Renal Endorsement Maintenance Steering Committee
Review of Vascular Access and Patient Education/QoL Measures and Follow-up
Conference Call September 9, 2011, 1:00pm – 3:00pm ET

Committee Members Present: Peter Crooks, MD (Co-Chair); Kristine Schonder, PharmD (Co-Chair); Constance Anderson, BSN, MBA; Jeffrey Berns, MD; Jerry Jackson, MD; Frederick Kaskel, MD, PhD; Andrew Narva, MD (ex officio); Harvey Wells.

NQF Staff Present: Karen Pace, PhD, RN, Senior Program Director; Lauren Richie, MA, Project Manager.

Others Present:
Katherine Ast; Amy Beckrich; Sarah Casino; Lisa McGonigal; Dale Singer; Kimberly Smith; Jennifer Stone.

The full transcripts and audio recordings from the meeting can be found here.

MEETING PROCESS

Dr. Schonder (Co-Chair) welcomed the Steering Committee members and thanked them for their continued participation. The Steering Committee members introduced themselves and Dr. Schonder reviewed the purpose and agenda.

The purpose of the call was to continue review of the vascular access, patient education, and quality of life measures that were not addressed at the Renal EM in-person meeting, including:

- evaluating the submitted measures according to NQF criteria to determine if suitable to recommend for endorsement as voluntary consensus standards; and
- identify related and competing measures for further evaluation of measure harmonization or to select the best measure from among competing measures.

The workgroup evaluation will serve as a recommendation to the full Steering Committee.

NQF staff briefly introduced the measures including a description of the measure and a summary of the compiled preliminary evaluation ratings and rationales, highlighting areas of concern or differences of opinion among those who evaluated the same measure. This introduction was followed by discussion by the Vascular Access and Patient Education/QoL workgroup and other Steering Committee members on the call. Measure developers were asked to respond to the Committee's questions regarding specific measures as they were evaluated during the call. The Steering Committee members determined if the preliminary evaluations were still relevant or needed modification or a revote. A NQF member and public comment period occurred at the end of the call. No comments were received.

EVALUATION OF RENAL MEASURES

The Steering Committee evaluated five measures listed below. A summary of the discussion is provided in the following tables. The Committee members decided to re-vote on three measures indicated with an asterisk.

Vascular Access

- **0256** Hemodialysis Vascular Access- Minimizing use of catheters as Chronic Dialysis Access
- **0257** Hemodialysis Vascular Access- Maximizing Placement of Arterial Venous Fistula (AVF)
- **0262*** Vascular Access—Catheter Vascular Access and Evaluation by Vascular Surgeon for Permanent Access

Patient Education/Quality of Life

- **0320*** Patient Education Awareness—Physician Level
- **0324*** Patient Education Awareness—Facility Level

Updates

0260 Assessment of Health-related Quality of Life in Dialysis Patients

NQF staff reported that the measure developer indicated it wishes to resubmit the information needed for the Steering Committee to evaluate the measure. If the developer submits information to assess the measure, it will be sent first to this workgroup for review and re-voting.

Vascular/Pt. Education/QoL Preliminary Evaluations Summary

The following tables compile a summary of the workgroup's discussion and ratings.

0256 Hemodialysis Vascular Access- Minimizing use of catheters as Chronic Dialysis Access..... 3
0257 **Hemodialysis** Vascular Access- Maximizing Placement of Arterial Venous Fistula (AVF) 5
0262 Vascular Access—Catheter Vascular Access and Evaluation by Vascular Surgeon for Permanent Access. 6
0324 Patient Education Awareness—Facility Level 7
0320 Patient Education Awareness—Physician Level 9

0256 Hemodialysis Vascular Access- Minimizing use of catheters as Chronic Dialysis Access
Description: Percentage of patients on maintenance hemodialysis during the last HD treatment of study period with a chronic catheter continuously for 90 days or longer prior to the last hemodialysis session. Numerator Statement: Patients who were continuously using a chronic catheter as hemodialysis access for 90 days or longer prior to the last hemodialysis session during the study period. Denominator Statement: Patients on maintenance hemodialysis during the last HD treatment of study period. Exclusions: Patients on acute hemodialysis, peritoneal dialysis, or patients <18 years of age. Adjustment/Stratification: No risk adjustment or risk stratification No risk adjustment necessary. No stratification is required for this measure. Level of Analysis: Facility Type of Measure: Process Data Source: Administrative claims, Electronic Clinical Data Measure Steward: Centers for Medicare & Medicaid Services
9/9 Workgroup Call Summary The following summarizes the workgroup's discussion and subsequent action (if any) for this measure: 1.Importance to Measure and Report - Yes 1a. Impact - Preliminary ratings indicated agreement that high impact was met. 1b. Performance Gap – Preliminary ratings indicated agreement that there is a performance gap. A Committee member questioned the data provided indicating average performance of 5% using catheters, which seemed to be lower than the actual experience but may be lower because of short data collection period. The developer responded that some facilities have as high as 47% chronic catheter use and cited data form Fistula first of 8% chronic catheters. The committee agreed that there is a significant performance gap. 1c. The evidence was not further discussed – although not presented according to new guidance, sufficient evidence does exist. 2. Scientific Acceptability of Measure Properties - Yes 2a. Reliability – One committee member expressed some reservations about whether correlating scores across points of time with different patients was an appropriate test of reliability. The developer submitted additional testing information for the reliability (precision) of the measure score: intraclass correlation was only 0.08, but that inter-unit reliability was 0.84 -indicating the measure distinguishes among facilities. The committee was satisfied with the developer's measure of reliability and the committee was in agreement that the criteria of reliability was met. 2b. Validity – Preliminary ratings indicated a concern by one committee member, which was resolved after reviewing the association of performance on chronic catheter use with performance on the mortality measure. A committee member questioned whether home hemodialysis patients should be excluded because infection does not seem to be as big a problem and some patients prefer catheter over needles when on daily schedule. The evidence is not specific to home HD patients but overall catheters are still considered less desirable. Ultimately the Committee members concluded that since there is little evidence available and so few home hemodialysis patients, the measure would not be greatly affected by the inclusion of home hemodialysis patients. 3. Usability - Preliminary ratings indicated agreement that usability was met. 4. Feasibility - Preliminary ratings indicated agreement that feasibility was met. 5. Suitable for endorsement- Yes Preliminary ratings indicated one disagreement regarding suitability for endorsement. However, that

0256 Hemodialysis Vascular Access- Minimizing use of catheters as Chronic Dialysis Access
was resolved with the review and clarifications noted above.

0257 Hemodialysis Vascular Access- Maximizing Placement of Arterial Venous Fistula (AVF)
Description: Percentage of patients on maintenance hemodialysis during the last HD treatment of month using an autogenous AV fistula with two needles Numerator Statement: Patients who were on maintenance hemodialysis (HD) using an autogenous AV fistula with two needles at the last HD treatment of month Denominator Statement: Patients on maintenance hemodialysis during the last HD treatment of month including patients on home hemodialysis Exclusions: Patients on acute hemodialysis, peritoneal dialysis, or patients <18 years of age Adjustment/Stratification: No risk adjustment or risk stratification No risk adjustment necessary. No stratification is required for this measure. Level of Analysis: Facility Type of Measure: Process Data Source: Administrative claims, Electronic Clinical Data Measure Steward: Centers for Medicare & Medicaid Services
9/9 Workgroup Call Summary (In attendance: Frederick Kaskel, Andrew Narva, Constance Anderson, Jeffrey Berns, Jerry Jackson, Kristine Schonder (co-chair), Peter Crooks (co-chair), Harvey Wells) The following summarizes the workgroup's discussion and subsequent action (if any) for this measure: 1.Importance to Measure and Report - Yes 1a. Impact- Preliminary ratings indicated agreement that the criteria of high impact was met. 1b. Performance Gap- Preliminary ratings indicated agreement that the criteria of performance gap was met. 1c. The evidence was not further discussed – although not presented according to new guidance, sufficient evidence does exist. 2. Scientific Acceptability of Measure Properties - Yes One committee member noted that a single needle device has been developed and should be added to definition of functional AVF. The recommendation was made to the measure developer who agreed to confer with CMS before making the change. NQF staff will follow up with measure developer and inform the Committee of any changes to the measure. One committee member questioned whether the measure should be focused on permanent access including working grafts. The measure developer noted that measures of catheter rate and fistula rate are linked and the remainder of patients would have an AVG. The Steering Committee's discussion at the in-person meeting was in the context of patients with working grafts not being sent for evaluation by surgeon every year. However, the current clinical recommendations are to optimize fistula creation so a change in the measure was not recommended. 2a. Reliability - Preliminary ratings indicated agreement that reliability was met. 2b. Validity - Preliminary ratings indicated agreement that validity was met. 3. Usability- Yes - Preliminary ratings indicated agreement that usability was met. 4. Feasibility - Yes - Preliminary ratings indicated agreement that feasibility was met. 5. Suitable for endorsement - Yes The recommendation from the group is that the measure is suitable for endorsement but the preference would be to add "single-needle device" to the definition of functioning fistula, which will be referred to CMS.

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 was 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 was 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.

0324 Patient Education Awareness—Facility Level
Description: Percentage of a physician´s end stage renal disease (ESRD) patients aged 18 years and older with medical record documentation of a discussion of renal replacement therapy modalities (including hemodialysis, peritoneal dialysis, home hemodialysis, transplants and identification of potential living donors, and no/cessation of renal replacement therapy) at least once during the 12-month reporting period. Numerator Statement: Number of patients from the denominator with medical record documentation of a discussion of renal replacement therapy modalities (including hemodialysis, peritoneal dialysis, home hemodialysis, transplants and identification of potential living donors, and no/cessation of renal replacement therapy) at least once during the 12-month reporting period. Denominator Statement: All ESRD patients aged 18 years and older. Exclusions: None. Adjustment/Stratification: No risk adjustment or risk stratification Not applicable. Not applicable. Level of Analysis: Facility Type of Measure: Process Data Source: Electronic Clinical Data : Electronic Health Record, Paper Records Measure Steward: Kidney Care Quality Alliance
Steering Committee Vote/Discussion Importance to Measure and Report (*based on decision logic*): Yes 1a. Impact: H-11; M-9; L-1; I-0; 1b. Performance Gap: H-4; M-10; L-1; I-6 Rationale: Although there are tremendous educational deficiencies among CKD and ESRD patients, it is not clear that this measure can address them. Data on impact is about pre-dialysis vs. this measure focused on dialysis patients. It was noted that it is good to repeat the education even after begin dialysis because patients forget or may be too overwhelmed when first given information. Limited data on performance from testing indicates no patients received testing on ALL modalities. Does the performance gap indicate lack of documentation vs. what education the patient reports received. In response to a question, it was clarified that education must be given every year and documented. Assessment of performance gap was before patient education on modalities became a condition of coverage. Big leap from giving information to understanding and effective decsionmaking. 1c. Evidence (*based on decision logic*): Yes IF a Health Outcome, rationale supports: NA Quantity: H-; M-2; L-6; I-13; Quality: H-1; M-3; L-4; I-13; Consistency: H-; M-1; L-4; I-16 Rationale: Some of the evidence referred to by the developer was obtained in pre-dialysis CKD patients and not in the ESRD population. The Right Start and Impact programs occur in first 90 days on dialysis so they are applicable to the population in this measure. The RightStart program involves multiple levels of intervention with education only one of several components. Thus, positive outcomes associated with the RightStart program cannot be attributed purely to the educational component. The developer also noted a new study on patient education on modality options (June 2011 AM J Kidney Disease). The Steering Committee decided to consider the measure further as an exception to evidence criterion. Exception to evidence: Y-18; N-3
Steering Committee Vote/Discussion 2. Scientific Acceptability of Measure Properties (*based on decision logic*): 2a. Reliability: H-0; M-11; L-8; I-2 2b. Validity: H-; M-; L-; I- Rationale: Although the developer submitted that the data will be obtained through CROWNWeb, it was noted that CROWNWeb currently does not include patient education. The developer stated that has had a conversation with CMS who expressed interest in including in CROWNWeb. Reliability testing was conducted in facilities - interabstractor reliability of data between facility abstractor and study abstractor. The kappa for the measure score was reported as (-0.0026). More errors were missed information resulting in under-reporting. The kappa for the same measure in physician office testing with interabstractor reliability between two study abstractors was high (0.8474) indicating that the measure can be reliable and that the conditions of coverage will increase attention to documentation. Measure requires checkbox not quality or effectiveness of education. It's good that the measure stipulates that regardless of whether the facility offers the various modalities. 2c. Disparities: H-; M-; L-; I- Rationale:
9/9 Workgroup Call Summary The following summarizes the workgroup's discussion and subsequent action (if any) for this measure: 1.Importance to Measure and Report The Steering Committee had already voted on Importance to Measure and Report at the in-person meeting and agreed to consider the measure further on the basis of an exception to the evidence criterion for expert opinion. 2. Scientific Acceptability 2a. Reliability – The Committee had already voted on reliability and it narrowly passed. Although the specifications indicate that CROWNWeb is the data source, currently there are no fields for patient education. NQF staff indicated that the measure is essentially a medical record measure as it was tested. That does not negatively impact reliability or validity, but could be a consideration under Feasibility.

0324 Patient Education Awareness—Facility Level
2b. Validity The committee discussed that the limiting issue is that this measure is essentially just checking off that the required education on modalities was provided; it does not address the content or quality of the education or patient comprehension. So, will it facilitate improvement or demonstrate quality? It may not be the best indicator of quality, but does it meet minimum criteria? Some reservations were expressed because the measure cannot distinguish between the physician and facility roles that contribute to a patient's education. However, from a patient perspective, it's better not to parse that out because the issue is whether the patient received the appropriate education, regardless of who provides it. 3. Usability –Preliminary ratings were spread across all the rating categories. The committee discussed that education on all modalities is addressed in the regulations and surveyor guidance and questioned the usefulness of a performance measure. The developer commented that surveys are only required every 3 years, and some states are very far behind. A committee member reported that some facilities have not been surveyed for 10 years. It also is unclear if surveyors review all patients or just a sample; and performance measures could be used to inform the survey process. Additionally, survey data often not publicly available so a performance measure could be useful if reported. 4. Feasibility – Preliminary ratings and comments indicated differences of opinion on feasibility. Currently, there is no data field in CROWNWeb to capture the patient education information. So if endorsed, it would be as a medical record abstraction measure. However, unless facilities have electronic records, much of the data for CROWNWeb require abstraction from the medical record. 5. Suitable for endorsement –The workgroup decided to re-vote on the measure.

0320 Patient Education Awareness—Physician Level
Description: Percentage of end stage renal disease (ESRD) patients aged 18 years and older with medical record documentation of a discussion of renal replacement therapy modalities (including hemodialysis, peritoneal dialysis, home hemodialysis, transplants and identification of potential living donors, and no/cessation of renal replacement therapy) at least once during the 12-month reporting period. Numerator Statement: Number of patients from the denominator with medical record documentation of a discussion of renal replacement therapy modalities (including hemodialysis, peritoneal dialysis, home hemodialysis, transplants and identification of potential living donors, and no/cessation of renal replacement therapy) at least once during the 12-month reporting period. Denominator Statement: All ESRD patients aged 18 years and older receiving renal replacement therapy. Exclusions: None. 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: The workgroup thought all their comments related to 0324 apply to this measure because it's essentially the same except for being applied to the individual clinician (please see 0324). The only additional discussion was a question of the need for a physician-level measure because Medicare has place responsibility on the facility. The developer responded that it sees patient education as a primary responsibility of the physician. The committee agreed that physicians have responsibility, but questioned the use of this measure. 5. Suitable for endorsement –The workgroup decided to re-vote on the measure.

NEXT STEPS

A voting tool will be sent to the Committee workgroup and other members who participated on the call. After the workgroup's final evaluations are compiled they will be sent to the full Steering Committee for a final vote on the measures. Any measure harmonization issues will be sent to the developers to resolve prior to making recommendations for endorsement final. The Steering Committee also will select the best measure from among competing measures.