

Public Comment Summary Report

Project Title:

End-Stage Renal Disease Access to Kidney Transplantation 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) develop Access to Kidney Transplantation measures (Standardized First Kidney Transplant Waitlist Ratio for Incident Dialysis Patients (SWR) and Percentage of Prevalent Patients Waitlisted (PPPW)). The contract name is ESRD Quality Measure Development, Maintenance, and Support. The contract number is HHSM-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 develop quality access to kidney transplantation measures. Specific objectives included:

- Develop quality measures that address important quality gaps across the spectrum of the kidney transplantation process, such as transplant education, referral, waitlisting, and transplant
- Provide input on relevant measures currently used as part of the provider feedback program Dialysis Facility Reports (DFR), including facility waitlisting rate and the Standardized Transplantation Ratio (STR).
- Consider the degree to which performance on a potential measure is under the control of the dialysis facility, as well as the strength of the link between performance on a measure and outcomes that are valued by patients
- Consider issues of data element availability and collection
- Discuss the potential need for exclusion criteria and/or risk adjustment

Information About the Comments Received:

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

Stakeholder Comments—General and Measure-Specific

General Comments

In general, commenters agreed on the importance of improving access to transplantation and commended the motivation for the waitlisting measures. However, many commenters expressed concern about holding the dialysis facility responsible for transplant waitlisting results for various reasons, particularly due to the transplant center's role in determining the waitlist decision. Several commenters highlighted the need for the patient to take responsibility for following through with the wait list process, while others stated that waitlisting is solely the responsibility of the transplant center.

Response: *Waitlisting for transplantation is the culmination of a variety of preceding activities. These include (but are not limited to) education of patients about the transplant option, referral of patients to a transplant center for evaluation, completion of the evaluation process and optimizing the health of the patient while on dialysis. These efforts depend heavily and in many cases, primarily, on dialysis facilities. Although some aspects of the waitlisting process may not entirely depend on facilities, such as the actual waitlisting decision by transplant centers, or a patient's choice about the transplantation option, these can also be nevertheless influenced by the dialysis facility. For example, through strong communication with transplant centers and advocacy for patients by dialysis facilities, as well as proper education, encouragement and support of patients during their decision-making about the transplantation option. The waitlisting measures were therefore proposed in the spirit of shared accountability, with the recognition that success requires substantial effort by dialysis facilities. In this respect, the measures represent an explicit acknowledgment of the tremendous contribution dialysis facilities can be and are already making towards access to transplantation, to the benefit of the patients under their care.*

Several commenters expressed concern that the measures may place significant burden on the dialysis facility, specifically on the social workers. Another commenter stressed the crucial role the nephrologist plays in determining patient eligibility.

Response: *The dialysis facility includes a multi-disciplinary health care team providing care to patients, involving, but not limited to, nephrologists, social workers and nurses, each of whom have particular expertise and contributions to make towards preparing, encouraging and supporting patients for potential transplant waitlisting. It is expected that they will share joint responsibility for activities contributing to successful waitlisting of patients, and accordingly this measure is proposed as directed to the dialysis facility rather than to a specific type of health care provider.*

Several commenters agreed that the dialysis facility plays a role in the waitlisting process; some of these commenters recommended that CMS pursue quality measures in the areas of transplant education and referral rather than waitlisting due to the various factors and barriers deemed to be outside of the control of the dialysis facility.

Response: *The Access to Transplantation TEP recommended for future development quality measures assessing patient education about kidney transplantation and referral for kidney transplant evaluation for ESRD patients. Currently the requisite data for the aforementioned measures are not collected on a national level. Ongoing efforts are planned towards developing methods to do so, with a view towards eventual proposal of related measures.*

One commenter recommended implementing 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.

Response: *We feel that a process that relies solely on attestation of transplant candidacy may be subject to gaming, with the potential to disadvantage patient access to transplantation. We would be interested to hear ideas from the community regarding methods of attestation that might avoid these limitations.*

Many commenters raised a concern that the decision to pursue transplantation was ultimately the patient’s choice, which the dialysis facility is not responsible for. The commenters cited many reasons that patients may refuse to pursue transplantation, such as cultural factors and fears about undergoing surgery.

Response: *We acknowledge the importance of patient autonomy to make decisions about transplantation. However, it is important that patients make informed decisions about their health. Many patients may refuse transplantation out of fears and anxieties that could be allayed with proper education and support about the benefits of transplantation, which can be provided by dialysis facilities. In this manner, dialysis facilities can have a substantial influence on decision-making by patients.*

Several commenters recommended additional adjustments and exclusion criteria relating to biologic factors and comorbidities, such as heart failure, infection, BMI/obesity, active drug and/or alcohol use, and other criteria assessed by transplant centers.

Response: *The issue of comorbidities was debated substantially as part of the Access to Transplantation TEP and there was no consensus with regards to whether to adjust for specific comorbidities and/or for which comorbidities in particular. We wish to re-emphasize that some indirect adjustment or exclusion for comorbidity is included in the current measure specifications in the form of exclusions for nursing home admission and age 75 years or greater, as well as adjustment for age. There were several arguments in favor of not adjusting further for comorbidity that informed the decision about the current measure specifications. Based on the literature, most patients on dialysis stand to benefit from transplantation and in fact it is difficult to identify any subgroups that don’t do better with transplantation as compared with remaining on dialysis. As such, adjustment or exclusion of patients with certain comorbidities risks disadvantaging their access to the benefits of transplantation. Furthermore, certain comorbid conditions (such as the presence of an active infection) may reflect poor care delivered at dialysis facilities*

and therefore may not necessarily be appropriate to adjust for. Another consideration is that in analyses performed by UM-KECC on the SWR measure, a model comparing the current specification to one additionally including comorbidities from the CMS Medical Evidence 2728 Form did not affect performance rankings of the vast majority (nearly 98%) of dialysis facilities. This suggests that the distribution of extreme comorbidity sufficient to preclude waitlisting is not highly imbalanced across dialysis facilities and/or that the current exclusions coupled with age adjustment already account for much of the comorbidity imbalance across facilities.

Commenters also recommended adjustment and exclusion criteria relating to various sociodemographic factors, such as family and social support, medication adherence, ability to seek follow-up care, rurality and/or distance from the transplant center, insurance type and access, and various financial factors such as patient resources that are contemplated by transplant centers. Of note, the majority of commenters recommending adjustment and exclusion criteria for these factors agreed that the measures should not include adjustments for race or ethnicity.

Response: *We agree that financial and other social issues can pose substantial barriers to waitlisting for patients. However, they do not take away from the fact that many patients with these issues will still stand to benefit substantially from transplantation as compared with remaining on dialysis. As such it is expected that dialysis facilities will work with transplant centers, advocate for patients and assist them in overcoming barriers to waitlisting to the extent possible. We also recognize that even with the best efforts, not all dialysis patients will ultimately be suitable candidates for waitlisting. Thresholds for the measures are assessed at the facility level. Examination of facility level measures essentially allows comparison of an individual facility's performance to a consensus standard, empirically set by the achievement of dialysis facilities across the nation. Through comparison with the performance of other facilities, these measures may help individual dialysis facilities identify opportunities for improvement in their waitlisting rates.*

Many commenters called for adjustments for geographic variation. One specific component of this concern pertained to the potential ability for the variation in waiting time to affect the prevalent measure results. For example, commenters argued that facilities in a region with long wait times may “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.

Response: *The specific concern regarding the impact of variations in time from waitlisting to transplantation on the prevalent measure is theoretically valid. We are currently investigating this issue further to determine its impact, though it has not yet been incorporated into the specifications.*

One commenter suggested the incorporation of a sophisticated modeling approach similar to the use of the discharging hospital in the SRR measure, which incorporates both patient

characteristics and external center characteristics. In this case, a similar effect could be implemented in the measures based on the transplant center.

Response: *With regards to adjustment for a transplant center effect, this issue is more complex than adjustments made for the SRR because of difficulties with attribution of dialysis facilities to transplant centers with respect to waitlisting (which as defined in the measures has a denominator at the facility level). Nevertheless, we continue to investigate the possibility of this type of adjustment although it has not yet been implemented.*

One commenter recommended that patients 70 years and older continue to be excluded from measurement.

Response: *The Access to Transplantation TEP debated this issue and consensus was reached to raise the age exclusion to patients aged 75 years and older, as many of these candidates may still stand to benefit substantially from transplantation (see for example, Rao et al. Transplantation 2007;83:1069-1074).*

Several commenters stressed the need to develop similar measures to the ones proposed, but directed at transplant centers and stated that the transplant centers should be required to notify dialysis facilities when patients are added to or removed from the waitlist. Ensuring the kidney transplant centers transmit up-to-date waitlist information to dialysis facilities would allow clear communication with patients regarding their status.

Another suggestion was made to develop a care coordination measure with mutual dialysis facility-transplant center responsibility.

Response: *There are already requirements in place for transplant centers per the CMS Conditions of Participation for communication of waitlisting status of patients to dialysis facilities. See Section 482.94(c): "Transplant centers must maintain up-to-date and accurate patient management records for each patient who receives an evaluation for placement on a center's waitlist and who is admitted for organ transplantation. This includes notification to patient (and patient's usual dialysis facility if patient is a kidney patient) of: 1) Patient's placement on the center's waitlist; the center's decision not to place the patient on its waitlist; or the center's inability to make a determination regarding the patient's placement on its waitlist because further clinical testing or documentation is needed 2) Removal from waitlist for reasons other than transplantation or death within 10 days." (<https://www.cms.gov/Regulations-and-Guidance/Legislation/CFCsAndCoPs/Downloads/trancenterreg2007.pdf>). Although waitlisting measures directed at the transplant center may also be potentially appropriate, the scope of this particular measure development effort was focused on dialysis facilities.*

One commenter recommended an alternative quality measure assessing the number of "active" patients on the UNOS kidney transplant waiting list.

Response: We chose to focus on any waitlisting as opposed to imposing an “active” status requirement as transplant centers vary in the criteria they use to decide on changing the status of already waitlisted patients.

Several commenters expressed concerns about potential unintended consequences related to the measures. These included concerns that patients who are uninterested in, ineligible, or not yet medically stable for transplant may be pushed to pursue transplantation as an option. Others highlighted the potential incentive for dialysis facilities to select patients who are more eligible for transplantation during the dialysis admission process.

Response: We acknowledge that it is important to consider the potential for unintended negative consequences that could result from implementation of the measures. With regards to referral of inappropriate or unsuitable candidates, the transplant center decision-making should provide a check against this. With regards to dialysis facilities limiting admission to patients eligible for transplantation, we would re-emphasize an earlier point that the measures are constructed as a means to allow comparison across facilities. In this way, facilities are being compared to a national standard, with no expectation that all patients should be waitlisted. As with any quality measure implemented by CMS, we intend to monitor for these and other unintended consequences on a continuing basis.

Measure Specific Comments

SWR:

One commenter requested that the SWR be specified as a rate instead of a ratio.

Response: Thank you for your comment. As noted in the Measure Information Form, the SWR measure is specified as a ratio, but can be expressed as a ratio or a rate.

A commenter asked for clarification on how the SWR measure will identify and accurately account for patients who are enrolled at more than one transplant center.

Response: For the SWR measure, only the first waitlisting event will be counted.

A commenter requested clarification on how the SWR measure will account for patients listed on both the deceased and living donor wait list who may be counted twice.

Response: There is only a deceased donor waitlist, and patients are only counted once for waitlisting (regardless of the number of centers at which they may be waitlisted).

One commenter stated that the number of incident patients per facility per 3 years may be very low for some facilities but also noted that the use of a three year metric may be somewhat insensitive to QI initiatives.

Response: There will necessarily be a balance between precision and usability of the measure results. Although a three year aggregation was used for the purposes of the

analyses presented in the specifications, this will continue to be re-assessed to achieve the best balance.

Several commenters questioned the exclusion of pre-emptively waitlisted patients, as a facility could theoretically be adversely affected if the referring providers are aggressive about referring pre-ESRD patients for transplantation. One commenter recommended that CMS additionally develop an alternative measure including incident patients on the transplant wait list prior to starting dialysis.

Response: *We agree that preemptively referring, waitlisting, and transplanting patients prior to the initiation of dialysis is a good practice that should be encouraged; however, as the proposed measures focus on dialysis facilities, they were limited to examination of activities that occurred once patients initiated dialysis. Of note, the prevalent measure (PPPW) does not exclude pre-emptively waitlisted patients.*

PPPW:

One commenter stated that the proposed measure fails to appropriately account for patients who are included on the waitlist and subsequently removed from the list without a transplant.

Response: *The prevalent measure examines waitlisting status monthly, so within the period of examination it will identify patients who were on the waitlist, then removed. For example, if over a 12 month period, a patient was waitlisted for the first 6 months, and then removed, the facility would receive credit for the 6 out of 12 months that the patient was waitlisted.*

Preliminary Recommendations

Based on the comments made, no specific changes to the measure specification will be implemented immediately. However, there will be ongoing investigation into the impact and potential need for adjustment, for the known regional variations in time from waitlisting to transplantation for the PPPW measure, as well as consideration of the possibility of a general transplant center effect adjustment.

Overall Analysis of the Comments and Recommendations

We appreciate the breadth and thoughtfulness of the comments provided. The major theme was concern over the extent to which the dialysis facility is responsible for waitlisting of patients. As discussed in our responses, dialysis facilities do play a very substantial part in most of the activities that ultimately contribute to the waitlisting of dialysis patients. As such, the proposed measures are a strong reflection of the care provided by dialysis facilities for their patients. Two specific concerns raised about the potential need for an adjustment for variations in time from waitlisting to transplant, and for a transplant center effect adjustment, are currently being investigated.

Public Comment Verbatim Report

Date Posted	Measure Set or Measure	Text of Comments	Name, Credentials, and Organization of Commenter	Type of Organization	Recommendations/Actions Taken
March 18, 2016	Access to Kidney Transplantati on Measure Set	See appendix	Maggie Carey, Chair, Kidney Patient Advisory Council, Forum of ESRD Networks	Individual	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	Access to Kidney Transplantati on Measure Set	See appendix	Marianne Moncrief, LMSW	Individual	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	Access to Kidney Transplantati on Measure Set	See appendix	Robin Grande, LMSW	Individual	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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March 18, 2016	Access to Kidney Transplantation Measure Set	See appendix	Anonymous	Individual	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	Access to Kidney Transplantation Measure Set	See appendix	Claudina Ortiz, LCSW, DCI Inc.	Individual	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	Access to Kidney Transplantation Measure Set	See appendix	Anonymous	Individual	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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March 18, 2016	Access to Kidney Transplantation Measure Set	See appendix	Kathleen Williams, LCSW	Individual	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	Access to Kidney Transplantation Measure Set	See appendix	Anonymous	Individual	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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March 18, 2016	Access to Kidney Transplantation Measure Set	See appendix	Sheri Hartman-Levine, MSW, LSW Social Worker US Renal Care - Bedford	Individual	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	Access to Kidney Transplantation Measure Set	See appendix	Anonymous	Individual	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	Access to Kidney Transplantation Measure Set	See appendix	Anonymous	Individual	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	Access to Kidney Transplantation Measure Set	See appendix	Cindy Richards, BSN, RN, CNN, President 2015-2016, 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.

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March 18, 2016	Access to Kidney Transplantation Measure Set	See appendix	Anonymous	Individual	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	Access to Kidney Transplantation 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.

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March 18, 2016	Access to Kidney Transplantation Measure Set	See appendix	Michael J Wierzbinski, LCSW	Individual	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	Access to Kidney Transplantation Measure Set	See appendix	Laura Sandifer, MSSW, CSW	Individual	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	Access to Kidney Transplantation Measure Set	See appendix	Suzanne Pope, MBA, American Urological Association (AUA)	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	Access to Kidney Transplantation 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.

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March 18, 2016	Access to Kidney Transplantation Measure Set	See appendix	<p>Paul T. Conway, President, the American Association of Kidney Patients (AAKP)</p> <p>Stephen Z. Fadem, MD, FASN, Chairman, AAKP Medical Advisory Board</p>	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	Access to Kidney Transplantation 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.
March 18, 2016	Access to Kidney Transplantation 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.

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March 18, 2016	Access to Kidney Transplantation 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	Access to Kidney Transplantation Measure Set	See appendix	Anonymous	Individual	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	Access to Kidney Transplantation Measure Set	See appendix	Jeffrey Hymes, MD, Chief Medical Office & Senior Vice President, Fresenius Medical Services (FMC)	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.



February 3, 2016

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Re: End-Stage Renal Disease Access to Kidney Transplantation 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) Access to Kidney Transplantation 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.

Standardized First Kidney Transplant Waitlist Ratio for Incident Dialysis Patients

ANNA appreciates the efforts of CMS and UM-KECC to increase access to kidney transplantation for individuals with kidney failure. We believe that a successful kidney transplant is the best treatment option for these individuals. People who undergo successful kidney transplants have improved outcomes compared to individuals remaining on dialysis, as measured by mortality, morbidity, cardiovascular complications, and quality of life. ANNA is supportive of all efforts to ensure the equitable placement of transplanted organs to reduce and/or eliminate disparities.

However, ANNA has some questions about the rationale for the standardized first kidney transplant waitlist ratio for incident dialysis patients (SWR) measure specifications. It is not clear why UM-KECC has chosen to include patients on the kidney or kidney-pancreas transplant waitlist who received a living donor transplant within the first year after initiation of dialysis, while excluding deceased donor transplants and patients who are listed on the kidney or kidney-pancreas transplant waitlist prior to the start of dialysis.

One of the overarching goals of nephrology practitioners is to ensure patients are included on the kidney or kidney-pancreas waitlist prior to beginning dialysis. ANNA has concerns with the plan for this measure to exclude patients who are waitlisted prior to beginning dialysis. ANNA also believes it may be difficult for dialysis facilities to determine which of their patients were placed on the kidney or kidney-pancreas transplant waitlist prior to the start of dialysis, which may inadvertently exclude some patients from analysis.

Additionally, ANNA encourages CMS and UM-KECC to consider excluding from the SWR measure those dialysis patients over 70 years of age, as the 70+ patient population is less likely to be referred and accepted for kidney transplantation as compared to younger patients.

The SWR measure, as currently drafted, indicates it will measure patients who received a living donor transplant within one year after initiating dialysis or who are placed on the deceased donor waitlist after starting dialysis. The majority of transplant centers place *all* accepted patients on the deceased donor kidney transplant waitlist, including those with a potential living donor. Since this is the standard practice, there always will be patients who fit both categories, and could be counted twice. To ensure accurate analysis, ANNA urges CMS and UM-KECC to give further consideration to these issues in how this measure may best be implemented.

As development of the SWR measure continues, we encourage CMS and UM-KECC to take into account the variability of each transplant center's acceptance criteria for transplant candidates and the weight given to the urgency or medical need for a transplant. ANNA urges CMS and UM-KECC to consider that not all referred patients will be eligible for transplantation and also to clarify how patients who are enrolled at more than one transplant center will be identified and accurately counted in this measure.

Percentage of Prevalent Patients Waitlisted

ANNA is supportive of the development of a measure for referral for transplant for incident patients. Research studies have shown that earlier transplantation results in positive patient outcomes and decreases the unnecessary utilization of limited health care resources. While we appreciate UM-KECC's efforts to assess ongoing placement on the kidney or kidney-pancreas transplant waitlist among prevalent dialysis patients, ANNA has several concerns about using the percentage of prevalent patients waitlisted (PPPW) measure as a quality measure for dialysis facilities.

Transplantation is a multi-step process that involves many variables, including not only referral by a health care practitioner, but also evaluation and approval by a transplant team. The length of time a patient waits before receiving a kidney or kidney-pancreas transplant varies greatly, partially dependent on organ availability as well as the length of time it takes to complete the patient evaluation. Often, patients are referred and begin “work-up,” but remain in this process for an extended period of time prior to inclusion on the waitlist and/or determination that the individual is not a suitable transplant candidate. Although dialysis facilities have little to no control over the steps of the transplant process, under the proposed measure, a dialysis facility could be held responsible for the delay of a patient’s transplant evaluation. We request CMS and UM-KECC clarify how those patients who are referred to transplant centers by dialysis units but are delayed in their work-up or are deemed not suitable candidates will be excluded by the measure.

ANNA also has concerns that the proposed measure fails to appropriately account for patients who are included on the waitlist and subsequently removed from the list without a transplant. In developing the finalized PPPW measure, ANNA encourages CMS and UM-KECC to address patients who fit within this category.

Additional concerns revolve around transplant evaluations that may result in the identification of barriers to kidney transplantation, including active drug and/or alcohol abuse, noncompliance with medical treatment, active illnesses that would compromise the success of a transplant, obesity, or insufficient social support. Patients are often required to overcome such barriers to be considered an appropriate candidate for kidney transplantation, and would be excluded from the kidney or kidney-pancreas waitlist until such barriers are resolved. ANNA has concerns that under the proposed measure, dialysis facilities would be “penalized” until patients resolve such conditions and are placed on the kidney or kidney-pancreas waitlist. ANNA encourages CMS and UM-KECC to adjust the measure to ensure such delays in listing after referral do not result in penalties for dialysis facilities.

It also is imperative that dialysis facilities are notified when its patients are added to the waitlist. Nephrology nurses provide education and support for transplantation to the patient, their family and support systems, and the community. Nurses are uniquely qualified health care professionals who can educate patients on their transplant status and guide a patient through the transplant process. Dialysis patients often mistakenly believe that they are on the kidney or kidney-pancreas waitlist, when in fact they are still undergoing the process of evaluation and have not received final approval from the transplant team. The dialysis facility or unit plays a significant and meaningful role in periodically verifying the patient’s transplant status.

While the current standard of practice (and transplant center regulations) require the transplant center to transmit the updated waitlist information to the patient, nephrologist, and dialysis facility, in many circumstances, the dialysis facility is not notified when one of its patients is added to or removed from the waitlist. Ensuring the kidney transplant centers

transmit up-to-date waitlist information to dialysis facilities would allow clear communication with patients regarding their status.

Finally, we encourage UM-KECC and CMS to consider the development of quality measures that measure the frequency with which transplant education is provided to patients who may be eligible for kidney or kidney-pancreas transplantation.

Conclusion

ANNA greatly appreciates the opportunity to share our comments on measures related to the ESRD patient's access to kidney or kidney-pancreas transplant. As the leading professional association representing nephrology nurses, we look forward to continuing to work with you 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

Aloha,

I am definitely in favor of coordinated efforts to offer the option of transplant to patients, specifically between the transplant centers and dialysis facilities. Many of those efforts are occurring as we speak.

However, I disagree that the dialysis staff, specifically the Social Worker, should be responsible for the # of referrals or listings. For a referral, if a patient and/or nephrologist refuses, then the process is stopped at that point. For a patient to get listed, there are multiple variables out of the control of the dialysis facility. I would suggest that a "transplant navigator" be assigned to each potential referral, since the process can be quite daunting for even resourceful patients.

Mahalo for your time and please feel free to contact me, if you have any further questions.

Hello, I would like to provide comments regarding the Project Title: End-Stage Renal Disease Access to Kidney Transplantation Measure Development.

I am a social worker at two dialysis clinics in Ohio, speaking for myself and not my employer. I have been in this field for 12 years and have worked for three dialysis corporations, and seven different dialysis clinics over the years.

I do not think the overall purpose of this project is a bad thing- if the purpose is to gather data and to address regional variations, procedural issues, and so on. However, there has been talk on the CNSW listserv that these measures will eventually be used to rate dialysis facilities on the numbers of eligible dialysis patients that are listed and the time it takes for eligible patients to get on transplant waiting lists. From my standpoint, that seems to be going against one of our operating principles, which is to empower patients to make their own decisions and direct their own care. Besides that, so much of what it takes to get patients waitlisted is completely out of our hands, and it seems odd that placing the burden on the dialysis clinic is even being considered.

The interdisciplinary team at the dialysis clinic is mandated to educate all patients about all treatment modalities, including transplant. We do this throughout the year, but are at least "officially" required to do this initially (within 30 days of admission) while completing a care plan with the patient, again in 90 days (with another care plan), and then annually after that. In addition, modality options is part of our monthly educational topics- again, it is mandated that we provide monthly education to all patients, and one of those topics include transplant. If a patient is interested in transplant evaluation, we refer them and provide the information the transplant center needs to begin the evaluation. We refer ALL patients interested. We have many patients who are interested with barriers to transplant- weight, comorbid issues, insurance issues- and we refer them. We have many patients who have no barriers to transplant, but for various reasons are opposed to a transplant evaluation. We educate them to the best of our abilities. We discuss their concerns, their fears, their experiences, and try to help them work through their preconceptions so they can see transplant as an option. We encourage them to simply make an appointment and meet with the transplant team to learn more and begin the evaluation process, and explain that even if they are screened and approved for the transplant list, they can change their mind at any time and ask not to be listed. So, we do go to great lengths to try and get all of our patients to understand their treatment options, and encourage them to pursue the option best suited to them, including transplant. However, ultimately it is the patient's choice, and there have been many perfect candidates who choose not to seek a transplant. Sometimes it is because they know someone who has had negative transplant experiences, or they themselves have had a failed transplant and choose not to try again. Sometimes it is because of the increased risk of cancer, or the fear of surgery, or the stories of antirejection medications costing thousands of dollars a month. Sometimes it is because they feel content with their current modality, or feel they are too old of a transplant and want to "let a younger person have that kidney." There are

many, many good reasons and not so good reasons, and we at the dialysis clinic have limits to our powers of persuasion.

Also, in my area, it is really, really challenging to get on a wait list. I work with four transplant centers and they all have different criteria, different evaluation procedures, and different standards for how they interact with the dialysis clinic and the patients. Even when a patient is incredibly persistent and does everything possible to speed up the process, it still moves along at a slow pace. The clinic has no control over that. In fact, a couple of the transplant centers discourage us from calling them to check on the status of an evaluation- they think the patient should be the one making that phone call. The way they see it, the more the clinic does for the patient, the more dependent the patient is on us- and they question the patient's ability to take care of themselves after a transplant.

Finally, what we consider a good candidate for a transplant at the clinic level does not always match what the transplant center thinks. In the past year, I have had one guy placed on the hold list because of psychological issues (he has had a diagnosis of PTSD and depression for 25+ years, has been attending a support group weekly for years and taking antidepressants which he states helps manage his symptoms; he has dealt with chronic illness for 20+ years, had no adjustment issues when starting in-center hemodialysis, had plenty of family support, and based on past performance, would have done just as well adjusting to a transplant- but the transplant center stated he needed to see a psychiatrist and counselor for six months, and then do the whole evaluation process again.). I had a 67 y.o. healthy patient who had been listed at the same center for almost 5 years, removed from the waiting list because their criteria changed, and they no longer list anyone over 60, diabetic, and who has another comorbid (in his case, he had a heart attack over 20 years ago, and no heart issues since- but because of that heart attack he was diagnosed as having heart problems.) I have had several patients placed on hold because of infections (but most of them were never in a nursing home, so would not be excluded from being counted in your measure, as far as I can tell). I have had several patients play phone tag with transplant intake workers for months.

Currently I am working with a patient who is a young, healthy, perfect transplant candidate, but she has been in the process of a kidney/pancreas transplant evaluation that has literally been taking years. First it was a matter of getting all her testing completed, which I estimate took 8 months. Then her friend who was a potential candidate had to be tested, and ended up not being a good candidate. (another several months.) Then her case was put in front of the committee (which incidentally meets once a month), and the surgeon determined she needed to lose 30 pounds before being listed. She was under the recommended BMI, but because of the distribution of her body fat, he wanted her on the lower end of the recommended BMI. The patient has been diligently dieting and exercising, but her weight loss has only been about 1-3 pounds a month. I called when she had lost around 25 pounds to report her weight loss and to see if they maybe would go ahead and take her case back to the committee to re-evaluate and get her on the wait list. I was told no (and that the patient should be calling to ask this, not me). She is

now 3 pounds away from what they are considering her optimal weight, and they decided to go ahead and review her. Last week, the patient told me that the financial coordinator called her to let her know the current hold up is that she has not explained what her plans are once her current COBRA policy ends. The financial coordinator told her to look into it and call back, and he would update the committee- and then they would review her case. The committee meets once a month, so this is yet another month this patient is not on the waiting list. There is absolutely no issues with her insurance. She has Medicare (which, as you know, will cover her for 3 years), and if she is not able to get secondary insurance once her COBRA ends (which in the state of Ohio, she probably will not have any options), she will be income eligible for Medicaid. It has been a frustrating experience for the patient and for the dialysis staff, but as I hope I have proved, it has not been anything that we could have prevented or changed. The patients ultimately are the ones who choose which transplant center we send their referrals to (and sometimes their insurance decides that). So if a patient chooses to go to the closest transplant center, as opposed to the center that gets patients on the waiting list the quickest, or the transplant center with the loosest criteria, we can't prevent that.

If you would like any more information or specific case examples, please feel free to contact me. As I said, I don't believe that the information you are gathering is unhelpful, but if it is being suggested that the reason patients are not on transplant waiting lists, or the length of time it takes for patients to get there, is because of the dialysis clinic staff - I stand behind my experience of being a very small factor of that problem.

I have been a dialysis social worker for over 25 yrs. I do not feel a dialysis unit should be held accountable for whether a patient becomes active for a kidney transplant. I do think it is the responsibility of the dialysis facility to provide the education and referral for transplant even if the MD does not agree that the patient is a dialysis candidate. Patients should also be given information about all the transplant centers in their area not just the one the MD is interested in patient attending. The dialysis unit should also be willing to draw the circulating antibodies as long as the transplant center or patient is responsible for the shipping cost .The dialysis facility should also not be held accountable if the patient or transplant center do not do the necessary testing and/or follow up for patient to become active. Dialysis is a choice and so is transplant. Patients need to be educated about this choice but the dialysis facility should not be penalized if patients do not immediately want to be referred for transplant. I do think nephrologist do need to do better with referring patients to transplant prior to starting dialysis as through the years I have had several patients tell me their dr said to wait until after starting dialysis before being referred.

I have great concerns regarding the proposals for ESRD Access Kidney Transplant Measure Development which makes dialysis facilities accountable for the transplant wait listing of dialysis patients.

While referral, education and collaboration with the transplant facility are important at the dialysis facility level, it does not seem reasonable to place a measure on the dialysis facility that makes them accountable for transplant listing.

It would seem appropriate that in regard to transplant listing there is a mutual accountability in addition to increased collaboration and an exchange of information between the transplant facility and the dialysis facility to accomplish wait listing. The measure that indicates that the dialysis center have accountability for transplant listing could have negative impact on patients in the dialysis the facility who are not transplant eligible. These patients, who may have multiple comorbidities and complex psychosocial needs, may receive fewer interventions at the dialysis facility due to the mandated focus on transplant listing and the unrealistic expectations this places on the dialysis facility. Additionally, this could lead to dialysis facilities selecting patients who are more transplant eligible during the dialysis admission process.

While people may think that this is unlikely to happen, my experience is that the reality is different from the ideal.

I support the measure that would create a system for dialysis facilities to be able to report education about transplant and appropriate referral. Even though this may take some time to create, it is better to have a reasonable system that works than to rush into having a system that is untenable to manage only because the data exists to make it happen now.

As a nephrology social worker of 32 years and past Chair of the Council of Nephrology Social Workers, I am a strong advocate of quality of life for CKD/ESRD patients and modality education including transplant.

I hope that this Panel will take a step back and review concerns brought forward in terms of real-life implementation of dialysis facilities being accountable for transplant wait listing of their patients.



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

To Whom It May Concern:

I would like to comment on concerns I have over making dialysis units accountable for their patients being accepted/waitlisted for transplant. To preface, I have been working in the dialysis setting for over 12 years and am the current chairperson for the local chapter of the Council of Nephrology Social Workers here in Central Florida. Over the years I have been involved with dialysis patients I have come to understand that this population has an enormous amount of challenges to face. All patients will tell you they hate dialysis to varying degrees. At the same time many will say they are not interested in transplant. Their reasons vary from fear of surgery, to concerns over side effects of the transplant drugs, to not wanting to lose their disability benefits. Here in Central Florida the transplant referral process can be somewhat cumbersome. Patients are required to have all pretesting done before the application will be considered. Stress test, colonoscopy, mammogram and PAP Smear results all have to accompany the application before it will be accepted. I educate my patients at least once a year, (those that are under 65 are approached more often) on the transplant process. The transplant centers encourage patient involvement to the point of telling the dialysis units to make the patients responsible for arranging all appointments and following up with them. The idea being patients that can manage the pre-transplant hurdles will better manage their post-transplant care. I would have to agree with that philosophy. We at the dialysis units are treating adults. As adults they need to be involved in their care. They also need to be responsible for their actions. Our responsibility is to educate, teach them how to navigate through the process and encourage/support them through the process. We cannot force the issue, penalizing the dialysis units for patients not wanting to have a transplant or for being noncompliant with the process is unfair. CMS is already skirting around the problem of too many patients on dialysis who should not be by penalizing hospitals/doctors/dialysis facilities through ever tightening standards so they will not have to pay as much instead of putting restrictions on who should be eligible for treatment. A better study would be how to help doctors come up with a standardized tool for determining who should be offered dialysis and who should not. Thank you for your time and consideration in this matter.



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

I have been a dialysis social worker for 30+ years and have always been involved in the referral process for a transplant. Over that time I saw many changes in all areas - from the actual evaluation process going from a two-day visit to the transplant center to a one day intensive evaluation; to the age restrictions being eliminated as to not only who can receive a kidney but also at what age someone can donate a kidney; and excluding a patient due to compliance issue. But the biggest and most beneficial change occurred when the transplant center made the PATIENT more responsible in their own care - including getting a transplant!

Before, we at the dialysis level did everything for the pt... from making the referral to scheduling the tests required to making sure the test results were received by the transplant center. Hell, I even drove someone to their transplant evaluation 2-1/2 hours away! But in the end it was determined that once transplanted all those "little helpers" in dialysis went away and the patient did not know how to negotiate the health care system!

It seems like "back tracking" to once again hold the responsibility to get a patient waitlisted for transplant on the dialysis unit. I have many patients in various stages of the referral/evaluation process at this very moment. I don't feel it is the dialysis unit's mission in life to make sure the patient with a BMI of 48 loses all their weight so their BMI is an acceptable level to be waitlisted. We can educate them on weight loss till we are blue in the face but unless that patient learns to become responsible for their own path in life and at least attempts to lose even a fraction of their weight - that responsibility must fall on the patient!

Another example is that I have a patient that cannot be waitlisted until he has a reliable car (per the transplant center). The patient is a mechanic and prides himself on his ability to fix up old cars. But with old cars you do have break downs and this particular patient does hit a deer or two every year. How is the dialysis unit responsible for this otherwise suitable candidate to be waitlisted for a transplant? Perhaps the transplant centers, themselves, have become too strict with the more "social side"?

I must add, however, that I know that the social issues must be dealt with because I have seen, firsthand, transplant patients lose their kidney due to social problems such as insurance issues, compliance issues etc.

Not sure why this is even looked at... I educate EVERYONE that initiates chronic dialysis at our center no matter what the age on the subject of transplant. I revisit the subject a couple times a year - no matter how long someone has been on dialysis and no matter if they told me they were not interested in transplantation in the past. Perhaps other units are NOT providing this education... I won't know.

Perhaps it should be noted somewhere the percentage of patients approached and refusing a transplant. I have had various reasons why someone (who otherwise seemed to be a suitable candidate) refuse... from stating they know they wouldn't be able to remember to take their medications to religious reasons to feeling blessed that they "lived this long" and wants a kidney to go to a younger person.

All in all, by holding the dialysis unit responsible for waitlisting the patients for transplant feels like I'm back in the 1980's again - only with less staff assistance and more governmental controls!!!!

Sheri L Hartman-Levine, MSW, LSW
US Renal Care - Bedford

Good Morning,

I am a dialysis social worker at a very small clinic in rural Wyoming. We work with two separate transplant centers with our patients. Our patients are self-referred but I do follow up with them. Our staff does an excellent job sending labs and other information to the transplant centers, but do not have the time or expertise to get a patient wait listed. This responsibility should stay with the Transplant as they are experts and they should be held accountable.



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

February 5, 2016

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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).

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

February 5, 2016

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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

At our center, I educate patients on the option of transplant. If they are interested they are told to speak with the nephrologist who has asked that he be consulted re the suitability of a given patient for transplant.

We have an elderly population, many with multiple co-morbidities.

We have had patients dropped from consideration because of their own failure to follow up with the transplant center.

To me the dialysis facility's responsibility regarding transplant should be to

- 1- Educate patients and families
- 2- Facilitate referral to transplant by forwarding medical information as needed
- 3- Remind patients the importance of communication with the transplant center and of going to all appointments
- 4- Drawing labs as requested by the transplant center

It is unrealistic, however, to expect that the doctors, nurses, and social workers at a dialysis unit have the ability to make sure a patient is listed for transplant. Too many of our patients have been put on hold due to: the need to stop smoking, to lose weight, to raise funds for post transplant meds., to stop any form of substance abuse.

Medical personal can educate dialysis patients, but we cannot control their actions and force compliance with medications, treatments, or meeting appointments for tests, or to meet with the transplant teams.

Please remember that each person has the right to refuse treatment, cancel appointments, and live their own life. We can only educate and help them understand the impact of their personal decisions.

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Brooklyn, NY

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Louis Diamond
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Washington DC

Cynthia Kristensen, MD
Castle Rock, CO

Forum Coordinator

Dee LeDuc
Birchwood, WI

January 21, 2016

RE: Call for Public Comment on Access to Transplantation Measures

The Forum of ESRD Networks appreciates the opportunity to submit comments on the proposed measures for Standardized First Kidney Transplant Waitlist Ratio for Incident Dialysis Patients and Percentage of Prevalent Patients Waitlisted from the work of the Technical Expert Panels convened by CMS and the University of Michigan Kidney Epidemiology and Cost Center; measures that will be considered for future inclusion in subsequent rule making for the Quality Incentive Program. These comments are representative of the patient voice and perspective and were generated by members of the Kidney Patient Advisory Council (KPAC) of the Forum.

The KPAC is pleased with the focus on improving the transplant referral process for dialysis patients – a process which is often incomprehensible and intimidating to patients who are experiencing the challenges of physical, emotional and cognitive loss. We agree that this process may best be monitored by units. Our particular attention was drawn by two conclusions:

CONCLUSIONS: Even patients with low function appear to live longer with kidney transplantation versus dialysis.

CONCLUSIONS: Listing and transplanting those with considerable co-morbidities is also cost-effective and achieves substantial survival gains compared with the dialysis alternative.

These conclusions quantify the thoughts of the KPAC and, indeed, the dialysis patient population as a whole. We offer our thanks for being able to bring these issues into consideration.

There are, however, two concerns that we feel must receive considerable attention before the measure can be implemented:

1. Adequate and unbiased staff and patient training will be the primary factor in the success of this program. Incomplete and/or conflicting information may do more harm than good in achieving these goals. We feel that a well-trained point person at each unit could prove to be a valuable tool. We also feel that clear, concise hand-outs should be available for patients. These can be used to explain the steps involved, decisions to be made, and define the terminology patients will be faced with – referral, listed, evaluation, etc. While these terms are commonly understood in the medical community, they can be very confusing to patients and lead to misunderstanding of where they stand in the process.

2. It must be noted that not all dialysis patients have an interest in pursuing transplant for a variety of reasons. One issue that is not reflected in the SWR is the issue of patient centered care and shared decision making. If a patient, who otherwise would be an eligible transplant candidate, simply does not want to pursue a transplant, how far should the unit go to push the patient to consider a transplant? At what point will a unit be sanctioned because they are respecting patient choice? Will some units simply list patients as being uninterested in a transplant without trying at all in order to reach their numbers while others might try to push a patient into making a decision contrary to their personal values? Both of these scenarios will affect the waitlist ratio without achieving the intent of the goals established by CMS.

With these concerns adequately addressed, we feel that this measure can be a very positive move in helping patients achieve the best possible health.

Sincerely,

Maggie Carey

Maggie Carey
Chair, Kidney Patient Advisory Council
Forum of ESRD Networks

Derek Forfang

Derek Forfang
Vice-Chair, Kidney Patient Advisory Council
Forum of ESRD Networks

As a renal Social Worker, I would like to comment on the ESRD Access to Kidney Transplantation Measure Development. I have over 20 years of experience working in dialysis and also cover for our kidney transplant social worker. While I recognize the significant importance of educating all dialysis patients about transplant and assisting with getting a referral, I have concerns with CMS possibly holding dialysis facilities accountable for getting their patients wait listed for transplant.

We routinely track statistics regarding the transplant status of our patients and address this in our monthly QAPI meeting, but there are a number of factors that play a role in how many patients actually follow through with the requirements necessary to be listed for transplant. Additionally, many patients express valid concerns about their ability to pay the cost of post-transplant medications, especially since Medicare coverage for the immunosuppressants ends 36 months after transplant.

The primary reasons I see that patients are unable to get listed include the following:

- BMI is too high
- Financial concerns
- Medical co-morbidities

Many patients have difficulty with weight loss for their BMI to meet the transplant criteria. Some patients request referrals to transplant facilities that allow a higher BMI, but they often have to travel out of town, or more often, out of state and many patients lack the financial stability to pay for transportation and lodging to travel several hundred miles to a transplant facility for the transplant workup. Not only do they need to pay for transportation and several days of lodging, but once they are listed, they have to go through the work up annually. Many of my lower income patients do not have the financial resources to go through this.

The financial concern for patients also limits their pursuit of a transplant since many patients will lose their Medicare coverage 36 months following the transplant and then will have no means to pay for the extremely expensive transplant medications. The transplant workup requires the patient provide documentation from the dentist that they are free from oral infection. Many of my patients cannot afford to get routine dental care and once they do see a dentist, they may require several thousands of dollars of dental work before they can be listed. There are extremely limited resources for low income adults to get dental care in the community. Typically, patients who struggle to pay for the dental workup are also likely to experience financial concerns with post-transplant medications.

While we are fortunate to have 2 transplant facilities in our community, the distance patients must travel to a transplant center must also be considered. Following the transplant, the patients

require close follow up and often must stay near the transplant hospital for several weeks after they are discharged from the hospital. If a patient must pay for lodging for several weeks it becomes financially infeasible for many low income patients to consider a transplant unless they live within the immediate vicinity. Following surgery our patients cannot drive, so they must have someone stay with them which can also be a concern if the caregiver also has to miss work and lose income for the weeks following transplant.

More and more of our dialysis patients are sicker and older when they begin dialysis. While patients can be referred for transplant up to age 80, many of our patients have significant cardiovascular problems or other co-morbidities that make them poor candidates for transplant.

Of course we recognize the immense benefits to patients that do get a transplant and we celebrate their victory over their illness. However, there are multiple factors that must be considered in the decision of whether or not a patient decides to pursue a transplant. One patient recently elected to not go through with the transplant work up because coming to dialysis provides socialization for him living alone and he has limited opportunities for human contact. This patient has been on dialysis for 14 years and feels we are almost like family.

Obviously CMS sees the benefit of transplant to patients and we will continue to help as many patients as possible work towards this goal. However, I think it would not be appropriate to penalize dialysis facilities if patients do not get wait listed.

Thank you for your consideration of my concerns.



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
Centers for Dialysis Care
DaVita
Dialysis Clinic, Inc.
Dialysis Patient Citizens
Fresenius Medical Care
Fresenius Medicare Care Renal Therapies
Greenfield Health Systems
Keryx
Kidney Care Council
National Renal Administrators Association
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 sequellae. 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

To whom it may Concern,

As a dialysis social worker of 2 years. I am concerned about being tasked with listing patients for transplant. I have seen over my last few years that there is a lot I do not know about transplant. I would be working out side of my knowledge base. One of my reasons for not supporting this is that dialysis centers are not represented on transplant committees and have no say in the decision to list patients. Also think of the damage that will be done to our ability to help our patients if they are not listed and we are responsible. I have to maintain a relationship with my patients to be able to help them on an ongoing bases. Please leave this in the hands of the transplant centers.

Entered on 02/05/2016 at 09:46:21 EST (GMT-0500) by spope@auanet.org:

The American Urological Association (AUA) appreciates the opportunity to comment on the measure on End Stage Renal Disease Access to Kidney Transplantation. It is important to track the number of patients at dialysis facilities who are on a transplant waitlist and determine if patients are being appropriately referred for transplant evaluation. The AUA supports kidney transplantation for patients with ESRD who are medically suitable for kidney transplantation as this can extend their lives and improve quality of life.

The ideal situation would be to have patients with progressive renal insufficiency and a GFR of less than 25 be referred for transplantation evaluation so they can be listed for renal transplant when the GFR is less than 20. This would potentially increase the number of pre-emptive kidney transplants and reduce the need for dialysis which is a very expensive and morbid endeavor for patients. Based on individual circumstances, living donors could be evaluated, or if necessary, dialysis access can be placed before the patient requires renal replacement therapy.

However, due to the complexity of insurance in the United States this becomes very difficult to monitor and enforce. Many patients do not have a nephrologist until after the need for dialysis is determined. Improved screening and treatment of hypertension and diabetes could have a major impact on reducing the risk of ESRD and the need for transplantation. Unless the patient is in a managed care environment, organizing this type of care is sporadic. All dialysis units are required to have a social worker and dietician. These positions need to have adequate funding to deliver the very important information regarding the risks and benefits of dialysis and organizing early referral to a transplant center.

Transplant centers also have wide variability in terms of criteria for listing on the national waiting list. Some centers will not accept complex patients with a significant history of prior surgery. The most accurate measure would be the number of patients who are "active" on the UNOS waiting list.

Again, thank you for the opportunity to provide comments on this important measure. Please let me know if you have any questions.

Suzanne Pope, MBA
Director of Quality
American Urological Association
1000 Corporate Boulevard
Linthicum, MD 21090
410-689-4026
[AUA2016-EmailFooter-Reg]<<http://www.aua2016.org/>>

I am commenting on behalf of myself and not the organization I work for.

In regards to dialysis center being responsible for listing a patient for transplantation, I feel the dialysis center should not be held accountable for this for many reasons:

The dialysis center is not represented on the transplant committee. We have absolutely no say as to whether or not a patient is approved by the transplant committee to be listed.

Patients have the right to decide for themselves whether or not they want to pursue a transplant. We can educate over and over but cannot force them to do an evaluation or have the surgery despite them being a wonderful candidate.

Dialysis centers cannot get every patient fully insured for transplant and cannot keep them fully insured post-transplant. The transplant centers I work with tend to refuse to work with patients who are not fully insured (i.e, will not work with patients with Medicare only). I will send in the request for evaluation for Medicare only patients but the patients usually receive a letter stating their evaluation is put on hold until they obtain supplemental insurance.

I am in a rural community and the closest transplant center is a two hour drive. This alone is a big barrier to my patients pursuing transplantation. If they cannot get there for the multiple evaluation appointments, then they can't get there for the surgery or all of the follow up appointments. The cost for one trip via a transportation service is very expensive (\$300-400) and my patients simply can't afford it. I can't secure funding for one trip much less 15 trips to the transplant center. I have several patients that would be good candidates and have transportation but they will not go to a big city. They don't like driving on the interstate and don't like big city traffic. I explore family members and friends who could go with them but they will not do it and this again speaks to the patient's right to choose.

I do feel responsible for educating patients, assisting them as they request with the evaluation process and as the transplant center allows me to assist, and communicating with the transplant center as needed. I send the paperwork in for any patient that requests it but what happens beyond that point is out of my control. I can't force a transplant center to see a patient or put them on the list. I agree with requesting evaluation for every patient that is interested in transplant but I do not feel it is appropriate to do this for every dialysis patient as this takes away the patient's right to choose and then burdens transplant centers with unnecessary appointments. Transplant is a wonderful option but it is not for everyone.

Laura Sandifer MSSW, CSW



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

I am writing to add a comment to the proposal of CMS rating units on their ability to get their patients listed for transplant. First I want to say that I fully believe that transplant is the best treatment for most patients. At our facility all of our staff make efforts to educate and encourage all patients to pursue transplant. However, our percentage of patients below the age of 70 that are listed is well below the national average.

We are in a rural community and the majority of our patients are Native Americans. This presents two barriers for us. The first is that the traditional culture does not support receiving a transplant from another individual. The belief is that this can lead to "bad spirits" and more problems in life. Secondly, we are anywhere from two and a half hours to six hours away from the transplant center. Our New Mexico patients can go to Albuquerque which has the two transplant programs in New Mexico. Our Arizona patients go to Phoenix for services. Being able to access transportation and housing so far away raises a barrier.

This also leads to the third major barrier for our patients. The majority of our patients qualify for some form of Medicaid and thus are at or below the poverty level. Some of those can access transportation through their Medicaid programs but most cannot. Additionally, the level of poverty makes it extremely difficult to access a care giver for post-transplant since family members can't afford this cost. Most jobs here are not salaried positions that allow people to use FMLA benefits. Self-employment is a major source of income for patients and family members and thus taking time out of work to be a care provider is not feasible.

While there are some programs that can provide some financial assistance, they are not sufficient enough to overcome this barrier for our patients. Transplant status, referrals, and barriers are topics covered at all of our quality improvement meetings. We have tried different ways of educating and encouraging patients with no changes to our transplant listing rates.

While I would dearly love to see more patients in our area receive transplants, there are major barriers that we are not always able to overcome. That is why I feel that the percentage of patients listed for transplant is not a true reflection of a unit's interest in transplant or their efforts on behalf of their patients. Each area is unique and has its own barriers to address. CMS needs to take this into consideration when looking at transplant. The national average for patients on the wait list is not applicable to our area due to the barriers listed above.

Thank you for your time,

To Whom It May Concern:

I am writing as an individual regarding public comment on ESRD Access to Kidney Transplantation Measure Development. I have worked as a dialysis social worker for the past four and half years, and another twenty years employed as an outpatient hospital social worker. With over 34 years of experience as a Social Worker I have learned two important lessons.

One, to give individuals the right of self-determination. Two, some individuals no matter what their goal may be or what they said does not match their behavior. I am not in agreement that the dialysis clinics be held accountable for the wait listing of kidney transplant patients. I educate my patients about their treatment options and encourage them to think about which treatment option matches their lifestyle and life goals. As I listed above, I allow the choice of self determination with my dialysis patients. Many are not interested in receiving a receiving a kidney transplant. They are satisfied with pursuing the treatment option of dialysis and not kidney transplant. There are various reasons why they are not interested such as various health issues and many are elderly.

Two, some of the patients say they are interested but after they have completed the application, then attend the education classes which explain about kidney transplant they tell me they do not have the energy to attend to the many appointments which are required for the evaluation. Some patients have many medical appointments, the transplant evaluation appointments become lost in the shuffle of keeping medical appointments. At times, patients forget they had a kidney transplant evaluation appointment so it must be rescheduled, then later they may forget about that appointment or another pressing appointment may have to be attended to. Hence the patient becomes lost in the shuffle of appointments. I have encounter patients who are being evaluated but lose the information about the transplant center and don't remember who their coordinator is and don't know how to reach them. Also, I can count on both hands the number of times patients have asked for second or third transplant application because they lost the first application I gave them.

In summary the dialysis clinics should not be held responsible and or accountable for the wait listing of dialysis patients. There are too many variables which are out of the hands of the dialysis clinic and staff.

Thank you for allowing public comment on this important matter.

Sincerely,

Michael Wierzbinski, LCSW
Social Worker
FMC/Dallas Central

I would think that the dialysis patient waitlist is already being monitor by the kidney transplant hospitals. Why would it be necessary to collect more stats?
Thanks for asking us to submit our comments, I appreciate it. -

Just a few thoughts from a nephrology social worker. The ID team educates and refers patients to transplant with MD as the person who decides if patient is well enough for referral. After referral, it is the patient that needs to be responsible for following through or not. Testing and follow up can be a grueling process but it must be patient driven. It is their motivation that is the necessary ingredient for success.

We cannot expect social workers to be held responsible for individual patient decisions and follow through or lack of follow through.

on transplant referrals.

Robin Grande LMSW

As a renal social worker who has worked in both the transplant setting and in dialysis facilities for different companies, I do not believe the responsibility of the amount of patients waitlisted for transplant should fall on the dialysis social worker. Patient population of course plays a big role in the number of possible patients to be referred. If all of our incident patients for a six month period, for example, are residing in SNF's and/or have multiple medical issues to preclude them from being candidates, then there is no rational manner in which to place a quota on transplant referrals.

I have found that most of my incident patients have not been educated about the transplant process. Education and referrals should be a multi-disciplinary effort. Although we are fortunate in my area to have several transplant centers relatively nearby, they each come with varying criteria - certain insurances are not accepted at some centers and testing processes and requirements vary. Transplant is not for everyone, we can't simply refer for the sake of referring. Many incident patients do not have the physical capability/stamina to complete the necessary testing required for transplant referrals. One of our local centers required all testing to be completed prior to submitting to an application. Barriers include financial costs of co-pays, deductibles, taking off work for caregivers. Another barrier to being waitlisted is financial constraints. Two of our local centers require most of our patients to provide proof of savings prior to continuation of the evaluation process.

Prevalent patients seeking referrals for kidney transplant has been rare in my experience. Many of these patients have been out of the work force and rely on disability benefits. Disability and Medicare in most cases will be terminated after a certain time frame post-transplant. I have been told by many patients that the fear of such loss of benefits/safety net does not motivate them to pursue transplant.

Patients have a right to self-determination and pursuing a transplant and meeting all the requirements ultimately rests with them. In the end, the dialysis social worker can provide education, support, guidance and resources to assist patients with the transplant process.

I hope this input is related to what the research is looking for. Please feel free to contact me if any information is needed.

I am writing to comment on Project Title: ESRD Access to Kidney Transplantation Measure Development; Contract name: ESRD Quality Measure Development, Maintenance and Support; Contract # HHSM-500-2013-130171

I have been a renal social worker in Texas for over 20 years. I have worked in the dialysis setting as well as the transplant setting, in both pre and post transplant environments. Today I continue to work in the post transplant setting.

I was able to review the research presented with this proposal. I have read the attached files to explain the reasoning for tracking this data. If I am understanding the proposal correctly, it would be the responsibility of the dialysis center to make sure the patient that is getting worked up for Kidney or Kidney/Pancreas transplant gets waitlisted. If this is a correct interpretation, I do not agree that the dialysis center should have this responsibility. I agree that it is important that dialysis patients get worked up and waitlisted in a timely manner, however, I do not believe that the dialysis center, particularly the social worker, should be the one to "own" this responsibility.

The social worker has responsibility to address psychosocial concerns for all of his/her patients on dialysis. Part of this is working to help patients become educated about transplantation, and to address psychosocial issues that may prevent their being ready for a transplant, such as referral for vocational rehabilitation, addressing depression and lack of social support. However, if dialysis facilities will be "assisting patients with completion of the transplant evaluation process and optimizing their health and functional status to get listed AND continuing with ongoing evaluation activities to stay listed" this would be a full time endeavor for several team members! Many dialysis patients are NOT transplant candidates and would not be able to get the same care and service from their team with this mandate in place.

What is described seems to be the focus of the PRE-TRANSPLANT team at the clinic or hospital where the work-up is being done. That team should have the responsibility of helping the patient understand what needs to be done to become and stay waitlisted. Certainly there is coordination of care with the dialysis team to bring this about, but it should not be the dialysis team's responsibility.

In order for a transplant to be successful long-term, the patient must have the ability to follow through with their care. Ultimately, getting listed should be between the patient and the center/hospital that does the work-up in coordination with the dialysis center. It could be argued that the way the patient responds to the things requested of him/her by the pre-transplant team, in order to be listed, will be an indication of how responsive they are to follow up and thus, a successful long term transplant.

I appreciate the opportunity to comment and I appreciate the impetus brought forward by the research that has been done, to help patients get ready for a successful transplant; however I do not believe burdening the dialysis center with this responsibility will result in better prepared patients.

We have a facility whose rural population is largely over 65 years of age. Several are even over the age cutoff for the nearest transplant hospital. We provide our patients with the tools they need to pursue a transplant, and if they choose to do so, then that is their right. However, it should NOT be the responsibility of the dialysis unit to get people waitlisted. That is up to the patient, and places unnecessary burden on the unit (likely the Social Worker) to use their already limited time to meet a regulation just for the sake of doing so. Not every patient wants a transplant! Not every patient can get a transplant! Don't make this a requirement. We already want the best for our patients, and we educate them about it. For those who look to be great candidates, we do what we can to support evaluation.

I am writing to express concern that Dialysis units are being evaluated for getting patients waitlisted vs. referred.

I cannot be held accountable for another's actions or lack of action. Patients have to want to go through the often cumbersome process of getting evaluated, having all the tests done and then maintaining those tests annually.

Dialysis units have a responsibility to provide information and encourage referrals; waitlisting is not our responsibility. That falls solely on a transplant program.

Our local transplant organization is asking pts to take more responsibility in scheduling their POC meeting with them and for making appointments with the cardiologist, etc. so it would seem logical for the pts to take the initiative. The entire process is long and the ones who are diligent are probably those that would take care of their health and their new kidney.

We as social workers can provide resources (such as finding affordable dental care) but the pt should want the transplant!

Hello,

I do feel the dialysis center has a responsibility to refer and encourage a Pt to engage in transplant. I do, however, feel that a barrier to transplant is the long wait time and motivation for Pt to be transplanted is the time spent waiting for an education session. That is my experience here.

I have been a nephrology social worker in a hospital-based unit for more than 20 years. I strongly believe in the value of transplant and have always endeavored to refer patients for transplant evaluation. However I do see potential problems if dialysis units are held too accountable for the listing of their patients.

First, we have no control over the transplant centers' criteria; some of which I have observed to be overly rigid and only list those patients with the highest potential for success (thus keeping their facility statistics high).

Secondly, there are logistical factors such as having transportation available both pre and post transplant to the center that is contracted with the patient's insurance. In our particular area many of the large insurers will only contract with centers that have a high volume; thus eliminating the two centers in this county. Public transportation here is not ideal, so if a person doesn't have automobile transportation to centers that with traffic can be 1 ½-2 hours away, transplant is not feasible.

Finally, and most importantly, we cannot control a person's motivation to complete the process and once listed to follow the regimen to maintain candidacy. We can encourage and educate and assess for barriers (which we definitely do), but ultimately these are adults who make their own choices. If a person lacks the motivation to complete the required testing or to properly follow their medical regimen, this does not portend well for their ability to adhere to the transplant regimen.

I am voicing opposition to any measure that would make dialysis units in general, and social workers in particular, responsible for making sure people pursue kidney transplantation. Though studies have shown transplantation to be a more effective treatment for ESRD patients statistically, some patients simply do not choose to pursue that choice. Choice is the key word. Social workers hold self-determination to be a key value for all human beings, and kidney dialysis patients are no exception. There are several reasons people may choose not to pursue transplantation and that is their right.

These views are my own - I am not speaking on behalf of the company I work for.

Thank you for the opportunity to comment.

Kathleen Williams, LCSW