Public Comment Summary Report

Project Title: Standardized Fistula Rate for Incident Patients

Dates:

The Call for Public Comment ran from March 1, 2022 to March 30, 2022.

Project Overview:

The Centers for Medicare & Medicaid Services (CMS) has contracted with the University of Michigan Kidney Epidemiology and Cost Center (UM-KECC) to develop facility-level measures in the area of vascular access for dialysis patients. The contract name is Kidney Disease Quality Measure Development, Maintenance, and Support. The contract number is 75FCMC18D0041, task order number 75FCMC18F0001. As part of its measure development process, UM-KECC requested interested parties to submit comments on the candidate or concept measures that may be suitable for this project. UM-KECC has been tasked by CMS to develop dialysis facility quality measures that allow measurement of differences across U.S. dialysis facilities' effectiveness of education of patients about dialysis modality options (i.e. In-center vs. home dialysis) and/or effective utilization of home dialysis modalities in the treatment of chronic kidney failure.

Information About the Comments Received:

The measure developer solicited public comments by email, and received 5 responses.

General Stakeholder Comments:

Patient Choice

Commenters emphasized the need to account for patient choice when considering vascular access metrics in order to ensure that they are patient centered; one commenter recommended excluding from the denominator patients who refuse consideration of AVF placement or use, despite >2 attempts spanning a 3-month period at education on the risks of catheters and benefits of AVF by their nephrologist and RN. Educational attempts should be documented by having the patients sign forms indicating that they have been informed and decline that option after repeated education has been completed (which can be reflected in EQRS).

> **Response:** We recognize the importance of patient choice when creating a vascular access plan, however at this time there are no standard criteria for how to validate an informed decision. A check-box attestation would likely be an insufficient test for accurately determining whether an informed choice was made by a patient. This is especially true for vulnerable patients. In addition, some patients who decline creation of an AVF do so after one or more previous

attempts at creating a surgical access. This scenario is less likely in the first year of dialysis where many patients are starting with a tunneled catheter.

Exclusions

There were several recommendations for additional exclusions for the measure.

Commenters recommended several claims-based exclusions, including history of steal syndrome (often affecting the partial or complete use of a limb), severe congestive heart failure, severe hematologic disorders placing patient at risk for bleeding diathesis, severe psychiatric illness, limited life expectancy, or other conditions in which the risk of surgery to place AVF, or use of AVF on dialysis, is deemed to be unacceptable by their physician.

> **Response:** The measure denominator already excludes patients that have limited life expectancy (patients under hospice care in the current reporting month; patients with: metastatic cancer, end-stage liver disease or coma or anoxic brain injury within the past 12 months). The measure also adjusts for patients with congestive heart failure (at ESRD incidence). Severity of a condition (e.g. steal syndrome, bleeding diathesis, psychiatric illness) is one limitation of claims-based exclusions in that it is not possible to differentiate mild disease where creation of an AVF may be quite reasonable relative to severe disease that would preclude AVF creation.

Several commenters recommended excluding patients who have exhausted all potential sites for AVF or AVG placement, or in whom there are no viable vessels for AVF placement. It was noted that facilities can report such patients in EQRS (formerly known as CROWNWeb) if a checkbox to indicate such patients is added.

> **Response:** The TEP spent a significant amount of time discussing the proposed exclusion for patients who have exhausted anatomic options for permanent access. The TEP agreed that this was an important exclusion, but they also recognized that it would be difficult to implement. A major concern was also that there are currently no validated data sources or infrastructure in place that would allow identification of patients who have no further surgical options for vascular access (e.g., in EQRS). Additionally, there was not consensus as to who was the most appropriate provider to make this assessment (e.g. nephrologist, vascular surgeon, or interventional radiologist/nephrologist) or on what bases (ultrasound, venography, number of prior failed accesses). We have evaluated historical vascular access data in EQRS to determine if a patient's prior vascular access history could be used to identify multiple failed vascular accesses, and in turn whether this information could define potential exclusion criteria for exhausting all potential options for AVF placement. Unfortunately, the reliability of prior vascular access data in EQRS was not sufficient to use this as an exclusion criteria.
>
> In addition, this measure focuses on <u>incident</u> hemodialysis patients. Although this population could have a small fraction of patients who have undergone attempted permanent vascular

access creation in the pre-dialysis period, there should be substantially fewer patients in this category when restricting to incident hemodialysis patients. In contrast, the previous SFR measure included patients with longer-term hemodialysis experience, a group expected to have a greater number of patients who have exhausted vascular access options.

One commenter recommended excluding patients with advanced age as evidence suggests these patients may benefit equally from AVG as AVF use on dialysis.

Response: The measure already adjusts for age, and excludes patients using a catheter with limited life expectancy.

One commenter recommended excluding patients with complex multi-morbid conditions or those whose main goal is palliative dialysis therapy.

Response: The measure denominator already excludes patients with a catheter that have limited life expectancy (patients under hospice care in the current reporting month; patients with: metastatic cancer, end-stage liver disease, or coma or anoxic brain injury within the past 12 months).

Performance scores

Commenters noted that the NQF Renal Standing Committee rejected the prior SFR measure because they believed it was effectively "topped out" at 64% for all patients for whom an AV fistula is clinically appropriate. As the new measure defines an incident patient as one who began maintenance hemodialysis within the prior twelve months, we believe UM-KECC's logic is flawed. Rather than supporting the premise of the measure, fistula rates climbing from less than 20% at dialysis initiation to greater than 60% within twelve months supports the notion that dialysis facilities are already placing fistulas in nearly all clinically appropriate new patients, once under their care, such that by the end of the first year of dialysis the population approaches that "topped out" AV fistula rate identified by NQF. The commenter believes the measure will not meaningfully increase fistula rates, and may lead to the creation of fistulas in patients such as those who are medically frail or otherwise not good candidates for such a procedure.

Response: We respectfully disagree with the commenters. There was no formal determination that SFR was topped out due to the national rate of 64%. Furthermore, there remains a significant performance gap between providers in AVF use at the facility level. This performance gap is magnified for incident patients and the current SFR for incident patients suggests there is significant room for improvement in AVFs in the first year of dialysis.

Evidence

One commenter stated that the SFR's loss of endorsement was precipitated by KDOQI's then-recent downgrading of the evidence supporting fistulas as the preferred access type, in favor of catheter avoidance and individualized ESKD Life plans. To support the premise for this new, incident-only measure, the commenter noted that the premise of the ISFR counters that the same guidelines do suggest that under favorable circumstances an AV fistula is preferred to an AV graft in incident patients due to fewer long-term vascular access events (e.g., thrombosis, loss of primary patency, interventions) and because "blood stream infection rates are the lowest in incident patients with AV fistula compared to long-term catheters." However, the KDOQI guideline explicitly indicates there is inadequate evidence to make a recommendation on choice of AV fistula vs AV graft for incident vascular access based on associations with infections; thus, here again, the KDOQI statement focuses on catheter reduction and takes no stance on the superiority of fistulas over grafts in this regard.

> **Response:** The KDOQI guidelines for vascular access continue to support AV fistula creation in incident patients. As the commenter noted, Guideline 2.5 indicates: "KDOQI suggests that if sufficient time and patient circumstances are favorable for a mature, usable AVF, such a functioning AVF is preferred to an AVG in incident patients due to fewer long-term vascular access events (e.g. thrombosis, loss of primary patency, interventions) associated with unassisted AVF use". The following Guideline 2.6 indicates: "KDOQI suggests that most incident patients starting dialysis with a CVC should convert to either an AVF or AVG, if possible, to reduce their risk of infection/bacteremia, infection-related hospitalizations, and adverse consequences." When taken together, this suggests that AV fistula provide lower risk of infection (acknowledging that AV grafts do as well) when compared to catheters, but that AV fistula also provide lower vascular access events when compared to AVG.

Reliability

One commenter pointed out that stratification of reliability scores by facility size was not detailed, and they were concerned the ISFR reliability may be unacceptably low for small facilities, effectively rendering the metric meaningless for use in performance measurement in this group of providers.

> **Response:** 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. Using the empirical null method, facilities are flagged if they have outcomes that are extreme when compared to the variation in outcomes for other facilities of a *similar size*. That is, smaller facilities have to have more extreme outcomes compared to other smaller facilities to be flagged.

Attribution

One commenter felt that optimizing vascular access among incident dialysis patients an appropriate focus for a measure for physicians and physician groups, but the proposed measure is misdirected at

dialysis facilities. A well-thought-out vascular access plan is patient-centered, and clinician led. Dialysis facilities who meet patients for the first time should not be primarily responsible for vascular access plans. Rather, this should be done under the direction of the patient's whole kidney care team, in which the patient and their nephrologist work closely with the providers placing access, such as the surgeon or interventionist.

> **Response:** Medicare ESRD regulations (CfC494) clearly hold the dialysis facility care team (Interdisciplinary Care Team with the treating clinician as a required member) responsible for patient vascular access education and facilitation. Per the CMS regulations, the required Interdisciplinary Care Team composition is clearly defined at V501, and again at V541. The regulations clearly identifying the responsibility of the IDT for assessment of vascular access (V511) and creation and maintenance of vascular access- with AVF preferred- are at V550 and V551. This cross-disciplinary care team is in the position of seeing the patient frequently, and should reinforce education on vascular access during the regular patient encounters at the facility. We also agree that the nephrologist should work closely with the vascular surgeon, but we maintain that the locus of responsibility begins with the dialysis facility care team which includes the nephrologist.

Measure-Specific Comments:

N/A

Preliminary Recommendations

Based on the comments made, no specific changes to the measure specification will be implemented at this time.

Overall Analysis of the Comments and Recommendations

we appreciate the breadth and thoughtfulness of the comments provided. There will be ongoing investigation into the impact and potential need for additional adjustments or exclusions in the future.

Public Comment Verbatim Report

You may attach this table as a separate file. Upon request from the Contracting Officer's Representative (COR), the measure developer may delete optional fields.

Comment Number*	Date Posted/ Received	Name, Credentials, and Organization of Commenter	Type of Organization*	Email Address*	Measure Set or Measure	Text of Comments	Response*
1	March 30, 2022	Timothy Pflederer, MD President, Renal Physicians Association (RPA)	Professional Organization	rpa@renalmd.org	Standardized Fistula Ratio (SFR)	See appendix	We thank you for your feedback. Stakeholder comments will be reviewed by measure developers and taken under consideration. Responses to comment themes are provided above.
2	March 30, 2022	Susan E. Quaggin, MD, FASN President American Society of Nephrology (ASN)	Professional Organization	ASN Regulatory and Quality Officer David L. White, dwhite@asn online.org	Standardized Fistula Ratio (SFR)	See appendix	We thank you for your feedback. Stakeholder comments will be reviewed by measure developers and taken under consideration. Responses to comment themes are provided above.
3	March 30, 2022	Kevin Longino, CEO and Transplant Patient Paul M. Palevsky, MD, President, National Kidney Foundation	Patient Advocacy Organization	Morgan Reid, Director of Transplant Policy and Strategy, morgan.reid@kidney.org Miriam Godwin, miriam.godwin@kidney.org	Standardized Fistula Ratio (SFR)	See Appendix	We thank you for your feedback. Stakeholder comments will be reviewed by measure developers and taken under consideration. Responses to comment themes are provided above.

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4	March 30, 2022	Kidney Care Council North American Transplant Coordinators Organization Nephrology Nursing Certification Commission Otsuka America Pharmaceutical, Inc. Renal Healthcare Association (formerly NRAA) Renal Physicians Association Renal Support Network Rockwell Medical Rogosin Institute Satellite Healthcare, Inc. U.S. Renal Care, Inc. Vertex Pharmaceuticals Vifor Pharma Ltd.	Professional Organization	Lisa McGonigal MD, MPH, Healthcare Quality Consultant, Kidney Care Partners, lisa@limacmd.com	Standardized Fistula Ratio (SFR)	See Appendix	We thank you for your feedback. Stakeholder comments will be reviewed by measure developers and taken under consideration. Responses to comment themes are provided above.

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5	March 30, 2022	David E. Henner, DO, President, Forum of ESRD Networks Kam Kalantar Zadeh, MD, , Chair, Forum Medical Advisory Council Derek Forfang, Co-Chair, Forum Kidney Patient Advisory Council Dawn Edwards, Co-Chair, Forum Kidney Patient Advisory Council Forum of ESRD Networks	Professional Organization	Kelly Brooks, MPA, Coordinator, Forum of ESRD Networks, kbrooks@esrdnetworks.org	Standardized Fistula Ratio (SFR)	See Appendix	We thank you for your feedback. Stakeholder comments will be reviewed by measure developers and taken under consideration. Responses to comment themes are provided above.

*Optional

Note: Measure developers may enter the text of comments verbatim without edits for spelling, punctuation, grammar, or any other reason and should ask their COR for specific guidance.