



May 17, 2018

National Quality Forum
1030 15th Street, NW – Suite 800
Washington, DC 20005

ATTN: Renal Project

Kidney Care Partners (KCP) appreciates the opportunity to comment on measures under consideration for endorsement for the National Quality Forum's (NQF) Renal Project 2018 Spring Cycle. 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). As an NQF member, we appreciate the opportunity to comment on the specifications for the two Transplant Waitlist measures submitted for endorsement consideration by the Centers for Medicare and Medicaid Services and offer the following comments.

NQF 3403: Percentage of Patients Waitlisted (PPPW)

NQF 3402: 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 that while a referral to a transplant center, initiation of the waitlist evaluation process, or completion of the waitlist evaluation process may be appropriate facility-level measures that could be used in ESRD quality programs, the Percentage of Prevalent Patients Waitlisted (PPPW) and Standardized First Kidney Transplant Waitlist Ratio for Incident Dialysis Patients (SWR) are not. Waitlisting per se is a decision made by the transplant center and is beyond a dialysis facility's locus of control. In reviewing these measures, we offer the following comments:¹

Comments Relevant to both the PPPW and SWR Measures

Several of KCP's concerns apply to both the PPPW and SWR measures:

- Facility attribution. KCP appreciated the Measure Applications Partnership (MAP) Hospital Workgroup's recommendation that the Waitlist measures also be reviewed by NQF's Attribution Expert Panel to assess KCP's and other stakeholders' concerns about the measures' attribution models. However, we strongly object to attributing successful/unsuccessful placement on a transplant waitlist to dialysis facilities and believe this is a fatal structural flaw. 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 PPPW and SWR for these or other delays is inappropriate; such

¹ **Note:** While information on the PPPW and SWR risk models were not released with the MUC list, we note that the measures' specifications are identical to those recently released by CMS for public review for use in Dialysis Facility Compare (DFC) Five Star Rating Program. We thus make the presumption that the technical details of the associated risk models also are unchanged.

misattribution is fundamentally misaligned with NQF's first "Attribution Model Guiding Principle", which states that measures' attribution models should fairly and accurately assign accountability.² KCP emphasizes our commitment to improving transplantation access, but we believe other measures with an appropriate sphere of control should be pursued.

- Age as the only sociodemographic risk variable. KCP appreciated the MAP Workgroup's recommendation that the Waitlist measures also be reviewed by NQF's Disparities Standing Committee to assess KCP's and other stakeholders' concerns about the measures' risk of potentiating existing health inequities. KCP strongly believes age as the only sociodemographic 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. 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, like the Access to Kidney Transplantation TEP, KCP does not support adjustment for waitlisting based on economic factors or by race or ethnicity.

Geography, for instance, should be examined, since regional variation in transplantation access is significant. Waitlist times differ regionally, which will ultimately change the percentage of patients on the waitlist and impact performance measure scores. 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.

- Hospice exclusion. We note that an exclusion for patients admitted to hospice during the month of evaluation has been incorporated into both measures. KCP agrees that the transplantation access measures should not apply to persons with a limited life expectancy and so is pleased to see this revision.
- Risk model fit. KCP appreciates the MAP Hospital Workgroup's recommendation that the Waitlist measures also be reviewed by NQF's Scientific Methods Panel to assess KCP's and other stakeholders' concerns about the measures' risk models. We note that risk model testing yielded an overall C-statistic of 0.72 for the PPPW and 0.67 for the SWR, raising concerns that the models will not adequately discriminate performance. Smaller units, in particular, might look worse than their actual performance. We reiterate our long-held position that a minimum C-statistic of 0.8 is a more appropriate indicator of a model's goodness of fit, predictive ability, and validity to represent meaningful differences among facilities.
- Stratification of reliability results by facility size. CMS has provided no stratification of reliability scores by facility size for either measure; we are thus unable to discern how widely reliability varies across the spectrum of facility sizes. We are concerned that the reliability for small facilities might be substantially lower than the overall IURs, as has been the case, for instance, with other CMS standardized ratio measures. This is of particular concern with the SWR, for which empiric testing has yielded an overall IUR of only 0.6—interpreted as "moderate"

² NQF. *Attribution: Principles and Approaches. Final Report.* December 2016.

<http://www.qualityforum.org/ProjectDescription.aspx?projectID=80808>. Accessed December 21, 2017.

reliability by statistical convention.³ To illustrate our concern, the Standardized Transfusion Ratio for Dialysis Facilities (STrR) measure (NQF 2979) also was found to have an overall IUR of 0.60; however, the IUR was only 0.3 (“poor” reliability) for small facilities (defined by CMS as ≤46 patients for the STrR). Without evidence to the contrary, KCP is thus concerned that SWR reliability is similarly lower for small facilities, effectively rendering the metric meaningless for use in performance measurement in this group of providers. KCP believes it is incumbent on CMS to demonstrate reliability for all facilities by providing data by facility size.

- Meaningful differences in performance. We note that with large sample sizes, as here, even statistically significant differences in performance may not be clinically meaningful. A detailed description of measure scores, such as distribution by quartile, mean, median, standard deviation, outliers, should be provided to allow stakeholders to assess the measure and allow for a thorough review of the measures’ performance.
- Additional language related to exclusions. We note that since KCP reviewed these measures and provided comment to CMS in 2016, one PPW exclusion has been altered with the following boldface text: *Patients admitted to a skilled nursing facility or hospice during the month of evaluation are excluded from that month; **patients admitted to a skilled nursing facility at incidence or previously according to Form CMS 2728 are also excluded.*** Similarly, one SWR exclusion has been altered with the following boldface/strikeout text: ***Preemptive patients: Patients at the facility who had the first transplantation prior to the start of ESRD treatment or** ~~Patients at the facility who were listed on the kidney or kidney-pancreas transplant waitlist prior to the start of dialysis.~~*

KCP supports these changes, but notes that the testing forms submitted by the developer do not provide information on the impact of these exclusions on performance, as required by NQF. We recommend the appropriate, required testing be reported.

Comment Relevant to PPPW Only

- Process vs. intermediate outcome measure. The Measure Submission Form identified the PPPW as a process measure. KCP believes the PPPW is an intermediate outcome measure and recommends it be indicated as such.

Comments Relevant to SWR Only

- Incident comorbidities incorporated into risk model. We note that eleven incident comorbidities—heart disease, inability to ambulate, inability to transfer, COPD, malignant neoplasm/cancer, PVD, CVD, alcohol dependence, drug dependence, amputation, and needs assistance with daily activities—have been incorporated into the SWR risk model. All are collected through the CMS Form 2728. As we have noted before, we continue to be concerned about the validity of the 2728 as a data source and urge CMS to work with the community to assess this matter.
- Rate vs. ratio. 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.

In sum and for the reasons stated above, KCP does not believe that the PPPW and SWR measures are appropriate for NQF endorsement.

³ Landis J, Koch G. The measurement of observer agreement for categorical data. *Biometrics*. 1977;33:159-174.

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 203.530.9524).

Sincerely,

A handwritten signature in black ink, appearing to read "AR Nissenson, MD". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

Allen R. Nissenson, MD, FACP
KCP Chair