

January 9, 2012

National Quality Forum
Renal Consensus Standards Endorsement Maintenance Project
1030 15th St NW
Suite 800
Washington, D.C. 20005

Re: National Voluntary Consensus Standards for Renal Disease - Renal Endorsement Maintenance draft report

To whom it may concern:

Thank you for the opportunity to provide comments on the National Quality Forum (NQF) National Voluntary Consensus Standards for Renal Disease Renal Endorsement Maintenance draft report. The American Society of Nephrology (ASN) represents more than 13,500 physicians, scientists and healthcare providers dedicated to providing the best care to kidney patients and developing future cures for kidney diseases. ASN and the professionals it represents are strongly committed to maintaining the integrity of the physician-patient relationship, and to equitable patient access to optimal quality care regardless of socioeconomic status, geographic location, or demographic characteristics.

The society appreciates the efforts of NQF, as well as the Renal Steering Committee, to develop measures that track and promote high-quality, appropriate renal care for patients with chronic kidney disease (CKD) and end-stage renal disease (ESRD). ASN recognizes the importance of evidence-based clinical practice measurements in advancing the quality of care.

However, the society is also concerned that implementation of certain quality measures or clinical practice guidelines could potentially hinder patient access to nephrology care. In certain circumstances, instituting such measures may render it difficult for some patients—particularly those who have multiple co-morbidities or are less adherent to prescribed regimens—to gain access to care. Patients who are racial/ethnic minorities or are socioeconomically disadvantaged would likely face the greatest risk of “cherry-picking.” These concerns are underscored in light of the consolidated dialysis market that offers limited choice in locations to obtain care.

In many areas of nephrology care, scant evidence exists demonstrating a direct relationship between an intervention (or the frequency of assessment) and improved patient outcomes. Where evidence does exist, despite physicians’ best efforts to provide evidence-based care, patient characteristics or non-adherence can sometimes nonetheless lead to suboptimal outcomes.

Given the potential for serious unintended consequences, and the current lack of evidence in nephrology supporting high-quality clinical performance measures, the society maintains reservations about endorsing *any* measures. Furthermore, ASN would support implementation of these quality measures only if the entity doing so had a rigorous and clearly defined plan to monitor and address any discrepancies in access to care in as close to real-time as possible. With this perspective, ASN offers the following comments regarding the draft report:

Mortality

0369 Dialysis Facility Risk-adjusted Standardized Mortality Ratio

ASN concurs with the Steering Committee that mortality is an important factor in gauging the quality of care. ASN also agrees that a four-year time period for analysis of this measure is appropriate, as a shorter time frame would be more likely to produce inaccurate results, especially in smaller dialysis units. ASN appreciates that the measure includes adjustment for age, sex, race, and other demographic variables described, but requests clarification regarding the specific co-morbidities that would be adjusted for in the model. ASN would be pleased to collaborate with NQF to determine the appropriate co-morbidity adjusters.

Without additional detail regarding the co-morbidities that the model would adjust for—especially in light of the society’s concern about unintended consequences including limited access to care for vulnerable patients—ASN cannot recommend the measure for endorsement.

Anemia

1666 Patients on Erythropoiesis Stimulating Agent (ESA)--Hemoglobin Level > 12.0 g/dL

ASN recognizes the potential value of a quality measure that identifies consistently and inappropriately high hemoglobin levels in many CKD IV-V and hemodialysis patients. However, the society has several concerns with the measure 1666, and s recommend that NQF endorse not this proposed measure.

ASN is concerned that this measure would impose a significant data collection and reporting burden for many nephrology practices. Hemoglobin and ESA dosing information is already reported to CMS for dialysis patients, but the vast majority of nephrology practices possess no infrastructure to report this data for patients with CKD, rendering actual implementation of the measure infeasible.

Furthermore, while there may be risk associated with targeting and maintaining hemoglobin levels above 12 g/dl in many CKD patients, the society is concerned that maintenance of hemoglobin levels at or near 12 g/dl may be appropriate in some circumstances. Moreover, some patients have intermittent hemoglobin level fluctuations that are clinically insignificant. ASN believes it is of utmost importance to preserve nephrologists’ flexibility to individualize ESA therapy, balancing anticipated risks and benefits with each patient individually. The society also holds that it is unfair to penalize physicians or other healthcare professionals for hemoglobin fluctuations that occur despite their best efforts to provide high quality care.

ASN urges that NQF not endorse this measure, primarily due to the undue administrative burden reporting hemoglobin values for patients with CKD stages IV and V would impose on nephrologists’ offices.

1667 (Pediatric) ESRD Patients Receiving Dialysis: Hemoglobin Level < 10g/dL

ASN concurs with endorsement of measure 1667 given the unique needs of the pediatric ESRD population, the absence of evidence that hemoglobin levels below 10 g/dl are appropriate and safe in this age group, and the existence of evidence that maintenance of higher hemoglobin levels is associated with risk of harm. *ASN supports NQF endorsement of measure 1667.*

In addition, ASN concurs with the Steering Committee’s recommendation to not recommend the other proposed anemia-related measures (0252 and 1660) for endorsement.

Cardiovascular

1633 Blood Pressure Management

An increasing body of evidence suggests that blood pressure management for patients with CKD stages III, IV, and V who also have proteinuria is beneficial. Additionally, the JNC- VIII is conducting a review of the evidence in this area and will soon release an updated, evidence-based recommendation.

It is reasonable that the measure be predicated on the existence of a documented plan of care to manage blood pressure in this patient population, rather than achieving a blood pressure at or below 130/80 mmHg at this time. In addition, ASN strongly supports the provision that the measure be eligible for modification pending release of the JNC-VIII document. *With the condition that the Blood Pressure Management measure will be modified to reflect the findings of the JNC-VIII report, the society supports measure 1633.*

1668 Laboratory Testing (Lipid Profile)

Mounting evidence indicates that lipid level control and outcomes in patients with CKD may be important, but is not yet sufficiently robust to justify a quality measure promoting specific target levels. Currently available evidence does not contraindicate a quality measure examining whether lipid level screening is performed. However, the society is generally not supportive of “process” measures that do not assess clinical care provided and patient outcomes. *Given the absence of evidence that assessment of lipid levels contributes to improved CKD patient outcomes, the society recommends that NQF not endorse this measure.*

Dialysis Adequacy

Overall, ASN concurs with the Steering Committee’s recommendations to endorse the four dialysis adequacy measures and supports using the Kt/V measurement rather than URR. While ASN believes that the measures are appropriate and adequately evidence-based overall, the society retains some concerns.

As previously mentioned, certain patients are chronically non-adherent to their dialysis regimen and, despite nephrologists’ and dialysis units’ best efforts, have suboptimal Kt/V levels. ASN is concerned that implementing this measure could result in the unintended consequence of units avoiding patients with a history of medical non-adherence.

Nonetheless, ASN agrees with the Steering Committee’s recommendations to include only hemodialysis patients who dialyze three times a week, and to institute a three-month exclusion period. ASN recommends including a recent measurement of residual kidney function in the Kt/V calculation for hemodialysis patients, allowing providers caring for larger patients or patients with other disparities to use a more reasonable dialysis prescription. ASN also recommends changing the hemodialysis numerator to patients with single Kt/V equal or greater than 1.2 if in-center, or standard Kt/V 2.1 to accommodate programs with a large fraction of home patients.

Finally, ASN recommends that NQF consider endorsing only one measure for both PD (0318 or 0321) and HD (0249 or 0323) instead of two. There is no meaningful difference between the two measures for both PD and HD, so endorsing both would be redundant. *The society suggests that NQF endorse 0321 Hemodialysis Adequacy: Solute and 0323 Peritoneal Dialysis Adequacy: Solute, as it is more reasonable to assess data over the full calendar year rather than on a month-to-month basis.*

Mineral Metabolism

0255 Measurement of Serum Phosphorus Concentration

ASN concurs with the Steering Committee that measurement of serum phosphorus is a fundamental part of typical dialysis care. However, measurement is only important if it leads to appropriate patient treatment decisions that improve patient outcomes. As noted in the draft report, the current state of science does not suggest a measure of intermediate outcome or intervention, leaving a measure of assessment frequency as the only option for a quality measure. The society regrets that there is not sufficient evidence to recommend treatment to a specific phosphorus value at this time. *However, given the strength of the evidence linking hyperphosphatemia to poorer outcomes, ASN would support this process measure for a limited time period only—no more than two to three years—with the provision that if data informing specific evidence-based treatment goals is not forthcoming in that time period, NQF would withdraw endorsement of measure 0255.*

0261 Measurement of Serum Calcium Concentration

While ASN believes there is likely an opportunity for improved patient care, and therefore a possible need for related performance measures in other areas of mineral metabolism, *the society agrees with the Steering Committee that insufficient evidence exists to support proposed measure 0261.* Future mineral metabolism measures should be evidence-based and have demonstrated a direct influence on clinical outcomes. ASN's view of this measure differs from the society's position regarding measure 0255 due to the marked differences in strength of evidence linking abnormalities of serum phosphorus levels and patient outcomes compared to that linking serum calcium level abnormalities to patient outcomes.

Vascular Access

0251 Vascular Access—Functional AVF or AV Graft or Evaluation by Vascular Surgeon for Placement

ASN concurs with the Steering Committee that considering the percent of patients who have a functional arteriovenous fistula (AVF) or arteriovenous (AV) graft—or who have been evaluated by a vascular surgeon for these accesses—is important. The society appreciates the Steering Committee's recognition that for some patients, grafts are more appropriate than fistulas. ASN also supports the recommended exclusion of patients who are enrolled in hospice care from this measure. Overall, the society supports measure 0251 Vascular Access, but requests that NQF clarify the terminology in the measure related to the word "incident."

ASN recognizes that waiting 90 days to begin assessing patients' access type—or whether a vascular surgeon has evaluated them—is an attempt to account for the often complicated process of obtaining the optimal access type. The society understands that many patients initiate dialysis with no prior nephrology consultation and fully agrees that it would be unfair to penalize facilities for having patients with suboptimal access within the first 90 days.

However, this measure proposes to define "incident" as day 90 of dialysis treatment, using the 90-day mark as the denominator for the measure. The term "incident" typically implies day one of a treatment or condition. Several other programs that promote or study fistula use, such as Fistula First and DOPPS, define "incident" as the first day on dialysis, and use the first day on dialysis as the denominator. The population proposed to be assessed by this measure is not a true incident population, and the society is concerned that this discrepancy will cause confusion within the nephrology community.

It is important that this measure explicitly clarify that the "incident" data does not include the first 90 days on dialysis. ASN suggests that a more accurate term to describe this patient population would be "scrubbed incident" data.

Furthermore, ASN requests clarification as to the frequency of reporting during the 12-month period. Will dialysis facilities be required to submit AVF, AV graft, or evaluation by vascular surgeon data on an annual, monthly, or other intermittent basis?

Some vascular surgeons prefer to postpone patient evaluation for vascular access until after the 90-day waiting period for Medicare coverage. Consequently, it is impossible for some patients to comply with the quality measure recommendations. While no obvious solution exists to address this issue, the society wishes to register that it affects a not insignificant number of patients.

Despite this concern, the society supports NQF endorsement of the measure 0251 Vascular Access on the condition that NQF clarify the definition to reflect that the measure examines patients who have been on dialysis for more than 90 days, rather than a true incident population. ASN also strongly believes that elderly patients and patients with very limited life-expectancy be excluded.

0256 Hemodialysis Vascular Access - Minimizing use of catheters as Chronic Dialysis Access

Minimizing use of catheters as chronic dialysis access is an extremely important goal for the dialysis care community. In general, the society concurs with the Steering Committee that NQF should endorse this catheter minimization measure.

While supportive of the measure, ASN wishes to register that some dialysis units are unlikely to be capable of identifying whether a patient is using a catheter continuously as a sole access, or has intermittently using a catheter while trying to establish a fistula. Some patients use a catheter as an alternative access when fistulas fail. The society recognizes and appreciates that the 90-day criteria is an attempt to differentiate between intermittent catheter users and chronic catheter users, but remains concerned that some units may not have the infrastructure to capture this nuanced but important detail.

ASN believes that minimizing catheter use is a vital goal for the nephrology care community, and overall supports NQF endorsement of this measure 0256.

0257 Hemodialysis Vascular Access - Maximizing Placement of Arterial Venous Fistula (AVF)

For many patients, an AVF is the optimal type of vascular access, and ASN strongly supports efforts to facilitate utilization of AVFs when appropriate. However, an AVF is not the most appropriate access type for every patient on dialysis. For some patients, establishing and maintaining a fistula is not physically feasible, or is not appropriate for their unique health status. A distinct population of patients are more appropriate candidates for an AV graft. This proposed measure inappropriately promotes fistula placement in patients who would benefit more from an AV graft. Patients who are at a high risk for a fistula failing are more likely to revert to using a catheter than a graft. The society is apprehensive that this measure would have the unintended consequence of increasing catheter use in patients who are not good candidates for an AVF, while doing nothing to encourage graft establishment when it is a more appropriate option than AVF.

A more appropriate quality measure would encourage maximizing AVF *when appropriate* and AV graft for other patients. Accordingly, the society strongly recommends that NQF endorse measure 0251 Vascular Access, which accounts for the diversity of care needs in the dialysis patient population, *and not endorse 0257 Hemodialysis Vascular Access.*

0259 Hemodialysis Vascular Access - Decision-making by Surgeon to Maximize Placement of Autogenous Arterial Venous Fistula

AVFs are the optimal vascular access type for many patients, however, an important minority of patients are better suited to dialyzing via a graft for a variety of medical or personal reasons. The option this measure introduces—allowing a surgeon to state that an AVF was not placed due to medical or patient reasons—is a sensible approach. ASN concurs with the measure developer that these exclusions are necessary to prevent a perverse incentive to place an AVF in a patient who is not a suitable candidate.

Although the Steering Committee expressed reservations about allowing surgeons to “declare any patient for whom a fistula was not constructed to be a non-candidate,” the society believes it is appropriate to allow surgeons to exercise flexible clinical judgment for each individual patient. Allowing this flexibility is important to preventing multiple fistula placement surgeries on patients who are not good candidates for the access type. While the vascular access type selection is a complex decision that should include the surgeon, the patient, family, and care team, it is reasonable to permit exclusions when appropriate.

ASN recognizes that besides concern over subjectivity, the absence of significant reliability or validity testing to support this submission also contributed to the Steering Committee’s decision to not recommend the measure for endorsement. *The society nonetheless believes the concept of permitting subjective decision-making regarding the appropriateness of potential candidates for AVF placement is reasonable, and would help limit AVF placement to patients who are well-suited to the access type.*

0262 Vascular Access—Catheter Vascular Access and Evaluation by Vascular Surgeon for Permanent Access

ASN concurs with the Steering Committee that measure 0262 Vascular Access—Catheter Vascular Access and Evaluation by Vascular Surgeon for Permanent Access is not appropriate for NQF endorsement. As noted in the draft report, the aspect of care that this measure proposed to examine is already addressed in measure 0251 Vascular Access, a measure ASN agrees NQF should endorse.

Patient Education

0324 Patient Education Awareness – Facility and 0320 Patient Education Awareness—Physician Level

The society understands that NQF, as well as the Steering Committee, recognizes the necessity of high-quality patient education regarding dialysis modality choice, transplantation and identification of living donors, and options regarding termination of dialysis. ASN hopes that in the very near future NQF will have another opportunity to consider patient education-related measures that meet NQF criteria for endorsement.

The society would like to work with NQF and other organizations in the kidney community to consider such measures, as well as measures addressing other areas of kidney patient care. For example, ASN helped the American Board of Internal Medicine (ABIM) develop a Practice Improvement Module (PIM) for CKD. In addition, ASN developed an ABIM-approved dialysis PIM earlier this year. Given ASN’s proven expertise in this arena, the society is a natural partner for NQF moving forward.

Conclusion

On behalf of ASN, thank you for your willingness to consider these comments for the draft National Voluntary Consensus Standards for Renal Disease. The society’s members are committed to providing the best possible care for patients with CKD and ESRD and believe that developing robust, evidence-based quality measures can be an effective tool in elevating the quality of care. ASN remains concerned, however, that implementation of quality measures and clinical practice measures endorsed by NQF do not compromise patient access to care. The society offers several recommendations for NQF to consider in this letter and stands ready to discuss any of these suggestions with NQF if it would be helpful.

ASN sincerely appreciates NQF’s willingness to consider input from the public, including ASN. The society is also grateful to NQF for extending the public comment period from December 31, 2011 to January 9, 2012, given the overlap of the comment period with the holiday season. However, ASN is concerned that the standard 23 days allotted for review and response to NQF for draft reports is not adequate to allow the most thorough assessment possible. The Steering Committee was unable to consider and vote on all the measures put before it during the allotted two-day meeting, and completed its deliberations in a series of conference calls. This extended consideration period attests to the

complexity—and importance—of renal-specific measures. Accordingly, it seems reasonable for NQF to consider extending the comment period in future years. ASN suggests that such an extension would permit even more nuanced, thoughtful responses from the nephrology community, translating to endorsement of superior renal quality measures.

Thank you again for your time and consideration. Again, the society welcomes the opportunity to continue to collaborate with NQF to refine and develop new measures for CKD and ESRD in future years. To discuss ASN's comments, please contact ASN Manager of Policy and Government Affairs Rachel N. Shaffer at rshaffer@asn-online.org or at (202) 640-4659.

Sincerely,

A handwritten signature in black ink, appearing to read "Ronald J. Falk". The signature is fluid and cursive, with a large initial "R" and "F".

Ronald J. Falk, MD, FASN
President