

Public Comment Summary Report

Project Title:

End-Stage Renal Disease Vascular Access Measure Development

Dates:

- The Call for Public Comment period opened on January 4, 2016 and closed on February 5, 2016.
- The Public Comment Summary was made available on March 18, 2016.

Project Overview:

The Centers for Medicare & Medicaid Services (CMS) has contracted with the University of Michigan Kidney Epidemiology and Cost Center (UM-KECC) to review the NQF endorsed Vascular Access measures (Minimizing Use of Catheters as Chronic Dialysis Access, and Maximizing Placement of Arterial Venous Fistula) and consider possible revisions to the existing measures, including potential risk adjustment. The contract name is ESRD Quality Measure Development, Maintenance, and Support. The contract number is HHS-500-2013-13017I. As part of its measure development process, CMS has requested interested parties to submit comments on the candidate or concept measures that may be suitable for this project.

Project Objectives:

The University of Michigan Kidney Epidemiology and Cost Center, through its contract with the Centers for Medicare and Medicaid Services, convened a technical expert panel to evaluate the existing NQF-endorsed vascular access measures. Specific objectives included:

- Review of the current NQF endorsed Vascular Access measures (Minimizing Use of Catheters as Chronic Dialysis Access, and Maximizing Placement of Arterial Venous Fistula)
- Consider revisions to the vascular access measure set
- Consider including potential risk adjustment

Information About the Comments Received:

- Public comments were solicited by email.
- 10 responses were received on this topic.

Stakeholder Comments—General and Measure-Specific

General Comments

Several commenters were generally supportive of the measures, and felt that they were an improvement over the existing NQF-endorsed vascular access measures. Commenters appreciated the addition of exclusions for limited life expectancy, and the removal of the catheter denominator requirement that the patient have ESRD for at least 90-days before they are included in the measure.

One commenter expressed disappointment at the lack of a graft measure and cited recent literature reporting that not all patients are candidates for successful fistula placement.

Response: The two vascular access measures, when used together, consider arterial venous fistula (AVF) use as a positive outcome and prolonged use of a tunneled catheter as a negative outcome. With the growing recognition that some patients have exhausted options for an arteriovenous fistula, or have comorbidities that may limit the success of AVF creation, pairing the measures accounts for all three vascular access options. The fistula measure adjusts for patient factors where fistula placement may be either more difficult or not appropriate and acknowledges that in certain circumstances an AV graft may be the best access option. This paired incentive structure that relies on both measures reflects consensus best practice, and supports maintenance of the gains in vascular access success achieved via the Fistula First/Catheter Last Project over the last decade.

One commenter requested that additional measures be added to evaluate: the percentage of patients who start hemodialysis with catheter; the percentage of patients who start hemodialysis with a fistula.

Response: The first year of dialysis is a critical time for vascular access since the majority of incident patients are starting with a catheter. However, facilities would not yet be able to influence the process of pre-dialysis access planning occurring before dialysis begins. Therefore facilities may be unfairly evaluated for outcomes that are attributed to care processes prior to patients beginning dialysis at the facility. In addition, a measure that evaluated the percentage of patients who start dialysis with a catheter could have the unintended consequences of limiting access to care for those patients. During the deliberations of these measures, the TEP did not identify a need to have separate measures for incident and prevalent patients.

Hemodialysis Vascular Access: Long-term Catheter Rate

Several commenters requested clarification of the phrase “limited life expectancy” as it relates to the exclusion criteria.

Response: We define “limited life expectancy” in two different ways. If patients were enrolled in hospice during the reporting month, then they were considered to have a limited life expectancy and are excluded from the measure if they also have a catheter as their dialysis access. “Limited life expectancy” is also defined by the presence of any one of the four comorbidities listed as exclusion criteria. Some of these conditions were recommended by the TEP and all of them are associated with a very high mortality rate in the 6 month period after they first appear in Medicare claims. However, no set time frame is used to define limited life expectancy, and the ‘< 6 months’ was provided only as an example. Other time frames, longer or shorter, would apply. The definition for limited life expectancy will be clarified in the denominator details.

Some commenters asked for clarification if the four exclusion comorbidities were the only ones applied or if they were used as examples as part of a larger set of comorbidity exclusions for the measures.

Response: The four comorbidity conditions are the only ones that are used as exclusion criteria. Other conditions were suggested by commenters, for example, advanced heart failure, that was also recommended by the TEP. However, advanced heart failure cannot be determined from claims that rely on ICD-9 codes. While codes exist for heart failure, there is not enough specificity as to the severity of the diagnosis. However, with ICD-10 codes that have recently been implemented, classification of heart failure, including ejection fraction, is now possible. We will evaluate additional diagnoses such as advanced heart failure with low ejection fraction in the future when available in Medicare claims.

Several commenters suggested specific conditions that may also be appropriate for exclusion including: heart failure, other non-renal end-stage organ failures, severe diffuse vascular disease, and multiple prior failed access attempts

Response: Many of these comorbidities are either associated with limited life expectancy or low likelihood of successful fistula placement. In some situations, the severity of the underlying diagnosis is difficult to ascertain from claims data, although like heart failure, we anticipate this will improve with the change and availability of ICD-10 codes. Therefore, other comorbidities will be evaluated in the future when claims data with ICD-10 data become available. Lastly, 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 this exclusion criterion will be evaluated when more historical vascular access data are available.

One commenter raised the concern that the catheter measure does not account for patients who transfer in to a facility with a vascular catheter during the measurement period, and therefore the catheter would be unfairly attributed to the intake facility during that period.

Response: We revised the measure such that to be included in the numerator of the catheter measure, a patient must be receiving dialysis at the same facility with a catheter for at least 3 full continuous reporting months. That is, when a patient with a catheter transfers from one facility to another, the 3-month time clock starts over, allowing time for the new facility to evaluate and potentially plan for a surgical access.

Hemodialysis Vascular Access: Standardized Fistula Rate

A number of comments included requests for clarification and expansion of exclusion criteria, including:

- Clarification and expansion of exclusions
- An exclusion for patients who, upon assessment, do not meet criteria for a successful fistula.
- A clarification of the definition of limited life expectancy, and whether it is only defined by the four exclusions listed in the specifications
- Suggestions to expand exclusions to include heart failure, other non-renal end-stage organ failures, severe diffuse vascular disease, multiple prior failed access attempts

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 not currently data sources or infrastructure in place that would allow identification of patients who have no further surgical options for vascular access. There would also need to be strong consensus on what determines whether patients do not meet criteria for successful fistula placement. We will evaluate this criterion and data availability to determine feasibility of adding this exclusion in a future iteration of this measure.

We define “limited life expectancy” two different ways. If patients were enrolled in hospice during the reporting month, then they were considered to have a limited life expectancy and are excluded from the standardized fistula measure if they also have a catheter as their dialysis access. “Limited life expectancy” is also defined by the presence of any one of the four comorbidities listed as exclusion criteria. Some of these conditions were recommended by the TEP. All of them are associated with a very high mortality rate in the 6 month period after they first appear in Medicare claims. However, there is no set time frame used to define limited life expectancy, and the ‘< 6 months’ was provided only as an example. Other time frames, longer or shorter, would apply. The definition for limited life expectancy will be clarified in the denominator details. Additionally, the four comorbidity conditions are the only ones that are used as exclusion criteria for the fistula measure.

Many of the comorbidities suggested by commenters are either associated with shortened life expectancy or low likelihood of successful fistula placement. In some situations, the severity of the underlying diagnosis is difficult to ascertain from claims data, although like heart failure, we anticipate this will be improved with the change to and availability of ICD-10 codes. Therefore, other comorbidities will be evaluated in the future when claims with ICD-10 data become available. Lastly, 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 this exclusion criterion will be evaluated when more historical vascular access data are available.

Commenters also suggested adjustments to the risk adjustment strategy for the measure, including a request to remove the adjustment for alcohol and replace it with an adjustment for IV drug dependence. Sex, history of multiple prior accesses, and presence of a cardiac device were also suggested as additional adjusters.

Response: The current model that was presented for the standardized fistula rate combined alcohol dependence and drug dependence into one comorbidity category. Drug dependence includes but is not limited to dependence on IV drugs (e.g., opioid dependence), but excludes conditions related to alcohol dependence. The alcohol dependence and drug dependence conditions were combined together when our initial analyses indicated that both conditions are relatively rare, with each diagnosis occurring in < 2% of dialysis patients, and both conditions had a similar impact on successful fistula creation in incident dialysis patients who were starting therapy with a tunneled catheter. In response to this comment, we conducted further analyses assessing the individual effects of each versus their combined effect in the model. With this approach, only drug dependence had a statistically significant impact, with a coefficient that was also larger than that for the combined category. Alcohol dependence did not yield a meaningful impact when both incident and prevalent patients were included, and was not statistically significant. As a result we revised the risk adjustor and limited this to drug dependence only.

Some commenters requested that female sex be included as an additional risk adjuster based on studies that report women have smaller veins than men, and thus lower likelihood of successful fistula creation. Separate analyses evaluating the impact of socioeconomic and sociodemographic factors (including sex) are being performed for both measures and will be described in the final draft of the measure's testing documentation.

At the present time, historical vascular access data in CROWNWeb are limited, but this exclusion criterion will be evaluated when more historical vascular access data are available. The standardized fistula rate does include an adjustment for the length of

time that patients have been receiving dialysis, since there is an association between having multiple prior failed vascular accesses and length of time on dialysis. Lastly, we appreciate the suggestion from several commenters requesting inclusion of a cardiac device as an adjuster. Inclusion of this risk covariate will be further evaluated for potential addition to future iterations of the standardized fistula rate.

There were several comments about the risk model (and associated c-statistic) used to calculate the measure. These comments included the following topics:

- The rationale for why the model uses categorical variables instead of continuous variables (age, dialysis vintage)
- A comment that the model should be subject to rigorous peer review, and that the C-statistic should be at least 0.80 for the model to be considered robust
- A concern that the standardization method used will disadvantage small facilities

Response: It is common practice to use age and dialysis vintage (and similar variables) categorically in models for vascular access use as demonstrated in the references below. For example, in other studies evaluating fistula and catheter use, age is commonly used as a categorical or dichotomous variable (e.g., age \geq 65 years or age \geq 75). Similarly, studies also use vintage categorically (e.g., \leq 6 mo; 6-12 mo; 1-5 yr; $>$ 5yr). We conducted multiple explanatory analyses to investigate sensitivity to the current definitions of both age and ESRD vintage variables, beginning with more granular categorical levels. Based on similarities in odds ratios, some categorical levels were combined as reported in the final model results.

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.

With regards to comments that our standardization method will disadvantage smaller facilities, we performed additional analyses to evaluate flagging rates for facilities that perform worse than expected as a function of facility size. We used a cutoff of 25 patients, which translates to approximately 4000 treatments per year, a commonly used definition for a low-volume facility. Facilities with \leq 25 patients had flagging rates that were lower (3%) than facilities with $>$ 25 patients (14%), providing reassurance that

smaller facilities are not disadvantaged by the standardization technique for the fistula measure.

1. Abbott K, Trespalacios F, and Agodoa L. Arteriovenous fistula use and heart disease in long-term elderly hemodialysis patients: Analysis of United States renal data system dialysis morbidity and mortality wave II. *J NEPHROL* 2003; 16: 822-830.
2. Hurst et al. Arteriovenous Fistulas among Incident Hemodialysis Patients in Department of Defense and Veterans Affairs Facilities. *J Am Soc Nephrol* 21: 1571–1577 2010.
3. Michael P. Lily et al. 2012. Prevalence of Arteriovenous Fistulas in Incident Hemodialysis Patients: Correlation With Patient Factors That May Be Associated With Maturation Failure. *American Journal of Kidney Diseases*. April 2012 Volume 59, Issue 4, Pages 541–549.
4. Lok C et al. Risk Equation Determining Unsuccessful Cannulation Events and Failure to Maturation in Arteriovenous Fistulas (REDUCE FTM I). *Am Soc Nephrol* 17: 3204–3212, 2006.
5. Masengu A, Maxwell A, Hanco J. AVF Failure to mature Investigating clinical predictors of arteriovenous fistula functional patency in a European cohort. *Clinical Kidney Journal*, 2016, vol. 9, no. 1, 142–147. doi: 10.1093/ckj/sfv131.
6. Nee et al. Impact of Poverty and Health Care Insurance on Arteriovenous Fistula Use among Incident Hemodialysis Patients. *Am J Nephrol* 2015;42:328–336

Several commenters requested clarification for the fistula measure as to whether a patient is included in the numerator if a fistula is being used to provide dialysis, but a vascular catheter (not in use) or a non-functioning graft is present.

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 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, we will work with CMS to refine the definitions for the vascular access options in CROWNWeb so that “AVF only” would not include cases where 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. 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.

Preliminary Recommendations

We plan to make the following adjustments to the measure specifications, based on public comment:

- Clarify the definition of limited life expectancy that is used to define exclusions in both measures
- Revise the risk adjustment in the Standardized Fistula Rate from “alcohol/drug dependence” to “drug dependence” only
- Revise the denominator of the catheter measure to account for patients who transfer facilities mid-month

Overall Analysis of the Comments and Recommendations

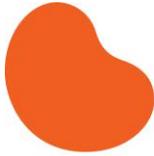
Comments were very constructive and led to several improvements in the measure specifications. CMS and UM-KECC appreciate the time dedicated to reviewing and providing comments on these measures.

Public Comment Verbatim Report

Date Posted	Measure or Measure Set	Text of Comments	Name, Credentials, and Organization of Commenter	Type of Organization	Recommendations/Actions Taken
March 18, 2016	Vascular Access Measure Set	See appendix	Kenneth Abreo, M.D. President, American Society of Diagnostic and Interventional Nephrology (ASDIN)	Professional Organization	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.
March 18, 2016	Vascular Access Measure Set	See appendix	Cindy Richards, BSN, RN, CNN President, American Nephrology Nurses Association (ANNA)	Professional Organization	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.
March 18, 2016	Vascular Access Measure Set	See appendix	Kidney Care Partners (KCP)	Patient Advocacy Organization	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.

Date Posted	Measure or Measure Set	Text of Comments	Name, Credentials, and Organization of Commenter	Type of Organization	Recommendations/Actions Taken
March 18, 2016	Vascular Access Measure Set	See appendix	Paul T. Conway, Transplant Recipient, President, American Association of Kidney Patients (AAKP) & Stephen Z. Fadem, MD, FASN Chairman, AAKP Medical Advisory Board	Patient Advocacy Organization	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.
March 18, 2016	Vascular Access Measure Set	See appendix	Rebecca Schmidt, DO, President, Renal Physicians Association (RPA)	Professional Organization	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.
March 18, 2016	Vascular Access Measure Set	See appendix	Raymond C. Harris MD, FASN President, American Society of Nephrology, (ASN)	Professional Organization	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.

Date Posted	Measure or Measure Set	Text of Comments	Name, Credentials, and Organization of Commenter	Type of Organization	Recommendations/Actions Taken
March 18, 2016	Vascular Access Measure Set	See appendix	Helen Currier, President, National Renal Administrators Association (NRAA)	Professional Organization	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.
March 18, 2016	Vascular Access Measure Set	See appendix	Cherilyn T. Cepriano, President, Kidney Care Council (KCC)	Professional Organization	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.
March 18, 2016	Vascular Access Measure Set	See appendix	Joseph Vassalotti, MD Chief Medical Officer, National Kidney Foundation (NKF)	Patient Advocacy Organization	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.
March 18, 2016	Vascular Access Measure Set	See appendix	Jeffrey Hymes, MD Chief Medical Officer & Senior Vice President Fresenius Medical Care (FMC) North America	Dialysis Provider Organization	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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February 5, 2016

University of Michigan Epidemiology and Cost Center
dialysisdata@umich.edu

Re: Vascular Access and Access to Kidney Transplant Measures

The National Kidney Foundation (NKF) appreciates the opportunity to comment on the development of quality measures to evaluate dialysis facilities performance in improving the care of patients. NKF is America's largest and oldest health organization dedicated to the awareness, prevention, and treatment of kidney disease for hundreds of thousands of healthcare professionals, millions of patients and their families, and tens of millions of people at risk. NKF has a network of 40,000 patient and family members as part of our constituent council membership and reaches tens of thousands more patients through our programs and education materials. In addition, NKF has provided evidence-based clinical practice guidelines for all stages of chronic kidney disease (CKD), including transplantation since 1997 through the NKF Kidney Disease Outcomes Quality Initiative (NKF KDOQI). We work with volunteers to offer the scientific, clinical and kidney patient perspective on what needs to be done to prevent kidney disease, delay progression, and better treat kidney disease and kidney failure. We offer the following comments on the proposed modifications of the vascular access measures and the development of transplant waitlist measures.

End-Stage Renal Disease Vascular Access Measure Development

Hemodialysis Vascular Access: Long-term Catheter Rate

NKF supports the addition of measure exclusions that are supported by the data (hospice, metastatic cancer, end stage liver disease and coma or anoxic brain injury). The implicit exclusions for peritoneal dialysis and age less than 18 years are sound. NKF recognizes a number of other potential exclusions are not feasible with

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the current data collection methodology. We encourage CMS to consider the impact of the proposed exclusions as well as explore additional exclusions in the future.

Adjusted percentage of adult hemodialysis patient-months using an autogenous arteriovenous fistula (AVF) as the sole means of vascular access.

The NKF supports this measure, which is modified by the identical exclusions of the aforementioned catheter measure and adds data-driven risk adjustments. The functioning AVF is superior to other access types, but AVF have a high primary failure rate. An area of controversy is how to best individualize care to match the optimal access to a specific patient. A KDOQI vascular access guideline update, under development, will address the current evidence base for access selection and management, which may better characterize the role of the AV graft.

**End-Stage Renal Disease Access to Kidney Transplantation Measure
Development**

Percentage of Prevalent Patients Waitlisted (PPPW)

NKF is very supportive of improving patient education about kidney transplantation and increasing the number of patients that are referred for transplant. We encourage CMS to further pursue the data collection necessary to develop measures in these areas. Of the transplant measures proposed, NKF believes the overall kidney transplant waitlist measure, the percentage of prevalent patients waitlisted (PPPW) is the most meaningful for patients. Dialysis facilities can help support patients in maintaining their active status on the waitlist for routine antibody and other periodic testing. This measure would incentivize greater care coordination by the dialysis facility with the transplant center. Many transplant centers have dialysis outreach programs to better educate facility staff and patients about the transplant process and the patient and dialysis facility role in the process. However, gaps in patients getting waitlisted remain. Patients continue to report that they were not fully informed about transplant or were provided misinformation that led them not to pursue transplant. Holding dialysis facilities accountable for ensuring their patient population is knowledgeable about transplant and supporting patients to maintain their status on the waitlist will help address this current gap in care.

However, we note concerns with the limited exclusions. Some patients under age 75 may not be eligible for transplantation due to other clinical reasons. In addition, in

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some cases even the most informed and educated patient may ultimately choose not to pursue a transplant. Limited, but additional exclusions to account for these circumstances should be evaluated. Ultimately, the decision on whether a patient is listed for a transplant is made by the transplant center that evaluated the patient (and the patient's desire for a transplant). These are complex decisions that take into account many factors and vary by transplant center and geographic region, which would make nationwide comparisons of waitlist percentages difficult to interpret. The effect of this variance in transplantation policy on dialysis facility performance on this measure should be considered prior to implementation.

Standardized First Kidney Transplant Waitlist Ratio for Incident Dialysis Patients

NKF appreciates the intent of this measure to ensure that patients are waitlisted as early as possible after starting dialysis, if they were not already waitlisted. However, we are concerned this measure is limited in terms of actionability by the dialysis center as the ultimate decision on waitlist status is made by the transplant center and the patient. As we highlight above, dialysis facilities have a role in educating patients about transplant and supporting their active listing. However, incident dialysis patients, who were not listed before starting dialysis, may be more complex and have comorbidities that make them ineligible for the waitlist during the first year. While it is the responsibility of the dialysis facility to work to improve the health and functional status of dialysis patients during the first year, much of the final decision is beyond their control. In addition, dialysis units involved in pre-education and care coordination in the transition of advanced CKD to ESRD would not be recognized for pre-emptively having patients on the waitlist. To better improve earlier wait listing, NKF instead encourages CMS to reconvene the TEP and explore measure development to evaluate transplant referrals and patient education within the first 12 months of initiating dialysis.

Sincerely,

Joseph Vassalotti

Joseph Vassalotti, MD
Chief Medical Officer



February 5, 2015

Mr. Andrew Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health & Human Services
Attention: CMS-1631-P
P.O. Box 8013
Baltimore, Maryland 21244-8013

Re: End-Stage Renal Disease Vascular Access Measure Development

Dear Acting Administrator Slavitt:

Thank you for providing the American Association of Kidney Patients (AAKP) the opportunity to submit comments on the proposed measures currently under development for vascular access and access to kidney transplantation for patients with end stage renal disease.

AAKP has distinguished itself as the oldest fully patient-centered organization dedicated to the protection and advancement of the best interests of American kidney patients. We have built a reputation for principled advocacy on a bi-partisan basis and work closely with patients, medical professionals and elected officials across the nation. The mission of AAKP is to improve the quality of life for kidney patients through education, advocacy and the fostering of patient communities.

AAKP strongly believes in providing patients the educational tools necessary in order for them to be active members of their health care team and allow for thoughtful input in health care decisions.

Thank you for considering these comments for revisions to the existing ESRD Vascular Access measures.

End-Stage Renal Disease Access to Kidney Transplant Measure Development

Standardized First Kidney Transplant Waitlist Ratio for Incident Dialysis Patients (SWR)

And Percentage of Prevalent Patients Waitlisted (PPPW)

1. The measure tracks the percentage of patients at each dialysis facility who were on the kidney or kidney-pancreas transplant waitlist. Results are averaged across patients prevalent on the last day of each month during the reporting year.
2. This measure tracks the number of incident patients at the dialysis facility under the age of 75 listed on the kidney or kidney-pancreas transplant waitlist or who received living donor transplants within the first year of initiating dialysis.

The measures are high priority and address a gap in service. The impact of this measure is to increase deceased donor transplantation by assuring a highly available pool of patients. One concern is that they will encourage patients who are not clearly eligible to be referred and inappropriately listed for a kidney transplant. Recommend that the language of the measure be changed to state “percentage of eligible patients” or “number of eligible incident patients.” It is tantamount to the success of this measure that nephrologists play an active role in helping determine eligibility. Tools used to facilitate this measure’s success should include a checklist

for eligibility and shared decision making with respect to kidney transplantation between the patient, the family and the nephrologist

It is felt that the criteria for transplant patient eligibility for purposes of this measure be standardized and published. In the rationale, it is suggested that the dialysis unit assists patient with completion of the transplant evaluation process. However, it should be noted that in many practices, the nephrologist handles this evaluation outside of the dialysis center. Therefore language should be changed to state “assist patient, nephrologist and transplant team with...”

Since many patients are evaluated for a kidney transplant before they reach the state of requiring dialysis, there should be a sub measure that includes incident patients who are on the transplant list prior to starting dialysis.

There are multiple barriers to fully supporting these measures. These include regional variation in wait list time, variation in insurance access and regional variation in access to transplantation and lack of control by the facility. A major concern regarding the waitlist ratio is that it would exclude patients listed prior to starting dialysis, something we are trying to promote.

End-Stage Renal Disease Vascular Access Measure Development

Hemodialysis Vascular Access: Standardized Fistula Rate

Hemodialysis Vascular Access: Long-term Catheter Rate

1. Adjusted percentage of adult hemodialysis patient-months using an autogenous arteriovenous fistula (AVF) as the sole means of vascular access.
2. Percentage of adult hemodialysis patient –months using a catheter continuously for 90 days or longer for vascular access
3. PROPOSED – Percentage of adult incident hemodialysis patients who start hemodialysis using a catheter
4. PROPOSED – Percentage of adult incident hemodialysis patients who start hemodialysis using an autogenous arteriovenous fistula

Denominator: It is felt that since many dialysis patients may not be candidates for an autogenous arteriovenous fistula because they have had repeated unsuccessful attempts, have arteries that do not have sufficient diameter to create a successful fistula, or have had run out of access sites. In some instances, the creation of a successful arteriovenous graft would have avoided complications that resulted in the patient requiring a long term catheter. Thus, we feel that the denominator should exclude those patients who upon assessment do not meet criteria for a successful fistula, and that a toolkit be developed to help facilitate this measures success. This toolkit should include instructions on how to assess an arm pre fistula placement, and determine if a fistula is possible. The high risk of complications of temporary catheters and the overall low AVF maturation rate explain why a universal policy of AVF 1st for all incident dialysis patients may not optimize clinical outcomes. Strong consideration should be given to a more patient-centered approach taking into account the likelihood of AVF maturation, and that older and smaller patients may not have the vessel size that allows for successful AVF and may therefore be candidates for a graft as alternative to a central venous catheter.

This measure is high priority. There is a gap in care characterized by 80% of patients starting hemodialysis with a catheter. The rationale for using a fistula merits attempting a fistula when possible, but it is most certain that a catheter, and its subsequent morbidities can be best avoided if the access is placed prior to the initiation of dialysis. It is recommended that CMS develop guidance that will waive hospital DRGs restrictions or

obstacles that encourage early hospital discharge of new dialysis patients, precluding the surgical placement of an access prior to hospital discharge. Instead, the placement of an AV access should be encouraged while the patient is still an inpatient.

AAKP appreciates the opportunity to provide comments to the Renal Disease Vascular Access Measures. We look forward to continuing to work with CMS to advance policies that support quality care for kidney patients.

Sincerely,

A handwritten signature in cursive script that reads "Paul T. Conway".

Paul T. Conway
Transplant Recipient
President

A handwritten signature in cursive script that reads "Steve".

Stephen Z. Fadem, MD, FASN
Chairman, AAKP Medical Advisory Board



February 3, 2016

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Re: End-Stage Renal Disease Vascular Access Measure Development

To Whom It May Concern:

On behalf of the American Nephrology Nurses Association (ANNA), I appreciate the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) and University of Michigan Kidney Epidemiology and Cost Center's (UM-KECC) proposed draft End-Stage Renal Disease (ESRD) Vascular Access measures. ANNA is supportive of CMS and UM-KECC's efforts to improve patient mortality by developing hemodialysis vascular access measures.

ANNA promotes excellence in and appreciation of nephrology nursing so that we can make a positive difference for people with kidney disease. Established as a nonprofit organization in 1969, ANNA has a membership of approximately 10,000 registered nurses in almost 100 local chapters across the United States. We are the only professional association that represents nurses who work in all areas of nephrology, including hemodialysis, chronic kidney disease, peritoneal dialysis, acute care, and transplantation. Most of our members work in freestanding dialysis facilities, hospital outpatient units, and hospital inpatient dialysis units.

ANNA develops and updates standards of clinical practice, educates practitioners, stimulates and supports research, disseminates knowledge and new ideas, promotes interdisciplinary communication and cooperation, and monitors and addresses issues encompassing the breadth of practice of nephrology nursing.

Hemodialysis Vascular Access: Long-term Catheter Rate

ANNA applauds CMS and UM-KECC's efforts to develop a hemodialysis vascular access long-term catheter rate measure. We are supportive of the work to build a vascular access measure that accounts for patient preference in addition to risk adjustment factors. An accurate count of the number of patients who use catheters more than 90 days as their access to hemodialysis is fundamentally important in the efforts to reduce overall utilization rates of central venous catheters (CVCs) for greater than 90

days, decrease the substantial morbidity and mortality associated with long-term catheter use, and limit the unnecessary use of health care resources.

As you are aware, there are numerous advantages to using an arteriovenous (AV) fistula (AVF) for hemodialysis as compared to a catheter or AV graft. The use of AVF 90 days after the initiation of hemodialysis has been found to be associated with reduced cardiovascular and all-cause mortality.¹ Additionally, the use of an AVF is “recognized as the optimal type of HD [hemodialysis] vascular access for its longer patency, fewer infectious complications, and is associated with lower all-cause mortality compared with the AV graft or central venous catheter (CVC).”² In those circumstances in which hemodialysis patients are unable to successfully establish or maintain an AVF, ANNA acknowledges that an AV graft is an acceptable alternative.

Moreover, we recognize that for those patients in whom kidney disease has progressed quickly, there may be insufficient time to prepare permanent vascular access before dialysis treatments are started. Choosing peritoneal dialysis as the treatment modality, rather than starting hemodialysis with a CVC catheter, has a mortality advantage of one to two years. For patients choosing peritoneal dialysis as their kidney replacement therapy, ANNA believes that urgent-start peritoneal dialysis to initiate dialysis is a superior alternative to initiating hemodialysis with a CVC for many patients. Research studies have demonstrated that the use of a CVC increases mortality risk compared with incident dialysis patients who initiated treatment with peritoneal dialysis, AVF, or an AV graft.³ We also would recommend that CMS recognize the potentially negative effect the CVC measure can have on small units with a larger population of peritoneal dialysis patients.

However, the proposed measure fails to allow for those individuals with ESRD who are unable to support internal access and whose only choice is a CVC. ANNA has concerns the long-term catheter rate measure, as currently drafted, will inappropriately penalize a dialysis facility that receives into its care a patient with a CVC who has transferred from a different facility or unit during the measurement period. ANNA encourages UM-KECC to consider how to account for such patients and avoid penalizing dialysis facilities and units in such circumstances.

¹ Wasse, Haimanot, Speckman, Rebecca A., and McClellan, William M. Arteriovenous Fistula Use is Associated with Lower Cardiovascular Mortality Compared with Catheter Use among ESRD Patients. *Seminars in Dialysis* 21.5 (2008): 483-489.

² Wasse, Haimanot, Kutner, Nancy, Zhang, Rebecca, and Huang, Yijian. Association of Initial Hemodialysis Vascular Access with Patient-Reported Health Status and Quality of Life. *Clinical Journal of the American Society of Nephrology* 2.4 (2007): 708-714.

³ Perl J, Wald R, McFarlane P, Bargman JM, Vonesh E, Na Y, Jassal SV, Moist L: Hemodialysis vascular access modifies the association between dialysis modality and survival. *Journal of the American Society of Nephrology* 22 (2011): 1113–1121.

Hemodialysis Vascular Access: Standardized Fistula Rate

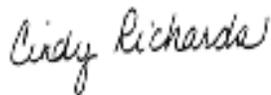
ANNA is pleased CMS and UM-KECC have created a vascular access measure that adjusts for patient-specific factors in instances when fistula placement may be difficult or not appropriate, and accounts for circumstances in which an AV graft may be the most viable option for vascular access. We are supportive of UM-KECC's proposal to adjust for provider-driven selection bias within the standardized fistula rate hemodialysis vascular access measure. Additionally, ANNA agrees with UM-KECC's proposed list of exclusions as well as the fistula rate model adjustments for age, body mass index (BMI), nursing home status, duration of ESRD, nephrologist care prior to ESRD, inability to ambulate/transfer, and incident and prevalent comorbidities.

ANNA is hopeful the standardized fistula rate and long-term catheter rate measures will help to improve the quality of dialysis care and urges CMS to proceed accordingly. We encourage CMS and UM-KECC to continue this work to develop a measure that will appropriately reduce the use of CVCs and increase the use of AVFs in incident dialysis patients.

Conclusion

ANNA greatly appreciates the opportunity to share our comments on the ESRD vascular access measures. As the leading professional association representing nephrology nurses, we look forward to continuing to work with you and CMS on these important issues. Should you have any questions, please contact me or have your staff contact our Health Policy Consultant, Kara Gainer (Kara.Gainer@dbr.com or 202-230-5649). We thank you for your consideration.

Sincerely,



Cindy Richards, BSN, RN, CNN
President, 2015-2016

February 5, 2016

Joel Andress, PhD
Measure Development Lead for ESRD
Division of Chronic and Post-Acute Care
Centers for Medicare and Medicaid Services
University of Michigan Epidemiology and Cost Center

RE: Public Comment on Hemodialysis Access and Transplantation Measures

Dear Dr. Andress:

On behalf of the American Society of Nephrology (ASN), we thank you for the opportunity to provide comments on the University of Michigan Kidney Epidemiology and Cost Center (UM-KECC) developed Access to Kidney Transplantation measures (Standardized First Kidney Transplant Waitlist Ratio for Incident Dialysis Patients (SWR) and Percentage of Prevalent Patients Waitlisted (PPPW)). ASN is the world's leading organization of kidney health professionals, representing more than 15,000 physicians, scientists, nurses, and health professionals who strive to improve the lives of patients with kidney disease every day. ASN and the professionals it represents are committed to maintaining patient access to optimal patient-centered quality care, regardless of socioeconomic status, geographic location, or demographic characteristics.

ASN appreciates the efforts of The Centers for Medicare & Medicaid Services (CMS), as well as those of the UM-KECC, to identify the best available healthcare performance measures for use in specific applications. ASN would continue to encourage development and validation of meaningful outcome measures for people affected by kidney disease. ASN recommends that CMS and the organizations it contracts with continue to work with the greater kidney community in developing patient focused outcome measures that would benefit patient's lives.

The society submits the following comments for your consideration.

Hemodialysis Vascular Access: Long-Term Catheter Rate and Standardized Fistula Rate.
ASN supports these measures with a request that CMS continue to investigate optimal risk factor adjustment and exclusions as well as a clarification regarding grafts.

While no measure is without limitations, this is a significant improvement on the existing vascular access measures given that the proposed measures take into account that fistulas may not be the optimal access for everyone. Through exclusions and adjustment, the proposed measures allow providers more flexibility than the current measures to individualize access decisions based on patient-specific factors. With that said, the society would like CMS to clarify that the concurrent presence of a thrombosed AV graft and a functional fistula be counted as a fistula only, reflecting that grafts, after they fail, are typically not removed and are felt to be very low risk of causing harm. We suspect that this was the intent of the TEP and the measure steward. With our support, we encourage CMS to:

- Continue exploration of refinements to the risk adjustment model and updating this as needed moving forward
- Continue exploration of refinements to the exclusions and updating this as needed moving forward

ASN understands that, at this time it may be difficult to capture this information, but future iterations could investigate the number of accesses a patient has previously had as there are some patients who unfortunately ultimately exhaust their access sites.

ASN continues to encourage transparency and requests that the coefficients in the adjustment model be available to the dialysis community so that performance on the metric can be computed by stakeholders.

Finally, assuming the eventual incorporation of the proposed metrics into current dialysis reporting systems, ASN encourages CMS to educate the public and regulators/inspectors that small to moderate changes in metric performance when transitioning from the prior measures to the proposed measures may not reflect a change in performance, particularly in smaller facilities.

Percentage of Prevalent Patients Waitlisted (PPPW) Standardized First Kidney Transplant Waitlist Ratio for Incident Dialysis Patients (SWR)

ASN would like to begin by thanking CMS for promoting transplant, reflecting that, for many patients, transplant is the optimal kidney replacement therapy. ASN understands and agrees that nephrologists, dialysis facilities and transplant centers can, and need to, do a better job facilitating transplant evaluation for potentially transplant eligible patients so that they can be listed as candidates for transplantation. Unfortunately, ASN cannot support the proposed measures as currently written.

ASN strongly supports measures in the nephrology arena promoting transplant access and would be pleased to work with CMS to help develop metrics moving forward. We recognize that there are perverse incentives for dialysis facilities to not facilitate referral of their healthiest patients for transplant and appreciate that a transplant access metric that is publicly available would be valuable to patients. For transplant measures, the society requests that CMS consider developing metric(s) that evaluate appropriate referral as a first step. To optimize this, CROWNWeb reporting and possibly UNOS reporting of transplant referral would be necessary, and there would need to be a method that is more than *pro forma* for physicians to attest that a patient is not a transplant candidate to reduce inappropriate resource utilization and patient burden. In order to advance a theoretical metric to the level at which it is a more balanced assessment of transplant waitlisting from the dialysis facility perspective, one possible strategy could incorporate a sophisticated modeling approach that, like the SRR, incorporates both patient characteristics and external center characteristics (for the SRR, this is the discharging hospital while, for a transplant metric, this would be the transplant center). ASN hopes to work with CMS to develop and support within the nephrology community a metric in this important kidney disease domain.

The current measures, as written, have substantial limitations that prevent ASN from supporting them at the current time. These reasons include:

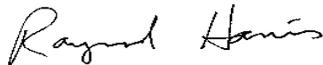
- Dialysis facilities have insufficient influence over whether a patient is listed for transplant, as transplant waitlisting is mostly at the discretion of the transplant center and the patient. While ASN acknowledges that dialysis facilities can modestly facilitate the transplant evaluation process by encouraging initial referral, potentially assisting with arranging local diagnostic testing necessary for transplant listing, and sending other tests requested by the transplant center, this amounts to only a modest portion of the transplant evaluation process. In the absence of similar metrics applying to transplant centers, who often, either rightfully or wrongly, interpret a patient's ability to complete the evaluation process as a sign of waitlisting suitability, the proposed metrics primarily target the incorrect entity.
- There is tremendous heterogeneity of habits among and perhaps even within individual transplant centers regarding consideration of patients as eligible for transplant listing.
- With the recent change in UNOS policy, the imperative to have a patient listed as soon as possible has diminished, reflecting that waiting time is now calculated by dialysis start date rather than by the date a patient was first listed. This policy change is unaccounted for in the proposed metrics and makes referral of patients for transplant evaluation before they are medically stable unnecessary and disadvantageous to patients and transplant centers.

As currently structured, ASN believes that the proposed metrics lack assessment of (1) patient choice as to whether or not they desire a transplant and (2) measures of patient comorbid conditions and other medical and socioeconomic factors that, currently, are closely evaluated by transplant centers when determining patient appropriateness for waitlisting. In essence, the proposed metrics predominantly evaluate the habits behavior of an outside entity (the transplant center) without accounting for the patient characteristics that the outside entity evaluates.

As stated above, ASN hopes to work with CMS to develop and support within the nephrology community a metric in this important kidney disease domain and hopes that this will occur sooner rather than later.

Again, thank you. If you have any questions about this letter or ASN's recommendations, please feel free to contact ASN Policy Associate, Mark Lukaszewski at 202-640-4635 or mlukaszewski@asn-online.org.

Sincerely,



Raymond C. Harris MD, FASN
President



February 5, 2016

Joel Andress, PhD
Centers for Medicare and Medicaid Services
University of Michigan Epidemiology and Cost Center
dialysisdata@umich.edu

RE: Public Comment on Hemodialysis Access and Transplantation Measures

Fresenius Medical Care North America (Fresenius Medical Care) is the largest provider of renal dialysis services in the United States, providing dialysis treatments to over 170,000 individuals with end stage renal disease (ESRD) at over 2,200 dialysis facilities nationwide. We appreciate the opportunity to comment on the draft specifications for the four measures developed under a CMS contract by the University of Michigan Kidney Epidemiology and Cost Center and posted on January 6, 2016. Fresenius Medical Care is a member of the Kidney Care Partners (KCP), and we support KCP's comments on these measures.

Hemodialysis Vascular Access: Long-Term Catheter Rate

Fresenius Medical Care supports the removal of the 90 day ESRD requirement from the denominator statement. We suggest that CMS clarify that the 90 day clock begins on the first day of outpatient dialysis, and that the permitted timeframe for catheter use in the numerator is 90 days.

With respect to the limited life expectancy exclusion, we urge CMS to broaden the categories of exclusion, as the four proposed subcategories do not represent the patients who are not dialyzing for rehabilitative needs, but for some less global goals. For certain patients, the AVF centric measure may not be in their best interest. patients in hospice, patients with metastatic cancer in the past 12 months, patients with end-stage liver disease in the past 12 months, and patients with coma or anoxic brain injury in the past 12 months.

Hemodialysis Vascular Access: Standardized Fistula Rate

Fresenius Medical Care believes that more recognition, visibility and acceptability of arteriovenous grafts is important. A number of hybrid grafts are coming to market that will be hard to classify as purely a graft due to the cell basis of the vessel that is implanted.

At our dialysis facilities, we count AVF or AVG *only* if the catheter has been removed... not based on whether a catheter is in place but is not being used. Patients with catheters are at risk for infection whether the catheter is used or not. We believe that standard should be applied to the dialysis industry, that is, credit should not be given if a catheter remains in place irrespective of whether an AVF is used.

We recommend that CMS clarify specifications to ensure that credit is received for a patient who is using an AVF as the sole means of access, but who may also have a non-functioning AV graft present. Risk adjust the AVF measure to account for AV Grafts. We are also concerned that ongoing problems with CROWNWeb may make it challenging to accurately and consistently identify Fistula + Graft or Fistula + Catheter. To ensure accurate and transparent reporting for all, it may be advisable to delay using a measure until valid and reliable data sources are available.

We agree that the proposed risk covariates improve on the current AFV measures. Additionally, we suggest that CMS consider that ventricular assist devices (VAD), other cardiac devices and socioeconomic variables that may yield different patient goals for their treatment, and take such factors into consideration as risk variables.

While the risk-adjusted metric is an improvement to the current model for the AFV measure, Fresenius Medical Care believes that this model does not adequately account for observed vs. expected outcomes, and may serve to place smaller dialysis facilities at a statistical disadvantage.

Percentage of Prevalent Patients Waitlisted (PPPW)

Fresenius Medical Care strongly believes in improving renal transplantation rates, and we believe that dialysis facilities should have some accountability for referral to a transplant center for evaluation. However, it is beyond the control of the dialysis facility to place patients on a transplant list, as these decisions are made by transplant centers. We recommend that CMS remove the proposed PPPW measure.

Thank you for the opportunity to provide comment to these important measures. Please contact Jeffrey Hymes, MD at 615-567-

4821



Jeffrey Hymes, MD
Chief Medical Officer & Senior Vice President
Fresenius Medical Services
Fresenius Medical Care North America



THE KIDNEY CARE COUNCIL

Providers of Quality Care for the Nation's Dialysis Patients

February 5, 2016

Joel Andress, PhD
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Dr. Andress:

On behalf of the Kidney Care Council (KCC), the nation's largest association of dialysis providers serving the complex clinical needs of more than 85 percent of individuals with End Stage Renal Disease (ESRD) in the United States, we appreciate the opportunity to provide comments on the Hemodialysis Access and Transplantation Measures. KCC is comprised of 11 of the nation's leading dialysis providers, including not for profit and for profit facilities serving patients in urban and rural geographies. KCC member companies are committed to improving clinical outcomes, patient safety, and quality of life measures, and are eager to ensure that individuals with ESRD have meaningful access to life-sustaining services through all Federal health care programs.

In sum, the KCC supports the detailed comments outlined in the KCP letter to CMS on these measures. However, we are writing separately to emphasize our concern and disappointment that the technical expert panel (TEP) has not addressed the problems associated with the lack of a graft measure and to urge CMS to redesign the transplant measures so that they are aligned with how waitlists work and the responsibilities of transplant centers and insurance companies.

I. Hemodialysis Vascular Access Measures

The KCC continues to believe that decreasing the number of catheters is critically important for improving overall patient outcomes. As you are aware, the KCC and the facility medical directors in particular have been concerned about the continued lack of a graft measure and the unintended negative consequences of focusing only on fistulas as an alternative to catheters. The importance of including a graft measure is clear from a recently published study that evaluated mortality associated with fistulas, grafts, and catheters. It found that patients with failed fistulas are unable to benefit from the advantages of fistulas over grafts. Furthermore, these results indicate that fistulas in older adults are associated with a higher number of access-related health care encounters compared with grafts, which effect quality of life and health care costs.¹

¹ Karen Woo, Dana P. Goldman, & John A. Romley, "Early Failure of Dialysis Access among the Elderly in the Era of Fistula First," CJASN ePress (August 7, 2015).

Comments on Hemodialysis Access and Transplantation Measures

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Therefore, we were pleased when CMS established a TEP to develop an appropriate graft measure. We are extremely disappointed, however, that the TEP has not put forward for comment a graft measure. We understand that UM-KECC staff told the TEP that risk adjusting the catheter and fistula measures and establishing appropriate threshold would be just as good as having a graft measure. The KCC has supported adding risk adjusters to both the fistula and catheter measures in previous comments and is pleased the TEP moved in this direction. However, there is nothing in the TEP report to memorialize the agreement that the lack of a graft measure can be addressed by setting the threshold requirements for the fistula and catheter measures so they do not add up to 100 percent and allow room for grafts to be used.

We understand that the TEP does not establish thresholds, but if the rationale for not creating a graft measure is based on an understanding that such thresholds are needed, CMS should clearly indicate that it will take this approach in the TEP report, as well as in other communications to the community. As the *Woo et al.* 2015 study shows, emphasizing fistulas over grafts for older adults can result in unnecessary medical complications. Not all patients are candidates for successful fistula placement. Surveillance of the landscape of the incident dialysis population will readily reveal that that certain patients (particularly the very elderly) may have veins of insufficient caliber to support development of a robust venous outflow tract, or may possess other advanced vascular disease related to diabetes or other common comorbidities of ESRD patients which simply may not support fistula growth.² Clinical evidence shows that either a graft or fistula is always preferable to a catheter.³ Therefore, we strongly encourage CMS to commit to addressing the issue through thresholds or require the TEP to develop a graft measure, as the kidney community has suggested.

A. Hemodialysis Vascular Access: Long-Term Catheter Rate

The KCC supports decision to remove the 90-day ESRD requirement from the denominator for the Long-Term Catheter Rate measure and the incorporation of the limited life expectancy exclusion. However, we ask for clarification of the use of the term “e.g.” It is not clear whether “less than six months” is the only option or if other timeframes would also apply. It is also not clear whether the four subcategories of limited life expectancy (patients in hospice, patients with metastatic cancer in the past 12 months, patients with end-stage liver disease in the past 12 months, and patients with coma or

²See American Association of Kidney Patients (AAKP), *Understanding Your Hemodialysis Access Options* <http://fistula.memberpath.com/LinkClick.aspx?fileticket=dS2HSHjdV4U%3d&tabid=202>.

³ See, e.g., R. K. Dhingra et al., *Type of Vascular Access and Mortality in U.S. Hemodialysis Patients*, 60 *KIDNEY INT'L* 1443-1443, 1449-50 (2001).

Comments on Hemodialysis Access and Transplantation Measures

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anoxic brain injury in the past 12 months) are the only exclusions or are merely examples. Providing this clarification would be extremely helpful.

B. Hemodialysis Vascular Access: Standardized Fistula Rate

The KCC believes the proposed measure contains some improvements on the current AV Fistula measure, but we seek additional clarification on the replacement of “autogenous = 2 Needles.” We are also concerned about the robustness of the proposed risk adjustment model.

The KCC asks that the TEP clarify the specifications so that facilities receive credit for a patient who is using an AV Fistula as the sole means of access, but who also may have a non-functioning AV graft present. We believe that this clarification is consistent with the TEP’s discussion. We agree that credit should not be provided when a catheter remains present. Patients with such catheters remain at risk for infection and other adverse events. However, the removal of a graft presents its own risks of complications, and it may be better for a patient to leave the graft in place. Therefore, we recommend that the numerator specify that patient must be on maintenance hemodialysis “using an AV Fistula *with two needles and without a dialysis catheter present.*”

The KCC is pleased that the TEP has considered risk adjusting the AV Fistula measure. In addition to recommending some specific modifications to the covariates, we strongly encourage CMS to commit to improve the model because of the low c-statistic. In terms of the covariates, the KCC recommends that CMS remove “alcohol” as a risk variable and use IV drug dependence. We also recommend adding gender as a risk variable because gender can contribute to a disparity in the AV fistula rates. In addition, we ask that the TEP include two additional variables to strengthen the model: a history of multiple prior accesses and the presence of a cardiac device.

We believe the proposed measure is an improvement, but are concerned that the proposed model is simply not robust enough because the reported c-statistic is 0.71. Such a low value suggests that the model will not adequately differentiate performance. This problem means that smaller units might look worse than they are. A minimum c-statistic of 0.8 is a more appropriate indicator of the model’s goodness of fit and validity to represent meaningful differences among facilities. We ask CMS to clarify in the TEP report and subsequent communications about the measure that it will commit to improve the model.



Comments on Hemodialysis Access and Transplantation Measures

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II. Transplantation Measures: Percentage of Prevalent Patients Waitlisted (PPPW) and Standardized First Kidney Transplant Waitlist Ratio for Incident Dialysis Patients (SWR)

As a threshold matter, the KCC supports efforts to improve access to transplant for patients with ESRD; however, the proposed measures would not achieve this goal. Therefore, we ask that if CMS pursues a transplant measure for facilities, it should focus on facility referrals of patients to transplant centers, initiation of the waitlist evaluation process, or completion of the waitlist evaluation process. If CMS pursues this path, similar measures should be created for transplant centers as well. For coordinated care pilot programs, CMS should explore a care coordination measure with responsibilities for both the facility and the transplant center. Simply put, transplantation involves multiple parties and the success of waitlisting depends upon the transplant center and insurance companies. If CMS wants to encourage increased access to transplant, it should design measures that evaluate facility performance on those aspects of transplant facilities can influence.

In terms of the specific measures, the KCC strongly opposes the facility attribution for both the PPPW and SWR measures. The attribution of patients is inappropriate because transplant centers have the sole discretion of deciding whether a patient is placed on a waitlist. A patient's insurance policies also can impact when or if a patient is placed on a waitlist. Penalizing a facility by attributing transplant patients to them will not impact either the transplant centers' decision-making process or the insurance companies' policies. It would be more appropriate to design a metric that measures facilities actions.

We are also concerned that the proposed measures seek to use age as the only risk adjuster. In addition to age, there are other biological and demographic factors that play an important role in transplantation. Regional variation in transplant access is significant. The definition of "not eligible" may also differ by a transplant center's evaluation of a patient's biological factors. Transplant centers also take into account a patient's support network, adherence to medication regimens, insurance, and other issues. Thus, any metric measuring waitlisting should account for these factors.

The KCC also recommends that the SWR measure be a rate rather than a ratio measure. The proposed specifications indicate that the measure can be calculated as a rate. As we have noted with other standardized ratio measures, the KCC believes CMS should use normalized rates or year-over-year improvement in rates instead of using standardized ratios. Rates will improve transparency and increase the utility of the measures.

Comments on Hemodialysis Access and Transplantation Measures

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III. Conclusion

The KCC appreciates the opportunity to provide comments on the proposed measures and look forward to working with you on addressing these comments. If you have any questions, please do not hesitate to contact Kathy Lester at 202.534.1773 or klester@lesterhealthlaw.com.

Sincerely,



Cherilyn T. Cepriano

President

Kidney Care Council



TO: Joel Andress, PhD
Centers for Medicare and Medicaid Services

University of Michigan Epidemiology and Cost Center
dialysisdata@umich.edu

DA: February 4, 2016

RE: Public Comment on Hemodialysis Access and Transplantation Measures

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 chronic kidney disease and end stage renal disease (ESRD). We appreciate the opportunity to comment on the draft specifications for the four measures developed under a CMS contract by the University of Michigan Kidney Epidemiology and Cost Center and posted on January 6, 2016.

Hemodialysis Vascular Access: Long-Term Catheter Rate

KCP reviewed this measure against NQF 0256, the catheter measure currently being used for the QIP and Dialysis Facility Compare/Five Star, and offers the following comments on the proposed specifications:

1. ***Change to denominator.*** We note the 90-day ESRD requirement has been removed from the denominator statement, which means the “clock” for the measure starts on the first day of dialysis in a non-hospital setting – but that the permitted timeframe for catheter use in the numerator is still 90 days. KCP supports this change.
2. ***Limited life expectancy exclusion.*** The proposed specifications add an exclusion for patients with a limited life expectancy. KCP has in previous comment letters recommended this approach, so is pleased to see this exclusion incorporated. We note, however, the following:
 - a. The draft specifications state “e.g., < 6 months.” As a matter of construction, we recommend against using ‘for example,’ which can be ambiguous and lead to variable implementation, depending on the interpretation.
 - b. The specifications identify the following four subcategories for the limited life expectancy exclusion: patients in hospice, patients with metastatic cancer in the past 12 months, patients with end-stage liver disease in the past 12 months, and patients with coma or anoxic brain injury in the past 12 months. KCP recommends clarification in the specifications on whether *only* these four subcategories are excluded, or if the four subcategories are illustrative examples, given they are presented as subsets of the “e.g., < 6 months” specification.

Hemodialysis Vascular Access: Standardized Fistula Rate

As with the catheter measure, KCP used the existing arteriovenous fistula (AVF) measure, NQF 0257, for context in our review. In addition to the comments on the proposed catheter measure, which also apply to this proposed AVF measure, we provide the following comments:

3. ***“Autogenous = 2 Needles” replaced.*** KCP notes the language in NQF 0257 that specifically defines an autogenous AVF as using 2 needles has been replaced with an autogenous AVF “as the sole means of vascular access.”
 - a. KCP seeks clarification on whether facilities would receive credit for patients using an AVF as the sole means of access, but who also have in place a graft or catheter that is no longer being used. We note patients with catheters remain at risk for infection and other adverse sequelae, and recommend the specifications be constructed so credit is not given when a catheter is present, even if an AVF is being used; based on our examination of the TEP report, we believe this is consistent with the TEP’s intent. Specifically, KCP recommends the numerator specify the patient must be on maintenance hemodialysis “using an AVF *with two needles and without a dialysis catheter present.*”
 - b. In contrast, removal of an AV graft is complex and not without risk of complications. KCP recommends the specifications be clarified so credit is 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.
4. ***Covariates.*** KCP believes the proposed measure improves on the current AVF measure, but has several comments about the model’s risk variables:
 - a. KCP questions the inclusion of “alcohol/drug dependence” as a covariate and believes only IV drug dependence is relevant.
 - b. KCP recommends including gender as a covariate. There is evidence smaller vein diameter in women – i.e., a “biological effect” – can contribute to a disparity in AVF rates between genders, so it should be included in the model.
 - c. KCP recommends two additional vasculature risk variables to strengthen the model: a history of multiple prior accesses and the presence of a cardiac device.
5. ***Risk model.*** KCP believes the risk-adjusted metric is an improvement to the simple AVF measure currently in use. Nevertheless, we have serious concerns about the robustness of the proposed model because of the low c-statistic (0.71). We are concerned the model will not adequately discriminate performance – particularly that smaller units might look worse than reality. We believe a minimum c-statistic of 0.8 is a more appropriate indicator of the model’s goodness of fit and validity to represent meaningful differences among facilities, and seek an ongoing commitment from CMS to improve the model.

Percentage of Prevalent Patients Waitlisted (PPPW)

Standardized First Kidney Transplant Waitlist Ratio for Incident Dialysis Patients (SWR)

KCP recognizes the tremendous importance of improving transplantation rates for patients with ESRD, but does not support the attribution to dialysis facilities of successful/unsuccessful waitlisting. KCP believes referral to a transplant center, initiation of the waitlist evaluation process, or completion of the waitlist evaluation process (with which a facility can often provide assistance) are more appropriate facility-level measures. In contrast, waitlisting per se is a decision made by the transplant center and beyond a dialysis facility’s locus of control. We further recommend CMS explore a care coordination measure with mutual facility-transplant

center responsibilities. Lastly, we note that a completion of the waitlist process measure and a waitlisting measure should be developed for transplant centers. Transplantation is a multi-party process: To optimally drive improvement, measurement of all parties should be deployed.

Our comments on the details of the proposed specifications are:

6. **PPPW and SWR: Facility attribution.** As just noted, KCP strongly objects to attributing successful/unsuccessful placement on a transplant waitlist to dialysis facilities. The transplant center decides whether a patient is placed on a waitlist, not the dialysis facility. One KCP member who is a transplant recipient noted there were many obstacles and delays in the evaluation process with multiple parties that had nothing to do with the dialysis facility – e.g., his private pay insurance changed the locations where he could be evaluated for transplant eligibility on multiple occasions, repeatedly interrupting the process mid-stream. Penalizing a facility each month through the PPW and SWR for these or other delays is inappropriate. Again, KCP emphasizes our commitment to improving transplantation access, but we believe other measures with an appropriate sphere of control should be pursued.
7. **PPPW and SWR: Age as the only risk variable.** KCP strongly believes age as the only risk variable is insufficient. We believe other biological and demographic variables are important, and not accounting for them is a significant threat to the validity of both measures.

Geography, for instance, should be examined, since regional variation in transplantation access is significant. For example, regional differences in waitlist times differ, which ultimately will change the percentage of patients on the waitlist and impact a performance measure score. That is, facilities in a region with long wait times will “look” better than those in a region with shorter wait times where patients come off the list more rapidly – even if both are referring at the same rate.

Additionally, criteria indicating a patient is “not eligible” for transplantation can differ by location – one center might require evidence of an absence of chronic osteomyelitis, infection, heart failure, etc., while another may apply them differently or have additional/different criteria. The degree to which these biological factors influence waitlist placement must be accounted for in any model for the measure to be a valid representation of waitlisting. Moreover, transplant centers assess a myriad of demographic factors – e.g., family support, ability to adhere to medication regimens, capacity for follow-up, insurance-related issues, etc. Given transplant centers consider these types of sociodemographic factors, any waitlisting measure risk model should adjust for them. Of note, KCP does not support, as the TEP did not support, adjustment for waitlisting based on economic factors or by race or ethnicity.

8. **PPPW only: Process vs. intermediate outcome measure.** The CMS Measure Information Form identifies the PPPW as a process measure. KCP believes the PPPW is an intermediate outcome measure and recommends the form indicate such.
9. **SWR only: Rate vs. ratio.** The proposed specifications for the SWR indicate the measure can be calculated as a rate. Notwithstanding our many concerns regarding attribution and risk adjustment of this measure, consistent with our comments on other standardized ratio measures (e.g., SHR, SMR), KCP prefers normalized rates or year-over-year improvement in rates instead of a standardized ratio. We believe comprehension, transparency, and utility to all stakeholders is superior with a scientifically valid *rate* methodology.

KCP again thanks you for the opportunity to comment on this important work. If you have any questions, please do not hesitate to contact Lisa McGonigal, MD, MPH (lmcgon@msn.com or 203.298.0567).

Sincerely,

AbbVie
Akebia
American Kidney Fund
American Nephrology Nurses Association
American Renal Associates
American Society of Nephrology
American Society of Pediatric Nephrology
Amgen
Astra Zeneca
Baxter
Board of Nephrology Examiners Nursing Technology
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Nephrology Nursing Certification Commission
Northwest Kidney Centers
NxStage Medical
Renal Physicians Association
Renal Support Network
Rogosin Institute
Sanofi
Satellite Healthcare
U.S. Renal Care

To: Joel Andress, PhD
Centers for Medicare and Medicaid Services
University of Michigan Epidemiology and Cost Center

Date: February 5, 2016

RE: Public Comment on Hemodialysis Access and Kidney Transplantation Draft Measures for the End-Stage Renal Disease Quality Improvement Program

The National Renal Administrators Association is a voluntary organization representing dialysis providers throughout the United States. Our membership primarily includes small for-profit and not-for-profit providers serving patients in urban, rural, and suburban areas in both free-standing and hospital-based facilities.

We support CMS efforts to improve the quality of care for patients with End-Stage Renal Disease (ESRD) through the Quality Improvement Program (QIP) and appreciate the ongoing recognition by CMS of the unique challenges posed to small and medium dialysis facilities of providing high quality care to ESRD patients. The NRAA welcomes the opportunity to comment on specifications for four draft QIP measures on hemodialysis access and kidney transplantation developed by the Michigan Kidney Epidemiology Cost Center on behalf of CMS posted January 6, 2016.

Percentage of Prevalent Patients Waitlisted (PPPW) and Standardized First Kidney Transplant Waitlisted Ratio for Incident Dialysis Patients (SWR)

The NRAA strongly emphasizes our support of the goal to improve kidney transplantation rates for ESRD patients. However, we believe the draft PPPW and SWR measures do not appropriately recognize the role of dialysis facilities in improving transplantation rates. Specifically, transplant centers – not dialysis facilities – decide if the patient joins the waitlist. Successful placement on the transplant waitlist is beyond the control of the dialysis facility. Rather, in the waitlist process, dialysis facilities refer patients to transplant centers and initiate and provide assistance with completion of the waitlist evaluation. As such, we suggest the following modifications to these draft measures.

1. **Do not attribute PPPW and SWR to dialysis facilities.** As stated above, transplant centers, not dialysis facilities, determine whether or not to place patients on the kidney transplant waitlist. Moreover, a number of obstacles in the evaluation process related to multiple parties completely unaffiliated with the dialysis facility can delay a patient's addition to the waitlist. For example, many employer health plans, Medicare Advantage plans, and state Medicaid programs require transplant services at specific centers that may necessitate patients traveling great distances for evaluations, thereby delaying completion of the waitlist process. Or, a patient's insurance may change midway through the process, potentially resulting in the patient having to undergo additional testing or meeting new transplant eligibility criteria, thus postponing joining the waitlist at the new transplant center. Hence, the NRAA believes it is inappropriate to penalize a dialysis facility waitlist delays due to obstacles and decisions beyond the facility's control.

Instead, we recommend that CMS should develop a waitlist placement measure for transplant centers to encourage the overall goal of improving transplant rates for ESRD patients.

2. **Develop alternate measures recognizing the dialysis facility's role in the transplant process.** We strongly support improving kidney transplantation rates and recognize the important role dialysis facilities play in the process. Therefore, we recommend the development of alternate measures for facilities to support improved transplantation rates. Specifically, the NRAA believes measures assessing referral to a transplant center or initiation of the waitlist evaluation process represent appropriate facility-level measures. We further suggest CMS consider developing a care coordination measure with mutual facility-transplant center responsibilities to help foster improved transplant rates.

3. **Include other risk variables beyond age in PPPW and SWR.** The NRAA believes validity of both PPPW and SWR measures would increase significantly if they included other variables, including geographic, biologic, sociodemographic, and financial factors.

- ***Geographic:*** Substantial variation exists in regional waitlist times across the United States. Dialysis facilities in a region with long wait times will “look” better than those in a region with shorter wait times where patients come off the list more quickly, even if both facilities refer at the same rate. Hence, the model appropriately should account for geographic variation.
- ***Biologic:*** Biologic eligibility criteria such as heart failure, infection, and the absence of chronic osteomyelitis may cause one transplant center to include or exclude a patient on the waitlist. The PPPW and SWR measures should consider biologic differences in waitlist eligibility criteria.
- ***Sociodemographic:*** Transplant centers evaluate many sociodemographic factors when making waitlist determinations such as family support, medication adherence, and patient ability to seek follow-up care. The model should account for the sociodemographic factors assessed by transplant centers.
- ***Financial:*** Some transplant centers require patients to have a specific level of cash reserve to cover the Medicare co-insurance payments required for immunosuppressive drugs and the living expenses required during the recuperation period if the patient is unable to maintain his normal income level. Consequently, the model specifically should consider patient financial resources contemplated by certain transplant centers when making waitlist determinations.

Of note, the NRAA agrees with the Technical Expert Panel that the waitlist measures should not include adjustments for race or ethnicity factors.

4. **Identify PPPW as an intermediate outcome measure.** The NRAA believes the PPPW is an intermediate outcome measure, rather than a process measure, as specified in the CMS Measure Information Form and recommends the form indicate as such.

5. **Calculate SWR as a rate rather than a ratio.** Notwithstanding our concerns outlined above related to facility attribution and risk adjustment, we prefer the calculation of SWR as a normalized rate or year-over-year improvement in rate rather than a standardized ratio. Use of this scientifically valid rate methodology would improve comprehension, transparency, and utility of the measure to all stakeholders.

Hemodialysis Vascular Access: Long-Term Catheter Rate

The NRAA has the following comments on this draft measure based on a comparison with NQF 0256, the existing catheter measure in the QIP and Dialysis Facility Compare/Five Star.

6. **We support the denominator change.** The NRAA supports the change removing the 90-day ESRD requirement from the denominator, which results in the assessment beginning on the first day of dialysis in a non-hospital setting while still allowing catheter use for 90 days.

7. **Clarify the limited life expectancy exclusion.** We appreciate the proposal to exclude patients with limited life expectancy from this measure. To ensure accurate data reporting, we recommend clarifying precisely those patients who the facility may exclude from this measure. Specifically, we seek clarification on: (1) the exact length of life expectancy permitted (six months, rather than “for example” six months), and (2) whether the four subcategories listed (patients in hospice, patients with metastatic cancer in the past 12 months, patients with ESRD in the past 22 month, and patients with coma or anoxic brain injury in the past 12 month) represent the only eligible subcategories or whether other subcategories may merit consideration for exclusion.

In addition, we suggest that CMS consider excluding patients from this measure whom a surgeon has determined have “no other options” for permanent vascular access. Reasons to grant such an exclusion could include: (1) patient refusal of fistula placement after multiple failed attempts; (2) conclusion by the surgeon that the patient’s poor vasculature will cause the fistula to fail; or (3) determination by the surgeon that the potential for an adverse outcome, including risk of death, exceeds the benefit of fistula placement. A second surgical opinion could validate such a conclusion.

Hemodialysis Vascular Access: Standardized Fistula Rate

The NRAA recommends the following with respect to the proposed arteriovenous fistula (AVF) measure as it compares to NQF 0257, the current AVF measure in the QIP. The above comments on the proposed catheter measure also apply to the proposed AVF measure.

8. **Make additional specifications to the autogenous AVF measure.** The draft measure proposes to redefine autogenous AVF “as the sole means of vascular access” rather than “using two needles,” as in the existing NQF 0257 measure. The NRAA notes that certain patients may use an AVF “as the sole means of vascular access,” but also may have unused catheters or AV grafts present. We suggest further specifying the measure to account for the existence of unused catheters or AV grafts.

- ***Catheters:*** Unused catheters carry risk for infection and other adverse sequelae. Hence, we recommend the proposed measure not credit a facility for use of an AVF when an unused catheter is present. Accordingly, we suggest that the numerator specify the

patient must be on maintenance hemodialysis “*using an AVF with two needles and without a dialysis catheter present.*” This recommendation aligns with the Technical Expert Panel’s intent outlined in the report.

- **AV Graft:** Removal of AV graft is complex and risks complications. As such, the NRAA recommends that the proposed measure not penalize facilities for the existence of an unused AV graft when patients use AVF as the sole means of vascular access.

9. **Alter certain covariates in the model.** The NRAA appreciates the proposed modifications to improve the risk variables associated with the current AVF measure. However, we suggest the following variations to strengthen the validity of the overall model to show meaningful differences among facilities: (1) replace “alcohol/drug dependence” with “IV drug dependence;” (2) add a gender variable to account for gender disparity in AVF rates; and (3) incorporate vasculature risk variables showing history of multiple prior accesses and the presence of a cardiac device.

10. **Continue to enhance the risk model.** We appreciate the proposed addition of risk adjustment to simple AVF model currently in use. However, we believe the model could be more robust to demonstrate meaningful differences in performance among dialysis facilities and recommend continued development and improvement of the risk model.

11. **Consider modifying the QIP such that inclusion of both the catheter and AVF measures does not penalize a dialysis facility twice for essentially the same vascular access measure.**

The NRAA notes that dialysis facilities that typically report low AVF rates also report high catheter rates for hemodialysis vascular access. Hence, as currently proposed, incorporating both the AVF and catheter vascular access measures in the QIP can penalize a facility twice for failing on essentially the same measure. As such, we suggest that CMS consider modifying the Quality Improvement Program so that facilities who fail to meet the vascular access measures do not experience double penalties in the QIP.

The NRAA thanks you again for the opportunity to comment on the draft ESRD QIP quality measures and looks forward to continue working with CMS to improve the quality, access, and cost of care for patients with renal disease. Please do not hesitate to contact us if you have any questions regarding our comments to the specifications for the four draft QIP measures. If you have any questions, please do not hesitate to contact Marc Chow at mchow@nraa.org or 215.564.3484 (ext. 2294).

Sincerely,



Helen Currier

President



February 5, 2016

Andrew Slavitt
Acting Administrator
Centers for Medicare and Medicaid Services
Room 445–G
Hubert H. Humphrey Building,
200 Independence Avenue, SW
Washington, DC 20201

RE: Development of End-Stage Renal Disease Vascular Access and Access to Kidney Transplantation Measures

Dear Acting Administrator Slavitt:

The Renal Physicians Association (RPA) is the professional organization of nephrologists whose goals are to ensure optimal care under the highest standards of medical practice for patients with kidney disease and related disorders. RPA acts as the national representative for physicians engaged in the study and management of patients with kidney disease. We are writing to provide comments on the End-Stage Renal Disease (ESRD) vascular access and access to kidney transplantation measures.

End-Stage Renal Disease Vascular Access Measure Development

Hemodialysis Vascular Access - Long-term Catheter Rate – RPA believes the addition of the exclusion for patients with limited life expectancy is appropriate; but is concerned about the limitation of these to the four specified categories listed (hospice care, metastatic cancer, end-stage liver disease and coma or anoxic brain injury). This list of conditions misses some important categories - most importantly, patients with severe heart failure (e.g. patients with a markedly reduced ejection fraction who are New York Heart Association Stage 3 or Stage 4), who have a similarly limited life expectancy. We therefore encourage CMS to expand the list of conditions specified under life limiting conditions to include other non-renal end-stage organ failures.

We also believe that CMS should consider an exception for patients with severe diffuse vascular disease and/or multiple prior failed access attempt(s) in whom attempted placement of an AV access is contraindicated. Including these patients in the denominator may result in the

unintended consequences including restricted access to care or patient harm from exposure to further access procedures.

Hemodialysis Vascular Access - Standardized Fistula Rate – Again, RPA is concerned about the four specified categories listed under limited life expectancy and encourages CMS to expand the list of specified conditions as described above. In addition, RPA has concerns related to the statistical methodology for the "standardization". There are some factors that are well recognized as associated with decreased fistula rates - for example, female sex, which is associated with decreased fistula rates due to smaller caliber of blood vessels - that are not included in the model. Further, it is unclear why some factors are included, such as alcohol dependence and why continuous variables, such as age and dialysis vintage, are included in the model as categorical ranges, which generally decreases model robustness.

Additionally, the strength of the model is relatively poor, with a C-statistic of 0.71, which is considered to be a relatively mediocre C-statistic (the C-statistic ranges from 0.5, which is equivalent to a coin flip, to 1.0, a perfect model; models with a value <0.8 are generally considered to be poor performing with high rates of misclassification). While it can be argued that this is better than the current unadjusted fistula rate, inadequate adjustment may adversely affect smaller units and introduces a degree of lack of transparency. If this measure is adopted, CMS is urged to not only revise the adjustment model, but also subject the methodology to rigorous peer review (as should also be the case for all other models used for calculation of standardized rates -such as for SMR, SHR, SRR, STR). The use of a standardized rate will preclude comparison to rates previously reported and potentially allow "gaming" of the system by aggressive reporting of comorbidities. Finally, RPA is concerned about the "pairing" of catheter and fistula rates described, and believe this needs additional clarification.

End-Stage Renal Disease Access to Kidney Transplantation Measure Development

Percentage of Prevalent Patients Waitlisted – While RPA lauds the goal of increasing access to transplant, we are concerned that this measure falls short, as the dialysis facility only controls a portion of the process for getting a patient waitlisted. The actual listing on the transplant waitlist is beyond the dialysis facility's control and delay or failure to be listed may be due to patient factors or due to the efficiency or lack thereof in the transplant center. Issues of geographic access (or insurance access) may further limit where a patient can be referred. There is also no consideration given to the effect that regional variation in transplant wait times might have on this metric - in a region where wait-times are longer, the percentage of prevalent patients on transplant waitlists should be higher at the same referral and listing rate than in regions where wait times are shorter. There is no adjustment for this. Further, there is insufficient data to establish a "target" level. For these reasons, RPA does not support this measure.

Standardized First Kidney Transplant Waitlist Ratio for Incident Dialysis Patients – RPA again believes the motivation for this measure is commendable, however we have strong concerns over the structure of this measure. For example, the measure excludes patients who were listed for transplant prior to start of dialysis; a facility could therefore be adversely affected if the referring providers are aggressive about referring pre-ESRD patients for transplant listing. Similarly,

differential rates of pre-dialysis evaluation for living donor transplant (LDT) could affect facility performance but may be outside of the facility's control. The statistical adjustment is only based on age, yet there are many other factors that come into play. Finally, the number of incident patients per facility per 3 years may still be very low for some facilities, and using a three year metric makes it somewhat insensitive to QI initiatives. For these reasons, RPA does not support this measure.

As always, RPA welcomes the opportunity to work collaboratively with CMS in its efforts to improve the quality of care provided to the nation's kidney patients, and we stand ready as a resource to CMS in its future endeavors. Any questions or comments regarding this correspondence should be directed to RPA's Director of Public Policy, Rob Blaser, at 301-468-3515, or by email at rblaser@renalmd.org.

Sincerely,

A handwritten signature in cursive script that reads "Rebecca Schmidt, DO".

Rebecca Schmidt, DO
President



February 3, 2016

Andrew Slavitt
Acting Administrator
Centers for Medicare and Medicaid Services
Room 445-G
Hubert H. Humphrey Building,
200 Independence Avenue, SW
Washington, DC 20201

RE: Development of End-Stage Renal Disease Vascular Access and Access to Kidney Transplantation Measures

Dear Acting Administrator Slavitt:

The American Society of Diagnostic and Interventional Nephrology (ASDIN) is the professional organization of interventional nephrologists who focus on procedures that obtain and maintain patient's optimal dialysis access. ASDIN also includes interventional physicians in other specialties who focus on providing dialysis access care. We are writing to provide comments on two of the End-Stage Renal Disease (ESRD) vascular access and access to kidney transplantation measures – the long term catheter rate and standardized fistula rate measures.

Hemodialysis Vascular Access - Long-term Catheter Rate – ASDIN believes the addition of the exclusion for patients with limited life expectancy is appropriate; but is concerned about the limitation of these to the four specified categories listed (hospice care, metastatic cancer, end-stage liver disease and coma or anoxic brain injury). We recommend the addition of one more category of patients – Systolic congestive heart failure with NYHA class 4 or ejection fraction of <15%. Patients with severe systolic heart failure often have low blood pressure that precludes fistula or graft placement due to risk of exacerbation of heart failure and access thrombosis. The most appropriate access for patients with such severe systolic heart failure may be a catheter.

Hemodialysis Vascular Access - Standardized Fistula Rate – Again, ASDIN is concerned about the four specified categories listed under limited life expectancy and encourages CMS add severe systolic heart failure to the list. In addition, ASDIN has concerns related to the statistical methodology for the "standardization" – including the factors chosen and weakness of the model's C-statistic. While it can be argued that this is better than the current unadjusted fistula rate, inadequate adjustment may adversely affect smaller units and introduces a degree of lack of transparency. The use of a standardized rate will preclude comparison to rates previously reported and potentially allow "gaming" of the system by aggressive reporting of comorbidities. We believe that continuing to use the unadjusted fistula rate is a better measure. Finally, ASDIN is concerned about the "pairing" of catheter and fistula rates described, and believe this needs additional clarification.

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Andrew Slavitt
RE: Development of End-Stage Renal Disease Vascular Access and
Access to Kidney Transplantation Measures
February 3, 2016

Page 2

As always, ASDIN welcomes the opportunity to work collaboratively with CMS in its efforts to improve the quality of care provided to the nation's kidney patients, and we stand ready as a resource to CMS in its future endeavors. Any questions or comments regarding this correspondence should be directed to ASDIN's Executive Director, Mary Lea Nations, at 601-924-2220, or by email at mnations@asdin.org.

Sincerely,

A handwritten signature in cursive script, appearing to read "K. Abreo".

Kenneth Abreo, M.D.
President, ASDIN