

NATIONAL QUALITY FORUM

CONFERENCE CALL FOR THE RENAL ENDORSEMENT MAINTENANCE STEERING COMMITTEE REVIEW OF MINERAL METABOLISM MEASURES

September 19, 2011

Committee Members Present: Peter Crooks, MD (Co-Chair); Kristine Schonder, PharmD (Co-Chair); Jeffrey Berns, MD; Michael Fischer, MD, MSPH; Alan Kliger, MD; Lisa Latts, MD, MSPH, MBA; Joseph V. Nally Jr., MD; Andrew Narva, MD (ex officio); Jessie Pavlinac, MS, RD, CSR, LD; Michael Somers, MD; Roberta Wager, RN, MSN.

NQF Staff Present: Helen Burstin, MD, MPH, Senior Vice President of Performance Measures; Lauren Richie, MA, Project Manager; Eugene Cunningham, Project Analyst.

Others Present: Amy Beckrich; Judy Chen; Dolph Chiano; Deanna Chyn; William Goodman; Renee Henry; Lisa McGonigal; Robyn Nishimi; Tom Nusbickel; Jeffrey Pearson; Kimberly Smith; Stuart Sprague; Jennifer Stone; Irina Yermilov.

The full transcripts and audio recordings from the meeting can be found [here](#).

MEETING PROCESS

Dr. Crooks welcomed the Steering Committee members and thanked them for their continued participation. The Steering Committee members introduced themselves, and Dr. Crooks reviewed the purpose and agenda.

The purpose of the call was to continue review of the mineral metabolism 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 they are 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 discussion among the Mineral Metabolism 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 re-vote. An NQF member and public comment period occurred at the end of the call. No comments were received.

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EVALUATION OF RENAL MEASURES

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

Mineral Metabolism

- **0255** * Measurement of Serum Phosphorus Concentration
- **0570** Chronic Kidney Disease (CKD): Monitoring Phosphorus
- **0261** * Measurement of Serum Calcium Concentration
- **0574** * Chronic Kidney Disease (CKD): Monitoring Calcium
- **0571** * Chronic Kidney Disease (CKD): Monitoring Parathyroid Hormone (PTH)

NOTE: The workgroup agreed to hold on re-voting on **0570** Chronic Kidney Disease (CKD): Monitoring Phosphorus until further information can be submitted from the measure developer on reliability and validity testing. Subsequent voting on this measure will occur after the workgroup has reviewed the additional information.

Overarching Issue for All the Measures

The preliminary ratings on high impact for all the measures were mixed. After discussion, it was identified that the differences stemmed from whether evidence was considered when rating high impact, i.e., whether there was evidence that the frequency of assessment impacts outcomes or that treatment of the abnormal value changed survival. Dr. Burstin clarified that the high impact subcriterion was more general to the topic of mineral metabolism and that in combination with the evidence and opportunity for improvement determined whether a measure was determined to be important to measure and report. The Steering Committee members agreed that mineral metabolism is a high-impact aspect of healthcare for end-stage renal disease (ESRD) and CKD patients. Each measure will be evaluated to determine whether it meets the other criteria.

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 before making recommendations for endorsement final. The Steering Committee also will select the best measure from among competing measures.

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Mineral Metabolism Preliminary Evaluations Summary

The following tables compile the preliminary evaluation ratings and comments for the five measures reviewed. Each table begins with brief information about the measure, followed by the staff notes to reviewers that were included in the original evaluation worksheets, the compiled workgroup ratings and comments including their votes and rationale, and finally, a summary of the workgroup’s discussion.

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0255 Measurement of Serum Phosphorus Concentration
<p>Description: Percentage of all adult (>= 18 years of age) peritoneal dialysis and hemodialysis patients included in the sample for analysis with serum phosphorus measured at least once within month.</p> <p>Numerator Statement: Number of adult (>= 18 years of age) dialysis patients included in denominator with serum phosphorus measured at least once within month</p> <p>Denominator Statement: All adult peritoneal dialysis and hemodialysis patients included in the sample for analysis.</p> <p>Exclusions: Transient dialysis patients (in unit < 30 days), pediatric patients and kidney transplant recipients with a functioning graft</p> <p>Adjustment/Stratification: No risk adjustment or risk stratification N/A N/A</p> <p>Level of Analysis: Facility</p> <p>Type of Measure: Process</p> <p>Data Source: Electronic Clinical Data</p> <p>Measure Steward: Centers for Medicare & Medicaid Services</p>
<p>9/19 Workgroup Call Summary (In attendance: Peter Crooks (Co-Chair); Kristine Schonder (Co-Chair); Jeffrey Berns; Michael Fischer; Alan Kliger; Lisa Latts; Joseph Nally; Andrew Narva, MD (ex officio); Jessie Pavlinac; Michael Somers; Roberta Wager)</p> <p>The following summarizes the workgroup’s discussion and subsequent action (if any) for this measure:</p> <p>1. Importance to Measure and Report</p> <p>1a. Impact–See discussion of high-impact, under/overarching issues. After discussion, the workgroup agreed that mineral metabolism was a high-impact aspect of healthcare for dialysis patients.</p> <p>1b. Performance Gap–The preliminary ratings were spread across all the rating categories. One member questioned whether the performance gap data indicating an average performance of 77% was accurate because most if not all inpatient dialysis facilities are already capturing phosphorus levels of those patients who are treated in the facility. After further discussion, the workgroup agreed that there is a performance gap for this measure.</p> <p>1c. Evidence–The preliminary ratings were spread across all the categories. The evidence is indirect, i.e., it is about the association between phosphorus and mortality rather than the frequency of assessment, and there was no information submitted about any studies that show a decrease in phosphorus levels will lead to better mortality outcomes. A Committee member noted the inferiority of a measure simply of the frequency of assessment, given the recent NOF guidance on the evaluation criteria. However, because the evidence does not support a measure of a specific phosphorus value (also noted by KDIGO), some Committee members were concerned misinterpretation of the importance if no measure related to serum phosphorus was recommended. One member noted that the evidence of the association between phosphorus levels and mortality (18% increase in mortality for every 1 mg/dL increase in serum phosphorus) is much stronger than for the association with calcium or PTH. Additionally, the information presented in validity testing demonstrated an association between facility performance on this measure and the facility-standardized mortality ratio.</p> <p>2. Scientific Acceptability of Measure Properties</p> <p>The preliminary ratings were spread across all the rating categories.</p>

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0255 Measurement of Serum Phosphorus Concentration

2a. **Reliability** The preliminary reliability ratings were mixed, but CMS did submit additional reliability testing that indicate the interunit reliability was 0.94.

2b. **Validity**—Validity testing demonstrated association between facility performance on this measure and the facility standardized mortality ratio. The lowest quintile of performance on this assessment measure had a 17% greater risk of mortality than the highest-performing quintile; and the risk of mortality decreased as the quintile of performance increased.

3. **Usability**—The preliminary ratings were spread across all the rating categories. Because of the limitations already noted under evidence, some Committee members did not think this measure would be that useful for evaluating quality.

4. **Feasibility**—Preliminary ratings indicated agreement that feasibility was met. One member just noted that phosphorus is measurable and should be relatively easy to get.

5. **Suitable for endorsement**—The preliminary ratings were spread across all the rating categories. One member noted that while it is an important issue, it is going to be measured as a part of a patient's general care plan and should not necessarily be a performance measure. Another member noted that the absence of RCTs and interventional trials would not support this as a performance measure. There was also concern that a monthly measurement is not necessary. However, another member noted that the absence of RCTs does not mean it should not be endorsed as a performance measure. There is some evidence that is important. And for phosphorus, the correlative data to survival is so remarkably strong that it is important enough to be a performance measure. The workgroup will re-vote on this measure.

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0261 Measurement of Serum Calcium Concentration
<p>Description: Percentage of all adult peritoneal dialysis and hemodialysis patients included in the sample for analysis with serum calcium measured at least once within month</p> <p>Numerator Statement: Number of adult (≥ 18 years of age) dialysis patients included in denominator with serum calcium measured at least once within month</p> <p>Denominator Statement: All adult peritoneal dialysis and hemodialysis patients included in the sample for analysis.</p> <p>Exclusions: Transient dialysis patients (in unit < 30 days), pediatric patients and kidney transplant recipients with a functioning graft.</p> <p>Adjustment/Stratification: No risk adjustment or risk stratification N/A N/A</p> <p>Level of Analysis: Facility</p> <p>Type of Measure: Process</p> <p>Data Source: Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Laboratory</p> <p>Measure Steward: Centers for Medicare & Medicaid Services</p>
<p>9/19 Workgroup Call Summary (In attendance: Peter Crooks (Co-Chair); Kristine Schonder (Co-Chair); Jeffrey Berns; Michael Fischer; Alan Kliger; Lisa Latts; Joseph Nally; Andrew Narva, MD (ex officio); Jessie Pavlinac; Michael Somers; Roberta Wager)</p> <p>The following summarizes the workgroup's discussion and subsequent action (if any) for this measure:</p> <ol style="list-style-type: none">1. Importance to Measure and Report<ol style="list-style-type: none">1a. Impact–The preliminary ratings were spread across all the rating categories. See discussion of high-impact under overarching issues. After discussion, the workgroup agreed that mineral metabolism was a high-impact aspect of healthcare for dialysis patients.1b. Performance Gap–The preliminary ratings were low to moderate. The mean performance rate was also 77% of this measure (as with the phosphorus assessment measure).1c. Evidence–The preliminary ratings mostly indicated that the evidence criteria were not met. The evidence is indirect, i.e., it is about the association between calcium and mortality rather than the frequency of assessment. Most of what the measure developer cites is tangential to the specific question about the benefit of measuring monthly calcium. A Committee member suggested that although this may not be the most important measure—it is a start and it is something that is measurable. Another Committee member noted that the data are far less convincing for that of calcium vs. phosphorus. One committee member noted that the big difference between this measure and the phosphorus measure has to do with a safety signal. Monitoring calcium is an opportunity to identify patients with potential hypercalcemia related to treatment. However, it was noted that a measure of hypercalcemia (#) was endorsed in the Phase I project. It was recommended that this measure of assessing calcium be combined with the recently endorsed measure of hypercalcemia. This recommendation was forwarded to the measure developer for consideration.2. Scientific Acceptability of Measure Properties<p>The preliminary ratings were spread across all the rating categories.</p><ol style="list-style-type: none">2a. Reliability–The preliminary reliability ratings were mixed, but CMS did submit additional reliability testing that indicate the interunit reliability was 0.94.and 2b. Validity–Validity testing demonstrated association between facility performance on this measure and the facility-standardized mortality ratio. The lowest quintile of performance on this assessment measure had a 16% greater risk of mortality than the highest performing quintile, and the risk of mortality decreased as the quintile of performance increased.3. Usability–The preliminary ratings were spread across all the rating categories.<p>One member noted that the measure was understandable but not useful or meaningful. The measure of hypercalcemia is more useful.</p>4. Feasibility–Preliminary ratings indicated agreement that feasibility was met.5. Suitable for endorsement–The preliminary ratings were spread across all the rating categories.<p>One member expressed that this measure should be harmonized with the hypercalcemia measure. Another member agreed that in order to detect a safety issue, it infers that it has to be measured. The workgroup will re-vote on this measure.</p>

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0570 CHRONIC KIDNEY DISEASE (CKD): MONITORING PHOSPHORUS
<p>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.</p> <p>Numerator Statement: Members with phosphorus level blood tests during the measurement year.</p> <p>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).</p> <p>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.</p> <p>Adjustment/Stratification: No risk adjustment or risk stratification N/A N/A</p> <p>Level of Analysis: Clinician : Group/Practice, Clinician : Individual, Clinician : Team, Health Plan</p> <p>Type of Measure: Process</p> <p>Data Source: Administrative claims</p> <p>Measure Steward: IMS Health</p>
<p>9/19 Workgroup Call Summary (In attendance: Peter Crooks (Co-Chair); Kristine Schonder (Co-Chair); Jeffrey Berns; Michael Fischer; Alan Kliger; Lisa Latts; Joseph Nally; Andrew Narva, MD (ex officio); Jessie Pavlinac; Michael Somers; Roberta Wager)</p> <p>The following summarizes the workgroup's discussion and subsequent action (if any) for this measure:</p> <ol style="list-style-type: none">1. Importance to Measure and Report<ol style="list-style-type: none">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 discussed further (see earlier discussion on Evidence in measure 0255).2. Scientific Acceptability of Measure Properties<p>The preliminary ratings were spread across all the rating categories. The reliability and validity testing was conducted using a large, aggregated data set. They do not compute the scores at the level for which they say they will 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.</p><ol style="list-style-type: none">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 further 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 recommendations for endorsement.
0571 CHRONIC KIDNEY DISEASE (CKD): MONITORING PARATHYROID HORMONE (PTH)

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0570 CHRONIC KIDNEY DISEASE (CKD): MONITORING PHOSPHORUS
<p>Description: To ensure that members with chronic kidney disease are monitored for PTH levels at least once annually.</p> <p>Numerator Statement: Members who received a PTH level test during the measurement year.</p> <p>Denominator Statement: Members with 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 the year prior (at least 1 of which must be during the year prior to the measurement year), or members on dialysis or who utilized dialysis during the year prior to the measurement year.</p> <p>Exclusions: Members who are in hospice during the measurement year.</p> <p>Adjustment/Stratification: No risk adjustment or risk stratification N/A N/A</p> <p>Level of Analysis: Clinician : Group/Practice, Clinician : Individual, Clinician : Team, Health Plan</p> <p>Type of Measure: Process</p> <p>Data Source: Administrative claims</p> <p>Measure Steward: IMS Health</p>
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0574 CHRONIC KIDNEY DISEASE (CKD): MONITORING CALCIUM
<p>Description: To ensure that members with chronic kidney disease (CKD), but who are not on dialysis, are monitored for blood calcium levels at least annually.</p> <p>Numerator Statement: Members who received a calcium level blood test during the measurement year.</p> <p>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).</p> <p>Time Window: The year prior to the measurement year.</p> <p>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.</p> <p>Adjustment/Stratification: No risk adjustment or risk stratification N/A N/A</p> <p>Level of Analysis: Clinician : Group/Practice, Clinician : Individual, Clinician : Team, Health Plan</p> <p>Type of Measure: Process</p> <p>Data Source: Administrative claims</p> <p>Measure Steward: IMS Health</p>
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