



January 9, 2012

National Quality Forum
1030 Fifteenth Street, NW
Suite 800
Washington, DC 20005

Subject: National Voluntary Consensus Standards for Renal Disease, NQF Member Comments

I. General Comments

Thank you for the opportunity to comment on the National Quality Forum's (NQF) draft document, *National Voluntary Consensus Standards for Renal Disease*. Kidney Care Partners (KCP) is a coalition of members of the kidney care community that includes the full spectrum of stakeholders related to dialysis care – patient advocates, health care professionals, dialysis providers, researchers, and manufacturers and suppliers – organized to advance policies that improve the quality of care for individuals with both chronic kidney disease and end stage renal disease (ESRD). We greatly appreciate NQF undertaking this important work.

The NQF report recommends that 13 measures (four new and nine previously endorsed) addressing the topics of mortality, anemia, cardiovascular care, dialysis adequacy, mineral metabolism, and vascular access be endorsed as national voluntary consensus standards. Our understanding is that NQF endorsement historically has been for the purposes of public reporting and internal quality improvement. As an operating premise, however, KCP has assumed that endorsement means the Centers for Medicare and Medicaid Services (CMS) may use a measure in the Quality Incentive Program (QIP) – i.e., for payment/value-based purchasing. And while CMS states it will use rulemaking to implement measures for the QIP, for purposes of clarity we have stated KCP's support for each measure in the context of intended use. Additionally, when considering previously endorsed measures, KCP assessed whether it should continue its previous support or opposition based on whether there have been changes in the science/evidentiary base since 2008 and whether performance on the measure has "topped out", leaving little or no room for improvement.

Again, thank you for undertaking this important project; we appreciate the opportunity to provide KCP's consensus comments. Please do not hesitate to contact us if you have any questions.

II. Measures Recommended by NQF

KCP's comments on the 13 measures recommended by NQF are as follows:

- a. **NQF 0369 Dialysis Facility Risk-Adjusted Standardized Mortality Ratio (CMS):** Risk-adjusted standardized mortality ratio (observed/expected deaths) for dialysis facility patients during a four-year time period.

Comment: KCP had previously supported this measure, believes greater transparency in the methodology must be provided.

- b. **NQF 1666 Patients on ESA with Hemoglobin Level >12.0g/dL (RPA/AMA PCPI):** Percentage of calendar months within a 12-month period during which a hemoglobin (Hgb) 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 [HD] or peritoneal dialysis [PD]) who are also receiving ESA therapy and have a Hgb level >12.0g/dL.
Comment: KCP supports this measure for public reporting and payment.
- c. **NQF 1667 Pediatric ESRD Patients Receiving Dialysis with Hgb Level <10g/dL (RPA/AMA PCPI):** Percentage of calendar months within a 12-month period during which patients aged 17 years and younger with a diagnosis of ESRD receiving HD or PD have a Hgb level <10g/dL.
Comment: KCP supports this measure for public reporting.
- d. **NQF 1633 Blood Pressure Management (RPA/AMA PCPI):** 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 <130/80mmHg OR \geq 130/80mmHg with a documented plan of care.
Comment: KCP supports this measure for public reporting.
- e. **NQF 1668 Laboratory Testing (Lipid Profile) (RPA/AMA PCPI):** 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 at least once with a 12-month period.
Comment: KCP supports this measure for both public reporting and payment.
- f. **NQF 0249 HD Adequacy CPM III—Minimum Delivered HD Dose (CMS):** Percentage of adult (\geq 18 years old) patients in the sample for analysis who have been on HD for 6 months or more and dialyzing thrice weekly whose average delivered dose of HD (calculated from the last measurements of the month using the UKM or Daugirdas II formula) was a $spKt/V \geq 1.2$ during the study period.
Comment: KCP supports this measure for both public reporting and payment.
- g. **NQF 0323 HD Adequacy—Solute (RPA/AMA PCPI):** Percentage of calendar months within a 12-month period during which patients aged 18 years and older with a diagnosis of ESRD receiving HD three times a week have a $spKt/V \geq 1.2$
Comment: KCP supports this measure for both public reporting and payment.
- h. **NQF 0318 PD Adequacy CPM III—Delivered Dose of PD Above Minimum (CMS):** Percentage of adult (\geq 18 years old) PD patients whose delivered PD dose was a weekly Kt/V_{urea} of at least 1.7 (dialytic + residual) during the 4-month study period.
Comment: KCP supports this measure for both public reporting and payment.
- i. **NQF 0321 PD Adequacy—Solute (RPA/AMA PCPI):** Percentage of patients aged 18 years and older with a diagnosis of ESRD receiving PD who have a total $Kt/V \geq 1.7$ per week measured once every 4 months.
Comment: KCP supports this measure for both public reporting and payment.
- j. **NQF 0255 Measurement of Serum Phosphorus Concentration (CMS):** Percentage of all adult (\geq 18 years old) PD and HD patients included in the sample for analysis with serum phosphorus measured at least once within the month.
Comment: KCP previously supported this measure; however, evidence provided by both small and large dialysis organizations within KCP indicate that performance on this

measure averages $\geq 97\%$. Given the minimal room for continued improvement, KCP recommends that the measure be moved to NQF reserve status.

- k. **NQF 0251 Vascular Access—Functional AVF or AV Graft or Evaluation by Vascular Surgeon for Placement (KCQA):** Percentage of ESRD patients aged 18 years and older receiving HD during the 12-month reporting period and on dialysis >90 days who (1) have a functional AVF [defined as two needles used or a single-needle device]; (2) have a functional AV graft; 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).

Comment: KCP supports this measure for public reporting.

- l. **NQF 0256 HD Vascular Access—Minimizing Use of Catheters as Chronic Dialysis Access (CMS):** Percentage of patients on maintenance HD during the last HD treatment of the study period with a chronic catheter continuously for 90 days or longer prior to the last HD session.

Comment: KCP supports this measure for both public reporting and payment.

- m. **NQF 0257 HD Vascular Access—Maximizing Placement of AVF (CMS):** Percentage of patients on maintenance HD during the last HD treatment of the month using an autogenous AVF with two needles.

Comment: KCP supports this measure for public reporting only. KCP recognizes the importance of appropriate vascular access selection and commends NQF for its ongoing work in this area. However, KCP believes that continued emphasis on maximizing fistula use does not reflect current evidence indicating that AV grafts are an acceptable alternative to fistulas and that the emphasis should be placed on maximizing permanent access—i.e., fistulas *and grafts*—and minimizing catheter use.

III. **Measures Not Recommended by NQF**

In addition to the measures just noted, KCP offers the following comments on the KCQA facility patient education measure that was not recommended by the Steering Committee. Specifically, we note that the NQF report indicated there was a “lack of clear consensus” on this measure (12 N, 10 Y). KCP strongly urges its reconsideration and that it be advanced for consideration and voting by all NQF Members.

- a. **NQF 0324 Patient Education Awareness—Facility Level (KCQA):** ESRD patients aged 18 years and older with medical record documentation of a discussion of renal replacement therapy modalities (including HD, PD, home HD, transplants and identification of potential living donors, and no/cessation of renal replacement therapy) at least once during the 12-month reporting period.

Comment: KCP supports this measure for public reporting and recommends that it be advanced to the voting phase. While the NQF Steering Committee expressed concerns that the measure does not address the quality of the education provided or patient comprehension of what was taught, KCP stresses that the sole intent of this measure is to ensure that all ESRD patients are being educated on all renal replacement therapy modalities on an annual basis, as is consistent with the Conditions for Coverage. KCP recognizes that patient comprehension and the quality of the education provided are important issues, but notes that expert opinion and a growing body of peer-reviewed evidence indicate that focus on patient education can dramatically improve outcomes for chronic dialysis patients—even when there is not a separate assessment of patient comprehension or the quality of education. For instance, *using standardized, readily available materials*, individuals participating in a recent national predialysis treatment

options program (TOPs) were found to more frequently select home dialysis, had lower catheter rates, and had half the 90-day mortality risk when compared with patients not participating.¹ As such, KCP maintains that this measure, as currently specified, is a critical and valuable component of the NQF ESRD measure set.

Additionally, while the NQF Steering Committee questioned whether the Standard Dialysis Facility Surveys required by CMS are sufficient to ensure that patient education is occurring on a yearly basis, KCP notes that CMS policy requires only that the time interval between surveys at any one facility be no more than 3.5 years,^{2,3} and that 19 states were unable to meet this requirement in 2009.⁴

Likewise, Medicare data indicate that as of October 2010, one in ten facilities hadn't had a top-to-bottom check in at least five years, and approximately 250 facilities hadn't had a full recertification inspection in seven years or more.³ KCP also notes that the In-Center Hemodialysis CAHPS survey was cited as a better way to assess patient experience with education. We note that this instrument also does not assess comprehension; moreover, the construction of items related to modality options is not clearly distinguished.

Finally, the NQF Steering Committee stated that it believes there is no evidence that the measure will be widely implemented and used if endorsed. KCP notes, however, that as the measure has been included in CMS's list of Phase III ESRD Clinical Performance Measures in effect April 1, 2008, the data elements are in fact ultimately intended for collection via CROWNWeb and thus would be widely used.

IV. Recommendations for Future Measure Development

KCP appreciates and supports the NQF Steering Committee's thoughtful recommendations for future measure development in the area of dialysis adequacy. In addition, KCP suggests that the following topics be prioritized in future measure development efforts:

- Bone and mineral metabolism;
- Dialysis treatment time;
- Patient education comprehension; and
- Timely referral of CKD Stage 4 patients to vascular surgeons for catheter reduction.

V. Summary

Again, thank you for undertaking this important project; we appreciate the opportunity to provide KCP's consensus comments. Please do not hesitate to contact Lisa McGonigal, MD, MPH (lmgon@msn.com or 203.298.0567) if you have any questions.

¹ Lacson E, Wang W, DeVries C et al. Effects of a nationwide predialysis educational program on modality choice, vascular access, and patient outcomes. *Am J Kidney Dis.* 2011;58(2):235-42.

² CMS. Timelines for Patient Assessment/Plan of Care, Version 1.3. Available at: www.esrdnetwork18.org. Accessed September 7, 2011.

³ United States General Accounting Office (GAO). Report to the Chairman, Committee on Finance, U.S. Senate. *Dialysis Facility Compliance: Problems Remain in Ensuring Compliance with Medicare Quality Standards.* October 2003. Available at: www.gao.gov/new.items/d0463.pdf. Accessed September 7, 2011.

⁴ Questions and Responses Regarding Federal Oversight of Dialysis Facilities and Public Access to Quality of Care and Safety Information. Available at: www.grassley.senate.gov. Accessed September 7, 2011.

Sincerely,

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January 9, 2012

Kathryn Streeter
National Quality Forum
1030 Fifteenth Street, NW - Suite 800
Washington, DC 20005

Dear Ms. Streeter:

RE: Comments on *National Voluntary Consensus Standards for Renal Disease*

The National Kidney Foundation, with its 50,000 patient and practitioner members, appreciates the opportunity to comment on the draft document that was posted on the NQF web site on December 9, 2011, *National Voluntary Consensus Standards for Renal Disease*. We support the analysis of the Steering Committee and the measures that the Steering Committee recommended for endorsement, with the qualifications noted below.

General Observations

A performance measure which defines Chronic Kidney Disease (CKD) only by administrative data is problematic since coding practices vary from institution to institution and between health care practitioners. That will make it difficult to compare performance.

A performance measure that is based upon reporting lab values is much less indicative of quality than one which evaluates performance when a lab value triggers an intervention or reflects an intervention.

Comments on Measures Not Recommended for Endorsement

Since there is an endorsed measure for hypercalcemia (1454), measure 0261 (Measurement of Serum Calcium Concentration in ESRD patients) is not necessary. Similarly we agree that measures for monitoring calcium (0574) and PTH (0571) in individuals with CKD, and assessment of iron stores of ESRD patients (0252), should not be endorsed. However, an exception to the principle listed under ***General Observations*** might be appropriate when baseline data are needed in anticipation of an outcome measure. We recommend that NQF reconsider endorsement of measures for monitoring phosphorus in CKD (0570) and ESRD patients since we believe that NQF should ultimately endorse a phosphorus outcome measure for both CKD and ESRD care. Although the Kidney Disease

Improving Global Outcomes (KDIGO) guidelines do not provide specific guidance in terms of a cutpoint, it is clear that very high phosphorus levels are associated with increased mortality. As stated in the background section of chapter 4 of the KDIGO Mineral and Bone Disorder guidelines: “Large epidemiologic studies have consistently demonstrated the importance of hyperphosphatemia as a predictor of mortality in CKD Stage 5 patients receiving dialysis. (References omitted.) Taken together, these observational data suggest that there is a need to control serum phosphorus in patients with CKD.” Kidney Disease: Improving Global Outcomes (KDIGO) MBD Work Group. KDIGO clinical practice guideline for the diagnosis, evaluation, prevention, and treatment of chronic kidney disease-mineral and bone disorder (CKD-MBD). *Kidney International* 2009; (Suppl 133): S1-S130.

Lack of Clear Consensus

0324 - Patient Education Awareness

Since the National Kidney Foundation is dedicated to patient empowerment, we believe that a measure that tracks the percentage of patients that a facility/provider has on home therapies or who have received a kidney transplant in the last 12 months (adjusted for characteristics of the patient population served) might be more informative for patients and their families when choosing a provider/facility than the process measure that was reviewed. Such an outcome measure would also take into account the Steering Committee’s concern about the effectiveness of patient education since it could be a proxy for comprehension.

Harmonization of Related Measures

0249 - Hemodialysis Adequacy (Minimum Delivered Dose)

0323 - Hemodialysis Adequacy (Solute)

The physician measure denominator is patient months rather than patients as in the facility measure. We recommend that patient months be used as the denominator in both measures since patient months are typically used in epidemiologic studies.

The physician measure has exclusion categories of medical reason and patient reason (as identified by the physician). We contend that there should be no exclusions in either measure. Every patient should be able to achieve an adequate dose of dialysis, regardless of vascular access.

In addition, we note these two measures differ with regard to residual renal function. In the former measure, all patients are included after the first three months whereas in the latter patients with residual renal function (RRF) are excluded. There

will be many more exclusions with 0323 since most hemodialysis patients have some residual renal function during the first 2-3 years of dialysis. While we understand the logistical problems of calculating RRF, ideally RRF should be a factor in both adequacy measures.

A final reason for making both measures identical is that it would enable facilities to identify physicians whose performance is not in line with that of their their peers.

Vascular Access Measures: 0251 (Physician) and 0256 and 0257 (Facility)

The facility measures do not have a hospice exclusion while the physician measure does. We agree with the Steering Committee that the exception should be included in all three measures because placement of permanent vascular access may not be a quality indicator for patients with limited life expectancy.

We agree with the Steering Committee recommendation that the definition of a functioning fistula be expanded from access with two needles to incorporate new single-needle devices. The physician measure did incorporate the single-needle device but the facility data system currently does not identify single-needle devices.

Competing Measures

The CKD hypertension measure (#1633) is competing with the more general measure (#0018). The measures differ in the following ways: The general measure (0018) includes all patients with a diagnosis of hypertension (including those with CKD) and excludes those with ESRD; the CKD measure (1633) includes all patients with CKD and proteinuria, not on renal replacement therapy (i.e., exclude ESRD). The general measure (0018) focuses on the percentage of patients with BP < 140/90; the CKD measure (1633) has a target BP of < 130/80 (which may change based on JNC 8).

The CKD measure (1633) also is met for BP greater than the target if there is a documented plan of care; the general measure (0018) is simply the intermediate outcome.

The majority of the Steering Committee voted that the CKD measure could be recommended on the condition of being modified if indicated by JNC 8 guidelines, but the majority also voted that 0018 would capture patients with CKD (unless there is a substantial number of CKD patients with proteinuria who do not have a diagnosis of hypertension). Since all hypertensive patients will not be diagnosed with high blood pressure, we favor 1633 over 0018 as it will also capture

undiagnosed patients. With regard to choosing blood pressure targets for CKD patients not on dialysis, we should await both the publication of JNC 8 and the upcoming KDIGO Hypertension guidelines.

Recommendations for Future Measure Endorsement

We recommend that NQF continue to consider for endorsement a measure like 1662 (Angiotensin Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy.) GUIDELINE 3 of the KDOQI Clinical Practice Guidelines and Clinical Practice Recommendations for Diabetes and Chronic Kidney Disease (MANAGEMENT OF HYPERTENSION IN DIABETES AND CHRONIC KIDNEY DISEASE) reads as follows: “Hypertensive people with diabetes and CKD stages 1-4 should be treated with an ACE inhibitor or an ARB, usually in combination with a diuretic.” GUIDELINE 8 (PHARMACOLOGICAL THERAPY: DIABETIC KIDNEY DISEASE) of the K/DOQI Clinical Practice Guidelines on Hypertension and Antihypertensive Agents in Chronic Kidney Disease recommends that “Patients with diabetic kidney disease, with or without hypertension, should be treated with an ACE inhibitor or an ARB.” Finally, GUIDELINE 9 (PHARMACOLOGICAL THERAPY: NONDIABETIC KIDNEY DISEASE) in the K/DOQI Clinical Practice Guidelines on Hypertension and Antihypertensive Agents in Chronic Kidney Disease provides: “Patients with nondiabetic kidney disease and spot urine total protein to creatinine ratio ≥ 200 mg/g, with or without hypertension, should be treated with an ACE inhibitor or ARB.”

Sincerely,

Lynda A. Szczech

Lynda A. Szczech, MD
President
National Kidney Foundation, Inc

The following comments are being submitted on behalf of PCPI Chair, Bernard M. Rosof, MD, MACP.

The Physician Consortium for Performance Improvement[®] (PCPI) appreciates the opportunity to comment on the National Quality Forum's (NQF) *National Voluntary Consensus Standards for Renal Disease* draft report.

Measure 1660- ESRD Patients Receiving Dialysis: Hemoglobin Level <10g/dL

1. PCPI believes that in order to assess Hgb management, there needs to be measures probing both the upper end and lower ends of the Hgb distribution curve.
2. Based on historical evidence, failure to treat anemia with ESAs results in Hgb levels <8 and is associated with marked worsening of quality of life.
3. Inadequate treatment of anemia with ESAs will increase the number of patients requiring avoidable transfusions with the multiple attendant risks.
4. Given the recent changes in reimbursement, there are financial incentives to minimize ESA use.
5. The combination of these financial drivers along with having a measure for the high end of anemia increases the risk of unintended consequences (ie, more patients with chronic anemia requiring avoidable transfusions with the multiple attendant risks).
6. PCPI acknowledges that the optimal target for anemia management is not known and that treatment of patients should be individualized. As a result, the specific Hgb level used on the "low-end" measure is arbitrary, and should not be construed as suggesting that this is the appropriate minimum Hgb; while a level of 10 was submitted, based on the fact that the measure was developed prior to the June 2011 change in ESA labeling by the FDA, a Hgb of 9.5 or 9.0 could be considered by the PCPI's Adult Kidney Disease Work Group as a revision to the measure.
7. This measure should not be used with the assumption that 100% of patients would have a Hgb above the given threshold, but to look at the percentage of patients below the threshold. Normative data will need to be established to assess what a reasonable percentage below threshold should be.
8. Measure 1667 (**Pediatric**) **ESRD Patients Receiving Dialysis: Hemoglobin Level < 10g/dL** was recommended for endorsement by this NQF committee. PCPI does not believe that the safety and quality of life issues related to a low hemoglobin level change once a patient with ESRD enters adulthood. In addition, pediatric nephrologists continue to see patients often until they are 21 years old. Therefore, since the pediatric Hgb < 10 measure is recommended for endorsement, capturing patients that suffer from anemia, these patients and other adults with anemia should also be captured.

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

This is the accepted treatment to slow progression of CKD in patients with proteinuric disease. PCPI believes this measure is highly reliable as shown by the inter-rater reliability testing performed in the CKD/ESRD testing project.

Measure 0369- Dialysis Facility Risk-adjusted Standardized Mortality Ratio (CMS)

PCPI suggests that the developer refine the statistical models used in the measure.



Established in 1969

American Nephrology Nurses' Association

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Dear National Quality Forum Renal Maintenance Project:

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Rowena Elliott

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In the December 9, 2011 draft NQF report, we noted that the NQF Steering Committee did not express a clear consensus on two measures and that NQF invited comments on them. This letter addresses one of those measures, *NQF 0324 Patient Education Awareness – Facility Level*, which was not recommended by a narrow margin(12-10).

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We strongly urge that NQF advance NQF 0324 for voting by NQF members. As nephrology nurses responsible for a significant amount of initial and ongoing patient education, we believe it is critical to measure whether facilities are providing patients with annual education on all modality options. There is clearly a performance gap in this area: performance at more than 50 facilities in which the measure was tested was 0-100%, with an average of ~16%.

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Patient education saves lives. Multiple studies published in the peer-reviewed literature are clear that educating patients improves outcomes – even when no assessment has been conducted on patient comprehension. Patients who have been educated on available renal replacement therapy modalities are:

North Central
Phyllis Wille

Western
Alice Luehr

- a. Less likely to have a catheter,
- b. Less likely to experience depression,
- c. More likely to use an arterial venous fistula (AVF), and/or select home hemodialysis, which has significantly lower morbidity and mortality,
- d. More likely to adhere to treatment and medication regimens, and
- e. More likely to survive and receive a transplant.

EXECUTIVE DIRECTOR
Michael Cunningham

In a 2011 paper, it was reported that a Fresenius Medical Care program found that attendees of a predialysis treatment options program had lower catheter rates and mortality during the first 90 days of dialysis (when patients are most fragile) when compared with period-prevalent incident patients not enrolled in the program.



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American Nephrology Nurses' Association

We recognize patient comprehension is important, but it is another complimentary facet to be measured; measuring whether the education has even taken place is equally important. Relying on the Conditions for Coverage and surveys to assess compliance is not sufficient, given the low frequency with which some facilities are surveyed due to budgetary constraints. In summary, we again strongly urge that you advance NQF 0324. Given the lack of consensus in the Committee, we believe it most fair that the measure advance so that broader voting by NQF members can be permitted.

Thank you for your consideration of these comments.

Sincerely,

Dr. Rowena Elliot, PhD, RN, CNN, BC, CNE
President
American Nephrology Nurses' Association

Sincerely,

Dr. Rowena Elliott, PhD, RN, CNN, BC, CNE
ANNA National President, 2011-2012

Attachments:

- Letter to Dr. Falk and Mr. Ibrahim - Advanced Practice Nurse Specialty Practice Network
- IOM Report: The Future of Nursing: Leading Change, Advancing Health
- ANNA Position Statement: *RPA/ASN and ANNA Joint Position Paper on Collaboration Between Nephrologists and Advanced Practice Nurses.*

cc: Donna Painter, ANNA President, 2010-2011
Glenda Payne, ANNA President, 2012-2013
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