



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