NATIONAL QUALITY FORUM

CONFERENCE CALL FOR THE RENAL ENDORSEMENT MAINTENANCE STEERING COMMITTEE REVIEW OF DIALYSIS ADEQUACY MEASURES

September 20, 2011

Committee Members Present: Peter Crooks, MD (Co-Chair); Kristine Schonder, PharmD (Co-Chair); Alan Kliger, MD; Michael Somers, MD; Roberta Wager, RN, MSN.

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

Others Present: Amy Beckrich, Diedra Joseph, Lisa McGonigal, Joe Messana, Robyn Nishimi, Dale Singer, Jennifer Stone, Robert Wolfe.

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

MEETING PROCESS

Dr. Schonder 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 dialysis adequacy measures that were not addressed at the Renal endorsement maintenance (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
- identifying 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 a discussion among the Dialysis Adequacy 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 another vote. An NQF member and public comment period occurred at the end of the call. No comments were received.

EVALUATION OF RENAL MEASURES

The following tables compile a summary of the workgroup's discussion and ratings and comments from re-voting, if indicated.

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0247 Hemodialysis Adequacy Clinical Performance Measure I: Hemodialysis Adequacy-Monthly measurement of delivered dose
Description: Percentage of all adult (>= 18 years old) HD patients in the sample for analyses with documented monthly adequacy measurements (spKt/V) or its components in the calendar month Numerator Statement: Number of patients in the denominator with documented monthly adequacy measurements (spKt/V) or its components in the calendar month. Denominator Statement: Number of adult patients (>=18 years) receiving in-center hemodialysis or home hemodialysis (irrespective of frequency of dialysis). Exclusions: None. 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: Electronic Clinical Data Measure Steward: Centers for Medicare & Medicaid Services
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–Preliminary ratings indicated agreement that there is a performance gap (1st quartile-67%; median-79%; 3rd quartile-88%). 1c. Evidence–The evidence is indirect–it is about dialysis adequacy, not frequency of measurement. Assessment is necessary but not sufficient to achieving adequate dialysis. The validity testing presented demonstrates a relationship to SMR. Measurement of spKt/V assumes everyone is on the same frequency and increasingly, patients are on different schedules. The Steering Committee strongly recommends that CMS refine measures to use standard Kt/V; CMS should have all the data elements required. The developer responded that CMS has the data but may need to validate the height and weight data. The Committee agreed that the three measures about dialysis adequacy should be combined into one measure that addresses method, frequency, and adequacy. 2. Scientific Acceptability of Measure Properties 2a. Reliability–The concern in the preliminary evaluations was that using correlation of scores across time is not an appropriate test of reliability for data elements or measure score as described in testing task force report. The developer responded they saw it as similar but not identical circumstances. However, the developer also provided additional analysis that demonstrated adequate interunit reliability (0.94) to distinguish among facilities. 2b. Validity–The testing results indicate that performance on this measure is associated with performance on standardized mortality ratio but primarily difference between the highest quintile and all others (8%-13% higher risk of mortality).

0247 Hemodialysis Adequacy Clinical Performance Measure I: Hemodialysis Adequacy-Monthly measurement of delivered dose
3. Usability–This measure is probably not needed—should be incorporated into adequacy measure. 4. Feasibility–The preliminary evaluations indicated no issues with feasibility. 5. Suitable for endorsement–The preliminary evaluations were divided, and the workgroup will re-vote on this measure.

0248 Hemodialysis Adequacy Clinical Performance Measure II: Method of Measurement of Delivered Hemodialysis Dose
Description: Percentage of all adult (>= 18 years old) hemodialysis patients in the sample for analyses for whom delivered HD dose was calculated using UKM or Daugirdas II during the study period and for whom the frequency of HD per week is specified. Numerator Statement: Number of patients in the denominator for whom delivered HD dose for a single dialysis session was calculated using UKM or Daugirdas II during the reporting period and for whom the frequency of HD per week is specified. Denominator Statement: Number of adult patients (>=18 years) receiving in-center hemodialysis or home hemodialysis. Exclusions: None. Adjustment/Stratification: No risk adjustment or risk stratification Not applicable. This measure is not stratified. Level of Analysis: Facility Type of Measure: Process Data Source: Electronic Clinical Data Measure Steward: Centers for Medicare & Medicaid Services
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–The performance gap (1st quintile-44%; 2nd quintile-63%; 3rd quintile-69%; 4th quintile-76%; 5th quintile-100%) is probably related to whether it is measured not the method–that is, if not measured at all, it will not be counted in the numerator. No exclusions are specified. 1c. Evidence—The evidence is indirect—it is about dialysis adequacy, not frequency of measurement. Assessment is necessary but not sufficient to achieving adequate dialysis. No evidence exists supporting one method over another. The validity testing presented demonstrates some relationship to SMR. Daugirdas II also can be used with standard Kt/V and different frequencies as long as the pre-dialysis interval is known. The Committee agreed that the three measures about dialysis adequacy should be combined into one measure that addresses method, frequency, and adequacy. 2. Scientific Acceptability of Measure Properties 2a. Reliability–The concern in the preliminary evaluations was that using correlation of scores across time is not an appropriate test of reliability for data elements or measure score as described in the testing task force report. The developer responded they saw it as similar but not identical circumstances. However, the developer also provided additional analysis that demonstrated adequate interunit reliability (0.96) to distinguish among facilities. 2b. Validity–The testing results indicate that performance on this measure is associated with performance on standardized mortality ratio but primarily difference between the highest quintile and all others (5%-12% higher risk of mortality). 3. Usability–This measure is probably not needed—should be incorporated into adequacy measure. 4. Feasibility–The preliminary evaluations indicated no issues with feasibility. 5. Suitable for endorsement–The preliminary evaluations were divided, and the workgroup will re-vote on this measure.

0318 Peritoneal Dialysis Adequacy Clinical Performance Measure III - Delivered Dose of Peritoneal Dialysis Above Minimum
Description: Percentage of all adult (>= 18 years old) peritoneal dialysis patients whose delivered peritoneal dialysis dose was a weekly Kt/Vurea of at least 1.7 (dialytic + residual) during the four month study period. Numerator Statement: Patients are included in the numerator if delivered peritoneal dialysis was a weekly Kt/Vurea of at least 1.7 (dialytic + residual) during the four month study period. Denominator Statement: All adult (>= 18 years old) peritoneal dialysis patients who have been on peritoneal dialysis for at least 90 days. Exclusions: None. Adjustment/Stratification: No risk adjustment or risk stratification None No stratification is required for this measure. Level of Analysis: Facility Type of Measure: Outcome Data Source: Electronic Clinical Data, Electronic Clinical Data : Laboratory Measure Steward: Centers for Medicare & Medicaid Services
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–The quartiles of performance scores demonstrate a performance gap (1st quartile-0%; median-27%; 3rd quartile-50%). The developer clarified that description of the data was for all patients, not just peritoneal dialysis patients, who comprise about 9% of dialysis patients. 1c. Evidence–The evidence indicates association between dialysis dose and mortality. A committee member noted that the PD measure includes endogenous renal function in the calculation but not in the HD adequacy measure. Although it was thought that HD patients lose renal function quickly, there can be wide variation. The developer responded that there is no direct evidence and that there is more renal function in peritoneal dialysis patients, but recent studies that show mortality differences between dialysis modalities may be an artifact of study design. Endogenous renal function is probably a large part of survival advantage, whatever the dialysis modality. 2. Scientific Acceptability of Measure Properties 2a. Reliability–The concern in the preliminary evaluations was that using correlation of scores across time is not an appropriate test of reliability for data elements or measure score as described in testing task force report. The developer responded they saw them as similar but not identical circumstances. However, the developer also provided additional analysis on interunit reliability. It indicated the IUR was only 0.57, a little above chance. The Committee discussed that it was likely due to small case volume and wide confidence intervals. 2b. Validity–The testing results indicated that performance on this measure is not associated with performance on standardized mortality ratio (all the confidence intervals for the relative risk included 1.0). The developer commented this also was probably due to small case volume and wide confidence intervals, but facilities with persistently low performance should be identified. 3. Usability–The preliminary evaluations indicated no issues with usability. 4. Feasibility–The preliminary evaluations indicated no issues with feasibility. 5. Suitable for endorsement–The preliminary evaluations were divided primarily due to the issues discussed under scientific acceptability, and the workgroup will re-vote on this measure.

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 = 1.7 per week measured once every 4 months Numerator Statement: Patients who have a total Kt/V = 1.7 per week measured once every 4 months Denominator Statement: All patients aged 18 years and older with a diagnosis of ESRD receiving peritoneal dialysis Exclusions: Documentation of medical reason(s) for patient not having a Kt/V = 1.7 per week (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
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 were not provided–quoted some statistics from 2008 CMS Clinical Performance Measures, but it is 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 =>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 >= 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 earlier 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)

0253 Peritoneal Dialysis Adequacy Clinical Performance Measure I - Measurement of Total Solute Clearance at Regular Intervals
Description: Percentage of all adult (>= 18 years old) peritoneal dialysis patients with total solute clearance for urea (endogenous residual renal urea clearance & dialytic) measured at least once in a four month time period. Numerator Statement: Patients with total solute clearance for urea (endogenous residual renal urea clearance & dialytic) measured at least once in a four month time period. Denominator Statement: All adult (>= 18 years old) peritoneal dialysis patients. Exclusions: None. Adjustment/Stratification: No risk adjustment or risk stratification None. No stratification is required for this measure. Level of Analysis: Facility Type of Measure: Process Data Source: Electronic Clinical Data Measure Steward: Centers for Medicare & Medicaid Services
9/20 Workgroup Call Summary 1. Importance to Measure and Report 1a. Impact–Preliminary ratings indicated agreement that high impact was met. 1b. Performance Gap–Preliminary ratings indicated agreement that there is a performance gap (1st quartile-0%; median-50%; 3rd quartile-80%). 1c. Evidence–The evidence is indirect–it is about dialysis adequacy, not frequency of measurement. Assessment is necessary but not sufficient to achieving adequate dialysis. The Committee agreed that the three measures about dialysis adequacy should be combined into one measure that addresses method, frequency, and adequacy. 2. Scientific Acceptability of Measure Properties 2a. Reliability–The concern in the preliminary evaluations was that using correlation of scores across time is not an appropriate test of reliability for data elements or measure score as described in testing task force report. The developer responded they saw them as similar but not identical circumstances. However, the developer also provided additional analysis that demonstrated adequate interunit reliability (0.78) to distinguish among facilities. 2b. Validity–The testing results did not demonstrate an association between performance on this measure with performance on standardized mortality ratio (confidence intervals for relative risk included 1.0). 3. Usability–This measure is probably not needed—should be incorporated into adequacy measure. 4. Feasibility–The preliminary evaluations indicated no issues with feasibility. 5. Suitable for endorsement–The preliminary evaluations were divided, and the workgroup will re-vote on this measure.

0254 Peritoneal Dialysis Adequacy Clinical Performance Measure II - Calculate Weekly KT/Vurea in the Standard Way
Description: Percentage of all adult (>= 18 years old) peritoneal dialysis patients with weekly Kt/V urea (endogenous residual renal urea clearance & dialytic) calculated in a standard way. Numerator Statement: Patients with: (1) Weekly Kt/Vurea used to measure delivered peritoneal dialysis dose and endogenous renal urea clearance; (2) Residual renal function (unless negligible [< 100mL urine in 24 hours]) assessed by measuring the renal component of Kt/Vurea and estimating the patient´s glomerular filtration rate (GFR) by calculating the mean of urea and creatinine clearance; (3) Total body water (V) estimated by either the Watson or Hume method using actual body weight, and BSA estimated by either the Dubois and Dubois method, the Gehan and George method, or the Haycock method of using actual body weight; during the four month study period. Denominator Statement: All adult (>= 18 years old) peritoneal dialysis patients. Exclusions: None. Adjustment/Stratification: No risk adjustment or risk stratification None. No stratification is required for this measure. Level of Analysis: Facility Type of Measure: Process Data Source: Electronic Clinical Data Measure Steward: Centers for Medicare & Medicaid Services
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–The performance gap is probably related to whether it is measured and not the method–that is, if not measured at all, it will not be counted in the numerator. No exclusions are specified (1st quartile-0%; median-33%; 3rd quartile-57%). 1c. Evidence—The evidence is indirect—it is about dialysis adequacy, not frequency of measurement. Assessment is necessary but not sufficient to achieving adequate dialysis. The Committee agreed that the three measures about dialysis adequacy should be combined into one measure that addresses method, frequency, and adequacy. 2. Scientific Acceptability of Measure Properties 2a. Reliability–The concern in the preliminary evaluations was that using correlation of scores across time is not an appropriate test of reliability for data elements or measure score as described in testing task force report. The developer responded they saw it as similar but not identical circumstances. However, the developer also provided additional analysis that demonstrated adequate interunit reliability (0.64) to distinguish among facilities. 2b. Validity–The testing results did not demonstrate an association between performance on this measure with performance on standardized mortality ratio (confidence intervals for relative risk included 1.0). 3. Usability–This measure is probably not needed–should be incorporated into adequacy measure. 4. Feasibility–The preliminary evaluations indicated no issues with feasibility. 5. Suitable for endorsement–The preliminary evaluations were divided, and the workgroup will re-vote on this measure.

Future Recommendations

In the future, developers need to use weekly std Kt/V urea instead of spKt/Vurea to measure urea kinetics for hemodialysis patients so that patients dialyzing frequencies other than 3x/wk can get meaningful results.

Also, residual renal function is included in urea kinetic measure of peritoneal dialysis, but not of hemodialysis. Developers should either include or exclude residual renal function for both.

Urea kinetic modeling is not the only, or perhaps not even the best, measure of dialysis adequacy. Developers should be encouraged to consider using other metrics for adequacy—patient volume expansion, time, ultrafiltration rate, Kt, QoL measures all are possible candidates.

Finally, all adequacy measures using Kt/V urea should be "harmonized" to make use easier and to make the measure the same at the facility or physician level of assessment.

NEXT STEPS

A voting tool will be sent to the Committee workgroup and other members who participated on the call. Additional information will be requested for measure #0321 before re-voting. 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 before making recommendations for endorsement final. The Steering Committee also will select the best measure from among competing measures.