NATIONAL QUALITY FORUM

CONFERENCE CALL FOR THE RENAL ENDORSEMENT MAINTENANCE STEERING COMMITTEE REVIEW OF ANEMIA AND CARDIOVASCULAR MEASURES

October 4, 2011

Committee Members Present: Kristine Schonder, PharmD (Co-Chair); Jeffrey Berns, MD; Lorien Dalrymple, MD, MPH; Frederick Kaskel, MD, PhD; Myra Kleinpeter, MD, MPH; Alan Kliger, MD; Kathe LeBeau; Michael Somers, MD; Rubin Velez, MD.

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

Others Present: Mark Antman, Akhtar Ashfaq, Amy Beckrich, Tom Dudley, Barbara Fivush, Renee Henry, Diedra Joseph, Lisa McGonigal, Karen Nakano, Robyn Nishimi, Tom Nusbickel, Holly Owens, Paul Palevsky, Jeffrey Pearson, Dale Singer, Jennifer Stone, David Vanwyck, Bani Vir.

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 review specific hemoglobin and cardiovascular measures, including:

- review the Committee's rationale for recommendation of endorsement for **1667 (Pediatric) ESRD Patients Receiving Dialysis: Hgb Level < 10g/dL**; 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 a discussion among the Anemia/Cardiovascular 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.

EVALUATION OF RENAL MEASURES

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

1667 (Pediatric) ESRD Patients Receiving Dialysis: Hemoglobin Level < 10g/dL
Description: Percentage of calendar months within a 12-month period during which patients aged 17 years and younger with a diagnosis of ESRD receiving hemodialysis or peritoneal dialysis have a Hemoglobin level <10 g/dL Numerator Statement: Calendar months during which patients have a Hemoglobin level <10 g/dL* *The hemoglobin values used for this measure should be the most recent (last) hemoglobin value recorded for each calendar month Denominator Statement: All calendar months during which patients aged 17 years and younger with a diagnosis of ESRD are receiving hemodialysis or peritoneal dialysis Exclusions: Documentation of medical reason(s) for patient having a Hemoglobin level <10g/dL (eg, patients who have non-renal etiologies of anemia [eg, sickle cell anemia or other hemoglobinopathies, hypersplenism, primary bone marrow disease, anemia related to chemo] 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 Evaluation 1. Importance to Measure and Report (*based on decision logic*): Yes 1a. Impact: H-8; M-10; L-0; I-0; 1b. Performance Gap: H-0; M-9; L-0; I-11 Rationale: 1b.Data presented were for adult measure; no data identified for pediatric patients. A Committee member noted that a prospective longitudinal cohort study identified that 40% of stage 2-4 CKD children are anemic. There should be some data in the literature that indicate performance gap, and PCPI should submit. 1c. Evidence (*based on decision logic*): Yes IF a Health Outcome, rationale supports: NA Quantity: H-1; M-17; L-1; I-1; Quality: H-0; M-11; L-7; I-0; Consistency: H-2; M-16; L-0; I-2 Rationale: The developer submitted the same evidence for the pediatric measure as the adult measure and highlighted the pediatric studies. The developer noted that the adult targets are considered only opinion-based for children. The pediatric studies included a single RCT with 11 children; 2 observational studies with size not reported; and a nonrandomized interventional study of 18 children. The pediatric members of the Committee advocated for the greater importance of adequate Hgb on growing children and discussed two studies. A newer observational study of 700 children (Ameral, 2006) showed a 70% difference in mortality with HB <10 and >10 and differences in rates of hospitalizations. A prospective cohort study of 105 adolescents (Gerson, 2004) showed that anemia negatively impacts health-related QoL, physical development, cognitive development, and school. Smaller studies showed improvement in measures of cardiac health as Hgb increases. A Committee member noted the problems with the conclusions made about Hgb in adults from the retrospective observational studies and asked if that could be an issue with the pediatric studies. The member emphasized that the committee should not think there is the same issue with high Hgb levels in children as in adult studies. The evidence demonstrated a substantial benefit of Hgb = >10, and there was no evidence of harm with ESAs in children as in the studies of adults that prompted the newest FDA safety announcement. The pediatric experts advocated that the benefits of treating anemia in children to Hgb =>10 greatly outweigh the potential harms of ESAs that may be used to treat anemia, and the Steering Committee agreed.
2. Scientific Acceptability of Measure Properties (*based on decision logic*): Yes 2a. Reliability: H-1; M-13; L-4; I-2 2b. Validity: H-0; M-16; L-1; I-2 Rationale: 2a1. Specifications—developer states could be implemented in one of 3 ways—medical record, CPT-II codes on physician

1667 (Pediatric) ESRD Patients Receiving Dialysis: Hemoglobin Level < 10g/dL
claims, or electronic health record. The Committee noted several problems with eSpecs, and they were removed from consideration with the measure. 2a2. Appears to be testing for the adult measure not the pediatric measure; however, there is no reason to expect a difference in reliability. Although the adult measure has been implemented in CMS PQRS program using CPT-II codes, reliability of data elements was tested for chart abstraction on a sample of 4 group practices. 2b2. Submitted systematic assessment of face validity using the expert group that developed the measure. Exclusions give good examples, but have open statement of "other medical reasons," which can be interpreted with wide variety 2c. Disparities: H-; M-12; L-1; I-7 Rationale: Race/ethnicity in eSpecs but not in specificaitons.
3. Usability: H-6; M-14; L-0; I-0 (*Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting and 3b. Quality Improvement)* Rationale:
4. Feasibility: H-12; 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-17; N-2; A-0 (All criteria met, but final recommendation pending further information and/or evaluation of related and competing measures) If applicable, Conditions/Questions for Developer: Please provide some data in the literature that indicate performance gap. eSpecs not considered because incorrect—would need crosswalk to specifications before further consideration. 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 within each terminology should be assessed as to whether they capture the concept in the performance measure. Pediatric Anemia Performance Gap Data: The KDOQI Clinical Practice Recommendation for anemia management in pediatric patients (2007 revision) recommends that the target hemoglobin for patients on ESA therapy should be 11-12.0 gm/dL and that hemoglobin concentration greater than 13 gm/dL should be avoided (CPM 2.1.2 and 2.1.3). For Q4 2010, 32.4% of pediatric patients had hemoglobin 11-12.0 gm/dL, which is about the same as Q4 2009 and compares to 48.7% in the adult hemodialysis patient population. Pediatric patients who were diabetic, on hemodialysis, and were adequately dialyzed had the highest percentage in the 11-12.0 gm/dL range (35.8% and 36.7% respectively). The lower tail (<10 gm/dL) of the hemoglobin distribution in pediatric dialysis patients by patient characteristics, according to the Elab Project Q4 2010, shows opportunities for improvement with 20% of patients with hemoglobin <10 gm/dL (increased over 2009 when 18.6% were <10 gm/dL). 24.5% of patients had hemoglobin ≥12 gm/dL. The normal distribution curve shows a slight improvement over the past 4 years, with mean hemoglobin of 11.10 ± SD 1.36. Elab 2010 and Trends Report, Renal Network of the Upper Midwest, St. Paul, MN. Steering Committee Follow-Up:
5. Related and Competing Measures (*5a. Harmonization; 5b. Superior to competing measures*) Comments:
10/4 Workgroup Call Summary The following summarizes the workgroup's discussion and subsequent action (if any) for this measure: The reason for reviewing this measure was to have a brief discussion with this workgroup about passing this measure but not the comparable adult measure. The workgroup and committee members on the call agreed that the issues for pediatric patients with hemoglobin <10 are considerable, and in the absence of harm data with ESA use that specifically included pediatric patients, they agreed that the benefits outweighed potential harm to pediatric patients. The key points are that the evidence shows that values <10 are detrimental to children, whereas with adults the detrimental effects are at values <10. With adults there is evidence and concern about harm with use of ESAs, but data on harm do not include pediatric patients with higher hemoglobin values. One committee member suggested there is a need to accumulate more data using such a measure.

0626 Chronic Kidney Disease - Lipid Profile Monitoring

Description: The percentage of patients with chronic kidney disease that have been screened for dyslipidemia with a lipid profile.
Numerator Statement: Patients who had a lipid profile.
Denominator Statement: All patients, males > 10 and females > 13 years of age, diagnosed with chronic kidney disease.
Exclusions: DENOMINATOR EXCLUSIONS
Specific Exclusions:
None
General exclusion:
Patients with active cancer or metastatic diseases.
Patients who were in a skilled nursing facility recently.
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, Electronic Clinical Data : Registry, Patient Reported Data/Survey
Measure Steward: ActiveHealth Management

Steering Committee Evaluation
1. Importance to Measure and Report (*based on decision logic*): No
1a. Impact: H-3; M-12; L-4; I-2; 1b. Performance Gap: H-0; M-8; L-5; I-7
Rationale: Lipids are a national health priority. No performance data on this previously endorsed measure, even though indicated measure is in use. Performance gap data is for all adults but measure also includes children. A lot of heterogeneity in the measure—children and adults, on/off dialysis, pre-existing CV disease—inlcudes primary and secondary prevention—evidence varies. Performance gap depends on evidence of whether should be doing it.
1c. Evidence (*based on decision logic*): No IF a Health Outcome, rationale supports: NA
Quantity: H-1; M-9; L-8; I-3; Quality: H-0; M-7; L-6; I-7; Consistency: H-0; M-4; L-5; I-12
Rationale: Assessing lipid levels is not proximal to desired outcome. Does lipid monitoring afect outcomes? Evidence from clinical practice guidelines. Observational study links CKD to hyperlipidemia, some small-volume studies that statins reduce microinflammation and may have beneficial effects in CKD. CKid study 690 children enrolled showing that more than half have lipid abnormalities, now studying affect on outcomes. Two bodies of evidence with RCTs not mentioned: 1) 4D trial German diabetic dialysis patients and Aurora counterpart both statin/placebo trials—negative trials with no specific difference in ESRD population; 2) newest SHARP trial of 6000 CKD patients 3000 on dialysis PD and HD patients on lipid lowering therapy showed fewer CV events but no difference in renal outcomes. Would strengthen the evidence for a measure, but not necessarily this one—perhaps a measure for use of lipid-lowering agents.

2. Scientific Acceptability of Measure Properties (*based on decision logic*): 2a. Reliability: H-; M-; L-; I- 2b. Validity: H-; M-; L-; I-
Rationale: Concern that CKD will be missed because of reliance on ICD or CPT codes, rather than low GFR. In registry majority are entered because of GFR rather than diagnosis by physician.
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:
If applicable, Conditions/Questions for Developer:
Developer Response:
Steering Committee Follow-up:

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

10/4 Workgroup Call Summary
The Steering Committee had voted that this measure did not pass the evidence criterion. The measure developer identified that it had more

0626 Chronic Kidney Disease - Lipid Profile Monitoring
evidence to support this measure and was asked to revise the submission form. Specifically, items that have been revised include: 1a.3, 1a.4, 1b.2, 1b.3, 1b.4, 1c.4, 1c.15, 2b2.3, 3.1, 5a.1, 5b.1. The measure developer has updated and edited their literature to reflect an emphasis on evidenced-based medicine and to support the measure more accurately as it is presented. They have also updated information regarding test results and evidence of performance gap. The workgroup members were asked to review the revised submission and re-evaluate 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 possible 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.