

July 13, 2015

National Quality Forum
1030 Fifteenth Street, NW
Suite 800
Washington, DC 20005
RE: NQF Renal Project

On behalf of the American Society of Nephrology (ASN), thank you for the opportunity to provide comments on the National Quality Forum (NQF) Renal Draft Report. ASN is the world's leading organization of kidney health professionals, representing more than 15,000 physicians, scientists, nurses, and other professionals who improve the lives of patients with kidney disease every day. ASN and the professionals it represents are committed to maintaining the integrity of the physician-patient relationship as well as simplifying 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 kidney 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. In general, the society supports the opinions outlined in the draft report, and offers the following specific comments regarding measures under consideration:

Measures recommended for endorsement

0251: Vascular Access—Functional Arteriovenous Fistula (AVF) or AV Graft or Evaluation for Placement (Kidney Quality Care Alliance – KCQA)

- ***ASN supports this measure.***

ASN concurs with the NQF that there should be either consideration of a threshold at which the measure becomes topped out, or consideration of factors that should result in removal of the individual from the denominator and/or numerator adjustment for patient factors. As noted in the NQF draft report discussion, this process will require a delicate balance in order to best maximize fistulas while avoiding loss of individualized care and inadvertent patient harm. Notably, the recent vascular access Technical Expert Panel (TEP) was tasked with this effort.

This consideration would allow, for example, for some individuals with short life expectancy to appropriately not have an AVF created. The same considerations should be taken into account for the catheter measure, such that either a certain percentage of catheters is quantified as consistent with high performance or there are denominator exclusions or numerator adjustments for specific patient factors. Patients who are undergoing a time-defined trial of hemodialysis or who have limited life expectancy are additional examples of exclusions from the denominator that may be appropriate.

Measure #0251 partially takes the above concerns into account with the requirement for evaluation by a vascular surgeon, other surgeon qualified in the area of vascular access, or an interventional nephrologist, but this evaluation could prove to be more of a formality (particularly given the annual requirement) than a true effort at delivering high-quality care. ASN favors denominator or numerator changes as discussed above rather than the 'evaluation' by a physician who places access as there is tremendous heterogeneity among practices in creating vascular access and, for people previously deemed to have no further access options, an annual evaluation can be an unnecessary burden.

Should the measure be implemented as written, the concerns raised above highlight the critical role of the nephrologist in serving as the "captain" of dialysis patients' care, taking responsibility to ensure that such evaluations are thorough and accurate assessments of patients' viability for an AVF. Nephrologists must steer this aspect of care even if and when a facility-level quality measure related to vascular access type is in place.

ASN would continue to support this measure while awaiting the TEP's work product.

1662: Angiotensin Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy (RPA)

- ***ASN supports this measure.***

Overall, ASN believes that this is a reasonable measure and supports its endorsement. However, the society observes that the measure could be improved with greater specificity and attention to differences between proteinuria and albuminuria as well as specificity regarding hyperkalemia and hypotension as being among the 'other medical reasons'.

Additionally, ASN notes that a UPCR of 300 mg/g and a UACR of 300 mg/g are not equivalent as the UPCR is less specific and will always be higher than the UACR. Additionally, urine protein assays are poorly standardized. It would make more sense to use a UPCR threshold of 500 mg/g if using a UACR threshold of 300 mg/g. Correcting these thresholds is consistent with the 2012 Kidney Disease Improving Global Outcomes (KDIGO) Clinical Practice Guideline for the Evaluation and Management of Chronic Kidney Disease.

2594: Optimal End Stage Renal Disease Starts (Kaiser)

- ***ASN strongly supports the concept of this measure.***

Ensuring an optimal, individualized start to dialysis care is a crucially important goal for every patient. ASN strongly supports efforts to encourage focus on this goal; perhaps no aspect of the practice of nephrology is in greater need of quality improvement than how patients typically initiate dialysis. In contrast to virtually all other measures in the ESRD Quality Incentive Program (QIP), which operate on the margins, the optimal start measure stands to significantly improve outcomes and quality of life for patients. The nephrology community must do a better job holding itself accountable to start improving patients' dialysis starts, and the society commends Kaiser for developing measure #2594 with this objective in mind.

Even among patients followed by a nephrologist for 6 months or more prior to initiation, the rate of starting dialysis with a catheter still exceeds 70%—a dismal trend that shows little sign of change overall. Although dialysis patient mortality in the US is improving, it remains significantly higher than other developed countries; only 50% of the patients on dialysis survive more than 3 years—which is double the average mortality rate for cancer patients. Notably, improvements in

dialysis patient mortality can be largely attributed to an increase in AVFs and a decline in catheter rates, and while AVFs are not the appropriate choice for every patient many more people would benefit from receiving this access prior to starting dialysis than do today.

Furthermore, experiences in certain areas of the country suggest that change is achievable. For example, one care facility in the Pacific Northwest serving a safety net population of predominantly uninsured/underinsured/undocumented individuals has reduced the proportion of patients that start dialysis with a catheter to less than 30%, compared to the national average of 70%. Another facility in that region serving socioeconomically disadvantaged patients has reduced this proportion to less than 50%.

Selection of access type is just one of numerous aspects involved in the initiation of dialysis that would be improved through greater emphasis on ensuring an optimal start for each patient. Pre-emptive transplantation is another underutilized and highly effective option that this measure would promote; nationwide, less than three percent of patients receive a pre-emptive transplant.

The society fully endorses the principles laid out in measure #2594 and concurs, in concept, that this is a superb area for quality measure development. As the NQF draft report notes, the prior coordination between PCPs and nephrologists necessary to achieve optimal—and individualized—starts (as defined by this measure) would best be facilitated in an integrated delivery care system. However, feasibility of implementation remains the issue. Indeed, Kaiser clarifies that “the measure is currently utilized in an integrated care delivery system,” and reiterated “difficulty in using the measure in any type of unit with less than 50 patients.” This measure is not a dialysis facility level metric but rather a health system level metric—albeit a metric that, lamentably, very few health systems are equipped to achieve to date.

ASN appreciates the concerns raised regarding whether this measure is feasible in the majority of care settings at this time. Care must be taken to ensure that this measure is only used in settings where providers have an opportunity to influence patient preparation for dialysis.

Looking beyond this specific measure, ASN suggests that as a starting point for pushing the community to do better, nephrologists should begin to create greater accountability by identifying some strata of patients under the care of the nephrology care team for some defined length of time to be the denominator in an assessment of optimal starts. Notably, this information is captured by Form 2728 in question 18 b, which stratifies the amount of time patients have been under the care of nephrologists for six months or less, 6-12 months, and > 12 months). ASN would consider it reasonable to start with patients under the care of nephrologists for at least six months and exclude patients who begin dialysis during an acute kidney injury episode.

The society would also encourage the Centers for Medicare and Medicaid Services (CMS) to begin rigorously tracking all available data related to optimal starts and collecting information about feasibility in integrated and non-integrated health systems. Collecting and sharing such data would help facilitate adoption of this and similar optimal start measures.

2701: Avoidance of Utilization of High Ultrafiltration Rate (≥ 13 ml/kg/hour) (KCQA)

- ***ASN supports this measure.***

ASN believes that fluid management is an important component to assess in the quality of patients' care. The society believes that #2701 is a superior measure to #2700, in large part due to the time component that ensures more consistent treatments over time.

Measures for which the Committee did not reach consensus

2702: Post-Dialysis Weight Above or Below Target Weight (KCQA)

- ***ASN does not support this measure for endorsement.***

ASN recognizes that post-dialysis weight assessment is an essential part of the care and assessment of patients on dialysis. However, ASN shares the concerns raised by NQF regarding this measure and the society is hesitant to endorse it. On the one hand, this measure may prompt the nephrology care team to re-assess a patient's weight more frequently and to perform additional hemodialysis or ultrafiltration sessions to achieve the target weight. This measure may also provide important data for internal quality improvement efforts as well as the ability to benchmark to other facilities.

On the other hand, ASN is concerned that this measure may be too easy to manipulate, with potentially adverse unintended consequences for patients as it is far simpler raise the target weight than to intervene meaningfully to achieve the initial target weight. While the society values the importance of achieving dry weight, #2707 is a process measure and thus, in and of itself, is unlikely to meaningfully improve the care of patients. Finally, in the absence of new methodologies and technologies, assessment of dry weight is somewhat arbitrary for many patients.

The society would support this measure as a reporting measure evaluating patient safety as data obtained from this measure could be helpful for within-facility quality improvement, but the society is reluctant to support this measure overall, or as a performance measure, as the potential unintended consequences and associated harms may outweigh the benefits if a financial incentive is attached to meeting a specific measure threshold.

Measures the Committee did not recommend for endorsement

1454: Proportion of patients with hypercalcemia (UM/CMS)

- ***ASN does not support this measure for endorsement.***

ASN concurs with NQF and supports non-endorsement of the hypercalcemia measure for the reasons listed in the draft report. ASN feels strongly that a poor measure may be worse than no measure (or a straightforward reporting measure) and concurs with the opinion of the NQF that a better Mineral-Bone Disorder measure is needed.

1460: Bloodstream Infection in Hemodialysis Outpatients (Centers for Disease Control and Prevention – CDC)

- ***ASN encourages clarification regarding methodological concerns with this measure, but recommends it for endorsement nonetheless.***

In principle, ASN continues to support the National Health Safety Network (NHSN) Bloodstream Infection Measure. The society agrees that this is an important topic but that the measure and

methods for data collection may need further refining and description. ASN has provided comments regarding these concerns to NQF on this topic in the past—most of which are noted in and are similar to those stated in the NQF draft report. Of particular concern is the Adjusted Ranking Metric (ARM). Based on a presentation by Mr. Jonathan Edwards of the CDC (the measure steward), the impetus for the ARM is a perceived need to differentiate among very low standardized infection rates, based on exposure characteristics. This has the effect of normalizing the distribution of otherwise left skewed standardized infection rates. ASN supports efforts to reduce the vulnerability of facilities to penalties for one or two events in the setting of low denominators but continues to stress that the need to rank order dialysis facilities is not necessarily helpful and that greater transparency regarding this methodology for adjustment is needed.

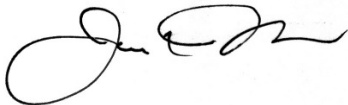
As such, while ASN supports the measure at this time, the society strongly encourages clarification regarding these and other methodological issues. If the measure is to be implemented, it must be implemented in a transparent manner.

Conclusions

The society hopes that the recommendations it offers in this letter are helpful and stands ready to discuss these comments. ASN welcomes the opportunity to continue to collaborate with NQF to refine or answer any questions related to these measures. Again, thank you for your time and consideration.

To discuss ASN's comments, please contact the ASN Manager of Policy and Government Affairs, Rachel Meyer, at rmeyer@asn-online.org or at (202) 640-4659.

Sincerely,

A handwritten signature in black ink, appearing to read 'Jonathan Himmelfarb', written in a cursive style.

Jonathan Himmelfarb, MD, FASN
President