

NATIONAL QUALITY FORUM

CONFERENCE CALL FOR THE RENAL ENDORSEMENT MAINTENANCE STEERING COMMITTEE

October 28, 2011

Committee Members Present: Peter Crooks, MD (Co-Chair); Kristine Schonder, PharmD (Co-Chair); Constance Anderson, BSN, MBA; Jeffrey Berns, MD; Lorien Dalrymple, MD, MPH; Michael Fischer, MD, MSPH; Rick Kaskel, MD, PhD; Myra Kleinpeter, MD, MPH; Alan Kliger, MD; Lisa Latts, MD, MSPH, MBA; Joseph Nally, MD; Andrew Narva, MD; Michael Somers, MD; Janet Welch, PhD, RN; Harvey Wells.

NQF Staff Present: Karen Pace, PhD, MSN, Senior Director; Kathryn Streeter, MS, Project Manager.

Others Present: Amy Beckrich, Dolph Chianchiano, Renee Henry, Aya Inoue, Diedra Joseph, Paul Palevksy, Lisa McGonigal, Joe Messana, Robyn Nishimi, Tom Nusbickel, Jay Rajda, Dale Singer, Jennifer Stone, Vani Bir.

The audio recording from the meeting can be found [here](#).

MEETING PROCESS

Dr. Crooks and Dr. Schonder (co-chairs) welcomed the Steering Committee members and thanked them for their continued participation.

The purpose of the call was to:

- review outstanding issues on measures submitted for consideration in this project—some measures were reviewed only by workgroup (not full committee) and follow-up information on some measures; and
- identify implications for measure evaluation or recommendations.

NQF staff briefly introduced the measures, including a description of the outcome of the workgroup discussions and any re-voting. The Steering Committee was encouraged to seek any clarifications or rationale to prepare for voting on the measures after the call. An NQF member and public comment period occurred at the end of the call.

EVALUATION OF RENAL MEASURES

The following tables compile a summary of the Steering Committee’s discussions and evaluation to date.

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Anemia

<p>1666 Patients on Erythropoiesis Stimulating Agent (ESA)--Hemoglobin Level > 12.0 g/dL</p> <p>Description: Percentage of calendar months within a 12-month period during which a Hemoglobin is measured for patients aged 18 years and older with a diagnosis of advanced CKD (stage 4 or 5, not receiving RRT) or ESRD (who are on hemodialysis or peritoneal dialysis) who are also receiving ESA therapy and have a Hemoglobin Level > 12.0 g/dL</p> <p>Numerator Statement: Calendar months during which patients have a Hemoglobin level > 12.0 g/dL*</p> <p>*The hemoglobin values used for this measure should be a most recent (last) hemoglobin value recorded for each calendar month</p> <p>Denominator Statement: All calendar months during which a Hemoglobin is measured for patients aged 18 years and older with a diagnosis of advanced CKD (stage 4 or 5, not receiving RRT) or ESRD (who are on hemodialysis or peritoneal dialysis) who are also receiving ESA therapy</p> <p>Definitions: RRT (Renal Replacement Therapy)-For the purposes of this measure, RRT includes hemodialysis, peritoneal dialysis, and kidney transplantation</p> <p>Exclusions: None.</p> <p>Adjustment/Stratification: No risk adjustment or risk stratification. This measure is not risk adjusted. We encourage the results of this measure to be stratified by race, ethnicity, gender, and primary language, and have included these variables as recommended data elements to be collected.</p> <p>Level of Analysis: Clinician : Group/Practice, Clinician : Individual, Clinician : Team</p> <p>Type of Measure: Outcome</p> <p>Data Source: Administrative claims, Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Registry, Paper Records</p> <p>Measure Steward: American Medical Association - Physician Consortium for Performance Improvement</p>
<p>Steering Committee 8/16-17</p> <p>Importance to Measure and Report (based on decision logic): Yes</p> <p>1a. Impact: H-16; M-5; L-1; I-0; 1b. Performance Gap: H-7; M-12; L-0; I-3</p> <p>Rationale: 1b. The data on performance gap was only for ESRD patients, not CKD patients who also are included in the measure and the prior ESRD measure also include plan of care. The developer stated that 63.5 of patients did not receive "optimal care" per USRDS. However, "optimal care" was not defined—does this refer to number of patients meeting guideline target (Hgb 10-12) or number of patients with Hgb > 12 per measure specification? THE PQRI performance data indicated variability on the ESRD measure with a median performance of 66.23%; 25th percentile of 38.17%; and 75th percentile of 84.04%.</p> <p>1c. Evidence (based on decision logic): Yes IF a Health Outcome, rationale supports: NA Quantity: H-4; M-17; L-0; I-0; Quality: H-1; M-18; L-1; I-0; Consistency: H-2; M-16; L-2; I-0</p> <p>Rationale: The evidence is clear about harm with higher Hgb values when on ESAs. This should be considered a safety measure. There is a difference between lack of evidence at low end vs. a safety signal.</p>
<p>2. Scientific Acceptability of Measure Properties (based on decision logic): Yes 2a. Reliability: H-4; M-9; L-5; I-3 2b. Validity: H-0; M-15; L-4; I-2</p> <p>Rationale: 2a1. Specifications—developer states could be implemented in one of 3 ways: medical record, CPTII codes on physician claims, or electronic health record. The Committee noted several problems with eSpecs, and they were removed from consideration with the measure. 2a2. Although measure has been implemented in CMS PQRS program using CPTII codes, reliability of data elements was tested on a small sample of 4 group practices. 2b2. Submitted systematic assessment of face validity using the expert group who developed the measure. A Committee member suggested that a measure of persistent high levels vs. single measurement would be a more valid indicator of poor care; however, the Committee did not recommend that change. The developer indicated that constructing the measure based on months rather than patients takes into account if a patient's Hgb is elevated for 1 out of 12 months vs. elevated for multiple months. That raised the question of whether the measure will obscure the signal for patients with chronic high levels.</p> <p>2c. Disparities: H-; M-; L-; I- Rationale: No disparities by race were identified.</p>
<p>3. Usability: H-2; M-13; L-3; I-2</p> <p>(Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting and 3b. Quality Improvement)</p> <p>Rationale: Used in CMS physician reporting initiatives, however performance data for physicians are not publicly available. Developer indicates will be used in 2011, but only information about participation in reporting not performance results are planned.</p>
<p>4. Feasibility: H-1; M-10; L-8; I-2</p> <p>(4a. Clinical data generated during care process; 4b. Electronic data; 4c. Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented)</p> <p>Rationale: CPTII codes seem to be currently feasible.</p>
<p>Preliminary Assessment of Criteria Met/Suitable for Endorsement: Y-15; N-6; A-0</p>

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1666 Patients on Erythropoiesis Stimulating Agent (ESA)--Hemoglobin Level > 12.0 g/dL

(All criteria met, but final recommendation pending further information and/or evaluation of related and competing measures)

Comments: eSpecs not considered because incorrect—would need crosswalk to specifications before further consideration. Does the construction using months instead of patients obscure the signal for patients with chronic high levels?

If applicable, Questions for Committee:

If applicable, Conditions/Questions for Developer: eSpecs not considered because incorrect—would need crosswalk to specifications before further consideration. Does the construction using months instead of patients obscure the signal for patients with chronic high levels?

Developer Response: PCPI appreciates the opportunity to review and provide an update of our eSpecifications. PCPI specifications staff is in the process of reviewing and updating the hemoglobin lab codes to ensure the appropriate laboratory codes for the hemoglobin level test are included for this measure. Additionally, we will review the dialysis procedure codes for accuracy. We have included procedure codes using SNOMED based on the guidance provided by the ONC Health Information Technology Standards Committee, but have also included CPT during this time of transition to EHRs. Because of the fact that SNOMED concepts are intended to capture clinical information within health IT systems, whereas CPT is designed for billing purposes, there will be differing levels of granularity in each terminology. The codes and concepts identified in each terminology should not be compared to each other but rather the allowable values in each terminology should be assessed as to whether they capture the concept in the performance measure.

We have provided a sample performance calculation to demonstrate how the performance calculation for a given physician would be calculated. The unit of measure for this performance measure is “months.” The use of “months” in the measure construction does not obscure the signal for patients with high levels, but rather allows for a more accurate assessment of a patient’s hemoglobin levels over the course of a year.

Dr. Smith's Patients							
(Lower performance - better quality)							
	Patient A	Patient B	Patient C				
Jan	12.3	11.6	12.1				
Feb	12.0	11.8	12.2				
March	11.9	12.1	12.0				
Apr	11.0	12.0	11.8				
May	11.5	12.0	11.7				
June	12.0	11.2	11.9				
July	12.4	11.5	11.8				
Aug	11.9	10.9	11.5				
Sept	11.8	11.3	11.9				
Oct	11.8	11.5	12.0				
Nov	11.5	12.3	12.1				
Dec	12.1	12.0	12.2				
Patient Calendar Months > 12.0	3	2	4				
Summary Calculation for Dr. Smith							
<table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%; padding: 5px;">Total # of levels >12.0 (for all patients)</td> <td style="width: 50%;"></td> </tr> <tr> <td style="padding: 5px;">Total # of patient calendar months (for all patients)</td> <td></td> </tr> </table>				Total # of levels >12.0 (for all patients)		Total # of patient calendar months (for all patients)	
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Total # of patient calendar months (for all patients)							

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1666 Patients on Erythropoiesis Stimulating Agent (ESA)--Hemoglobin Level > 12.0 g/dL				
	Dr. Smith's Performance	(3+2+4) (12+12+12)	9/36=25%	
Steering Committee Follow-up: Reviewed on the 10/28 call—no further action suggested.				
5. Related and Competing Measures (5a. Harmonization; 5b. Superior to competing measures) Comments:				
Steering Committee Recommendation for Endorsement: <u>Y-15; N-6; A-0</u> Rationale:				

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Cardiovascular

0627 Chronic Kidney Disease with LDL Greater than or equal to 130 – Use of Lipid Lowering Agent

Description: The percentage of patients with chronic kidney disease and an LDL greater than or equal to 130 mg/dl that have a current refill for a lipid lowering agent.

Numerator Statement: Patients with a current refill for a lipid lowering agent.

Denominator Statement: All patients, ages 18 and older, diagnosed with chronic kidney disease, including CKD stage 5, dialysis, or kidney transplant, and an LDL level above 130 mg/dL.

Exclusions: Specific Exclusions:

None

General Exclusions:

- Evidence of metastatic disease or active treatment of malignancy (chemotherapy or radiation therapy) in the last 6 months
- Patients who have been in a skilled nursing facility in the last 3 months
- Patient or provider feedback indicating allergy or intolerance to the drug in the past
- Patient or provider feedback indicating that there is a contraindication to adding the drug

Adjustment/Stratification: No risk adjustment or risk stratification. No risk model applied to this measure. The results are not stratified.

Level of Analysis: Clinician : Group/Practice, Clinician : Individual, Clinician : Team, Facility, Health Plan, Integrated Delivery System, Population : Community, Population : County or City, Population : National, Population : Regional, Population : State

Type of Measure: Process

Data Source: Administrative claims, Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Laboratory, Electronic Clinical Data : Pharmacy, Patient Reported Data/Survey

Measure Steward: ActiveHealth Management

Steering Committee 8/16-17

Importance to Measure and Report (based on decision logic): **No**

1a. Impact: H-3; M-14; L-3; I-0; **1b. Performance Gap:** H-0; M-3; L-1; I-16

Rationale: In response to a question about whether the target population is CKD 5 (dialysis and transplant), the developer clarified that the NOS codes are in conjunction with creatinine clearance so not intended to limit to CKD stage 5. 1b. Performance gap data is for CKD stage 3-4 - less than half had LDL levels less than 100. No information on performance on this previously endorsed measure as specified, though developer stated it is in use. Developer stated that the performance gap is based on KDOQI guidelines. Developer stated it could supply data on performance if given the opportunity.

1c. Evidence (based on decision logic): **No** IF a Health Outcome, rationale supports: **NA**

Quantity: H-0; M-6; L-9; I-5; Quality: H-0; M-4; L-11; I-5; Consistency: H-0; M-3; L-10; I-7

Rationale: Small number of dated studies cited with no RCT information as discussed under 0626. A SC member asked what was the achieved LDL in the SHARP study and another responded cholesterol 5.3 international units (about 230 with LDL about 120).

NKF and KDOQI strongly supported measurement.

2. Scientific Acceptability of Measure Properties (based on decision logic): **2a. Reliability:** H-; M-; L-; I- **2b. Validity:** H-; M-; L-; I-

Rationale:

2c. Disparities: H-; M-; L-; I- **Rationale:**

3. Usability: H-; M-; L-; I-

(Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting and 3b. Quality Improvement)

Rationale:

4. Feasibility: H-; M-; L-; I-

(4a. Clinical data generated during care process; 4b. Electronic data; 4c. Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented)

Rationale:

Preliminary Assessment of Criteria Met/Suitable for Endorsement: Y-; N-; A-

(All criteria met, but final recommendation pending further information and/or evaluation of related and competing measures)

Comments: What is the data on the performance gap for this measure as specified? Is there specific evidence supporting the effectiveness of lipid lowering drugs in CKD5?

If applicable, Questions for Committee:

If applicable, Conditions/Questions for Developer: What is the data on the performance gap for this measure as specified? Is there specific evidence supporting the effectiveness of lipid lowering drugs in CKD5?

Developer Response: Based on data collected from a population of 13 million, we found 185 people who fulfilled the denominator. Out of these, the compliance for use of a lipid-lowering agent in people with chronic kidney disease and an LDL greater than or equal to 130 was

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0627 Chronic Kidney Disease with LDL Greater than or equal to 130 – Use of Lipid Lowering Agent

found to be 54%.

Several studies have evaluated the use of HMG Co-A reductase inhibitors (statins) in patients with stage 5 CKD/ ESRD/ on renal replacement therapy. A Cochrane meta-analysis published in 2009 evaluated the role of statins in patients getting dialysis and included 14 studies that recruited 2086 patients in the final analysis (1). The analysis found a lower incidence of non-fatal cardiovascular events in ESRD patients on statins (RR 0.86, 95% CI 0.74 to 0.99), but no difference in overall mortality. Also, there were significant reductions in total cholesterol, LDL cholesterol and triglycerides. Moreover the incidence of rhabdomyolysis and elevated liver enzymes was similar in the statin and placebo groups. The authors concluded that statins reduced cholesterol levels in dialysis patients similar to the general population. As the studies included were of short duration, the effect of statins on decreasing mortality in ESRD patients remained unclear, but they appeared to be safe to use in this high risk population, and that larger studies of longer duration could provide greater insight on the efficacy of mortality reduction in dialysis patients.

A randomized, controlled study of simvastatin plus ezetimibe versus placebo in 9270 patients with CKD was published in 2011 (2). This study included 3023 patients on dialysis. After 4.9 years of follow up, patients on simvastatin plus ezetimibe had a 17% proportional reduction in the primary outcome, major atherosclerotic events (RR 0.83; 95% CI 0.74 to 0.94). Non-significantly fewer patients allocated to simvastatin plus ezetimibe had a non-fatal myocardial infarction or died from coronary heart disease and there were significant reductions in non-haemorrhagic stroke (2.8% vs 3.8%; RR 0.75, 95% CI 0.60-0.94) and arterial revascularization procedures (6.1% vs 7.6%; RR 0.79, 95% CI 0.68-0.93). After weighting for subgroup-specific reductions in LDL cholesterol, there was no good evidence that the proportional effects on major atherosclerotic events differed from the summary rate ratio in any subgroup examined, and, in particular, they were similar in patients on dialysis and those who were not. The excess risk of myopathy was only two per 10,000 patients per year of treatment with this combination (9 [0.2%] vs 5 [0.1%]). There was no evidence of excess risks of hepatitis, gallstones, or cancer and there was no significant excess of death from any non-vascular cause.

Another multicenter, randomized, double-blind prospective study done in 2005 on over 1200 patients who had type 2 diabetes and were on hemodialysis, showed that while the composite number of deaths from cardiac causes showed no significant difference, the number of all cardiac and cerebrovascular events combined was statistically lower in those people taking atorvastatin as compared with the placebo group (3).

Also worth noting is the statement made by an international, multicenter, randomized, double-blind, prospective trial involving 2776 patients, between the ages of 50 and 80, who were undergoing maintenance hemodialysis(4). Although the study did not show added benefit with the addition of a statin, it is important to note that the authors pointed out that a selection bias may have occurred in the study because they excluded patients already on a statin and because their baseline LDL level was relatively low (100), the study population did not represent the denominator population for our proposed measure. In addition, there existed a high withdrawal rate in this study due to either adverse drug effects or transplantation, which could potentially mask the effects of statins.

Our measure focuses on the use of lipid lowering therapy in patients with CKD/ ESRD who specifically have an elevated LDL cholesterol levels above 130, putting them at even greater risk of cardiovascular morbidity, and making them even more likely to benefit from lipid lowering therapy.

(1) [Navaneethan SD, Perkovic V, Johnson DW](#), et al. HMG CoA reductase inhibitors (statins) for kidney transplant recipients. [Cochrane Database Syst Rev](#). 2009 Apr 15;(2):CD005019.

(2) [Baigent C, Landray MJ, Reith C](#), et al. The effects of lowering LDL cholesterol with simvastatin plus ezetimibe in patients with chronic kidney disease (Study of Heart and Renal Protection): a randomised placebo-controlled trial. [Lancet](#). 2011 Jun 25;377(9784):2181-92. Epub 2011 Jun 12.

(3) [Wanner C, Krane V, März W](#), et al. Atorvastatin in patients with type 2 diabetes mellitus undergoing hemodialysis. [N Engl J Med](#). 2005 Jul 21;353(3):238-48.

(4) [Fellström BC, Jardine AG, Schmieder RE](#), et al. Rosuvastatin and cardiovascular events in patients undergoing hemodialysis. [N Engl J Med](#). 2009 Apr 2;360(14):1395-407. Epub 2009 Mar 30.

Steering Committee Follow-up: Conference call 10/28 and re-evaluation

5. Related and Competing Measures (5a. Harmonization; 5b. Superior to competing measures)

Comments:

10/28 Steering Committee Conference Call

1.Importance to Measure and Report

1b. Performance gap The developer response on performance gap was inadvertently left off the previous table. The developer reported that from its database of 13 million that 185 individuals met the denominator specifications for CKD and LDL value > 130; of those 54% met the numerator specifications for lipid lowering refill. No distribution of performance by physician reported. The developer stated the reason for the low denominator was lack of lab value data in the database. A committee member noted that the performance issue could be lack of monitoring; however, that cannot be determined from just the lack of lab value data in the database.

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1c. Evidence The developer provided the additional evidence requested specifically on CKD5.

The Steering Committee did not discuss the remaining criteria. Prior preliminary evaluations noted the following.

2. Scientific Acceptability of Measure Properties No reliability testing was conducted. The developer referred to NQF testing report that indicated electronic data and methods will result in repeatable data elements. However, in that case, the testing guidance indicates that data element validity should be demonstrated and that testing also was not conducted.

3. Usability Measure previously endorsed and not currently publicly reported or used in any accountability application with no specific plan to do so.

4. Feasibility If only 185 patients could be identified, then feasibility of matching claims and lab data questioned.

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1633 Blood Pressure Management

Description: Percentage of patient visits for those patients aged 18 years and older with a diagnosis of CKD (stage 3, 4 or 5, not receiving RRT) and proteinuria with a blood pressure <130/80 mmHg OR >= 130/80 mmHg with a documented plan of care

Numerator Statement: Patient visits with blood pressure < 130/80 mmHg OR >= 130/80 mmHg with a documented plan of care*

Definitions:

Plan of Care: *A documented plan of care should include one or more of the following: recheck blood pressure within 90 days; initiate or alter pharmacologic therapy for blood pressure control; initiate or alter non-pharmacologic therapy (lifestyle changes) for blood pressure control; documented review of patient's home blood pressure log which indicates that patient's blood pressure is or is not well controlled

Numerator Instructions: If multiple blood pressure measurements are taken at a single visit, use the most recent measurement taken at that visit.

The PCPI recommends that this measure be reported as follows:

% of patient visits meeting blood pressure < 130/80 mmHg (component 1)

% of patient visits meeting blood pressure >= 130/80 mmHg with plan of care (component 2)

% of patient visits meeting blood pressure < 130/80 mmHg AND patient visits meeting blood pressure >= 130/80 mmHg with plan of care (total measure score)

Denominator Statement: All patient visits for those patients aged 18 years and older with a diagnosis of CKD (stage 3, 4 or 5, not receiving RRT) and proteinuria

Definitions:

Proteinuria:

1. >300mg of albumin in the urine per 24 hours OR
2. ACR >300 mcg/mg creatinine OR
3. Protein to creatinine ratio > 0.3 mg/mg creatinine

RRT (Renal Replacement Therapy)-For the purposes of this measure, RRT (Renal Replacement Therapy) includes hemodialysis, peritoneal dialysis, and kidney transplantation

Exclusions: None

Adjustment/Stratification: No risk adjustment or risk stratification This measure is not risk adjusted. We encourage the results of this measure to be stratified by race, ethnicity, primary language, and gender, and have included these variables as recommended data elements to be collected.

Level of Analysis: Clinician : Group/Practice, Clinician : Individual, Clinician : Team

Type of Measure: Outcome

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

Measure Steward: American Medical Association

Steering Committee 8/16-17

Importance to Measure and Report (based on decision logic): **No**

1a. Impact: H-20; M-1; L-0; I-0; 1b. Performance Gap: H-14; M-6; L-0; I-0

Rationale: Hypertension is a high impact topic. Performance on this measure from PQRS data demonstrated median performance at 67.53%; 25th percentil 25.76%; and 75th percentile 92.54%. Data on differences in Bp control among races cited.

1c. Evidence (based on decision logic): **No** IF a Health Outcome, rationale supports: **NA**

Quantity: **H-8; M-4; L-2; I-6**; Quality: **H-0; M-7; L-3; I-10**; Consistency: **H-0; M-7; L-6; I-8**

Rationale: No studies for this patient population, extrapolating from other populations. Proteinuria is a worse prognostic indicator, but studies with or without proteinuria not done. KDOQI review is 7-8 yrs old; KDIGO indicates not a high grade for evidence. JNC8 recommendations scheduled for release in November 2011. JNC using a different process and will be strictly evidence-based and it is likely will see different numbers.

Encourage resubmission based on latest evidence reviews and recommendations after they are published.

2. Scientific Acceptability of Measure Properties (based on decision logic): **2a. Reliability: H-; M-; L-; I-** **2b. Validity: H-; M-; L-; I-**

Rationale:

2c. Disparities: H-; M-; L-; I- **Rationale:**

3. Usability: H-; M-; L-; I-

(Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting and 3b. Quality Improvement)

Rationale:

4. Feasibility: H-; M-; L-; I-

(4a. Clinical data generated during care process; 4b. Electronic data; 4c. Susceptibility to inaccuracies/ unintended consequences identified
4d. Data collection strategy can be implemented)

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1633 Blood Pressure Management

Rationale:

Preliminary Assessment of Criteria Met/Suitable for Endorsement: Y-; N-; A-

(All criteria met, but final recommendation pending further information and/or evaluation of related and competing measures)

Comments:

If applicable, Questions for Committee:

If applicable, Conditions/Questions for Developer:

Developer Response: The developer requested reconsideration of this measure.

This measure is designed to address the critical need of BP Management in CKD and is consistent with the recent NephSAP review which found: **“Presently, it appears that a target BP of 130/80 mm/Hg in patients with CKD is better for renoprotection than a higher level in the presence of proteinuria.”**¹⁰ It is for this reason that our measure denominator includes patients with CKD and proteinuria. In addition, based on the Steering Committee’s recommendation, we have updated the definition of proteinuria in the measure. The SC provided feedback that the requirement for evidence was not met. However, this measure is based on KDOQI’s 2004 clinical practice guidelines on hypertension and antihypertensive agents in chronic kidney disease (CKD), which is based on JNC 7 and other evidence that is currently available. Despite the *current* guidelines and reviews supporting the measure, the SC hesitated to move forward with a measure based on guidelines that are in the process of being updated and for which a publication date is imminent. While we can appreciate the concern, we would like to call attention to the NQF Cardiovascular Steering Committee’s recent decisions regarding measures related to blood pressure and cholesterol targets that will be similarly affected by upcoming guideline updates, including JNC 8. **The Cardiovascular SC recommended several of these measures for endorsement, provided that the measure developers agree to modify the measures as appropriate upon the release of the updated guidelines.** The PCPI has a process in place to update our measures once new evidence becomes available. We therefore respectfully request that the SC reconsider recommending this BP Management measure. . Several recent studies (Chronic Renal Insufficiency Cohort [CRIC], Third National Health and Nutrition Examination Survey [NHANES III], Kidney Early Evaluation Program) have confirmed that in many patients with chronic kidney disease (CKD), blood pressure (BP) is not controlled to the target of < 130/80 mm Hg as recommended in most clinical practice guidelines.¹¹ To help support greater efforts to control hypertension in patients with CKD, we submitted a BP management measure aimed at improving the number of patients with blood pressure controlled at < 130/80 mmHg. The plan of care component of the measure allows for patients to have blood pressure ≥ 130/80 mmHg with a plan of care (i.e., recheck blood pressure within 90 days; initiate or alter pharmacologic therapy for blood pressure control) in place. Accurate measurement in CKD is especially important, because hypertension is more common in CKD, and because JNC 7 identifies CKD as a “compelling indication” for more aggressive antihypertensive therapy because of the higher risk of CVD in CKD than in the general population.¹² Hypertension is both a cause and a complication of CKD; more than 50% to 75% of patients with CKD have blood pressure > 140/90 mm Hg. In addition, hypertension is a risk factor for progression of kidney disease and for CVD.¹³ *Ultimately, by not recommending measure 1633, there will be no NQF-endorsed measure for blood pressure control in patients with CKD.* We hope that these explanatory comments better clarify the evidence upon which our proposed measure is based and further explain that we have a process in place for updating measures. We therefore request that the SC reconsider recommending this BP Management measure to further emphasize the importance of tracking the outcomes of care *and* the care provided to patients with CKD.

Steering Committee Follow-up: Conference call 10/28 and re-evaluation

5. Related and Competing Measures (5a. Harmonization; 5b. Superior to competing measures)

Comments:

10/28 Steering Committee Conference Call

The Steering Committee was divided on whether to reconsider this measure (Y-10; Unsure-2; N-10). NQF staff noted that a measure currently under endorsement maintenance 0018 Controlling high blood pressure, (see specifications that follow) includes CKD patients.

1.Importance to Measure and Report

1c. Evidence A committee member reported that JNC8 is taking a very rigorous review of the evidence and the recommended value of < 130/80 for CKD patients is likely to change. Some committee members do not want to recommend a measure that will not be supported by the evidence; others were concerned about waiting for the evidence review from JNC8 and not having a blood pressure measure (however, 0018 does include CKD patients with hypertension). Other committee members noted that the guideline cited was significantly opinion based and that the data at that time supported a BP in the 130s rather than < 130.

The Steering Committee did not review the remaining criteria, however some previous preliminary comments included the following.

2. Scientific Acceptability of Measure Properties

2a1.1-3Please review specifications – the measure numerator is control <130/80 or a documented plan of care. Theoretically, are there any patients who wouldn’t meet one or the other numerator components? It’s indicated that they should be reported separately in addition to the total, but the performance data reported in 1b 2 and 2b5 is only one percentage so appears to be only the total.

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1633 Blood Pressure Management

2a1.4-7 The developer also revised the denominator definition of albuminuria
 2a2 Reliability testing in medical records although measure is implemented using CPT-II codes on claims.
 2b2. Validity testing only face validity.

3. Usability

4. Feasibility

Some committee members asked if they could vote on this measure with the condition that it be modified when JNC8 guidelines are published. NQF staff checked with management and the response is as follows:

1. The Steering Committee should first review 0018 (see below) to determine if another measure is needed. Measure 0018 will be modified when JNC8 guidelines are published (including different values for different diagnoses). NQF prefers to have one measure that applies to all relevant patient populations and settings as supported by the evidence. Measure 0018 would include all CKD patients (except ESRD) with a diagnosis of hypertension. The key question is related to CKD patients without a diagnosis of hypertension – is that a problem?
2. If so, then if the measure met NQF criteria, it could be recommended on the condition of modification based on JNC8.

0018 Controlling High Blood Pressure	
Steward	National Committee for Quality Assurance 1100 13th Street NW, Suite 1000 Washington District Of Columbia 20005
Description	The percentage of patients 18–85 years of age who had a diagnosis of hypertension (HTN) and whose blood pressure (BP) was adequately controlled (<140/90) during the measurement year.
Type	Outcome
Data Source	Electronic administrative data/claims, Electronic Clinical Data, Electronic Health/Medical Record, Paper medical record/flow-sheet
Level	Clinicians : Group, Clinicians : Individual
Setting	All settings, Ambulatory Care : Amb Surgery Center, Ambulatory Care : Clinic, Ambulatory Care : Emergency Dept, Ambulatory Care : Hospital Outpatient, Ambulatory Care : Office
Numerator Statement	The number of patients in the denominator whose most recent, representative BP is adequately controlled during the measurement year. For a member's BP to be controlled, both the systolic and diastolic BP must be <140/90mm Hg.
Numerator Details	<p>Time Window: The measurement year.</p> <p>The number of patients in the denominator whose most recent, representative BP is adequately controlled during the measurement year. For a member's BP to be controlled, both the systolic and diastolic BP must be <140/90mm Hg. Follow these steps to identify the representative BP:</p> <ul style="list-style-type: none"> -Identify the most recent blood pressure reading noted during the measurement year. The reading must occur after the date when the diagnosis of hypertension was made or confirmed. Do not include readings that meet the following criteria: taken during an acute inpatient stay or an ED visit, taken during an outpatient visit that was for the sole purpose fo having a diagnostic test or surgical procedure performed (e.g., sigmoidoscopy, removal of a mole), taken the same day as a major diagnostic procedure (e.g., stress test, administration of IV contrast for a radiology procedure, endoscopy), reported by or taken by the patient, documentation of "VS within normal limits" or "vital signs normal". -Identify the lowest systolic and lowest diastolic reading from the most recent blood pressure notation in the medical record. If multiple readings were recorded for a single date, use the lowest systolic and the lowest diastolic reading on that date as the representative blood pressure. Results do not need to come from the same reading.
Denominator Statement	Patients 18-85 with hypertension. A patient is considered hypertensive if there is at least one outpatient encounter with a diagnosis of HTN during the first six months of the measurement year.
Denominator Categories	Female; Male 18-85 years
Denominator Details	<p>Time Window: Age range verified as of December 31st of the measurement year, while the hypertensive diagnosis is verified in the first 6months of the measurement year.</p> <p>Patients 18-85 as of December 31st of the measurement year who meet the following inclusion criteria: Continuous enrollment using health plan data: Patients continuously enrolled during the measurement year with no more than one gap in enrollment of up to 45 days during the measurement year. Continuous enrollment using non-health plan data: any enrollment, claim or encounter transaction any time during the measurement year.</p>

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0018 Controlling High Blood Pressure	
	<p>Event/Diagnosis: Hypertensive: At least one outpatient encounter (Table CBP-B) with a diagnosis of hypertension (Table CBP-A) during the first six months of the measurement year.</p> <p>Table CBP-A: Codes to Identify Hypertension</p> <p>Description ICD-9-CM Diagnosis Hypertension 401</p> <p>Table CBP-B: Codes to Identify Outpatient Visits</p> <p>Description CPT Outpatient visits: 99201-99205, 99211-99215, 99241-99245, 99384-99387, 99394-99397</p> <p>The diagnosis of hypertension must be confirmed by chart review on or before June 30 of the measurement year finding notation of one of the following: HTN, High BP, Elevated BP, Borderline HTN, Intermittent HTN, History of HTN, Hypertensive vascular disease, Hyperpiesia, Hypertpiesis.</p>
Exclusions	Exclude from the eligible population all patients with evidence of end-stage renal disease (ESRD) (including dialysis or renal transplant), all patients who are pregnant, and all patients who had an admission to a nonacute inpatient setting on or prior to December 31 of the measurement year.
Exclusion Details	<p>Exclude from the eligible population all patients with evidence of end-stage renal disease (ESRD) on or prior to December 31 of the measurement year. Documentation in the medical record must include a dated note indicating evidence of ESRD. Documentation of dialysis or renal transplant also meets the criteria for evidence of ESRD.</p> <ul style="list-style-type: none"> •Exclude from the eligible population all members with a diagnosis of pregnancy during the measurement year. •Exclude from the eligible population all members who had an admission to a nonacute inpatient setting any time during the measurement year. <p>Table CBP-C: Codes to Identify ESRD and Pregnancy Exclusions</p> <p>Description: CPT HCPCS ICD-9-CM ICD-9-CM UB UB POS Diagnosis Procedure Revenue type of Bill</p> <p>Evidence 36145, 36800, G0257 585.5, 38.95 0367 72X 65 of ESRD 36810, 36815, G0308-G0313 585.6, 39.27 080x 36818, 36819, G0314-G0319 V42.0, 39.42 082x 36820, 36821, G0322 V45.1 39.43 085x 36831-36833, G0323 V56 39.53 088x 50300, 50320, G0326 39.93-39.95 50340, 50360, G0327 54.98 50365, 50370, G0392 55.6 50380, 90920, G0393 90921, 90924, S9339 90925, 90935, 90937, 90939, 90940, 90945, 90947, 90989, 90993, 90997, 90999, 99512</p> <p>Evidence of Pregnancy: ICD-9-CM Diagnosis: 630-679, V22, V23, V28</p> <p>Table FUH-B codes to identify non-acute inpatient exclusions:</p> <p>Hospice: UB Rev (0115, 0125, 0135, 0145, 0155, 0650, 0656, 0658, 0659), UB Type Bill (81x, 82x), POS (34)</p> <p>SNF: UB Rev (019x), UB Type Bill (21x, 22x, 28x), POS (31, 32)</p> <p>Hospital Transitional Care: UB Type Bill (18x)</p> <p>Rehabilitation: UB Rev (0118, 0128, 0138, 0148, 0158)</p> <p>Respite: UB Rev (0655)</p> <p>Intermediate Care Facility: POS (54)</p> <p>Residential Substance Abuse Treatment Facility: UB Rev (1002), POS (55)</p> <p>Psychiatric Residential Treatment Facility Center: HCPCS (T2048, H0017-19), UB Rev (1001), POS (56)</p> <p>Comprehensive Inpatient Rehabilitation Facility: POS (61)</p>
Risk Adjustment	no risk adjustment necessary None.
Stratification	N/A

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	0018 Controlling High Blood Pressure
Type Score	Rate/proportion better quality = higher score
Algorithm	

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1662 Angiotensin Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy

Description: Percentage of patients aged 18 years and older with a diagnosis of CKD (not receiving RRT) and proteinuria who were prescribed ACE inhibitor or ARB therapy within a 12-month period

Numerator Statement: Patients who were prescribed ACE inhibitor or ARB therapy within a 12-month period

*The above list of medications/drug names is based on clinical guidelines and other evidence. The specified drugs were selected based on the strength of evidence for their clinical effectiveness. This list of selected drugs may not be all-inclusive or current. Physicians and other health care professionals should refer to the FDA's web site page entitled "Drug Safety Communications" for up-to-date drug recall and alert information when prescribing medications.

Definitions:

Prescribed – May include prescription given to the patient for ACE Inhibitor or ARB therapy OR patient already taking ACE Inhibitor or ARB therapy as documented in the current medication list

Denominator Statement: All patients aged 18 years and older with the diagnosis of CKD (Stages 1-5, not receiving RRT) and proteinuria

Definitions:

Proteinuria:

1. >300mg of albumin in the urine per 24 hours OR
2. ACR >300 mcg/mg creatinine OR
3. Protein to creatinine ratio > 0.3 mg/mg creatinine

RRT (Renal Replacement Therapy)-For the purposes of this measure, RRT includes hemodialysis, peritoneal dialysis, and kidney transplantation

Exclusions: Documentation of medical reason(s) for not prescribing ACE inhibitor or ARB therapy (eg, pregnancy, history of angioedema, cough due to ACE Inhibitor or ARB therapy, allergy to medications, other medical reasons)

Documentation of patient reason(s) for no

Adjustment/Stratification: No risk adjustment or risk stratification. As a process measure, no risk adjustment is necessary. We encourage the results of this measure to be stratified by race, ethnicity, primary language, and gender, and have included these variables as recommended data elements to be collected.

Level of Analysis: Clinician : Group/Practice, Clinician : Individual, Clinician : Team

Type of Measure: Process

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

Measure Steward: American Medical Association

Steering Committee 8/16-17

Importance to Measure and Report (based on decision logic): **Yes**

1a. Impact: H-13; M-7; L-0; I-0; 1b. Performance Gap: H-2; M-14; L-2; I-2

Rationale: Hypertension is a high impact topic. 1b State that among patients with CKD, use of ACEi/ARBs is 56-57% - but what about use among those with albuminuria/proteinuria (focus of measure)? Performance data on this measure from PQRS: median performance 62.5%; 25th percentile 33.3% and 75th percentile 100%. Disparity in care demonstrated for prevalence of hypertension, but not for use of ACEi/ARB.

1c. Evidence (based on decision logic): **Yes** IF a Health Outcome, rationale supports: **NA**

Quantity: **H-1; M-19; L-0; I-1**; Quality: **H-1; M-18; L-1; I-1**; Consistency: **H-1; M-17; L-1; I-1**

Rationale: Although numerous studies have been completed there are still considerable discrepancies in the final outcomes of treatment in various cohorts with high blood pressure and albuminuria, with and without diabetes. Does not clarify quantity of studies examining ACEi/ARB use for CKD with albuminuria independent of blood pressure (measure does not require patients to be hypertensive). However, hard to find patients with no hypertension. Most studies in diabetes with hypertensive patients demonstrate benefit. One-quarter of diabetic patients did not have hypertension and had same benefit. Evidence strong for normotensive diabetics with >300 proteinuria. Most trials include hypertensive patients. What are data to support 300? Most benefit shown at 500. Overt albuminuria is a critical definition in this measure, but few patients may have a 24-hour urine for albuminuria - developer stated working on better definition for proteinuria (>300 in urine over 24 hr, albumin/creatinine ratio >300, protein/creatinine ratio >0.3).

2. Scientific Acceptability of Measure Properties (based on decision logic): **No** **2a. Reliability: H-0; M-7; L-11; I-3 2b. Validity: H-0; M-7; L-12; I-1**

Rationale: eSpecs have problems, so removed from consideration for now. Reliability testing in 4 practices for chart abstraction only. What was reliability and validity of exclusion data? Face validity systematically assessed by expert group who developed the measure. There was an 18% exception rate and it may be an issue when using electronic record. Some reasons identified for exceptions are actually reasons patient should be on ACE/ARB - demonstrates problem with lack of standardized defined exclusions that are then defined by each individual physician.

2c. Disparities: H-; M-; L-; I- Rationale:

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<p>1662 Angiotensin Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy</p>
<p>3. Usability: H-; M-; L-; I- <i>(Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting and 3b. Quality Improvement)</i> Rationale:</p>
<p>4. Feasibility: H-; M-; L-; I- <i>(4a. Clinical data generated during care process; 4b. Electronic data; 4c. Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented)</i> Rationale:</p>
<p>Preliminary Assessment of Criteria Met/Suitable for Endorsement: Y-; N-; A- <i>(All criteria met, but final recommendation pending further information and/or evaluation of related and competing measures)</i> Comments: If applicable, Questions for Committee: If applicable, Conditions/Questions for Developer: Developer Response: The developer requested reconsideration. With regards to our proposed ACE/ARB measure, this measure is highly reliable as shown by the inter-rater reliability testing performed in the CKD/ESRD testing project. In addition, we have performed extensive research and analysis on ACE/ARB measure exception reliability in our Cardio-HIT project. Measure 1662 is identical to the measure tested in Cardio-HIT, differing only in populations. <i>In the Cardio-HIT project, over 90% of exceptions automatically reported were validated upon manual review of the medical record.</i>¹⁴ Some SC members expressed concern about difficulty in documenting the “high” exception rate (18%) in the medical record. We are unaware of any specific evidence that speaks to difficulty in documenting exceptions. On the contrary, we request the opportunity to present the PCPI methodology regarding including exceptions in our measures, as well as data from our Cardio- HIT published study¹⁴ to refute concerns regarding the reliability and validity of the exceptions (Appendix A). We hope that our explanatory comments will better clarify the PCPI exception methodology and lessons learned from the Cardio-HIT and other projects, and we respectfully request that the SC reconsider recommending this ACE/ARB measure to further emphasize the importance of tracking the outcomes of care <i>and</i> the care provided to patients with CKD. Our proposed ACE/ARB measure was tested in the same measure testing project as our other CKD/ESRD performance measures. Four nephrology practice sites representing various types, locations and sizes were identified to participate in testing the measures: □The number of physicians per site ranged from 5-62 physicians □The sites were located in four different regions: Midwestern, Western, Eastern, and Southern □Patient visit volume ranged from 60-2,250 CKD patients and 240-2,800 ESRD patients seen per month □Sample size per physician organization ranged from 24-30 for a total of 112 patients with Chronic Kidney Disease (CKD) □Sample selection: Data were collected from the medical records of the first 35 patients seen at each site after July 1, 2007 Data abstracted from patient records were used to calculate inter-rater reliability for the measure. Patients were randomly selected from visits for chronic kidney disease. Data analysis included: • Percent agreement • Kappa statistic to adjust for chance agreement Results from this testing project showed the measure to be highly reliable, and were as follows: Measure (N, % Agreement, Kappa (95% Confidence Interval)) ACE Inhibitor or ARB Therapy Measure (73, 93.15%, 0.8047 (0.6395- 0.9699)) Exceptions included medical reasons and patient reasons—they were analyzed for frequency and variability across providers. The exception rate for this measure was 18%. <i>There is no reason to think that this rate reduces the reliability of the measure (Appendix A). Out of 112 cases, the chart abstractors agreed on 107 of them, for a 95.5% reliability percentage. These numbers include the 13 cases that were coded as exceptions.</i> In a test of exceptions for CAD measures, on average, exceptions in 92.6% (CI, 90.3% to 94.9%) of patients were appropriate.¹⁴ We found no difference between the percentage of valid reported exceptions for the 2 sites that reported exceptions only when the drug was not prescribed versus the percentage for the 3 sites that reported all exceptions (<i>P</i> = 0.38; chi-square test).¹⁴ Agreement between automatically reported and manually reported exceptions ranged from 88.6% (CI, 81.3% to 95.4%) for antiplatelet therapy to 93.9% (CI, 90.8% to 97.0%) for therapy to lower LDL cholesterol level, although that pairwise difference was not statistically significant (<i>P</i> = 0.128; chi-square test).¹⁴ In summary, our ACE/ARB measure was designed to highlight specific therapy that has been shown to slow the progression of CKD in patients with CKD and proteinuria. In addition, based on the Steering Committee’s recommendation, we have updated the definition of proteinuria in the measure. <i>We believe that our ACE/ARB measure exception reliability is the same as that tested in our Cardio-HIT project (Appendix A), differing only in populations.</i> We hope that these explanatory comments better clarify the PCPI exception methodology and lessons learned from the Cardio-HIT and other projects, and we request that the SC reconsider recommending this ACE/ARB measure to further emphasize the importance of tracking the outcomes of care <i>and</i> the care provided to patients with CKD.</p>
<p>Steering Committee Follow-up: Conference call 10/28 and re-evaluation</p>
<p>5. Related and Competing Measures <i>(5a. Harmonization; 5b. Superior to competing measures)</i> Comments:</p>
<p>10/28 Steering Committee Conference Call The Steering Committee was split on whether to reconsider this measure (Y-10; Unsure-3; N-9). 1.Importance to Measure and Report One committee member stated that the evidence to support >300 rather than a higher level was weak. Another noted that it does not take into</p>

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account other considerations such as comorbidities, history of progression or stability, whether hypertensive.

2. Scientific Acceptability of Measure Properties

2a1.4-7 The developer also revised the denominator definition of albuminuria

2a. A committee member asked about reliability of the CPT-II codes; however that was not tested. The developer conducted reliability testing on interabstractor agreement using medical records, even though the measure was implemented using CPT-II codes on claim forms. The reported reliability statistic appears to be for the overall score, so information on the individual data elements such as the exceptions is not available.

2b. The issue regarding broad exceptions and individual physicians identifying incorrect reasons for an exception is about validity and potential impact on comparability across physicians. There was an 18% exception rate for this measure. (See items 2a1.8-9 and 2b3.1-3).

3. Usability

4. Feasibility

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1668 Laboratory Testing (Lipid Profile)

Description: Percentage of patients aged 18 years and older with a diagnosis of CKD (stage 3, 4 or 5, not receiving RRT) who had a fasting lipid profile performed and results documented at least once within a 12-month period

Numerator Statement: Patients who had a fasting lipid profile performed and results documented at least once within a 12-month period

Denominator Statement: All patients aged 18 years and older with a diagnosis of CKD (stage 3, stage 4 or 5, not receiving RRT)

Defintion:

RRT (Renal Replacement Therapy)-For the purposes of this measure, RRT includes hemodialysis, peritoneal dialysis, and kidney transplantation

Exclusions: Documentation of patient reason(s) for not performing a fasting lipid profile (eg, patient declined, other patient reasons)

Adjustment/Stratification: No risk adjustment or risk stratification As a process measure, no risk adjustment is necessary. We encourage the results of this measure to be stratified by race, ethnicity, primary language, and gender, and have included these variables as recommended data elements to be collected.

Level of Analysis: Clinician : Group/Practice, Clinician : Individual, Clinician : Team

Type of Measure: Process

Data Source: Administrative claims, Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Laboratory, Electronic Clinical Data : Registry, Paper Records

Measure Steward: American Medical Association

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Importance to Measure and Report (based on decision logic): **Yes**

1a. Impact: H-6; M-14; L-1; I-0; 1b. Performance Gap: H-5; M-13; L-0; I-1

Rationale: Performance gap data for PQRI program median performance 46.7% and 56.6% of patients did not receive lipid profile.

1c. Evidence (based on decision logic): **Yes** IF a Health Outcome, rationale supports: **NA**

Quantity: H-13; M-6; L-; I-1; Quality: H-1; M-19; L-1; I-0; Consistency: H-0; M-16; L-4; I-1

Rationale: Evidence from clinical practice guidelines. No data on final quantity of studies but started with 100s. Assessing lipid levels is not proximal to desired outcome. Does lipid monitoring affect outcomes? Primary reason is to reduce ACVD, which is unproven; affect on progression of CKD was speculative until SHARP trial which demonstrated no affect on renal outcomes. Inferring what's good for general pop may be good for CKD population. The SHARP trial directly addresses the question of benefit - 9000 patient study nondialysis avg GFR at baseline was 27 among 6,000 nondialysis patients - includes CKD3 - treating improves CV outcomes, which strengthens evidence that screening is worthwhile. SHARP only one so far that treatment improves CV mortality in dialysis patients; 4D and Aurora show improvement with CKD patients.

2. Scientific Acceptability of Measure Properties (based on decision logic): **Yes** **2a. Reliability: H-2; M-14; L-4; I-0 2b. Validity: H-1; M-13; L6; I-1**

Rationale: Reliability testing in 4 nephrology practices only for chart abstraction. eSpecs include CPT-II or actual lab data for numerator but eSpecs need to be checked and cross walked. Face validity systematically assessed by expert group that developed measure. CD coding may miss large numbers of CKD patients cared for by non-nephrologists. Is that a function of the measure or the process? Developer considering adding 2 GFR results <60. Two papers have demonstrated that ICD-9 not sensitive to identify CKD therefore will under-report CKD. No upper age limit - is it necessary to do lipid testing in 85-90 year olds? NHANES arbitray cut-off of 85. No evidence either way. In the very old this as risk factor fades away because will die of something.

2c. Disparities: H-; M-; L-; I- Rationale:

3. Usability: H-2; M-16; L-2; I-0

(Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting and 3b. Quality Improvement)

Rationale: The measure using CPT-II codes is reported but physician performance data not publicly available. Stated will be used in 2011 physician reporting; no information on when publicly available.

4. Feasibility: H-; M-12; L-8; I-1

(4a. Clinical data generated during care process; 4b. Electronic data; 4c. Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented)

Rationale: If using medical record what if no note about review of result? The measure is not about review just that result is in the chart. Referring to "documentation" may be confusing.

Preliminary Assessment of Criteria Met/Suitable for Endorsement: Y-18; N-3; A-

(All criteria met, but final recommendation pending further information and/or evaluation of related and competing measures)

Comments: Developer considering adding 2 GFR results <60. eSpecs include CPT-II or actual lab data but eSpecs need to be checked and crosswalked. No upper age limit - is it necessary to do lipid testing in 85-90 year olds? Referring to "documentation" may be confusing.

If applicable, Questions for Committee:

If applicable, Conditions/Questions for Developer: Developer considering adding 2 GFR results <60. eSpecs include CPT-II or actual lab

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data but eSpecs need to be checked and crosswalked. No upper age limit - is it necessary to do lipid testing in 85-90 year olds? Referring to "documentation" may be confusing.

Developer Response: PCPI appreciates the opportunity to review and provide an update of our eSpecifications. PCPI specifications staff is in the process of reviewing and updating the eSpecifications for accuracy. For this measure, we identify patients with Chronic Kidney Disease using a diagnosis code, that would be expected to be present in the problem list in an EHR. One of the requirements of the CMS EHR Incentive Program (Meaningful Use) is that the problem list in the EHR is maintained and current. For this reason, and given that these measures are intended for use for patients with known Chronic Kidney Disease, we use the diagnosis to identify eligible patients for this measure. Per the Steering Committee request, we have removed the language of "results documented" from the measure.

In regards to an upper age limit for this measure, the Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel IV) is expected to be released for public comment sometime in the Fall of 2011, while the expected release date is not until 2012. The Adult Treatment Panel III (ATP III) does not indicate an upper age limit for lipid testing. On the contrary, ATP III states: "Risk for coronary disease increases steeply with advancing age in men and women. At any given level of LDL cholesterol, risk for CHD is higher in older than in younger people. The principal reason that risk rises with age is that age is a reflection of the progressive accumulation of coronary atherosclerosis, which in turn reflects the cumulative exposure to atherogenic risk factors, both known and unknown. On average, older persons have more coronary atherosclerosis than do younger persons. Once atherosclerosis develops, the coronary plaque itself becomes a 'risk factor' for development of clinical CHD. This is because plaque ruptures produce acute coronary events (unstable angina or myocardial infarction), or when plaques grow large, coronary obstructive symptoms (angina pectoris) occur. Recent clinical trials indicate that older persons benefit from LDL-lowering therapy similarly to middle-aged individuals.

Evidence statement: Advancing age is a major, independent risk factor for CHD (C1).

Recommendation: Age should count as a risk factor to modify LDL-cholesterol goals in primary prevention.

Approximately two-thirds of first major coronary events occur in persons ≥ 65 years. Many asymptomatic older persons have advanced coronary atherosclerosis. Recent clinical trials have revealed that aggressive LDL-lowering therapy is effective in reducing risk for CHD. Therefore, the prospects for reducing clinical CHD in the United States by intensive LDL lowering are good. To maximize this benefit, LDL-lowering drugs will be needed for many persons at higher risk." (National Heart, Lung, and Blood Institute, National Institutes of Health. Third Report of the National Cholesterol Education Program [NCEP] Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults [Adult Treatment Panel III]. September 2002.)

In addition, no upper age limit for lipid testing is indicated in the KDOQI Clinical Practice Guidelines for Managing Dyslipidemias in Chronic Kidney Disease (*American Journal of Kidney Diseases*, Vol 41, No 4, Suppl 3 (April), 2003: pp S1-S2).

Steering Committee Follow-up: Reviewed on the 10/28 call – the developer will revise specifications removing language about documentation and two GFR results < 60. No further action suggested.

5. Related and Competing Measures (5a. Harmonization; 5b. Superior to competing measures)

Comments:

Steering Committee Recommendation for Endorsement:

Rationale:

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Dialysis Adequacy

<p>0249 Hemodialysis Adequacy Clinical Performance Measure III: Hemodialysis Adequacy--HD Adequacy-- Minimum Delivered Hemodialysis Dose</p> <p>Description: Percentage of all adult (>=18 years old) patients in the sample for analysis who have been on hemodialysis for 6 months or more and dialyzing thrice weekly whose average delivered dose of hemodialysis (calculated from the last measurements of the month using the UKM or Daugirdas II formula) was a spKt/V >= 1.2 during the study period.</p> <p>Numerator Statement: Number of patients in denominator whose delivered dose of hemodialysis (calculated from the last measurements of the month using the UKM or Daugirdas II formula) was a spKt/V >= 1.2.</p> <p>Denominator Statement: All adult (>= 18 years old) patients in the sample for analysis who have been on hemodialysis for 6 months or more and dialyzing thrice weekly.</p> <p>Exclusions: Patients on HD less than 6 months; HD patients dialyzing <3 times per week or >3 times per week.</p> <p>Adjustment/Stratification: No risk adjustment or risk stratification Not applicable. No stratification for this measure.</p> <p>Level of Analysis: Facility</p> <p>Type of Measure: Outcome</p> <p>Data Source: Electronic Clinical Data</p> <p>Measure Steward: Centers for Medicare & Medicaid Services</p>
<p>Steering Committee 8/16-17</p> <p>Importance to Measure and Report (based on decision logic): Yes</p> <p>1a. Impact: H-19; M-1; L-0; I-0; 1b. Performance Gap: H-1; M-19; L-1; I-0</p> <p>Rationale: CROWNWeb data 2010 shows better adherence to adequacy "standard" than before, but still shows an important performance gap. No disparities in performance were observed.</p> <p>1c. Evidence (based on decision logic): Yes IF a Health Outcome, rationale supports: NA Quantity: H-17; M-4; L-0; I-0; Quality: H-6; M-15; L-0; I-0; Consistency: H-10; M-11; L-0; I-0</p> <p>Rationale: Evidence still supports better mortality in highest Kt/V group. There is a consistent correlation with mortality in observational retrospective studies. No RCTs other than HEMO which studied the target specified in this measure and a 16% higher dose, which did not demonstrate a survival advantage. DOPPS data not from an RCT but is prospective and provides evidence for 1.2 in spKt/V. Some DOPPS data on duration of dialysis indicates an independent affect on outcome. No substantial additional studies to address whether Kt/V is the best measure.</p>
<p>2. Scientific Acceptability of Measure Properties (based on decision logic): Yes 2a. Reliability: H-12; M-9; L-0; I-0 2b. Validity: H-2; M-19; L-0; I-0</p> <p>Rationale: The developer submitted additional testing information. Precision of the measure score was analyzed and for this measure the interunit reliability was 0.97.</p> <p>When using spKt/V rather than standard Kt/V can only compare if same frequency but there is an increasing # of patients on different frequencies who will not be included in the measure, so the Committee urges the developer to explore changing to standard Kt/V. A question was raised as to whether this measure should address persistent values vs. every month. The developer stated the numerator and denominator are in months but the specifications do not appear that way. Concern was expressed about the exclusion time of 6 mo and asked if the developer could provide some analysis about reducing to 3 mo. It was noted that there is facility variation on proportion of referred patients on a catheter which could differentially affect performance on this measure for a shorter time. Others suggested that would increase the incentive to not use catheters. Validity testing demonstrated that lower performance scores on dialysis adequacy were associated with higher standardized mortality ratio (especially for the 2 lowest quintiles of performance, not strictly linear). One way to potentially game this measure is to encourage patients to stay maximum time for last dialysis session of the month, which is used to calculate the spKt/V.</p> <p>2c. Disparities: H-; M-; L-; I- Rationale: No disparities in performance were observed.</p>
<p>3. Usability: H-17; M-4; L-0; I-0 (Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting and 3b. Quality Improvement)</p> <p>Rationale:</p>
<p>4. Feasibility: H-21; M-0; L-0; I-0 (4a. Clinical data generated during care process; 4b. Electronic data; 4c. Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented)</p> <p>Rationale: One way to potentially game this measure is to encourage patients to stay maximum time for last dialysis session of the month, which is used to calculate the spKt/V.</p>
<p>Preliminary Assessment of Criteria Met/Suitable for Endorsement: Y-21; N-0; A-0 (All criteria met, but final recommendation pending further information and/or evaluation of related and competing measures)</p> <p>Comments: The developer stated the numerator and denominator are in months but the specifications do not appear that way. Concern was expressed about the exclusion time of 6 mo and asked if the developer could provide some analysis about reducing to 3 mo.</p>

NATIONAL QUALITY FORUM

0249 Hemodialysis Adequacy Clinical Performance Measure III: Hemodialysis Adequacy--HD Adequacy-- Minimum Delivered Hemodialysis Dose

If applicable, Questions for Committee:

If applicable, Conditions/Questions for Developer: The developer stated the numerator and denominator are in months but the specifications do not appear that way. Concern was expressed about the exclusion time of 6 mo and asked if the developer could provide some analysis about reducing to 3 mo.

Developer Response:

The current measure specifications for measure #0249: *Hemodialysis Adequacy ESRD- HD Adequacy CPM III: Minimum Delivered Hemodialysis Dose for ESRD* require patients to be on hemodialysis for at least 6 months. The NQF Steering Committee has requested analyses in order to determine if this requirement can be reduced from 6 months to 3 months. Attached are descriptive statistics, reliability and validity analyses, and graphical displays of both measures.

Facility-level performance by measure specification

Pearson correlation coefficient showed facility-level performance on these two measures was highly correlated in all measurement months, with coefficients ranging from 0.956 to 0.999. All correlation coefficients were highly significant at $p < 0.0001$.

Table 1 (below) presents the distribution of facility level performance by percentile using CROWNWeb data from January 2010. Using the 6 month measure, 66% of facilities had at least 70% of patients meeting the $\text{spKt/V} \geq 1.2$ dose requirement, compared to 67% if the measure is change to 3 months on dialysis. However, approximately 27% of facilities had at least 90% of patients meeting the 6 month measure requirements, compared to only 10% of facilities with 90% or more patients meeting the 3 month measure requirements.

Reliability Testing

For both measures, reliability was assessed by calculating facility-level month-to-month correlations. Pearson correlation coefficients were calculated between the current performance month and previous month for reporting months July 2009 through October 2010. Results are displayed in Table 2. Correlation coefficients ranged from 0.89 to 0.98 for the 6 month measure, and 0.88-0.98 for the 3 month measure, indicating very high month-to-month correlations and reliable data elements for both measures.

Additionally, the NQF document "Guidance for Measure Testing and Evaluating Scientific Acceptability of Measure Properties" from January 2011 suggests using ANOVA to perform a signal-to-noise analysis. ANOVA was performed on patient level data from October 2010 using each measure as the independent variable and facility as the dependent variable. The intraclass correlation coefficients for the HD adequacy measures were the same ($\text{ICC} = 0.34$) regardless of whether a patient has been on hemodialysis for at least 6 months or 3 months. The interunit reliability was also the same for both measures ($\text{IUR} = 0.97$).

Validity testing

Validity was assessed using Poisson regression models to measure the association between facility level quintiles of performance scores and the 2009 standardized mortality ratio (SMR). Facility-level performance scores were divided into quintiles and the relative risk (RR) of mortality was calculated for each quintile. The highest quintile was used as the reference group. Thus, a $\text{RR} > 1.0$ for the lower performance score quintiles would indicate a higher relative risk of mortality. Results are presented in Tables 4 and 5. Results are nearly the same for both measures, and indicate indicated lower performance scores were significantly associated with a higher SMR ($p < 0.01$).

Disparities by population group

For each facility, the percent of patients by demographic group including sex, race, ethnicity, and age category, was calculated. Facilities were then divided into quintiles based on their percentage within each demographic category. Within each facility-level quintile, the average of each facility's performance measure was calculated. The means were examined for trend across quintile. No disparities in performance were observed by race, sex, ethnicity, or age. The range in percent of patients with $\text{spKt/V} \geq 1.2$ across quintiles is presented in Table 6 below. The national performance for both measures, using CROWNWeb data from 7/2009 through 10/2010, was plotted by month (Figure 1) to determine if trends between measures were similar over time. Although the overall performance decreased slightly over time, the monthly performance rates were nearly the same for both measures.

National performance by measure specification

CROWNWeb data from January 2010 were used to assess the differences in measure performance by measure specification. In 2010, a total of 178,883 patients were eligible for the 6 month measure, and 190,101 were eligible for the 3 month measure. Thus, 11,218 patients would be included in the 3 month measure, but not the 6 month measure. Table 7 presents the measure performance for the 3 month measure, 6 month measure, and the subset of patients in the 3 month measure, but not the 6 month measure.

National performance by month since start of dialysis

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0249 Hemodialysis Adequacy Clinical Performance Measure III: Hemodialysis Adequacy--HD Adequacy-- Minimum Delivered Hemodialysis Dose

In Figure 2, Box plots of Kt/V are displayed by time (in months) since the start of dialysis for patients in their first year of hemodialysis. As shown below, patients in the first 3 to 4 months of hemodialysis had lower mean Kt/V compared to patients on dialysis longer.

Steering Committee Follow-up: Review response and data presented below. On the 10/28 call the Steering Committee recommended the exclusion be 3 months instead of 6 months. CMS agreed and will revise the specifications. Measure harmonization issues with 0323 persist. See comparison table at the end of this document.

5. Related and Competing Measures (5a. Harmonization; 5b. Superior to competing measures)

Comments:

Steering Committee Recommendation for Endorsement:

Rationale:

Table 1. Measure Description: Summary of Distribution of Measure HA III: Minimum Delivered Hemodialysis Dose defined using time on dialysis as 6 months and 3 months from January 2010 Crownweb data

Facility Performance (Percent of Patients Meeting

Excluding first 6 months the Measure) Excluding first 3 months

	<i>Facilities</i>	<i>%</i>	<i>Facilities</i>	<i>%</i>
No Patients Included in the Denominator	94	2.71	79	2.29
0%-10%	554	15.94	497	14.44
10%-19%	1	0.03	15	0.44
20%-29%	5	0.14	14	0.41
30%-39%	15	0.43	15	0.44
40%-49%	21	0.60	26	0.76

<i>Facility Performance (Percent of Patients Meeting the Measure)</i>	<i>Excluding first 6 months</i>		<i>Excluding first 3 months</i>	
	<i>Facilities</i>	<i>%</i>	<i>Facilities</i>	<i>%</i>
50%-59%	116	3.34	109	3.17
60%-69%	374	10.76	385	11.18
70%-79%	591	17.01	801	23.26
80%-89%	780	22.45	1163	33.78
90%-99%	788	22.68	332	9.64
100%	136	3.91	7	0.20

Table 2. Reliability Testing: Facility Level Month to Month Correlation of Measures Pearson's Correlation Coefficient

<i>Crownweb Data</i>	<i>Excluding first 6 months</i>		<i>Excluding first 3 months</i>	
	<i>Correlation with Previous Month</i>	<i>P-value</i>	<i>Correlation with Previous Month</i>	<i>P-value</i>
August 2009	0.89	<.0001	0.88	<.0001
September 2009	0.95	<.0001	0.95	<.0001

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October 2009	0.93	<.0001	0.94	<.0001
November 2009	0.95	<.0001	0.95	<.0001
December 2009	0.95	<.0001	0.96	<.0001
January 2010	0.95	<.0001	0.95	<.0001
February 2010	0.90	<.0001	0.91	<.0001
March 2010	0.97	<.0001	0.97	<.0001
April 2010	0.93	<.0001	0.93	<.0001
May 2010	0.97	<.0001	0.97	<.0001
June 2010	0.97	<.0001	0.97	<.0001
July 2010	0.96	<.0001	0.96	<.0001
August 2010	0.98	<.0001	0.98	<.0001
September 2010	0.93	<.0001	0.93	<.0001
October 2010	0.92	<.0001	0.92	<.0001

Table 3. ANOVA signal-to-noise results by measure using CROWNWeb 2010 data

<i>Measure</i>	<i>Intraclass Correlation (ICC)</i>	<i>R²</i>	<i>F</i>	<i>Interunit Reliability (IUR=1-(1/F))</i>	<i>P-value for F test</i>
#0249 Minimum Delivered Hemodialysis Dose- excluding first 6 months	0.34	0.35	28.66	0.97	<.0001
Minimum Delivered Hemodialysis Dose- excluding first 3 months	0.34	0.36	31.10	0.97	<.0001

Table 4. Mortality Model for Measure #0249 Minimum Delivered Hemodialysis Dose for patients undergoing dialytic treatment for 6 months or more

<i>Facility Level Quintiles</i>	<i>Relative Risk of Mortality</i>	<i>RR 95% CI</i>	<i>P-val</i>	<i>Overall Test</i>
Q1:0-65% of patients	1.11	(1.07,1.15)	<0.001	<.0001
Q2:65%-79% of patients	1.13	(1.09,1.17)	<0.001	.
Q3:79%-87% of patients	1.08	(1.05,1.12)	<0.001	.
Q4:88%-93% of patients	1.09	(1.05,1.13)	<0.001	.
Q5:93%-100% of patients	1.00	(1.00,1.00)	.	.

Table 5. Mortality Model for Measure #0249 Minimum Delivered Hemodialysis Dose for patients undergoing dialytic treatment for 3 months or more

<i>Facility Level Quintiles</i>	<i>Relative Risk of Mortality</i>	<i>RR 95% CI</i>	<i>P-val</i>	<i>Overall Test</i>
Q1:0-65% of patients	1.12	(1.08,1.16)	<0.001	<.0001
Q2:65%-79% of patients	1.13	(1.09,1.17)	<0.001	.

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Q3:79%-87% of patients	1.07	(1.04,1.11)	<0.001	.
Q4:88%-92% of patients	1.10	(1.06,1.14)	<0.001	.
Q5:92%-100% of patients	1.00	(1.00,1.00)	.	.

Table 6. Facility-level %Kt/V \geq 1.2 by Population Group and Measure Specification

Population Group	Excluding first 6 months	Excluding first 3 months
	Range (min, max)	Range (min, max)
Females	70.2%-72.5%	70.3%-72.2%
Black	69.0%-73.8% ^a	69.0%-73.5% ^a
White	68.6%-74.1% ^b	68.5%-73.7% ^b
Hispanic	67.7%-75.5% ^c	67.8%-75.3% ^c
Age	70.6%-73.6%	70.4%-73.5%

^aHighest performance in facilities with 69% or more Black

patients ^bHighest performance in facilities with 0-27% or more

White patients ^cHighest performance in facilities with 19% or more Hispanic patients

Table 7. Measure performance by specification based on January 2011 CROWNWeb data

	<i>Patients in Denominator</i>	<i>Patients in Numerator (% of Denominator)</i>
Excluding first 6 months	178,883	129,079 (72.2%)
Excluding first 3 months	190,101	135,716 (71.4%)
Months 4-6 only	11,218	6,637 (59.2%)

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Figure 1.

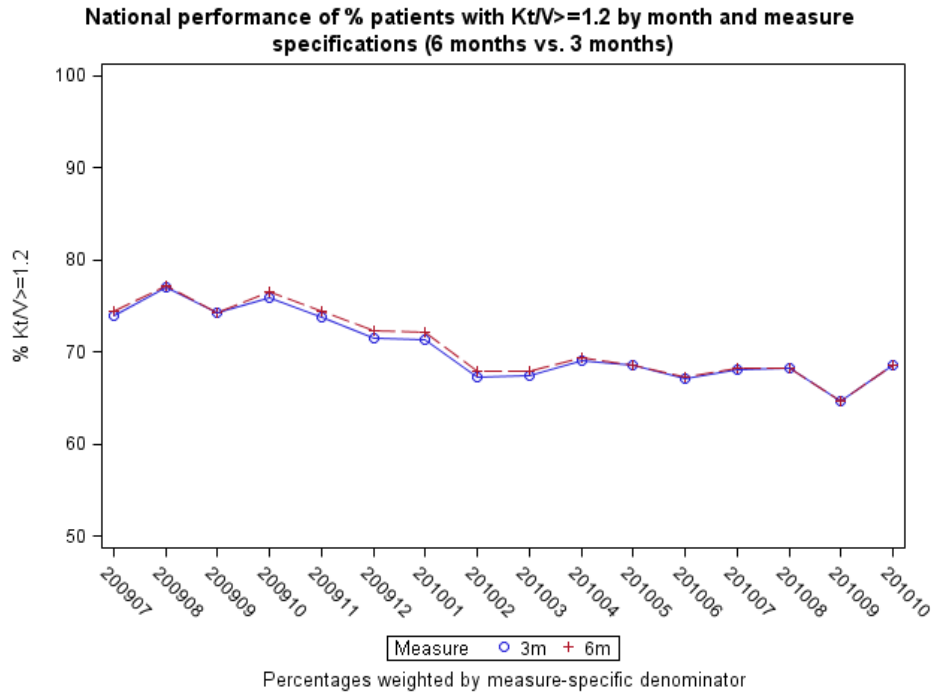
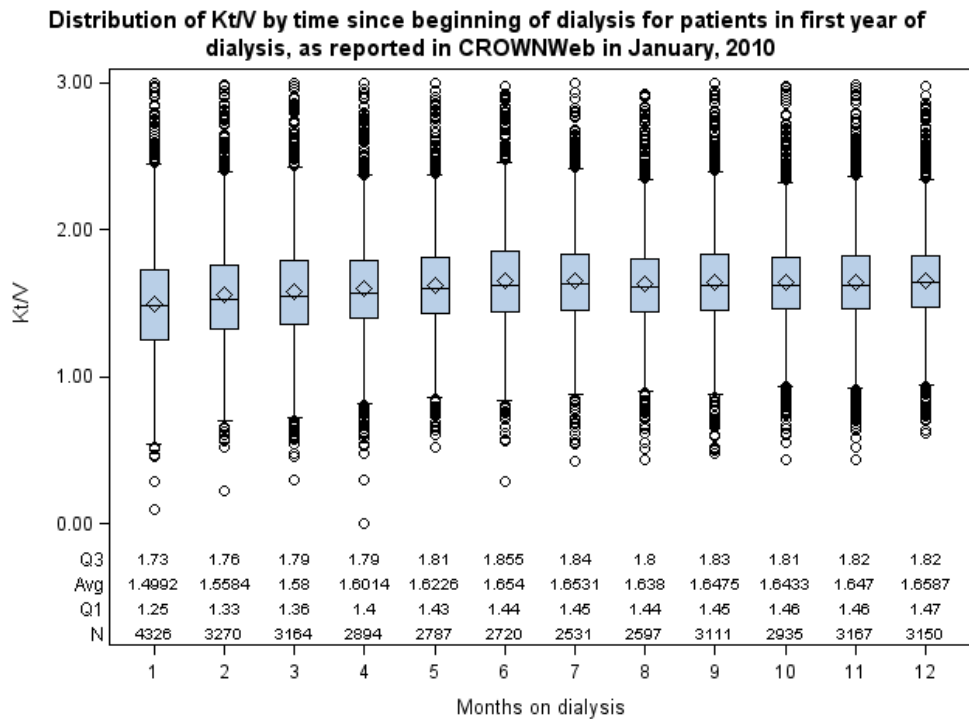


Figure 2.



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0323 Hemodialysis Adequacy: Solute

Description: Percentage of calendar months within a 12-month period during which patients aged 18 years and older with a diagnosis of ESRD receiving hemodialysis three times a week have a spKt/V > or = 1.2

Numerator Statement: Calendar months during which patients have a spKt/V > or = 1.2

Denominator Statement: All calendar months during which patients aged 18 years and older with a diagnosis of ESRD are receiving hemodialysis three times a week

Exclusions: Documentation of medical reason(s) for patient not having a spKt/V > or = 1.2 (eg, patient has residual kidney function, other medical reasons)

Adjustment/Stratification: Other We account for risk adjustment by inclusion of the exceptions for this measure. Exceptions for this measure are listed above, in section 2a1.8. We encourage the results of this measure to be stratified by race, ethnicity, gender, and primary language, and have included these variables as recommended data elements to be collected.

Level of Analysis: Clinician : Group/Practice, Clinician : Individual, Clinician : Team

Type of Measure: Outcome

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

Measure Steward: American Medical Association - Physician Consortium for Performance Improvement

Steering Committee 8/16-17

Importance to Measure and Report (based on decision logic): **Yes**

1a. Impact: H-20; M-0; L-0; I-0; 1b. Performance Gap: H-4; M-17; L-0; I-0

Rationale: 2008 PQRI data indicate 41% of patients did not achieve Kt/V of 1.2; physician performance at 25th percentile 29.77%, median at 60%, and 75th percentile at 79.29%. Disparities old data from the 90s.

1c. Evidence (based on decision logic): **Yes** IF a Health Outcome, rationale supports: **NA**

Quantity: **H-17; M-4; L-0; I-0**; Quality: **H-5; M-16; L-0; I-0**; Consistency: **H-4; M-16; L-1; I-0**

Rationale: Observational studies show better outcomes with higher dialysis dose. Relatively few RCTs, and one major (HEMO) does not show evidence of improved outcomes with higher Kt/V urea. HEMO dose separation between test and control groups was only about 15% different.

2. Scientific Acceptability of Measure Properties (based on decision logic): **Yes 2a. Reliability: H-0; M-17; L-2; I-2 2b. Validity: H-0; M-18; L-1; I-2**

Rationale: Electronic specs removed from consideration due to inaccuracies until developer checks and crosswalks to specifications. Measure has been implemented using CPT-II codes but reliability testing conducted with inter-rater reliability for chart abstraction in 4 physician practices. Chart abstraction demonstrated good reliability. Prior measure included a plan of care component, which has been eliminated; but added a non-specific exclusion of "medical reason" that is determined by each physician being measured. No data were provided on this new exclusion. Face validity systematically assessed by group who developed the measure.

2c. Disparities: H-; M-; L-; I- **Rationale:** Developer stated results can be stratified by race, gender, etc., to examine potential disparities.

3. Usability: H-14; M-7; L-0; I-0

(Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting and 3b. Quality Improvement)

Rationale:

4. Feasibility: H-13; M-8; L-0; I-0

(4a. Clinical data generated during care process; 4b. Electronic data; 4c. Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented)

Rationale:

Preliminary Assessment of Criteria Met/Suitable for Endorsement: Y-20; N-1; A-0

(All criteria met, but final recommendation pending further information and/or evaluation of related and competing measures)

Comments: eSpecs need to be checked and crosswalked to specifications. Please provide more up-to-date data on disparities.

If applicable, Questions for Committee:

If applicable, Conditions/Questions for Developer: eSpecs need to be checked and crosswalked to specifications. Please provide more up-to-date data on disparities.

Developer Response: PCPI appreciates the opportunity to review and provide an update of our eSpecifications. PCPI specifications staff is in the process of reviewing and updating the dialysis procedure codes for accuracy. We have included procedure codes using SNOMED based on the guidance provided by the ONC Health Information Technology Standards Committee, but have also included CPT during this time of transition to EHRs. Because of the fact that SNOMED concepts are intended to capture clinical information within health IT systems, whereas CPT is designed for billing purposes, there will be differing levels of granularity in each terminology. The codes and concepts identified in each terminology should not be compared to each other but rather the allowable values within each terminology should be assessed as to whether they capture the concept in the performance measure.

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0323 Hemodialysis Adequacy: Solute

HD Adequacy: Solute Disparities Data:

The proportion of all patients with an adequate hemodialysis dose increased 2-fold from 43% in 1993 to 86% in 2000. In 1993, 46% of white patients and 36% of black patients received an adequate dose. Corresponding figures for 2000 were 87% and 84%, respectively. Thus, the gap between white and black patients decreased from 10% to 3%. In 1993, 54% of female patients and 31% of male patients received an adequate hemodialysis dose. Corresponding figures for 2000 were 91% and 82%, respectively. Thus, the gap between female and male patients decreased from 23% to 9%. In addition, the magnitude of gaps between whites and blacks and between women and men varied by region. Eleven regions had race gaps of 4% or less. However, no region had similarly small sex gaps.

Sehgal AR. Impact of Quality Improvement Efforts on Race and Sex Disparities in Hemodialysis. JAMA, February 26, 2003-Vol 289, No. 8.

Steering Committee Follow-up: Reviewed on the 10/28 call. No further action related to disparities indicated. Measure harmonization issues with 0323 persist. See comparison table at the end of this document.

5. Related and Competing Measures (5a. Harmonization; 5b. Superior to competing measures)

Comments:

NATIONAL QUALITY FORUM

0321 Peritoneal Dialysis Adequacy: Solute

Description: Percentage of patients aged 18 years and older with a diagnosis of ESRD receiving peritoneal dialysis who have a total Kt/V \geq 1.7 per week measured once every 4 months

Numerator Statement: Patients who have a total Kt/V \geq 1.7 per week measured once every 4 months

Definition:

Total Kt/V includes residual kidney function and equals peritoneal dialysate Kt/V plus renal Kt/V

Denominator Statement: All patients aged 18 years and older with a diagnosis of ESRD receiving peritoneal dialysis

Exclusions: None

Adjustment/Stratification: We encourage the results of this measure to be stratified by race, ethnicity, gender, and primary language, and have included these variables as recommended data elements to be collected. This measure is not risk adjusted.

Level of Analysis: Clinician : Group/Practice, Clinician : Individual, Clinician : Team

Type of Measure: Outcome

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

Measure Steward: American Medical Association - Physician Consortium for Performance Improvement

9/20 Workgroup Call Summary

The following summarizes the workgroup's discussion and subsequent action (if any) for this measure:

1.Importance to Measure and Report

1a. Impact – Preliminary ratings indicated agreement that high impact was met.

1b. Performance Gap – Performance data for this previously endorsed measure was not provided – quoted some statistics from 2008 CMS Clinical Performance Measures but unclear how to interpret for this measure.

1c. Evidence – The Committee members thought it was difficult to evaluate this measure without knowing if it incorporates residual kidney function in the value of \geq 1.7 or how the exception of residual kidney function is defined.

2. Scientific Acceptability of Measure Properties

2a. Reliability – In response to a question, the developer confirmed that the specifications should be \geq 1.7. It was noted that the prior specifications included a plan of care component in the numerator, which has been removed and replaced with the denominator exclusions. The testing was based on the prior specifications. The Committee asked if there was any analysis of the exclusions.

2b. Validity

3. Usability

4. Feasibility

5. Suitable for endorsement The Committee requested clarification from the developer on whether the measure incorporates endogenous kidney function and precise definitions for the exclusions (exceptions of residual kidney function and medical reasons)

If applicable, Conditions/Questions for Developer:

Regarding the Specifications:

- Please define total Kt/V, specifically accounting for endogenous kidney function.
- Please clarify in the Numerator Statement and Numerator Details Kt/V greater than or equal to 1.7, listing specific details for endogenous kidney function.

Regarding the Exclusions:

- Please clarify your definition of residual kidney function.
- Please list and define "other medical reasons" as currently named in the Exclusions.
- Please provide an analysis of the defined "other medical reasons" from the testing for this measure. If testing data is not available, what additional information can be provided to support the exclusions?

Developer Response: (See also revised measure submission form)

With regards to the Peritoneal Dialysis Adequacy: Solute measure, we have added a definition to account for endogenous kidney function and have completely removed the exception (exclusion) language from the measure. The numerator statement and measure description have also been updated within the form. The online form has been resubmitted, along with the updated e-specifications for this measure.

Steering Committee Follow-up: Conference call on 10/28/11 and re-evaluate.

10/28 Steering Committee Conference Call

1.Importance to Measure and Report The clarification that total clearance includes residual kidney function and removal of exclusions

NATIONAL QUALITY FORUM

0321 Peritoneal Dialysis Adequacy: Solute

allows the continuation of the full evaluation.

2. Scientific Acceptability of Measure Properties

3. Usability

4. Feasibility

NATIONAL QUALITY FORUM

Mineral Metabolism

0570 Chronic Kidney Disease (CKD): Monitoring Phosphorus

Description: To ensure that members with chronic kidney disease (CKD) who are not on dialysis are monitored for blood phosphorus levels at least once annually.

Numerator Statement: Members with phosphorus level blood tests during the measurement year.

Denominator Statement: Members with at least 1 inpatient diagnosis of chronic kidney disease during the year prior to the measurement year or members with at least 2 diagnoses of chronic kidney disease in an outpatient setting during the measurement year or year prior (at least 1 of which must be during the year prior to the measurement year).

Exclusions: Members who are on dialysis or in hospice during the measurement year. Members who were hospitalized during the numerator time frame and did not fulfill numerator criteria.

Adjustment/Stratification: No risk adjustment or risk stratification N/A N/A

Level of Analysis: Clinician : Group/Practice, Clinician : Individual, Clinician : Team, Health Plan

Type of Measure: Process

Data Source: Administrative claims

Measure Steward: IMS Health

9/19 Workgroup Call Summary (In attendance: Peter Crooks(Co-Chair); Kristine Schonder (Co-Chair); Jeffrey Berns; Michael Fischer; Alan Klinger; Lisa Latts; Joseph Nally; Andrew Narva, MD (ex officio); Jessie Pavlinac; Michael Somers; Roberta Wager)

The following summarizes the workgroup's discussion and subsequent action (if any) for this measure:

1.Importance to Measure and Report –

1a. Impact- The preliminary ratings were spread across all the rating categories.

One member noted that since this is an annual measurement and the focus is to detect early bone disease, it is an area of high impact.

1b. Performance Gap- The preliminary ratings were low to moderate. The developer did not provide performance data on this previously endorsed measure as specified for clinician level performance. The Committee agreed that there is an opportunity for improvement because there are many people who have different degrees of CKD and suspect that fairly low numbers of them actually have serum phosphorus measured annually.

1c. Evidence – The preliminary ratings were spread across all the rating categories.

The evidence was not further discussed (see prior discussion on Evidence in measure 0255).

2. Scientific Acceptability of Measure Properties

The preliminary ratings were spread across all the rating categories. The reliability and validity testing was conducted using a large, aggregated data set. They don't compute the scores at the level for which they say it's going to be used to assess performance. And the measure is reported at the clinician level but no clinician level data were provided in the results for the testing.

2a. Reliability – The Committee members questioned whether reliability was demonstrated merely by correlating scores for two plans across two years. The measure developer responded that the reason for their correlation coefficients was because they do not have access to electronic medical records or charts to perform any other reliability tests.

2b. Validity – One member expressed concern with use of the appropriate inpatient and outpatient codes. He questioned if the measure appropriately identifies individuals with CKD. The measure developer clarified that the way they defined the CKD denominator population was in line with the literature – reported sensitivity and specificity of claims data. (That could be submitted in support of validity.) One member commented that the testing also did not reveal the accuracy of their data. The measure developer agreed to submit additional information to support their reliability and validity testing results. That information will be forwarded to the workgroup for review.

3. Usability - A member questioned whether this measure would be usable beyond a closed system that has access to all the claims data. Another said that usability depends on whether it is reliable and valid.

4. Feasibility - The preliminary ratings were spread across all the rating categories.

One member expressed that it may not be very feasible to implement because the majority of patients in America with CKD are not identified in large health systems. If a measure is endorsed, how will it be assessed and monitored? It was questioned if there was any difference between endorsing ESRD measures that would be implemented by CMS in a closed, federal system and the endorsing this measure that might be used in a variety of systems. It was clarified that there is really no difference and any entity could use the measure as specified.

5. Suitable for endorsement - The preliminary ratings were spread across all the rating categories.

The workgroup agreed to review the developer's additional information on reliability and validity testing before voting again or making any

NATIONAL QUALITY FORUM

0570 Chronic Kidney Disease (CKD): Monitoring Phosphorus

recommendations for endorsement.

If applicable, Conditions/Questions for Developer: Please provide additional information to demonstrate a performance gap for this measure. Do you have any data at the provider level to support this measure? Also, what is the rationale for comparing plan level scores to a range found in the literature as a demonstration of validity (accuracy) of the data elements? NQF is asking for evidence of the validity of either: 1) the data used in the measure (e.g., accuracy of the lab date, lab method, dialysis dose); or 2) the measure score (correctness of conclusion about quality). Can you provide evidence of accuracy of patient-level data?

Developer Response: (See revised measure submission form.)

The developer provided performance on this measure in 2b5 (but did not enter in 1b2) demonstrating performance gap.

Plan A

n = 644 (number of providers scored)

Mean score = 55%, median = 50%, SD = 24%, Min = 0, Max = 100% 25 percentile = 36%, 75th percentile = 69%

Plan B

n = 835 (number of providers scored)

Mean = 52%, Median = 53%, SD = 18%, Min = 0%, Max = 100% 25th percentile = 41%, 75th percentile = 63%

The developer submitted additional reliability testing using method for signal to noise analysis as identified in the NQF measure testing report. See 2a2

Plan A reliability score = 0.72, Plan B reliability score = 0.88

The response to validity is not actual validity testing of the measure as specified, but could support face validity. See description in 2b2

Steering Committee Follow-up: Conference call on 10/28/11 and re-evaluate.

10/28 Steering Committee Conference Call

1.Importance to Measure and Report The Steering Committee approved a related measure for monthly monitoring of serum phosphorus in dialysis patients (0255). Does the evidence support annual monitoring in CKD patients (excluding dialysis) as defined in the measure?

2. Scientific Acceptability of Measure Properties The revised submission form included the requested information requested on performance gap, reliability and validity but not all of it was in the committee memo. Please see summary above and review revised submission form. One committee member noted concern about definition of CKD and potentially too many people being included for annual phosphorus monitoring – see detailed specifications provided in 2a1.4-9 for denominator and exclusion information.

3. Usability

4. Feasibility

NATIONAL QUALITY FORUM

Vascular Access

0251 Vascular Access—Functional AVF or AV Graft or Evaluation by Vascular Surgeon for Placement

Description: Percentage of end stage renal disease (ESRD) patients aged 18 years and older receiving hemodialysis during the 12-month reporting period and on dialysis >90 days who:

- (1) have a functional autogenous AVF (defined as two needles used or a single-needle device [NOT one needle used in a two-needle device]) (computed and reported separately);
- (2) have a functional AV graft (computed and reported separately); or
- (3) have a catheter but have been seen/evaluated by a vascular surgeon, other surgeon qualified in the area of vascular access, or interventional nephrologist trained in the primary placement of vascular access for a functional autogenous AVF or AV graft at least once during the 12-month reporting period (computed and reported separately).

Reporting should be stratified by incident versus prevalent patients, as defined by USRDS

Numerator Statement: Number of patients from the denominator who:

- (1) have a functional autogenous AVF (defined as two needles used or a single-needle device) (computed and reported separately); or
- (2) have a functional AV graft (computed and reported separately); or
- (3) have a catheter but have been seen/evaluated by a vascular surgeon, other surgeon qualified in the area of vascular access, or interventional nephrologist trained in the primary placement of vascular access for a functional autogenous AVF (defined as two needles used or a single needle device) or AV graft at least once during the 12-month reporting period (computed and reported separately).

Reporting should be stratified by incident versus prevalent patients, as defined by USRDS.

Denominator Statement: All ESRD patients aged 18 years and older receiving hemodialysis during the 12-month reporting period and on dialysis for greater than 90 days.

This measure includes both in-center and home hemodialysis patients.

Exclusions: Patients enrolled in hospice..

Adjustment/Stratification: No risk adjustment or risk stratification Not applicable. Not applicable.

Level of Analysis: Clinician : Individual

Type of Measure: Process

Data Source: Electronic Clinical Data : Electronic Health Record, Paper Records

Measure Steward: Kidney Care Quality Alliance

Steering Committee 8/16-17

Importance to Measure and Report (based on decision logic): **Yes**

1a. Impact: H-20; M-0; L-0; I-0; 1b. Performance Gap: H-3; M-17; L-0; I-1

Rationale: This is a physician-level measure; there is a separate facility-level CMS measure (0257). Data on performance gap is from data collected in testing (from facility and physician records) indicated a mean physician performance rate of 72%; no distribution reported. Should this be interpreted as a gap from 100%? In question about improvement, the developer stated that the measure was originally endorsed under time-limited status and this is the testing information completed in 2010.

1c. Evidence (based on decision logic): **Yes** IF a Health Outcome, rationale supports: **NA**

Quantity: **H-0; M-20; L-0; I-0;** Quality: **H-0; M-19; L-2; I-0;** Consistency: **H-7; M-14; L-0; I-0**

Rationale: No RCTs. Evidence supports that fistula have lower rates of complications. Evidence not directly about evaluation by surgeon. Not a strong case that evaluation mandated in measure will affect outcomes.

2. Scientific Acceptability of Measure Properties (based on decision logic): **No** **2a. Reliability: H-0; M-17; L-4; I-0** **2b. Validity: H-0; M-8; L-13; I-0**

Rationale: Although specified for data from CROWNWeb, information on evaluation for AVF not currently in CROWNWeb. It was clarified there is no exclusion for hospice patients. Documentation - nephrologist, surgeon, staff note and if decide not to place an AVF reason must be documented. In response to the question of how "other qualified surgeon" is defined, the developer noted that in some rural areas may not have vascular surgeon and some other surgeon places AVF. The term "qualified" infers a judgment call that is hard to capture in measure. Not just surgeons - could be interventional nephrologist. Also there are different skill levels so a fistula from one surgeon may fail that another surgeon is able to place. Practices vary so may be better to just say "evaluated by vascular surgeon or other physician for an AVF." Definition of functioning fistula requires only one occurrence of 2 needles - is that sufficient?

Tested using facility records and physician records - interrater reliability of data was high for the resulting score. For patients who have graft that's functioning well, that person would not need evaluation for fistula - could lead to overuse of yearly evaluation for approximately 15% of patients with functioning graft. What about patients who have been evaluated as not being a candidate for AVF? Representativeness of study sample isn't demonstration of validity of the data or the measure. Face validity was assumed because of prior endorsement, but no systematic assessment. The NQF measure testing TF did not consider that in its guidance. The developer stated the expert group who developed the

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<p>0251 Vascular Access—Functional AVF or AV Graft or Evaluation by Vascular Surgeon for Placement</p> <p>measure is in the additional information section. Is evaluation every year warranted if patient has functioning graft? Developer stated it was amenable to redirecting to functional permanent access. What about when catheter is only option, e.g., congenital heart disease, behavior/cognitive problems don't tolerate 2 needles. An unintended consequence of fistula first was to ignore patient choice and stratification by need. In the FHN study, home patients use catheters and complications have not been as big a problem. Evaluation may indicate AVF not appropriate. For example vein mapping might be done before would refer to surgeon and could change whether even refer to surgeon. A Committee member suggested that all the potential exceptions identified will be minimal and may not need to be in the measure. Performance on the measure does not have to be 100% and if potential exclusions don't vary substantially across physicians then should not be an issue for comparing performance. Regarding patient choice/readiness, don't want to institutionalize a system to just let it go - need to bring up again.</p> <p>2c. Disparities: H-; M-; L-; I- Rationale:</p> <p>3. Usability: H-; M-; L-; I- (Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting and 3b. Quality Improvement) Rationale:</p> <p>4. Feasibility: H-; M-; L-; I- (4a. Clinical data generated during care process; 4b. Electronic data; 4c. Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented) Rationale:</p> <p>Preliminary Assessment of Criteria Met/Suitable for Endorsement: Y-; N-; A- (All criteria met, but final recommendation pending further information and/or evaluation of related and competing measures) <u>Comments:</u> Ask the developer to consider: functioning grafts, potential exclusions hospice, elderly, patient choice, patient doesn't follow through. Definition of functioning fistula only requires one occurrence of 2 needles - is that sufficient? If applicable, Questions for Committee: If applicable, Conditions/Questions for Developer: Ask the developer to consider: functioning grafts, potential exclusions: hospice, elderly, patient choice, patient doesn't follow through. Definition of functioning fistula only requires one occurrence of 2 needles - is that sufficient? Developer Response: KCQA appreciates the opportunity to respond to the suggestions of the NQF Steering Committee in regards to Measure 0251: Vascular Access—Functional AVF or Evaluation by Vascular Surgeon for Placement. Our responses are as follows:</p> <ul style="list-style-type: none"> • Functioning Grafts: The KCQA Steering Committee agrees to incorporate functional arteriovenous grafts in the numerator statement to allow physicians to receive credit for patients with this safe and effective permanent access type. We note, however, that the measure was originally specified so as to align with <i>NQF 0257 Maximizing Placement of AVF (CMS)</i> and so have concern about harmonization issues if that measure is not similarly changed and seek NQF's guidance on how best to address this matter. • Hospice Exclusion: The KCQA Steering Committee agrees that this modification is reasonable and would bring the specifications into alignment with the other KCQA vascular access measure (<i>NQF 0262</i>), which <u>does</u> exclude hospice patients. However, KCQA agrees to adopt the exclusion only if the CMS AVF (<i>NQF 0257</i>) and catheter (<i>NQF 0256</i>) measures related to vascular access also incorporate this exclusion, so that all relevant NQF-endorsed measures are harmonized. If the CMS measures do not incorporate this exclusion, KCQA seeks NQF's guidance on how best to address the issue of measure harmonization. We note that only 2 of 1,057 patients were in hospice status during KCQA's testing. • Elderly Patient Exclusion: KCQA does not agree to incorporate an exclusion for elderly patients on the grounds that there is ample evidence indicating that AVFs and AV grafts are safe and effective vascular access options for the majority of patients of advanced age. KCQA believes that this exclusion would be a disincentive to ensuring that all eligible patients are appropriately evaluated for permanent access placement and thus compromise the quality of care provided to elderly ESRD patients. • Patient Choice and Patient Failure to Follow Up Exclusions: KCQA does not agree to incorporate an exclusion for patient choice or patient failure to follow up on the grounds that such exclusions would compromise the measure's intent to incentivize evaluation for permanent access (and concomitant education on the significant benefits of AVFs and AV grafts over catheters during that evaluation), and would make the measure susceptible to gaming. • Functional AVF Definition: The KCQA Steering Committee has concern that revising the definition of "functioning AVF" would compromise harmonization with the NQF-endorsed CMS AVF measure, which also defines functional AVFs in this manner. Moreover, we note that as currently specified, the KCQA measure does <u>not</u> require only one occurrence of two needles. Rather, the measure requires that all hemodialysis patients receive a vascular access status assessment on a yearly basis if they do not have a functioning AVF (and now AV graft). Thus if a previously functioning AVF is no longer functioning (i.e., two needles used), that patient must be evaluated by a vascular surgeon, other surgeon qualified in the area of vascular access, or interventional radiologist at least once during the 12-month reporting period for permanent access placement. • Physicians Eligible to Conduct Vascular Access Evaluation: Though not noted above, the NQF Steering Committee suggested during the meeting that KCQA refine the definition of what types of physicians are eligible to conduct the evaluation for permanent access placement. The current specifications read "vascular surgeon or other qualified surgeon." The NQF Committee noted that interventional radiologists or nephrologists would be excluded under the current construct. The purpose of the measure is for
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0251 Vascular Access—Functional AVF or AV Graft or Evaluation by Vascular Surgeon for Placement

primary placement – something the KCQA Steering Committee thought was not in the purview of interventional nephrologists or interventional radiologists, but rather vascular/other qualified surgeons; HOWEVER, if that's the Steering Committee thinks that is the only issue standing between a recommendation to advance and not, KCQA is willing to modify.

Steering Committee Follow-up: Conference call 10/28 and re-evaluation

5. Related and Competing Measures (5a. Harmonization; 5b. Superior to competing measures)

Comments:

10/28 Steering Committee Conference Call

1. Importance to Measure and Report

2. Scientific Acceptability of Measure Properties The Steering Committee acknowledged the developer changes so that patients with a functioning graft would not need to be evaluated annually and also exclude hospice patients from being referred for evaluation. Some committee members still wanted to include interventional nephrologist as qualified to do the evaluation. The developer responded that they did not think interventional radiologist was qualified and also the interventional nephrologist for primary placement. After further discussion the committee and developer agreed to language similar to that for “other surgeon qualified in the area of vascular access.” Some committee members questioned the data source and the developer responded that all the data except for evaluation are currently in CROWNWeb and that in testing they found the data in facility records so that it will be possible for facilities to enter into CROWNWeb. Some questioned who would make the determination of “qualified” and decided that would require local judgment. The committee also questioned whether measure 0262 was needed as it was a subset of this one and suggested that identification of new vs. chronic patients would be useful.

3. Usability

4. Feasibility

If applicable, Conditions/Questions for Developer: The developer was asked to address interventional nephrologist, having only measure 0251 instead of both 0251 and 0262, and new vs. chronic patients.

Developer Response: The developer included “interventional nephrologist trained in the primary placement of vascular access” The developer also specified it to stratify by incident and prevalent patients.

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0262 Vascular Access—Catheter Vascular Access and Evaluation by Vascular Surgeon for Permanent Access

Description: Percentage of patients aged 18 years and older with a diagnosis of end stage renal disease (ESRD) with a catheter after 90 days on hemodialysis who are seen/evaluated by a vascular surgeon or other surgeon qualified in the area of vascular access for permanent vascular access at least once during the 12-month reporting period.

Numerator Statement: Number of patients from the denominator who are seen/evaluated by a vascular surgeon or other surgeon qualified in the area of vascular access for permanent vascular access at least once during the 12-month reporting period.

Denominator Statement: All patients aged 18 years and older with a diagnosis of ESRD with a catheter after 90 days on hemodialysis.

Exclusions: Patients enrolled in hospice.

Adjustment/Stratification: No risk adjustment or risk stratification Not applicable. Not applicable.

Level of Analysis: Clinician : Individual

Type of Measure: Process

Data Source: Electronic Clinical Data : Electronic Health Record, Paper Records

Measure Steward: Kidney Care Quality Alliance

9/9 Workgroup Call Summary

The following summarizes the workgroup's discussion and subsequent action (if any) for this measure:

This is a companion measure for 0251 that was evaluated at the in-person meeting but did not advance due to questions about specifications and not passing Scientific Acceptability of Measure Properties (the developer has since responded).

1.Importance to Measure and Report

1a. Impact- Preliminary ratings indicated agreement that high impact was met.

1b. Performance Gap – Preliminary ratings were spread across all the rating categories. There was some confusion because it's a physician level measure, but facility level data were provided as additional evidence of performance gap. The developer clarified that the physician performance form testing in 4 practice sites was 18% and at the facilities, performance ranged from 0% to 99% with a mean performance of 69.3. The Committee discussed the discrepancy between the two results, and it was clarified that the physicians were not associated with the facilities. The committee noted that some of the performance gap may simply be due to lack of documentation, but ultimately agreed that there probably was a performance gap

1c. Evidence. One committee member noted that he was not sure there is evidence that links being seen by the surgeon with decreasing catheter prevalence and increasing fistula prevalence – the evidence is about the problems with catheters. The goal is permanent access with AVF and there is a facility measure on AVF and catheters. If facility (or physicians) doing poorly on rate of AVF, one thing to assess is whether patients are being referred or seen for evaluation.

2. Scientific Acceptability of Measure Properties

2a. Reliability – Preliminary ratings were spread across all the rating categories. It was suggested that the measure include interventional nephrologists as being an acceptable alternative to seeing a vascular surgeon. The measure developer indicated it was willing to add and had responded to include interventional radiologists for 0251 and would do so with this measure as well. Although the specifications indicate that CROWNWeb is the data source, currently there are no fields for the evaluation data. NQF staff indicated that the measure is essentially a medical record measure as it was tested. That does not negatively impact reliability but could be a consideration under Feasibility. A committee member questioned whether it was appropriate to expect facility documentation for a measure about communication between the vascular surgeon and nephrologist; however, another commented that the information is often in the facility records.

2b. Validity – Preliminary ratings were spread across all the rating categories. Validity testing is questionable based on the explanation given. There is not sufficient documentation of face validity methodology. The developer relies on face validity based on prior NQF endorsement and its expert panel (a list of experts can be found in Additional Information Ad.1 of measure submission form).

3. Usability - The developer indicated that the measure was on the April 2008 list of performance measures. The [2008 final rule for ESRD facilities](#) includes "vascular access" as a topic that must be measured, but does not specify specific measures or indications for physician-level measures. Unsure if there is a list of measures or if referring to physician reporting program.

4. Feasibility - One committee member noted concern that measure would have to rely on the surgeon or the interventionist to provide confirmation the patient was evaluated to the nephrologist (or the facility if relying on CROWNWeb. and puts a burden on facilities). There currently is no data field in CROWNWeb for the evaluation component, so the measure requires medical record abstraction. The developer pointed out that unless facilities have electronic records, much of the data for CROWNWeb require abstraction from the medical record.

5. Suitable for endorsement – Given the amount of questions and discussion, the workgroup will re-vote on this measure.

The following evaluation ratings and comments are from the Workgroup and Committee members who participated on the call
(comments separated by asterisks)

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0262 Vascular Access—Catheter Vascular Access and Evaluation by Vascular Surgeon for Permanent Access

Importance to Measure and Report (based on decision logic): Yes

1a. Impact: H-4; M-3; L-0; I-0 1b. Performance Gap: H-0; M-4; L-2; I-1

Rationale: performance gap listed for facility level. Presumed to apply to physician level as well. **Clearly the performance gap is not the difference between the results of physician office testing and facility testing--this was comparing apples to oranges. But the range of performance among facilities does suggest a large performance gap. I did not rate this "high" because the testing was facility level and this measure is a physician level measure. In actual practice, the patients at a facility will be accredited to their own MD who sees them there and the performance of this measure by the facility would be attributed to that MD. This sort of makes sense should, say, the facility fail to achieve its corresponding facility measure but within that facility a given MD passes the clinician level measure--the medical director could then see with which other MD who practices there is not performing as desired. But it does not appear that the developer directly addressed the MD level performance gap in either the original submission (2007) or in any subsequent testing. **Performance gap not demonstrated. High level of patients starting dialysis with an AVF. Other measure available

1c. Evidence (based on decision logic): No

Quantity: H-1; M-2; L-3; I-1 Quality: H-1; M-2; L-4; I-0 Consistency: H-1; M-2; L-1; I-3

Rationale: Indirect evidence presented for vascular access relationship to outcomes. **I do not believe there is any science linking this behavior (evaluation by a vascular surgeon or other qualified provider) to improved outcomes (decreased catheters). It makes sense, but the link hasn't been proven. **The evidence is strong that healthcare outcomes are best for HD pts with a functional fistula. But there is no study presented to us that shows that merely being seen by a surgeon (who may or may not be qualified to do good fistula surgery) leads to such good healthcare outcomes. At best, this measure is very distal to the outcome and the evidence for the measure focus is lacking. Rather, it requires a leap of faith. **Quantity of evidence only related to 9 peer reviewed publications with 15 clinical studies but no listing of the publications. Quality cites KDOQI which does not evaluate performance of surgeons and referrals. Consistency relates to catheter complication not the measure as stated

2. Scientific Acceptability of Measure Properties (based on decision logic): No

2a. Reliability: H-0; M-3; L-4; I-0 2b. Validity: H-0; M-2; L-5; I-0

Rationale: include interventional nephrologists in specifications. Reliability and validity testing were strong for facility level, but weaker for physician level. **The adherence to the measure in the tested facilities and practices vary across the board. Does this reflect adversely on reliability of the measure? The process of the measure requires referral to the surgeon, the patient being given an appt then keeping the appt, the surgeon evaluating the patient and presumably formulating a plan of care with the pt, the surgeon communicating back to the MD or facility, then the recording of that surgical evaluation in the patient's facility record. The testing did not confirm that this could all be done reliably and consistently. But the specifications are clear as long as the process is followed. Comments re validity are the same as in the previous commentary box. **Measurement to be in GROWNWEB but not available yet.

3. Usability: H-0; M-3; L-3; I-1

Rationale:

4. Feasibility: H-0; M-2; L-5; I-0

Rationale: Usability and Feasibility based on presumption that this data will be included in Crownweb (not currently available) ** 3a and 3b There seems to be some uncertainty about the transfer of information to accurately evaluate the data. 4c The collection of data and how it's recorded creates uncertainty **This is not very feasible on a large scale when it involves chart abstraction. There is an intention for Crown Web to add this, but it is unknown if and when this will occur **I really struggle with how to vote on these individual sections. If my voting did not allow it to pass on Scientific Acceptability, then I would favor a waiver, and here is why. Obviously, the bottom line for a given facility or for a given MD's group of pts is the catheters > 90 day prevalence and the fistula prevalence. We have a pair of CMS measures that will tell us that information. This KCQA measure is more of an earlier process measure in the chain leading to the intermediate outcome of catheter and fistula prevalence. It and its facility companion could potentially give the facility managers additional information. For instance, if the intermediate outcome is poor, then you could go to this measure and tell if or if not the patient had been seen and evaluated by the surgeon in a high % of cases. If that is "yes" you would then know you have a problem with the surgeon and deal with that. If "no" you would know you have a problem with referral, scheduling, pt compliance, etc. So pragmatically, I favor re-endorsement of the measure, but with great qualms over the status of the submission and lack of evidence on the measure focus.

Preliminary Assessment of Criteria Met/Suitable for Endorsement: Y-2; N-5

Rationale: Physician level measure is complement to facility measure. **0262 There seems to be too much confusion and discussion on this measure about the collection and transfer of data. **While it seems a good idea, there is no evidence linking this specific performance to the desired outcome. Validity testing is weak. I am also concerned about feasibility (could this ever be done on a large scale?), and also I believe it has limited usefulness. **based on my comments in the previous commentary box--this is a very qualified "yes for endorsement" vote

If applicable, Conditions/Questions for Developer: No recommendations have yet been made because the full Steering Committee did not discuss the workgroup evaluations.

Developer Response: It wasn't entirely clear whether there would be any forthcoming recommendations for modification sent to the developer (e.g., assess only the number of patients with catheters, eliminating the evaluation by a qualified surgeon or interventional

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0262 Vascular Access—Catheter Vascular Access and Evaluation by Vascular Surgeon for Permanent Access

radiologist or nephrologist). While KCQA believes that the process component of the measure is important, it believes that the need for a physician-level measure addressing this aspect of care is imperative. As the CMS measure (#0256) is limited to the facility-level, we would be thus willing to take a recommendation for such a modification back to our Committee for consideration so to ensure that there is physician-level accountability in minimizing catheter use.

Steering Committee Follow-up: Conference call 10/28 and re-evaluation

10/28 Steering Committee Conference Call

1. Importance to Measure and Report

2. Scientific Acceptability of Measure Properties The committee and developer agreed the same issue regarding interventional nephrologist applied to this measure. The Steering Committee questioned whether this measure was needed any longer because it is a subset of 0251. With 0251 now including functioning AV graft, the “failures” on both measures would be patients with catheters who are not evaluated. Several committee members commented that it would be useful to stratify by new vs. chronic patients.

3. Usability

4. Feasibility

If applicable, Conditions/Questions for Developer: The developer was asked to address interventional nephrologist, having only measure 0251 instead of both 0251 and 0262, and new vs. chronic patients.

Developer Response: The developer agreed this measure was not needed in addition to 0251 and withdrew it. It specified 0251 to stratify by incident and prevalent patients.

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<p>0259 Hemodialysis Vascular Access - Decision-making by Surgeon to Maximize Placement of Autogenous Arterial Venous Fistula</p> <p>Description: Percentage of patients with advanced chronic disease (CKD4 or 5) or end-stage renal disease (ESRD) undergoing open surgical implantation of permanent hemodialysis access who receive an autogenous arteriovenous fistula (AVF).</p> <p>Numerator Statement: CKD4, CKD5 or End-stage renal disease patient requiring hemodialysis vascular access documented by surgeon to have received autogenous AV fistula OR Fistula not Performed for Medical Reasons OR Fistula not Performed for Patient Reasons.</p> <p>NOTE: This measure will be reported as the total of the three categories of numerators and also as the three numerators reported separately.</p> <p>Denominator Statement: Patients with CKD4, CKD5 or End-stage renal disease who undergo open surgical placement of permanent hemodialysis access ICD-9 585.3, 585.4, 585.5, 585.6 or 996.73 AND CPT 36818, 36819, 36820, 36821, 36825, or 36830</p> <p>Exclusions:</p> <p>Adjustment/Stratification: No risk adjustment or risk stratification</p> <p>Level of Analysis: Clinician : Group/Practice, Clinician : Individual</p> <p>Type of Measure: Process</p> <p>Data Source: Administrative claims</p> <p>Measure Steward: Society for Vascular Surgery</p>
<p>Steering Committee 8/16-17</p> <p>Importance to Measure and Report (based on decision logic): No</p> <p>1a. Impact: H-17; M-3; L-1; I-0; 1b. Performance Gap: H-0; M-0; L-2; I-18</p> <p>Rationale: Without data to review on this measure as specified it is not possible to know if there is a performance gap. If the surgeon excludes patients who aren't candidates for AVF as specified in the measure, then generally the result will be 100% unless the measure focuses on success rate of a functioning fistula (so it won't distinguish performance). Large prospective randomized study (JAMA 2008) shows 60% failure rate - fistulas were in but not usable. The developer thinks the exclusions are necessary to prevent a perverse incentive to place a fistula even if not an appropriate candidate. Developer said the PQRI data probably shows high performance but because that doesn't include all surgeons, it won't be definitive answer on performance gap. The SC agrees there is room for improvement in placing fistulas, but the concern is whether this metric will identify that gap.</p> <p>1c. Evidence (based on decision logic): IF a Health Outcome, rationale supports: NA Quantity: H-; M-; L-; I-; Quality: H-; M-; L-; I-; Consistency: H-; M-; L-; I- Rationale:</p>
<p>2. Scientific Acceptability of Measure Properties (based on decision logic): 2a. Reliability: H-; M-; L-; I- 2b. Validity: H-; M-; L-; I- Rationale:</p> <p>2c. Disparities: H-; M-; L-; I- Rationale:</p>
<p>3. Usability: H-; M-; L-; I- (Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting and 3b. Quality Improvement) Rationale:</p>
<p>4. Feasibility: H-; M-; L-; I- (4a. Clinical data generated during care process; 4b. Electronic data; 4c. Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented) Rationale:</p>
<p>Preliminary Assessment of Criteria Met/Suitable for Endorsement: No (All criteria met, but final recommendation pending further information and/or evaluation of related and competing measures) Comments: What is the performance on this measure as specified? If applicable, Questions for Committee: If applicable, Conditions/Questions for Developer: What is the performance on this measure <u>as specified</u>? Developer Response: See PQRI (now PQRS) data that addresses the question the committee had about the performance gap for our measure. There is only data for 2009, 2010 is not yet available, or at least not publically. Since they seemed to only be concerned about the data regarding the performance gap and stopped there without moving forward with any other parts of the measure, this seems the only pertinent information requested at this time. We're happy to provide any other additional information the committee needs if requested.</p>

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0259 Hemodialysis Vascular Access - Decision-making by Surgeon to Maximize Placement of Autogenous Arterial Venous Fistula

133 physicians participated and had a mean performance rate of 91.18%.

Steering Committee Follow-up: Conference call 10/28 and re-evaluation

5. Related and Competing Measures (5a. Harmonization; 5b. Superior to competing measures)

Comments:

10/28 Steering Committee Conference Call

1.Importance to Measure and Report The data on performance gap was acknowledged but some committee members aid it was not convincing.

2. Scientific Acceptability of Measure Properties The Committee voiced their original concern that the measure construction would result in very high rates. The developer had not been asked to address that previously when asked for performance gap data. The developer stated additional information was submitted and NQF staff will follow up.

3. Usability

4. Feasibility

If applicable, Conditions/Questions for Developer: The developer was asked to resubmit the measure with any additional information.

Developer Response: See resubmission

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Comparison of Related Hemodialysis Adequacy Measures

	0249 Hemodialysis Adequacy Clinical Performance Measure III: Hemodialysis Adequacy--HD Adequacy-- Minimum Delivered Hemodialysis Dose	0323 Hemodialysis Adequacy: Solute
Steward	Centers for Medicare & Medicaid Services	American Medical Association - Physician Consortium for Performance Improvement
Description	Percentage of all adult (>=18 years old) patients in the sample for analysis who have been on hemodialysis for 6 months or more and dialyzing thrice weekly whose average delivered dose of hemodialysis (calculated from the last measurements of the month using the UKM or Daugirdas II formula) was a spKt/V >= 1.2 during the study period.	Percentage of calendar months within a 12-month period during which patients aged 18 years and older with a diagnosis of ESRD receiving hemodialysis three times a week have a spKt/V > or = 1.2
Developer comments on harmonization	<p>As for the AMA measures we feel that there are too many methodological issues that would make it difficult to harmonize at this time; however, we certainly be open to working towards harmonizing these measures in the future. Our rationale for harmonization not being practical at this time are:</p> <ol style="list-style-type: none"> 1. The number of exclusions and methodology for the AMA measure would defeat our goal for achieving better patient outcomes through the delivery of adequate. For example: <ol style="list-style-type: none"> a. The AMA exclusion criteria "Documentation of medical reason(s) for patient not having a spKt/V > or = 1.2 (eg, patient has residual kidney function, other medical reasons)" would likely result in many patients being dropped from the calculation of the measure based on what one could describe as "subjective" criteria. A Kt/V value of 1.2 is the accepted "minimum" value throughout the renal community and excluding a patient with a Kt/V of <1.2 because of residual function or "other medical reasons" should not excuse the clinician from making appropriate prescription adjustments to attain the minimum outcome level. Residual renal function for the HD population drops off to an insignificant level within 6 months of the initiation of dialysis making the rationale for dropping patients based on this unreasonable. b. The AMA measure does not specify the the formula that is used to calculate the Kt/V which could result in "gaming" to achieve the desired value. However, this is something that should easily be worked out between CMS and AMA since Daguardis 2 and UMK are accepted formulas throughout the renal community and CMS already requires providers to use these formulas. c. CMS and AMA would need to arrive at some agreement on the time period used for calculating the Kt/V outcome. <p>The facility level measure is being used in the QIP program and the specifications</p>	<p>We have reviewed the request by the NQF Renal Endorsement Maintenance Steering Committee, for harmonization of measures 0249 and 0323. Our RPA/ASP/PCPI Kidney Disease expert Work Group panel provided the following feedback, explaining their belief that the measures are already effectively harmonized.</p> <p>Regarding the calculation method for Kt/V, we are happy to add the calculation method to the measure, consistent with the CMS measure. UKM or the second generation Daugirdas formula are the most appropriate ways to calculate spKt/V, and the only two accepted methods for calculating Kt/V per the KDOQI guidelines.</p> <p>The CMS measure, 0249, is appropriate for monthly reporting, which is required for the CPM project that relied on data from the last three months of the calendar year. Reporting this as percentage of calendar months, as our measure does, increases the denominator and therefore makes this measure more interpretable at the individual physician level, where the number of patients may be smaller. In reality, the results using reporting method for the CMS measure and for our measure should converge as the denominator increases.</p> <p>Finally, the exclusion for the first 6 months in the CMS measure is the way they try to deal with residual kidney function; our measure, on the other hand, makes residual kidney function a denominator exception (exclusion). Our Work Group highlighted that there is no reason to think that in the first months of dialysis that a Kt/V <1.2 would be appropriate in the absence of residual kidney function; therefore, the approach taken in measure 0323 is actually a bit more rigorous.</p>

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	0249 Hemodialysis Adequacy Clinical Performance Measure III: Hemodialysis Adequacy--HD Adequacy-- Minimum Delivered Hemodialysis Dose	0323 Hemodialysis Adequacy: Solute
	are outlined in the rule in place through payment year 2014 and any change would require going through rulemaking.	
Type	Outcome	Outcome
Data Source	Electronic Clinical Data CROWNWeb URL http://www.projectcrownweb.org URL http://projectcrownweb.org/crown/index.php?page=Public_Documents&subPage=Release_Documents	Administrative claims, Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Registry, Paper Records N/A Attachment AMA-PCPI_AKID-10_Hemodialysis Adequacy Solute.pdf
Level	Facility	Clinician : Group/Practice, Clinician : Individual, Clinician : Team
Setting	Dialysis Facility	Ambulatory Care : Clinician Office, Dialysis Facility, Home Health, Other, Post Acute/Long Term Care Facility : Nursing Home/Skilled Nursing Facility
Numerator Statement	Number of patients in denominator whose delivered dose of hemodialysis (calculated from the last measurements of the month using the UKM or Daugirdas II formula) was a spKt/V ≥ 1.2 .	Calendar months during which patients have a spKt/V ≥ 1.2
Numerator Details	Time Window: The entire calendar month. The numerator will be determined by counting the patients in the denominator for whom "Kt/V Hemodialysis Method" is 'Daugirdas II' OR 'UKM' AND "Kt/V" is greater than or equal to 1.2.	Time Window: Once during the measurement period. See attached for EHR specifications. For Claims/Administrative: Report CPT II code 3XXXF: spKt/V greater than or equal to 1.2 (single-pool clearance of urea [Kt]/volume[V])
Denominator Statement	All adult (≥ 18 years old) patients in the sample for analysis who have been on hemodialysis for 6 months or more and dialyzing thrice weekly.	All calendar months during which patients aged 18 years and older with a diagnosis of ESRD are receiving hemodialysis three times a week
Denominator Details	Time Window: The entire calendar month. The duration of hemodialysis treatment will be calculated as the difference between the first "Kt/V Collection Date" and "Date Regular Chronic Dialysis Began". The denominator will include all in-center hemodialysis patients ≥ 18 years old who have been on dialysis for 6 months or longer and "Sessions per Week" is equal to 3. The patient's age will be determined by subtracting the patient's date of birth from the first day of the reporting month. In-center hemodialysis patients are defined as follows: "Admit Date" to the specified facility is prior or equal to the first day of the study period, AND the patient has not been discharged ("Discharge Date" is null or blank), OR "Discharge Date" from the facility is greater than or equal to the last day of the study period AND "Treatment Dialysis Broad Start Date" is prior or equal to the first day of the study period, AND "Dialysis Broad Type of Treatment" = 'HD', AND "Primary Dialysis Setting" = 'Dialysis Facility/Center' on the last day of the study period, AND "Date Regular Chronic Dialysis Began" is prior to the first day of the study period.	Time Window: 12 consecutive months. See attached for EHR specifications. For Claims/Administrative: See coding tables attached for coding (ICD-9-CM, ICD-10-CM, CPT)
Exclusions	Patients on HD less than 6 months; HD patients dialyzing < 3 times per week or > 3	Documentation of medical reason(s) for patient not having a spKt/V ≥ 1.2 (eg, patient

NATIONAL QUALITY FORUM

	0249 Hemodialysis Adequacy Clinical Performance Measure III: Hemodialysis Adequacy--HD Adequacy-- Minimum Delivered Hemodialysis Dose	0323 Hemodialysis Adequacy: Solute
	times per week.	has residual kidney function, other medical reasons)
Exclusion Details	Exclusions to this measure include patients who are not receiving dialysis thrice weekly ("Sessions per Week" not equal to 3) and have not been on dialysis at least 6 months. The duration of hemodialysis treatment will be calculated as the difference between the first "Kt/V Collection Date" and "Date Regular Chronic Dialysis Began".	Append modifier to CPT II code 3XXXf-1P
Risk Adjustment	No risk adjustment or risk stratification Not applicable.	Other We account for risk adjustment by inclusion of the exceptions for this measure. Exceptions for this measure are listed above, in section 2a1.8.
Stratification	No stratification for this measure.	We encourage the results of this measure to be stratified by race, ethnicity, gender, and primary language, and have included these variables as recommended data elements to be collected.
Type Score	Rate/proportion better quality = higher score	Rate/proportion better quality = higher score
Algorithm	The duration of hemodialysis treatment will be calculated as the difference between the first "Kt/V Collection Date" and "Date Regular Chronic Dialysis Began". The denominator will include all in-center hemodialysis patients >=18 years old who have been on dialysis for 6 months or longer and "Sessions per Week" is equal to 3. The patient's age will be determined by subtracting the patient's date of birth from the first day of the reporting month. In-center hemodialysis patients are defined as follows: "Admit Date" to the specified facility is prior or equal to the first day of the study period, AND the patient has not been discharged ("Discharge Date" is null or blank), OR "Discharge Date" from the facility is greater than or equal to the last day of the study period AND "Treatment Dialysis Broad Start Date" is prior or equal to the first day of the study period, AND "Dialysis Broad Type of Treatment" = 'HD', AND "Primary Dialysis Setting" = 'Dialysis Facility/Center' on the last day of the study period, AND "Date Regular Chronic Dialysis Began" is prior to the first day of the study period. The numerator will be determined by counting the patients in the denominator for whom "Kt/V Hemodialysis Method" is 'Daugirdas II' OR 'UKM' AND "Kt/V" is greater than or equal to 1.2. Attachment Appendix C CPM Calculation Flow charts_a 5.pdf	Calculation algorithm is included in data dictionary/code table attachment (2a1.30).