MJ, Patel PR. Preventing infections in patients undergoing hemodialysis. *Expert Rev Anti Infect Ther*. 2010;8:643-55.

Linnemann CC Jr, First MR, Schiffman G. Revaccination of renal transplant and hemodialysis recipients with pneumococcal vaccine. *Arch Intern Med*. 1986;146:1554-6.

Messana J, Wisniewski K, Shearon T, et al. Facility influenza vaccination (IV) practice: Associations with mortality and hospitalizations in the US dialysis population. *J Am Soc Nephrol*. 2010;21:467A.

Medicare and Medicaid Programs; Conditions for Coverage for End-Stage Renal Disease Facilities; Final Rule. Federal Register / Vol. 73, No. 73 / Tuesday, April 15, 2008 / Rules and Regulations, pp. 20369-20484.

National Quality Forum (NQF). National Voluntary Consensus Standards for Influenza and Pneumococcal Immunizations. Washington, DC, 2008.

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

Ribot S, Rothstein M, Goldblat M, et al. Duration of hepatitis B surface antigenemia (HBs Ag) in hemodialysis patients. *Arch Intern Med*. 1979;139:178-80.

Robinson J. Efficacy of pneumococcal immunization in patients with renal disease--what is the data? *Am J Nephrol*. 2004;24:402-9.

Rytel MW, Dailey MP, Schiffman G, et al. Pneumococcal vaccine immunization of patients with renal impairment. *Proc Soc Exp Biol Med*. 1986;182:468-73.

Snydman DR, Bregman D, Bryan JA. Hemodialysis-Associated Hepatitis in the United States, 1974. *J Infect Dis* 1977;135(4):687-91.

Talbot TR, Bradley SE, Cosgrove SE, et al. Influenza vaccination of healthcare workers and vaccine allocation for healthcare workers during vaccine shortages. *Infect Control Hosp Epidemiol*. 2005;26(11):882-90.

Thomas RE, Jefferson T, Lasserson TJ. Influenza vaccination for healthcare workers who work with the elderly. *Cochrane Database of Syst Rev*. 2010;(2):CD005187.

Tokars JJ, Finelli L, Alter MJ, Arduino MJ. National surveillance of dialysis-associated diseases in the United States, 2001. *Semin Dial*. 2004;17(4):310-9.

U.S. Department of Health and Human Services. Office of Disease Prevention and Health Promotion. Healthy People 2020. Washington, DC. Available at <http://www.healthypeople.gov/2020/topicsobjectives2020/objectiveslist.aspx?topicId=23>. Accessed 05/13/2013.

United States Renal Data System, USRDS 2012 Annual Data Report: Atlas of Chronic Kidney Disease and End-Stage Renal Disease in the United States, National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, USA (2012).

End Stage Renal Disease (ESRD)
Quality Measure Development and Maintenance
Preventive Care Clinical Technical Expert Panel Addendum to the Summary Report
Prepared by: Arbor Research Collaborative for Health and The University of Michigan Kidney
Epidemiology and Cost Center
Sent to CMS on July 12, 2013

Contract No. 500-2008-00022I, Task Order No. HHSM-500-T0001

Table of Contents

1. Introduction.....	3
2. Influenza Vaccination Among Dialysis Patients.....	3
2.1 Update to Scientific Evidence for Influenza Vaccination.....	3
3. Pneumococcal Vaccination Among Dialysis Patients	4
3.1 Update to New Measure Development	4
3.2 Update to the Proposed Measures	7
4. Influenza Vaccination Among Healthcare Personnel	8
4.1 Update to Existing Measure	8
5. Conclusion	9
6. Preventive Care TEP Members	9
7. References	10

1. Introduction

The CMS ESRD Preventive Care Technical Expert Panel (TEP) was convened in Baltimore, MD, on April 16-17 to make recommendations regarding the development of quality measures for preventive care among dialysis patients as well as healthcare personnel (HCP) that would reflect consideration of the scientific literature, current clinical practice guidelines, and relevant pre-existing quality measures. Specifically, the TEP was charged to consider measures for the following areas:

- 1) Influenza vaccination among dialysis patients
- 2) Pneumococcal vaccination among dialysis patients
- 3) Hepatitis B vaccination and testing among dialysis patients
- 4) Influenza vaccination among healthcare personnel
- 5) Hepatitis B vaccination and testing among healthcare personnel

A summary of the proceedings of the in-person meeting is provided in the Preventive Care Clinical Technical Expert Panel Final Summary Report. Following the in-person meeting, further discussion was requested for the following areas:

- 1) Influenza vaccination among dialysis patients
- 2) Pneumococcal vaccination among dialysis patients
- 3) Influenza vaccination among healthcare personnel

This addendum to the Preventive Care Clinical Technical Expert Panel Final Summary Report summarizes the discussions subsequent to the in-person meeting. Communications occurring during a conference call held June 10 with follow-up via e-mail through July 11 are included in this addendum.

2. Influenza Vaccination Among Dialysis Patients

2.1 Update to Scientific Evidence for Influenza Vaccination

The TEP was presented with an update to the relevant published literature regarding the impact influenza vaccination has on achieving desired health outcomes. It was noted that the publications presented at the in-person meeting largely focused on patient-level analyses demonstrating a sizable association of influenza vaccination on all-cause mortality for dialysis patients vaccinated versus not vaccinated (Bond 2012 OR = 0.71; Gilbertson 2003 ORs ranged 0.70-0.83). In addition, at the in-person meeting, the TEP was provided with facility-level influenza vaccination results based on Medicare claims data that were previously published by Arbor Research/UM-KECC as an abstract. This work indicated significantly lower standardized mortality (SMR) and hospitalization (SHR) ratios in 2008 in US dialysis facilities having a larger fraction of their Medicare dialysis patients vaccinated for influenza in Sept-Dec 2007 (Messana 2010). These results further showed mean SMRs of 1.08 and 0.91, respectively, for facilities in the lowest quintile (<52% vaccination rate) versus highest quintile (>77% vaccination rate) of facility-level influenza vaccination.

Following the in-person meeting, it was noted that additional literature indicates there is substantial uncertainty regarding the magnitude of survival benefit associated with influenza vaccination, particularly among the elderly. While results from Bond et al (2012) and Gilbertson et al (2003) found a strong association between influenza vaccination and decreased odds of mortality, McGrath et al (2012) provide evidence that this strong association between patient-level influenza vaccination and mortality is likely due to confounding. Their results showed that when the influenza vaccination/mortality relationship was examined for years when the vaccine was well-matched versus not well-matched with the circulating virus, there was a considerably smaller effect of influenza vaccination on mortality and morbidity for ESRD patients than previously published (McGrath 2012). It

was further noted that Wong et al (2012) suggest a much smaller effect of influenza vaccination on mortality and hospitalization in a recent study applying an instrumental variable approach in people >65 yrs old in Ontario over nine consecutive influenza seasons. Other recent work among non-ESRD geriatric populations suggests the survival benefit seen in standard Cox models comparing vaccinated versus non-vaccinated patients may be due in part to treatment by indication bias in which healthier patients are preferentially vaccinated leading to a larger apparent effect size than would be seen in the absence of this confounding (Simonsen 2007).

In response to some of these findings, Arbor Research/UM-KECC recently conducted an analysis of Medicare claims data examining the association of facility-level vaccination and all-cause mortality (represented by SMR) and hospitalization (represented by SHR) over five consecutive influenza seasons. Facility influenza vaccination rate was inversely associated with mortality and hospitalization for all 5 seasons. For mortality, the association was strongest during the 2006-2007 season (2.3% lower SMR per 10% higher facility influenza vaccination rate, $p<0.01$), and weakest during the 2010-2011 season (0.8% lower SMR per 10% higher facility influenza vaccination rate, $p<0.01$). The association between facility influenza vaccination rate and hospitalization was relatively stable over time (1.6-2.2% lower SHR per 10% higher facility influenza vaccination rate, all $p<0.01$). Over this five season time period, facility-level influenza vaccination rates ranged from <47% of facility patients vaccinated to >78% of facility patients vaccinated for the lowest versus highest quintile, respectively. Associations between facility influenza vaccination rate and lower hospitalization appeared robust across seasons, whereas those with mortality were less stable and suggest a more modest effect than previously published. It was emphasized that variation in vaccine efficacy and seasonal severity may contribute to fluctuations in these associations over time, and these factors should be considered when evaluating results from all observational studies examining influenza vaccination effectiveness.

It was noted that despite the uncertainty surrounding the magnitude of survival benefit due to influenza vaccination, however, it is important to consider that influenza is a substantial health problem in the US, causing numerous deaths and hospitalizations each year. Even a partially effective vaccine would be better than no vaccine at all, a notion supported by current CDC guidelines which recommend universal annual vaccination (CDC 2010a).

Following presentation of the updated literature, the TEP was invited to make comments in response, particularly any that might relate to the TEP recommendations for influenza vaccination measures made at the in-person meeting. It was noted that the articles by Wong et al (2012) and Simonsen et al (2007), which cite an attenuated association between immunization and reduced mortality, refer to the general population and thus may not be applicable to the dialysis population. It was emphasized that, in contrast, the studies by Gilbertson et al (2003) and Bond et al (2012), which were specifically conducted in the dialysis population, showed a much stronger health benefit.

Overall, it was noted that the additional evidence, in combination with the literature presented at the in-person meeting, represented an accurate and balanced view of the current observational data related to effectiveness of influenza vaccination. Further, the additional evidence presented following the in-person meeting did not indicate revision of the patient influenza vaccination measures was needed. The TEP's recommendations for two dialysis patient influenza vaccination measures, therefore, remain unchanged.

3. Pneumococcal Vaccination Among Dialysis Patients

3.1 Update to New Measure Development

The issues of scientific evidence and feasibility were central to the TEP's continued discussion of whether or not to pursue recommendations for pneumococcal vaccination measures. Concerns were raised regarding the lack

of published data showing a significant effect of the 13-valent pneumococcal conjugate vaccine (PCV13) on improved health outcomes specifically in the dialysis population. In response, one TEP member highlighted the CDC guidelines, which classify pneumococcal vaccination among those with immunocompromising conditions as a Category A recommendation, indicating a strong evidence base (CDC 2012; CDC 2013). It was emphasized that the CDC guidelines were clear in their inclusion of chronic renal failure as an immunocompromising condition. In addition, studies cited in the guidelines indicate that mortality rates for pneumonia in hemodialysis patients are 14-16 times higher than in the general population and that at least 50% of invasive pneumococcal infection is attributable to serotypes included in the PCV13 vaccine (CDC 2010b, CDC 2012). Furthermore, the Department of Health and Human Services (HHS) Office for Disease Prevention and Health Promotion has recently released the National Action Plan to Prevent Health Care-Associated Infections, which includes immunization of ESRD patients for influenza and pneumococcal infections as a priority (<http://www.hhs.gov/ash/initiatives/hai/actionplan/index.html>). Ultimately, the TEP members agreed that both the 23-valent pneumococcal polysaccharide vaccine (PPSV23) and PCV13 should be administered to dialysis patients according to the CDC guidelines. Questions remained regarding situations when the guidelines are unclear. In particular, issues were raised over the limited guidance related to the treatment of patients with unknown vaccination status. It was noted that the CDC recommends these patients be vaccinated, with PCV13 given first if vaccination status for a patient is unknown for both PCV13 and PPSV23 (CDC 2013). Some TEP members expressed concerns about safety risks in these situations, considering many patients who enter dialysis units may not know their vaccination status. A measure could result in facilities overvaccinating patients to avoid being penalized. It was noted that the CDC guidelines cited studies evaluating the safety of pneumococcal vaccines, and the incidence of adverse events was found to be less than two percent for both vaccines, which largely were events documented as redness, swelling, or pain near the injection site (CDC 2012). However, it was also suggested that the CDC should clarify the risk/benefit ratio of revaccination with either pneumococcal vaccine among immunocompromised patients.

While broad consensus was achieved regarding the importance of providers adhering to the guidelines and administering both vaccines to their dialysis patients, doubts were raised concerning the ability to define a measure that would be consistent with the guidelines and simultaneously feasible to implement. It was expressed that the effort needed for providers to track vaccination histories would be overly burdensome. It was argued that determining up-to-date vaccination status would require knowing a long history of pneumococcal vaccination for each patient, at least with respect to PPSV23, and that this would be difficult to achieve since it would depend on a facility's ability to obtain vaccination records from other providers. Questions were raised about pneumococcal vaccination measures in other settings, for example hospitals, which might reasonably influence a patient's vaccination status prior to entry at a dialysis facility. A representative from the Centers for Medicare and Medicaid Services (CMS) indicated that a hospital measure had been in development but was rescinded. The primary reason for postponing further consideration of the hospital-based measure was due to the inability to resolve the many combinations of acceptable dosing schedules (depending on timing and type of first vaccination), which would be required in order to determine patient status and calculate the measure.

In light of the feasibility and logistical challenges raised as well as the CMS experience with a hospital-based measure, TEP members reconsidered their recommendation for the PCV13 measure (Table 1). Ultimately, many TEP members supported the idea of postponing recommendation, particularly given that the guidelines for delivery are relatively new and perhaps still in flux. There was agreement, however, that this topic should be revisited in the future when more data are available. This was heavily challenged by one strongly dissenting member. In addition to citing the CDC guidelines as Category A recommendations that should be supported by a quality measure, the dissenting opinion also noted problems with the hospital inpatient comparison, calling concerns over feasibility into question:

1. An inpatient's average stay is only a few days, so obtaining lengthy vaccination histories would understandably be difficult. This is not the case for dialysis patients, who are connected to dialysis facilities for months to years. Consequently, there is more opportunity in a dialysis unit setting compared to a hospital setting to document whether a patient has been administered PCV13, and thus should be more feasible.
2. Most hospital patients are not chronically immunocompromised, so the risk associated with missed vaccination opportunities is lower than with dialysis patients.
3. Most dialysis organizations maintain several years worth of patient records and so are able to analyze data related to patient histories with limited burden.

Further, it was noted that since the measure for pneumococcal vaccination in hospitals has been deferred, there is no mandate in this setting. This makes it all the more important for dialysis units, the routine providers of care for dialysis patients, to be responsible for ensuring vaccination status, as hospitals will not be doing this. Indeed, this might even make it easier for dialysis facilities to assume this responsibility, as there will not be competing efforts. It was also noted that patients on dialysis typically attend clinics three times per week and clinics now have fairly sophisticated methods for tracking billable items, such as pneumococcal vaccination, for several years, so it should not be difficult for units to maintain accurate vaccination histories. Other TEP members acknowledged the validity of the points raised by the dissenting opinion. Though there was general consensus that vaccination is important and providers should be accountable, the majority of the TEP maintained that it would be appropriate to defer recommendation of the PCV13 vaccine measure until a later date.

The TEP also discussed alternatives to the PPSV23 measure developed and recommended during the in-person meeting (Table 2). It was suggested that for the purpose of learning more about vaccination practices in dialysis facilities, a measure requiring facilities to report general patient vaccination status would be more reasonable, given concerns about tracking the two vaccines separately. A measure collecting data regarding whether either vaccine was administered to the patient, either previously or in the dialysis facility, was proposed (Table 3). This was expanded to reflect the multi-part numerator included in the other vaccination measures recommended by the TEP (patient refusal, etc). The primary motivation for this new measure was concern over meeting NQF's criterion for feasibility, with additional questions related to sufficient scientific evidence, particularly with respect to PCV13. This alternate generic measure would allow dialysis facilities to begin collecting more detailed data on pneumococcal vaccination status, enabling this measure area to be revisited in the future, at which time consideration of valence-specific measures might be more appropriate.

Collapsing the two vaccines into a single measure was opposed by multiple TEP members. Earlier statements regarding the significance of the Category A recommendations for vaccination were reiterated. It was emphasized that providers have a responsibility to vaccinate their patients, but the data suggest that vaccination rates are unacceptably low. Consequently, specific measures should be developed regardless of the burden being placed on the facility. In addition, there was concern that a general measure could actually discourage complete pneumococcal vaccination, because if a patient receives one, there is no incentive to provide the other. Since CDC recommends both vaccines, the general measure could reduce the number of patients receiving appropriate immunization. The rationale for deferring recommendation of a PCV13 measure was acknowledged, but it was suggested that a PPSV23 measure would be cleaner than a combined measure. It was noted that PPSV23 vaccination for dialysis patients is a long-standing recommendation and despite its inclusion in the Measures Assessment Tool (MAT) used by dialysis facility surveyors, vaccination coverage is still low. Therefore, there is reason to believe such a measure could improve care. Also, a measure for PPSV23 alone would not reduce delivery of PCV13, whereas a combined measure might. Other TEP members agreed that the importance of vaccination should not be understated but reiterated concerns related to the feasibility and reliability of collecting these data.

The TEP agreed to a vote on all three proposed measures. The combined measure received 4 votes, the PPSV23 measure received 3 votes, and the PCV13 measure received 1 vote. Two TEP members did not submit votes for any of the measures. Because there was not clear consensus regarding which measure(s) to recommend as a group, all three measures, accompanied by the varied TEP member views as described above, will be provided to CMS for consideration in making final decisions regarding pneumococcal vaccination quality measures.

3.2 Update to the Proposed Measures

The three pneumococcal vaccination measures proposed by the Preventive Care TEP during and following the in-person meeting are presented below (Tables 1-3).

Table 1. PCV13 Vaccination Measure Recommended During the In-Person Meeting.

Denominator	<p>The following patients are included in the denominator:</p> <ol style="list-style-type: none"> 1) Aged ≥ 5 years at the start of the reporting period 2) On chronic dialysis ≥ 30 days in a facility at any point during the 12-month reporting period (in-center or home dialysis) <p>The following patients are excluded from the denominator:</p> <ol style="list-style-type: none"> 1) Patients who received PPSV23 vaccination within 12 months prior to the start of the reporting period
Numerator	<p>Number of patients from the denominator who (to be calculated and reported separately):</p> <ol style="list-style-type: none"> 1) ever received the PCV13 vaccination (documented by the dialysis provider or documented off-site vaccination) 2) were offered PCV13 vaccination but declined 3) were determined to have a medical contraindication

Table 2. PPSV23 Vaccination Measure Recommended During the In-Person Meeting.

Denominator	<p>The following patients are included in the denominator:</p> <ol style="list-style-type: none"> 1) Aged ≥ 2 years at the start of the reporting period 2) On chronic dialysis ≥ 30 days in a facility at any point during the 12-month reporting period (in-center or home dialysis)
Numerator	<p>Number of patients from the denominator who (to be calculated and reported separately):</p> <ol style="list-style-type: none"> 1) have up-to-date PPSV23 vaccine status or received the vaccine during the 12-month reporting period 2) were offered PPSV23 vaccination but declined 3) were determined to have a medical contraindication

Table 3. Combined Pneumococcal Vaccination Measure.

Denominator	<p>The following patients are included in the denominator:</p> <ol style="list-style-type: none"> 1) Aged ≥ 2 years at the start of the reporting period 2) On chronic dialysis ≥ 30 days in a facility at any point during the 12-
-------------	---

month reporting period (in-center or home dialysis)

Numerator	Number of patients from the denominator who (to be calculated and reported separately): <ol style="list-style-type: none">1) have ever received either the PPSV23 or PCV13 vaccine (documented by the dialysis provider or documented off-site vaccination)2) were offered PPSV23 or PCV13 vaccination but declined3) were determined to have a medical contraindication
-----------	--

4. Influenza Vaccination Among Healthcare Personnel

4.1 Update to Existing Measure

At the in-person meeting, the TEP discussed the possibility of recommending a measure for influenza vaccination among healthcare personnel (HCP). In developing and finalizing their recommendations, the TEP carefully considered a pre-existing National Quality Forum (NQF)-endorsed measure developed by the Centers for Disease Control and Prevention (CDC). Subsequent to the in-person meeting, the denominator statement for this measure (NQF #0431) was modified, effective May 24. A summary of the recent change was provided to the TEP. It was described that the measure as originally endorsed required facilities to report the vaccination status of personnel working in the facility **for at least 30 days** during the October 1 through March 31 reporting period. Feedback from acute care hospitals reporting to NHSN this year indicated that determining whether HCP were present in the facility for at least 30 days placed a substantial additional burden on entities reporting these data beyond what was required to collect vaccination status. Based on this feedback, the measure was revised to include all HCP working **one day or more** between October 1 and March 31. All other aspects of the measure remain the same. Authors of the revision suggested that the updated measure will do a better job of capturing all HCP at risk of acquiring or transmitting healthcare-associated influenza infection. The key elements of the pre-existing measure are presented in Table 4 below, with the revised portion indicated in bold.

Table 4. Key components of the CDC quality measure for influenza vaccination among HCP.

Description	Percentage of healthcare personnel (HCP) who receive the influenza vaccination.
Denominator	Number of HCP who are working in the healthcare facility for ≥1 working day between Oct 1 and Mar 31 of the following year, regardless of clinical responsibility or patient contact. To be calculated separately for: <ol style="list-style-type: none">1) Employees: all persons who receive a direct paycheck from the reporting facility2) 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 facility3) Adult students/trainees and volunteers: include all adult students/trainees and volunteers who do not receive a direct paycheck from the reporting facility
Numerator	HCP in the denominator population who during the time from Oct 1 (or when the vaccine became available) through Mar 31 of the following year (to be calculated separately): <ol style="list-style-type: none">1) Received an influenza vaccination administered at the healthcare facility, or reported in writing or provided documentation that influenza vaccination was received elsewhere2) Were determined to have a medical contraindication

- 3) Declined influenza vaccination
- 4) Persons with unknown vaccination status or who do not otherwise meet any of the definitions of the above-mentioned numerator categories

The TEP was invited to make comments in response to the revised measure, particularly any that might relate to the recommendation for a HCP influenza vaccination measure made at the in-person meeting. There was some initial agreement with the change in time frame from ≥ 30 days to ≥ 1 day, as it was felt to be easier to track vaccination status for HCP at any time they come into the unit versus trying to track HCP working in a 30-day time frame. It was further stated that this would result in no additional burden to the dialysis facility to provide this level of tracking.

Others expressed concern over the 1-day criterion, however, particularly for trainees and volunteers. It was stated that while this might be doable, it would require a fair amount of coordinated effort. The lack of clarity associated with 1 day was also emphasized. Did this mean 24 hours, 8 hours, less than 8 hours? The difficulty of implementation was echoed by others, in particular, the feasibility challenges of documentation and veracity confirmation. It was noted that employees, physicians, and extenders all fall under standard management processes, but other personnel do not. Tracking vaccination status for other personnel, volunteers, and trainees would become very challenging, perhaps calling the feasibility criterion into question.

Ultimately, consensus was not reached regarding the change in HCP time frame from ≥ 30 days to ≥ 1 day. As a result, it was decided to make no changes to the recommendations from the in-person meeting. However, it was noted that the topic would remain open for further discussion.

5. Conclusion

The Preventive Care TEP discussed the development of quality measures in the areas of influenza and pneumococcal vaccination among dialysis patients and healthcare personnel. After careful consideration of the information provided subsequent to the in-person meeting, the TEP decided to make no changes to their recommendations regarding patient and HCP influenza vaccination measures. However, TEP members indicated considerable difference in opinion regarding a pneumococcal measure following the in-person meeting, resulting in the following updates:

- In addition to the two valence-specific measures, the TEP developed a third measure for lifetime vaccination status for either pneumococcal vaccine (PPSV23 or PCV13).
- A vote was held for all three measures that failed to produce clear consensus. Therefore, all three measures will be provided to CMS.

6. Preventive Care TEP Members

<i>Name</i>	<i>Title</i>	<i>Organization</i>
Constance Anderson, BSN, MBA	Vice President of Clinical Operations	Northwest Kidney Centers
Kevin Chan, MD, MSC	Senior Director of Clinical Outcomes Research and Medical Analytics	Fresenius Medical Care North America
Alfred K. Cheung, MD	Professor of Medicine, Division of Nephrology & Hypertension	University of Utah
David Gilbertson, PhD	Executive Director of Epidemiology	United States Renal Data System

<i>Name</i>	<i>Title</i>	<i>Organization</i>
	and Biostatistics	
Raymond Hakim, MD, PhD	Attending Physician/Nephrologist	Vanderbilt University
Celeste Castillo Lee	Senior Project Manager, Office of the Provost	University of Michigan
Paul Martin, MD, FRCP, FRCPI	Chief, Division of Hepatology	University of Miami Miller School of Medicine
Alicia Neu, MD	Professor, Pediatric Nephrology	John Hopkins Medicine
David Van Wyck, MD	Vice President, Clinical Services	DaVita

7. References

Bond TC, Spaulding AC, Krisher J, et al. Mortality of dialysis patients according to influenza and pneumococcal vaccination status. *Am J Kidney Dis*. 2012;60:959-65.

Centers for Disease Control and Prevention (CDC). Prevention and Control of Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR* 2010a;59(RR-8):1-62.

Centers for Disease Control and Prevention (CDC). Invasive Pneumococcal Disease in Young Children Before Licensure of 13-Valent Pneumococcal Conjugate Vaccine --- United States, 2007. *MMWR* 2010b;59(09):253-257.

Centers for Disease Control and Prevention (CDC). Use of 13-Valent Pneumococcal Conjugate Vaccine and 23-Valent Pneumococcal Polysaccharide Vaccine for Adults with Immunocompromising Conditions: Recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR* 2012;61(40):816-9.

Centers for Disease Control and Prevention (CDC). Advisory Committee on Immunization Practices (ACIP) recommended immunization schedule for adults aged 19 years and older – United States, 2013. *MMWR* 2013;62(Supplement)9-12.

Gilbertson DT, Unruh M, McBean AM, et al. Influenza vaccine delivery and effectiveness in end-stage renal disease. *Kidney Int*. 2003;63:738-43.

McGrath LJ, Kshirsagar AV, Cole SR, et al. Influenza vaccine effectiveness in patients on hemodialysis: an analysis of a natural experiment. *Arch Intern Med*. 2012;172(7):548-54.

Messana J, Wisniewski K, Shearon T, et al. Facility influenza vaccination (IV) practice: Associations with mortality and hospitalizations in the US dialysis population. *J Am Soc Nephrol*. 2010;21:467A.

Simonsen L, Taylor RJ, Viboud C, et al. Mortality benefits of influenza vaccination in elderly people: an ongoing controversy. *Lancet Infect Dis*. 2007;7:658-66.

Wong K, Campitelli MA, Stukel TA, et al. Estimating influenza vaccine effectiveness in community-dwelling elderly patients using the instrumental variable analysis method. *Arch Intern Med*. 2012;172(6):484-91.