TO: NQF Members

FR: NQF Staff

RE: Voting Draft Report: NQF-Endorsed Renal Measures

DA: October 5, 2016

Background

Renal disease is a leading cause of morbidity and mortality in the United States. More than 20 million adults (10 percent of the population) in the United States have chronic kidney disease (CKD). Untreated CKD can result in end-stage renal disease (ESRD) and a host of other health complications. Currently, over half a million people in the United States have received a diagnosis of ESRD, the only chronic disease covered by Medicare for people under the age of 65. Considering the high mortality rates, high healthcare utilization and costs associated with ESRD, the need to focus on quality measures for patients with renal disease is particularly important.

On June 28, 2016, the Renal Standing Committee evaluated 3 newly-submitted measures and 3 measures undergoing maintenance review against NQF's standard evaluation criteria. Four measures were recommended for endorsement and the Committee did not recommend 2 measures. During the post-comment call, the Committee reconsidered the two not recommended measures and altered their decision for one of the measures.

Comments Received

NQF solicits comments on measures undergoing review in various ways and at various times throughout the evaluation process. First, NQF solicits comments on endorsed measures on an ongoing basis through the Quality Positioning System (QPS). Second, NQF solicits member and public comments prior to the evaluation of the measures via an online tool located on the project webpage. Third, NQF opens a 30-day comment period to both members and the public after measures have been evaluated by the full committee and once a report of the proceedings has been drafted.

Pre-evaluation comments

The pre-evaluation comment period was open from May 31, 2016 to June 13, 2016 for all measures under review. A total of 29 pre-evaluation comments were received. All of these pre-evaluation comments were provided to the Committee prior to their initial deliberations held during the in-person meeting.

Post-evaluation comments

The Draft Report went out for Public and Member comment August 5, 2016 to September 6, 2016. During this commenting period, NQF received 17 comments from 2 member organizations:

Consumers – 0	Professional – 0
Purchasers – 0	Health Plans – 1
Providers – 0	QMRI – 1
Supplier and Industry – 0	Public & Community Health - 0

A complete table of comments submitted pre- and post-evaluation, along with the responses to each comment and the actions taken by the Standing Committee, is posted to project page on the NQF website, along with the measure submission forms.

The Committee reviewed all comments received and considered the pre-meeting comments prior to making an endorsement recommendation. They also assessed and responded to all post-evaluation comments prior to making their final recommendation. Revisions to the draft report and the accompanying measure specifications are identified as red-lined changes. (Note: Typographical errors and grammatical changes have not been red-lined, to assist in reading.)

Comments and their Disposition

Measure Specific Comments

The following comments were brought to the attention of the Committee during the Post-Comment call and served as the basis for discussion. Comments received that were specific to reconsideration of measures not-recommended can be found in the table of comments.

2977: Hemodialysis Vascular Access: Standardized Fistula Rate

The Kidney Care Partners (KCP) has recommended the developer consider the following modifications to improve the measure going forward:

- Stating that the specifications for #2977 are too imprecise, suggest the numerator specifies the patient must be on maintenance hemodialysis "using an AVF with two needles and without a dialysis catheter present." Additional, credit should be received for a patient who is using an AVF as the sole means of access, but who also may have a non-functioning AV graft present.
- Suggests that two additional vasculature risk variables that could strengthen the model be added: a history of multiple prior accesses and the presence of a cardiac device.

Developer Response: The intent of the fistula measure, as recommended by the TEP, is to only include patients in the numerator if they are using an AVF as the sole means of access and no dialysis catheter is present. The phrase "as the sole means of vascular access" was added to address the scenario where a patient receives dialysis through an AVF but still has a tunneled catheter present that has not been removed. This includes the scenarios where a patient is using both an AVF and a catheter (e.g. one lumen of the catheter and one needle in the AVF) for their access and would have been included in the previously endorsed AVF measure (#0257) as well as the scenario where the AVF is being used with two needles, but the catheter has not yet been removed.

Unfortunately, the current vascular access definitions in CROWNWeb do not support the ability to report presence of catheter not in use. The option in CROWNWeb that indicates "AVF with catheter" is specifically for the situation when one lumen of the catheter is being used and one needle is used in the AVF. The "AVF Only" option in CROWNWeb specifies that two needles are being used, but does not explicitly indicate that no dialysis catheter is present. A facility can select the "AVF only" option, even if a catheter is present but not in use, therefore that patient will still be included in the numerator of the measure. While this does not occur frequently, CMS intends to refine the definitions for the vascular access options in CROWNWeb so that "AVF only" would

not include cases were a catheter is not in use but still present. Once this definition is revised and implemented these patients would not be counted in the numerator. Although Medicare claims can currently provide this level of granularity with regards to whether a catheter is present, but not in use, the TEP did not want to limit the measure only to Medicare beneficiaries. Lastly, and similar to the scenario described above for catheter, the "AVF Only" as currently defined in CROWNWeb does allow for reporting a patient as having a fistula, even if a graft is present but not in use. These patients will still be counted in the fistula numerator if they have an AVF that is currently in use, even if there is a graft present, so long as the graft is not in use.

Multiple prior failed vascular access attempts were considered by the TEP as an exclusion criterion, however consensus was not reached within the TEP on how best to implement this exclusion. At the present time, historical vascular access data in CROWNWeb are limited, but we intend to evaluate adjustment for the number of prior vascular accesses when more historical vascular access data are available. For now, the measure uses ESRD vintage as a surrogate for the number of prior vascular accesses.

The ability to determine the presence of a cardiac device from Medicare claims is limited in that the laterality of the device is not apparent. We anticipate this level of specificity will improve with the change and availability of ICD-10 codes. Therefore, this and other comorbidities will be evaluated in the future as Medicare claims with ICD-10 data become available.

We evaluated multiple iterations of our standardized fistula rate to obtain the most robust model possible. We believe that the C-statistic of 0.74 is considered to be a good fit based on recent literature and note that it is similar in magnitude to other current NQF endorsed quality measures that have been implemented by CMS. Several references are listed below from peer-reviewed literature that report C-statistics of similar magnitude to the one achieved in our model. As we refine the risk model in the future, we will work to improve the model's ability to discriminate performance between facilities. In addition, the standardized fistula model was reviewed and endorsed by the TEP, providing both face validity and an element of peer review for the measure.

Committee Response: The Committee discussed the comment submitted and the developer's response. The Committee agreed with the suggestions and recommended that the developer work toward these goals for future iterations of this measure.

2979: Standardized Transfusion Ratio(STrR) for Dialysis Facilities

KCP notes that during the last project, this Standing Committee reviewed the STrR as measure #2699 and did not recommend it. The commenter expresses concerns about the specifications, reliability, validity (risk model), and harmonization. In regards to validity, the commenter does not believe the new measure addressed the Committee's concerns about hospital- and physician-related factors. Overall, they remain concerned about the reliability, as well as the specifications and validity. The commenter strongly encouraged the Committee to reconsider the reliability testing data, which document reliability issues with the STrR for small facilities, and comment specifically on the STrR's reliability for such facilities.

Developer Response: We respectfully disagree that STrR, a measure of transfusion avoidance, is required to be harmonized with a measure of hospitalization. Each metric is capturing different outcomes.

As described in the STrR measure submission, the measure adjusts for each separate incident comorbidity. See S.14 in the NQF MIF (excerpt below). "Comorbidities at ESRD incidence are determined using a selection of comorbidities reported on the CMS-2728 namely, alcohol dependence, atherosclerotic heart disease, cerebrovascular disease, chronic obstructive pulmonary disease, congestive heart failure, diabetes (includes currently on insulin, on oral medications, without medications, and diabetic retinopathy), drug dependence, inability to ambulate, inability to transfer, malignant neoplasm, cancer, other cardiac disease, peripheral vascular disease, and tobacco use (current smoker). Each comorbidity is included as a separate covariate in the model."

The categories for the Age and Duration of ESRD covariates in the risk adjustment models were empirically derived when the SMR and SHR models were first developed, and are based on model fit specific to each outcome. This accounts for the use of different groupings for each model. The STrR was developed using an adaptation of the SHR methodology, and the age groupings were left in-tact.

Regarding the definition of facility size, we will consider using consistent groupings in the future, to improve interpretation. Thank you for the feedback.

During the most recent 2016 Standing Committee review of this measure, committee members discussed the shared accountability aspect of STrR. Literature evidence supporting the strong association between prior achieved hemoglobin and subsequent transfusion risk was reviewed. In addition, the committee was presented with RBC transfusion guidelines endorsed by the American Red Cross and other national organizations describing the central role of patient hemoglobin in determining need for RBC transfusion, while considering the clinical context of the transfusion decision. In addition, the committee reviewed additional recent peer review publication evidence describing the role of facility anemia management processes of care in predicting subsequent transfusion risk. Although there is some truth to the commenter's statement the "physicians independently, or following hospital protocols, make decisions about whether or not to transfuse a specific patient", the national recommendations and the physician decisions appear to be based in large part on the patient's hemoglobin.

In addition to their responsibility for anemia management and achieved hemoglobin, with its aforementioned contribution to determination of transfusion need, both dialysis providers and the nephrologist members of their Interdisciplinary Teams have an important responsibility to educate patients, their families, and other providers involved in the care of their patients about the potential unintended consequences of RBC transfusions in transplant-eligible dialysis patients. After this evidence review and discussion, the Standing Committee did recommend endorsement of STrR in 2016, as

currently specified. We believe the Standing Committee made the correct decision in 2016.

There is no published research or study demonstrating the CMS 2728 data have been shown to be invalid. We acknowledge the 2728 data have been shown to be insensitive in a few studies. Inclusion of the 2728 data is one component of a more comprehensive risk adjustment strategy. The 2012 Anemia Management Technical Expert Panel recommended development of additional risk adjustment strategies that utilized prevalent comorbidities specifically related to conditions that would impact anemia management in ESRD patients. We utilize prevalent comorbidities as exclusions rather than covariates in the risk adjustment model to minimize the risk of underestimating their impact in the care of dialysis patients.

The STrR C-statistic of 0.65 is similar in magnitude to several other current NQF endorsed quality measures that have been endorsed by NQF and implemented by CMS in ESRD quality programs, as well as for other settings. This level is considered to be a good fit as demonstrated in peer-reviewed studies reporting similar goodness of fit statistics for outcome based models (see accompanying list of references). As we refine the risk model in the future, we will work to improve the model's ability to discriminate performance between facilities.

Committee Response: The Committee thoroughly reviewed the specifications, reliability, and validity of the measure during the in-person meeting and maintained that the measure meets the NQF criteria.

1463: Standardized Hospitalization Ratio for Dialysis Facilities

KCP believes hospitalization is an important outcome to measure, but has concerns about the specifications, reliability, validity (risk model), and harmonization issues. The commenter strongly encouraged the Committee to reconsider the reliability testing data, which demonstrate significant reliability issues with the one-year SHR for small facilities, and comment specifically on the SHR's reliability for such facilities.

Developer Response: We recognize the importance of the scientific standard of measure reliability, and note SHR satisfied this condition. All components of measure reliability were reviewed in detail at the NQF ESRD Standing Committee's meeting in June, 2016. The reliability result reported in the NQF submission showing the overall IURs of 0.70-0.72 across all facilities was determined acceptable by the NQF Standing Committee as the measure passed on the reliability criterion, and passed on scientific acceptability overall. The evaluation and voting process and result adhered to consensus development guidelines in the evaluation, thereby reinforcing acceptance of the reliability results.

Given the established effect of sample size on IUR calculations, it is expected that large facilities will have higher IUR values and small facilities will have lower IUR values for any given measure. Reliability results by facility size were not required by NQF. However

the decision to include reliability based on tertiles of facility size was intended to enhance interpretation of the detail provided in the measure submission.

In response to the commenter's statement about a required IUR of 0.70 and "a reliability statistic of 0.7 is often considered as "good" reliability", we are not aware of any formal and prescriptive NQF guideline or standard that sets or requires this test result value as a minimum threshold for passing reliability. The commenters may be referring to a non-peer reviewed prior RAND Report referenced by NQF as an example of signal to noise methods that can be used for reliability testing. Additionally, there is no formal required threshold identified by NQF, as demonstrated in the endorsement of other quality metrics that have a range of reliability statistics, several that are below the threshold of 0.7. Specifically, the SHR reliability results are comparable to the reliability test results for other NQF-endorsed risk adjusted outcome measures used in public reporting. For example, four NQF endorsed cause-specific hospital mortality measures demonstrated similar levels of reliability (e.g. #0229 Heart failure measure, ICC: 0.55; #0468 Pneumonia mortality measure, ICC: 0.79; #1893 COPD mortality measure, ICC: 0.51; #2558 CABG mortality measure, ICC: 0.32).

Committee Response: The Committee thoroughly reviewed the specifications, reliability, and validity of the measure during the in-person meeting and maintained that the measure meets the NQF criteria.

NQF Member Voting

Information for electronic voting has been sent to NQF Member organization primary contacts. Accompanying comments must be submitted via the online voting tool.

Please note that voting concludes on October 24, 2016 by 6:00 PM ET – no exceptions.