NATIONAL QUALITY FORUM
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Renal Spring 2022 Cycle: Public and Member Comments

Contents

Post-Evaluation Measure-Specific Comments on Renal Spring 2022 Submissions

NQF #3659 Standardized Fistula Rate for Incident Patients (Not Recommended)

Dr. Lisa McGonigal, MD, MPH, Kidney Care Partners

Comment ID#: 8132 (Submitted: 08/22/2022)

Council / Public: QMRI

Level of Support: Member Does NOT Support

Comment

KCP supports the Standing Committee's recommendation against the Standardized Fistula Rate for Incident Patients Measure. KCP maintains that vascular access is one of the most important clinical considerations for patients making decisions about dialysis facilities, and we continue our strong support of CMS's Long-Term Catheter Rate Measure (NQF 2978) in the ESRD QIP to reduce catheter use. However, we do not believe that merely narrowing the target population of the prior, all-patient iteration of the Standardized Fistula Rate Measure (SFR, previously NQF 2977) effectively addresses the issues that led to its loss of NQF endorsement in 2020. We note that the SFR's loss of NQF endorsement was precipitated by KDOQI's then-recent downgrading of the evidence supporting fistulas as the preferred access type, in favor of catheter avoidance and individualized ESKD Lifeplans. To support the premise for this new, incident-only measure, CMS now counters that the same guidelines do suggest that under favorable circumstances an AV fistula is preferred to an AV graft in incident patients due to fewer long-term vascular access events (e.g., thrombosis, loss of primary patency, interventions) and because "blood stream infection rates are the lowest in incident patients with AV fistula compared to long-term catheters." We note, however, that the KDOQI guideline explicitly indicates there is inadequate evidence to make a recommendation on choice of AV fistula vs AV graft for incident vascular access based on associations with infections; thus, here again, the KDOQI statement focuses on catheter reduction and takes no stance on the superiority of fistulas over grafts in this regard. CMS also indicates that the Incident SFR was developed to focus on the subset of dialysis patients that evidence suggests may benefit the most during a time of intense vascular access creation, noting that while greater than 80% of incident dialysis patients begin treatment with a tunneled catheter, AV fistula rates exceed 60% by twelve months after dialysis initiation. Here we note that NQF's Renal Standing Committee also rejected the prior SFR because they believed the measures was effectively "topped out" at 64% for all patients for whom an AV fistula is clinically appropriate. As the new measure defines an incident patient as one who began maintenance hemodialysis within the prior twelve months, we believe CMS's logic here is flawed. Rather than supporting the premise of the measure, fistula rates climbing from less than 20% at dialysis initiation to greater than 60% within twelve months supports that dialysis facilities are already placing fistulas in nearly all clinically appropriate new patients, once under their care, such that by the end of the first year of dialysis the population approaches that "topped out" AV fistula rate identified by NQF. We also note that stratification of reliability scores by facility size was not detailed; 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 IUR, as has often been the case with other CMS standardized measures. Without evidence to the contrary, KCP is thus concerned the Incident

SFR reliability may be unacceptably low 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. Taking all of the above into consideration, we do not believe limiting the SFR population to incident patients effectively addresses the previously identified issues with the original measure. We maintain that catheter avoidance is the appropriate focus for vascular access in both the incident and prevalent dialysis populations, and we believe the Standardized Fistula Rate for Incident Patients is an unnecessary solution to a problem already being effectively addressed by the existing vascular access measure.

Developer Response

Point 1: Performance Gap We respectfully disagree with the commenters. There was no formal determination that SFR was topped out due to the national rate of 64%. Furthermore, there remains a significant performance gap between providers in AVF use at the facility level. This performance gap is magnified for incident patients and the current SFR for incident patients suggests there is significant room for improvement in AVFs in the first year of dialysis. Point 2: Evidence The KDOQI guidelines for vascular access continue to support AV fistula creation in incident patients. As the commenter noted, Guideline 2.5 indicates: “KDOQI suggests that if sufficient time and patient circumstances are favorable for a mature, usable AVF, such a functioning AVF is preferred to an AVG in incident patients due to fewer long-term vascular access events (e.g. thrombosis, loss of primary patency, interventions) associated with unassisted AVF use”. The following Guideline 2.6 indicates: “KDOQI suggests that most incident patients starting dialysis with a CVC should convert to either an AVF or AVG, if possible, to reduce their risk of infection/bacteremia, infection-related hospitalizations, and adverse consequences.” When taken together, this suggests that AV fistula provide lower risk of infection (acknowledging that AV grafts do as well) when compared to catheters, but that AV fistula also provide lower vascular access events when compared to AVG. Point 3: Reliability Given the established effect of sample size on IUR calculations, it is expected that large facilities will have higher IUR values and small facilities will have lower IUR values for any given measure. Using the empirical null method, facilities are flagged if they have outcomes that are extreme when compared to the variation in outcomes for other facilities of a similar size. That is, smaller facilities have to have more extreme outcomes compared to other smaller facilities to be flagged.

NQF Response

Thank you for your comment. It has been shared with the Standing Committee and measure developer.

NQF Committee Response

N/A

Ms. Kelly Brooks, MPA, The National Forum of ESRD Networks
Comment ID#: 8166 (Submitted: 09/05/2022)

Council / Public: QMRI

Level of Support: N/A

Comment

The National Forum of ESRD Networks ("the Forum") is appreciative of the opportunity to comment on the National Quality Forum ("NQF") on the specific measures evaluated by its Renal Standing Committee. With the input of our Medical Advisory Council (MAC) and Kidney Patient Advisory Council (KPAC), we would respectfully submit our following comments and recommendations with regard to NQF #3659 Standardized Fistula Ratio for Incident Patients: The Forum has long-held the believe that the Fistula-First focus has led to many patients being poorly served by the nephrology community. We recognize that the AV fistula is an ideal conduit for hemodialysis in most patients, however, quality metrics focused on AV fistula creation as a rule have led to many patients suffering through unnecessary (and often, futile) procedures when they would have been better served with an AV graft (and even rarely by a long-term tunneled dialysis catheter). We continue to recommend a hemodialysis access metric that focuses on informed decision making with the patient and ultimate efforts to encourage "catheter last" rather than "fistula first." Recommendation: The Forum agrees with the NQF in not supporting Standardized Fistula Ratio for Incident Patients measure. We thank you once again for your time and consideration. Respectfully submitted, David Henner, DO, President, Forum of ESRD Networks; Daniel Landry, DO, Chair, Medical Advisory Council; Derek Forfang, Co-Chair, Kidney Patient Advisory Council; Dawn Edwards, Co-Chair, Kidney Patient Advisory Council

Developer Response

We recognize the importance of patient choice when creating a vascular access plan, however at this time there are no standard criteria for how to validate an informed decision. A check-box attestation would likely be an insufficient test for accurately determining whether an informed choice was made by a patient. This is especially true for vulnerable patients. In addition, some patients who decline creation of an AVF do so after one or more previous attempts at creating a surgical access. This scenario is less likely in the first year of dialysis where many patients are starting with a tunneled catheter.

NQF Response

Thank you for your comment. It has been shared with the Standing Committee and measure developer.

NQF Committee Response

N/A

NQF #2594 Optimal End Stage Renal Disease (ESRD) Starts (Recommended)

Alvina Sundang, The Permanente Federation
Comment ID#: 8122 (Submitted: 08/09/2022)

Council / Public: HPL

Level of Support: N/A

Comment

TO: NQF Renal Standing Committee, FROM: Leonid Pravoverov, MD, Physician Lead, Kaiser Permanente National Renal Care Services. Dear Members of the National Quality Forum Renal Standing Committee, Kaiser Permanente is one of the nation's largest not-for-profit health plans, serving 12.6 million members. At Kaiser Permanente, physicians are responsible for medical decisions. The Permanente Medical Groups, which provide care for Kaiser Permanente members, continuously develop and refine medical practices to help ensure that care is delivered in the most efficient and effective manner possible. As steward of this measure, we at Kaiser Permanente want to thank you for the opportunity to clarify a question from the recent June 2022 Measure Evaluation Standing Committee Meeting: The Optimal ESRD Starts measure is meaningful only in integrated delivery care systems or large physician groups, and is not applicable to individual dialysis facilities, individual nephrology practitioners or small provider groups. Based on our internal experience, and previous assessment, there should be over 50 Optimal Start events per year, to reflect practice patterns, make operational interventions and quality improvement efforts meaningful, as well as for the measure result to be statistically reliable. Additionally, we also learnt that the 12 rolling months is the most meaningful reporting period that is consistent with other reported quality measures. In our 2015 submission, we had recommended a reporting period of 18-24 months to ensure a minimum collection of 50 ESRD patient; however, we now believe that a rolling 12 month period is more appropriate. If you have any questions after reviewing the comment above, please feel free to contact Leonid Pravoverov, MD (Leonid.Pravoverov@kp.org). Sincerely, Kaiser Permanente and Permanente Medical Groups

Developer Response

N/A

NQF Response

Thank you for your comment. It has been shared with the Standing Committee.

NQF Committee Response

N/A

Ms. Kelly Brooks, MPA, The National Forum of ESRD Networks
Comment ID#: 8164 (Submitted: 09/05/2022)

Council / Public: QMRI

Level of Support: N/A

Comment

The National Forum of ESRD Networks ("the Forum") is appreciative of the opportunity to comment on the National Quality Forum ("NQF") on the specific measures evaluated by its Renal Standing Committee. With the input of our Medical Advisory Council (MAC) and Kidney Patient Advisory Council (KPAC), we would respectfully submit our following comments and recommendations on NQF #2594 Optimal End-Stage Renal Disease (ESRD) Starts as follows: Members of our KPAC were in favor of supporting this measure but did wish to offer the following comments: "We feel that ALL patients should be considered to be home patients until they are ruled out for some reason. For most patients, it would be most optimal to get a transplant before ever starting dialysis. Unfortunately, few of us currently get that opportunity. The largest percentage of patients should start at home with only the remainder starting in-center as the last choice. We also feel supportive care or conservative management should be taken into consideration. That option of not starting dialysis at all might be optimal for some patients. So, an optimal start is a good thing for patients, but in-center should be used only after other options are exhausted. We also need a shared decision measure to accompany this measure to make sure the patient is included in deciding what is truly optimal for them." Members of our MAC also felt that a shared decision-making tool would be ideal and should include the family. Oftentimes, patients decisions are based upon how certain choices will impact, or burden, the family without ever making sure that those who could be impacted are fully informed about the choices (e.g., home dialysis versus in-center dialysis). This view of burden is more likely to be expressed by individuals who are already struggling with limited resources and never given the opportunity to make the most informed decisions with the patient. Recommendation: In summary, while the Forum sees room for growth and opportunity when it comes to monitoring quality through the Optimal End-Stage Renal Disease Starts measure, we fully support the NQF's decision to endorse this measure. We thank you once again for your time and consideration. Respectfully submitted, David Henner, DO, President, Forum of ESRD Networks; Daniel Landry, DO, Chair, Medical Advisory Council; Derek Forfang, Co-Chair, Kidney Patient Advisory Council; Dawn Edwards, Co-Chair, Kidney Patient Advisory Council

Developer Response

Dear members of the National Forum of ESRD Networks ("the Forum"): Kaiser Permanente Federation is grateful to have your support for NQF measure #2594 Optimal ESKD Starts (OES). We welcome your comments and are looking forward to addressing the recommendations. OES is a composite measure incorporating most beneficial long-term outcomes for patient with advanced CKD transitioning to ESKD: receiving a pre-emptive kidney transplant (and avoiding dialysis altogether); starting kidney replacement therapy with home dialysis modalities (PD or HHD); and being fully prepared for in-center HD with a mature and ready-to-use AV fistula or graft. These outcomes are considered markers of optimal pre-ESKD chronic kidney disease care as provided by a multidisciplinary care team (MCT), including successful patient and caregiver engagement, with a full complement of education and decision support regarding every option of care, including conservative care without dialysis. OES is fundamentally based on shared decision making by patients and caregivers with the efforts of a highly functioning MCT to provide comprehensive,

optimized CKD care. By necessity, this incorporates all available kidney care options and is capable to support every decision a patient and their family make. The OES measure categorizes home dialysis as an optimal ESKD start. While we fully support wider use of home dialysis, there are certain clinical and social issues that drive patients' and caregivers' decisions in choice of therapy. We strongly encourage a "Home First" approach, while providing balanced education to support individualized decisions that ensure safe transitions to kidney replacement therapy. We support a patient's decision not to initiate dialysis and have developed palliative care options to ensure their goals of care are well documented and supported by systems of care to include palliative treatments for uremia-associated symptoms, as well as hospice and end-of-life care. Patients who choose conservative therapy are not included into the OES numerator or denominator, so this measure fully supports patients who choose not to start dialysis. Our workgroups continuously evaluate opportunities to improve patient's access to kidney transplantation, including live donation, donor exchange programs, and partnerships with multiple transplant centers to ensure adequate access to kidney transplantation. We are looking forward to collaborating with National Forum of ESRD Networks, and other organizations focusing on kidney care, to develop additional refinements of the measure to promote optimal CKD care in the transition to ESKD.

NQF Response

Thank you for your comment. It has been shared with the Standing Committee and measure developer.

NQF Committee Response

N/A

NQF #3689 First Year Standardized Waitlist Ratio (FYSWR) (Not Recommended)

Dr. Lisa McGonigal, MD, MPH, Kidney Care Partners

Comment ID#: 8124 (Submitted: 08/22/2022)

Council / Public: QMRI

Level of Support: Member Does NOT Support

Comment

KCP recognizes the tremendous importance of improving transplantation rates for patients with ESRD, but does not support the attribution of successful or unsuccessful waitlisting to individual practitioners or group practices and thus cannot support these measures. KCP believes that while referral to a transplant center and initiation or even completion of the waitlist evaluation process might be appropriate measures for these levels of analysis that could be used in CMS's quality programs, the newly proposed practitioner/group level Percentage of Prevalent Patients Waitlisted (PPPW), Percentage of Prevalent Patients Waitlisted in Active Status (aPPPW), and First Year Standardized Waitlist Ratio (FYSWR) measures are not. Waitlisting per se is a decision made by the transplant center and is beyond the locus of control of any of the providers targeted in these measures. In reviewing these measures, we offer the following comments: I. Overarching Concerns.

Several of KCP's concerns apply to all three proposed transplant access measures: a. Attribution. As above, we strongly object to attributing successful/unsuccessful placement on a transplant waitlist to individual clinicians or practitioner group practices and believe this is a fatal structural flaw with these measures. The transplant center decides whether a patient is placed on a waitlist, not the practitioner or group practice. KCP patient members who are transplant recipients have noted there are many obstacles and delays in the evaluation process with multiple parties that have nothing to do with the facility or practitioner—e.g., one patient noted their private pay insurance changed the locations where they could be evaluated for transplant eligibility on multiple occasions, repeatedly interrupting the process mid-stream. Penalizing a practitioner/group practice each month through the PPPW, aPPPW, and FYSWR for these or other delays is inappropriate; such misattribution is fundamentally misaligned with NQF's first "Attribution Model Guiding Principle," which states that measures' attribution models should fairly and accurately assign accountability. KCP emphasizes our commitment to improving transplantation access, but we believe other measures with an appropriate sphere of control should be pursued. For instance, our sister organization, the Kidney Care Quality Alliance (KCQA), has developed a dialysis facility-level Transplant Access Measure Set that will be submitted to NQF for endorsement consideration later this year. The set pairs a referral rate metric with a measure assessing the waitlisting rate specifically among those patients who were referred by the facility within the preceding three years. Because the KCQA waitlisting measure denominator is limited to those patients specifically identified as appropriate transplant candidates and deliberately referred by the dialysis facility within a defined time period, facilities have considerably more agency over the measure than less precise metrics like the PPPW; this construct will also provide a counterbalance to the referral measure, curbing the tendency to indiscriminately refer patients who are not appropriate transplant candidates, preventing unnecessary patient and transplant center burden. The same approach could be applied at the practitioner/group level. b. Variation in Transplant Center Eligibility Criteria. We also note that criteria indicating a patient is "not eligible" for transplantation can differ by location. For instance, one center might require evidence of an absence of chronic osteomyelitis, infection, heart failure, etc., while another may apply eligibility exclusions differently or have additional or 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. c. Stratification of Reliability Results by Group Size and Performance Scores Absent. We also note that CMS has provided no stratification of reliability scores by provider size for the measures; we are thus unable to discern how widely reliability varies across the spectrum of practitioner/group practice sizes. We are concerned that the reliability for small providers 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 FYSWR, for which empiric testing has yielded an overall IUR of only 0.64—interpreted as "moderate" reliability by statistical convention. 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 concerned that FYSWR reliability is similarly lower for small groups, effectively rendering the metric meaningless for use in performance measurement in this subset of providers. KCP believes it is incumbent on CMS to demonstrate reliability for all providers by stratifying data by practice size.

Developer Response

Being waitlisted for kidney transplantation is the culmination of a variety of preceding preparatory activities. These include, but are not limited to, education of patients about the option of transplantation, 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 practitioner groups. Although some aspects of the waitlisting process may not entirely depend on dialysis practitioner groups, 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 practitioner groups. For example, through coordination of care, strong communication with transplant centers, and advocacy for patients by dialysis practitioner groups, as well as comprehensive education, encouragement, and support of patients during their decision-making about the transplantation option. The practitioner level access to transplant waitlisting measures were therefore proposed in the spirit of shared accountability, with the recognition that success requires substantial effort by dialysis practitioner groups. In this respect, the measures represent an explicit acknowledgment of the tremendous contribution dialysis practitioner groups can be, and are already, making towards access to transplantation, to the benefit of the patients under their care. Although waitlisting measures directed at the transplant center may also be potentially appropriate, the scope of this particular measure development effort was focused on performance of dialysis practitioner groups. The developer agrees that measures directed at referral and transplant education would be potentially valuable, but limitations in national data availability on referral and appropriate tools to capture quality of transplant education pose practical hurdles to development of such measures. We agree with KCQA that referral is an important metric to report at the dialysis facility level, and we have done a lot of work over the years (including holding two TEPs) in support of development of a measure/collection of referral data. Although we agree that information on referral can be valuable for incorporation into access to transplantation measures, there is currently no mechanism to capture data on referral on a national scale. Further, in light of known ongoing disparities in access to transplantation, and in the spirit of ensuring fair access to kidney transplantation, we believe a denominator including all dialysis patients is still appropriate, rather than only those the dialysis facilities chooses to refer We agree that there is variation across transplant centers in eligibility criteria and that underlying patient comorbidities may affect their candidacy. All three waitlisting measures accordingly include adjustment for a wide range of comorbidities, and furthermore include adjustment for transplant center characteristics. An example is waitlist mortality, which can be viewed as a proxy for stringency of center waitlisting criteria. Further, the prevalent waitlisting measures include adjustment for transplant center random effects, capturing broad aspects of each transplant center's tendency to waitlist patients. Given the established effect of sample size on IUR calculations, it is expected that large facilities will have higher IUR values and small facilities will have lower IUR values for any given measure. Using the empirical null method, facilities are flagged if they have outcomes that are extreme when compared to the variation in outcomes for other facilities of a similar size. That is, smaller facilities have to have more extreme outcomes compared to other smaller facilities to be flagged.

NQF Response

Thank you for your comment. It has been shared with the Standing Committee and measure developer.

NQF Committee Response

N/A

Dr. Lisa McGonigal, MD, MPH, Kidney Care Partners

Comment ID#: 8127 (Submitted: 08/22/2022)

Council / Public: QMRI

Level of Support: Member Does NOT Support

Comment

KCP recognizes the tremendous importance of improving transplantation rates for patients with ESRD, but does not support the attribution of successful or unsuccessful waitlisting to individual practitioners or group practices and thus cannot support these measures. KCP believes that while referral to a transplant center and initiation or even completion of the waitlist evaluation process might be appropriate measures for these levels of analysis that could be used in CMS's quality programs, the newly proposed practitioner/group level Percentage of Prevalent Patients Waitlisted (PPPW), Percentage of Prevalent Patients Waitlisted in Active Status (aPPPW), and First Year Standardized Waitlist Ratio (FYSWR) measures are not. Waitlisting per se is a decision made by the transplant center and is beyond the locus of control of any of the providers targeted in these measures. In reviewing these measures, we offer the following comments: I. Overarching Concerns. Several of KCP's concerns apply to all three proposed transplant access measures: a. Attribution. As above, we strongly object to attributing successful/unsuccessful placement on a transplant waitlist to individual clinicians or practitioner group practices and believe this is a fatal structural flaw with these measures. The transplant center decides whether a patient is placed on a waitlist, not the practitioner or group practice. KCP patient members who are transplant recipients have noted there are many obstacles and delays in the evaluation process with multiple parties that have nothing to do with the facility or practitioner—e.g., one patient noted their private pay insurance changed the locations where they could be evaluated for transplant eligibility on multiple occasions, repeatedly interrupting the process mid-stream. Penalizing a practitioner/group practice each month through the PPPW, aPPPW, and FYSWR for these or other delays is inappropriate; such misattribution is fundamentally misaligned with NQF's first "Attribution Model Guiding Principle," which states that measures' attribution models should fairly and accurately assign accountability. KCP emphasizes our commitment to improving transplantation access, but we believe other measures with an appropriate sphere of control should be pursued. For instance, our sister organization, the Kidney Care Quality Alliance (KCQA), has developed a dialysis facility-level Transplant Access Measure Set that will be submitted to NQF for endorsement consideration later this year. The set pairs a referral rate metric with a measure assessing the waitlisting rate specifically among those patients who were referred by the facility within the preceding three years. Because the KCQA waitlisting measure denominator is limited to those patients specifically

identified as appropriate transplant candidates and deliberately referred by the dialysis facility within a defined time period, facilities have considerably more agency over the measure than less precise metrics like the PPPW; this construct will also provide a counterbalance to the referral measure, curbing the tendency to indiscriminately refer patients who are not appropriate transplant candidates, preventing unnecessary patient and transplant center burden. The same approach could be applied at the practitioner/group level. b. Variation in Transplant Center Eligibility Criteria. We also note that criteria indicating a patient is "not eligible" for transplantation can differ by location. For instance, one center might require evidence of an absence of chronic osteomyelitis, infection, heart failure, etc., while another may apply eligibility exclusions differently or have additional or 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. c. Stratification of Reliability Results by Group Size and Performance Scores Absent. We also note that CMS has provided no stratification of reliability scores by provider size for the measures; we are thus unable to discern how widely reliability varies across the spectrum of practitioner/group practice sizes. We are concerned that the reliability for small providers 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 FYSWR, for which empiric testing has yielded an overall IUR of only 0.64—interpreted as "moderate" reliability by statistical convention. 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 concerned that FYSWR reliability is similarly lower for small groups, effectively rendering the metric meaningless for use in performance measurement in this subset of providers. KCP believes it is incumbent on CMS to demonstrate reliability for all providers by stratifying data by practice size.

Developer Response

Being waitlisted for kidney transplantation is the culmination of a variety of preceding preparatory activities. These include, but are not limited to, education of patients about the option of transplantation, 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 practitioner groups. Although some aspects of the waitlisting process may not entirely depend on dialysis practitioner groups, 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 practitioner groups. For example, through coordination of care, strong communication with transplant centers, and advocacy for patients by dialysis practitioner groups, as well as comprehensive education, encouragement, and support of patients during their decision-making about the transplantation option. The practitioner level access to transplant waitlisting measures were therefore proposed in the spirit of shared accountability, with the recognition that success requires substantial effort by dialysis practitioner groups. In this respect, the measures represent an explicit acknowledgment of the tremendous contribution dialysis practitioner groups can be, and are already, making towards access to transplantation, to the benefit of the patients under their care. Although waitlisting measures directed at the transplant center may also be potentially appropriate, the scope of this particular

measure development effort was focused on performance of dialysis practitioner groups. The developer agrees that measures directed at referral and transplant education would be potentially valuable, but limitations in national data availability on referral and appropriate tools to capture quality of transplant education pose practical hurdles to development of such measures. We agree with KCQA that referral is an important metric to report at the dialysis facility level, and we have done a lot of work over the years (including holding two TEPs) in support of development of a measure/collection of referral data. Although we agree that information on referral can be valuable for incorporation into access to transplantation measures, there is currently no mechanism to capture data on referral on a national scale. Further, in light of known ongoing disparities in access to transplantation, and in the spirit of ensuring fair access to kidney transplantation, we believe a denominator including all dialysis patients is still appropriate, rather than only those the dialysis facilities chooses to refer We agree that there is variation across transplant centers in eligibility criteria and that underlying patient comorbidities may affect their candidacy. All three waitlisting measures accordingly include adjustment for a wide range of comorbidities, and furthermore include adjustment for transplant center characteristics. An example is waitlist mortality, which can be viewed as a proxy for stringency of center waitlisting criteria. Further, the prevalent waitlisting measures include adjustment for transplant center random effects, capturing broad aspects of each transplant center's tendency to waitlist patients. Given the established effect of sample size on IUR calculations, it is expected that large facilities will have higher IUR values and small facilities will have lower IUR values for any given measure. Using the empirical null method, facilities are flagged if they have outcomes that are extreme when compared to the variation in outcomes for other facilities of a similar size. That is, smaller facilities have to have more extreme outcomes compared to other smaller facilities to be flagged.

NQF Response

Thank you for your comment. It has been shared with the Standing Committee and measure developer.

NQF Committee Response

N/A

Ms. Kelly Brooks, MPA, The National Forum of ESRD Networks

Comment ID#: 8167 (Submitted: 09/05/2022)

Council / Public: QMRI

Level of Support: N/A

Comment

The National Forum of ESRD Networks ("the Forum") is appreciative of the opportunity to comment on the National Quality Forum ("NQF") on the specific measures evaluated by its Renal Standing Committee. With the input of our Medical Advisory Council (MAC) and Kidney Patient Advisory Council (KPAC), we would respectfully submit our following comments and

recommendations with regard to NQF #3689 First Year Standardized Waitlist Ratio (FYSWR): The Forum applauds all efforts focusing on the development of measures that targeted waitlisting in order to improve access to kidney transplantation, however, we also share many of the NQF's concerns to include measuring at the provider level rather than the transplant facility level, excluding patients from the measure who are waitlisted prior to starting dialysis, or preemptively waitlisted, as well as including patients in the measure who choose not to undergo a transplant. Recommendation: The Forum agrees with the NQF in not supporting the FYSWR measure. We thank you once again for your time and consideration. Respectfully submitted, David Henner, DO, President, Forum of ESRD Networks; Daniel Landry, DO, Chair, Medical Advisory Council; Derek Forfang, Co-Chair, Kidney Patient Advisory Council; Dawn Edwards, Co-Chair, Kidney Patient Advisory Council

Developer Response

Being waitlisted for kidney transplantation is the culmination of a variety of preceding preparatory activities. These include, but are not limited to, education of patients about the option of transplantation, 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 practitioner groups. Although some aspects of the waitlisting process may not entirely depend on dialysis practitioner groups, 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 practitioner groups. For example, through coordination of care, strong communication with transplant centers, and advocacy for patients by dialysis practitioner groups, as well as comprehensive education, encouragement, and support of patients during their decision-making about the transplantation option. The practitioner level access to transplant waitlisting measures were therefore proposed in the spirit of shared accountability, with the recognition that success requires substantial effort by dialysis practitioner groups. In this respect, the measures represent an explicit acknowledgment of the tremendous contribution dialysis practitioner groups can be, and are already, making towards access to transplantation, to the benefit of the patients under their care. Although waitlisting measures directed at the transplant center may also be potentially appropriate, the scope of this particular measure development effort was focused on performance of dialysis practitioner groups. With respect to the focus of the measure on the first year after dialysis initiation, the majority of potential candidates for waitlisting reach dialysis without waitlisting and this measure is specifically intended to incentivize rapid attention to them.

NQF Response

Thank you for your comment. It has been shared with the Standing Committee and measure developer.

NQF Committee Response

N/A

NQF #3694 Percentage of Prevalent Patients Waitlisted in Active Status (aPPPW) (Not Recommended)

Dr. Lisa McGonigal, MD, MPH, Kidney Care Partners

Comment ID#: 8128 (Submitted: 08/22/2022)

Council / Public: QMRI

Level of Support: Member Does NOT Support

Comment

KCP recognizes the tremendous importance of improving transplantation rates for patients with ESRD, but does not support the attribution of successful or unsuccessful waitlisting to individual practitioners or group practices and thus cannot support these measures. KCP believes that while referral to a transplant center and initiation or even completion of the waitlist evaluation process might be appropriate measures for these levels of analysis that could be used in CMS's quality programs, the newly proposed practitioner/group level Percentage of Prevalent Patients Waitlisted (PPPW), Percentage of Prevalent Patients Waitlisted in Active Status (aPPPW), and First Year Standardized Waitlist Ratio (FYSWR) measures are not. Waitlisting per se is a decision made by the transplant center and is beyond the locus of control of any of the providers targeted in these measures. In reviewing these measures, we offer the following comments: I. Overarching Concerns. Several of KCP's concerns apply to all three proposed transplant access measures: a. Attribution. As above, we strongly object to attributing successful/unsuccessful placement on a transplant waitlist to individual clinicians or practitioner group practices and believe this is a fatal structural flaw with these measures. The transplant center decides whether a patient is placed on a waitlist, not the practitioner or group practice. KCP patient members who are transplant recipients have noted there are many obstacles and delays in the evaluation process with multiple parties that have nothing to do with the facility or practitioner—e.g., one patient noted their private pay insurance changed the locations where they could be evaluated for transplant eligibility on multiple occasions, repeatedly interrupting the process mid-stream. Penalizing a practitioner/group practice each month through the PPPW, aPPPW, and FYSWR for these or other delays is inappropriate; such misattribution is fundamentally misaligned with NQF's first "Attribution Model Guiding Principle," which states that measures' attribution models should fairly and accurately assign accountability. KCP emphasizes our commitment to improving transplantation access, but we believe other measures with an appropriate sphere of control should be pursued. For instance, our sister organization, the Kidney Care Quality Alliance (KCQA), has developed a dialysis facility-level Transplant Access Measure Set that will be submitted to NQF for endorsement consideration later this year. The set pairs a referral rate metric with a measure assessing the waitlisting rate specifically among those patients who were referred by the facility within the preceding three years. Because the KCQA waitlisting measure denominator is limited to those patients specifically identified as appropriate transplant candidates and deliberately referred by the dialysis facility within a defined time period, facilities have considerably more agency over the measure than less precise metrics like the PPPW; this construct will also provide a counterbalance to the referral measure, curbing the tendency to indiscriminately refer patients who are not appropriate transplant candidates, preventing unnecessary patient and transplant center burden. The same approach could be applied at the practitioner/group level. b. Variation in Transplant Center

Eligibility Criteria. We also note that criteria indicating a patient is “not eligible” for transplantation can differ by location. For instance, one center might require evidence of an absence of chronic osteomyelitis, infection, heart failure, etc., while another may apply eligibility exclusions differently or have additional or 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. c. Stratification of Reliability Results by Group Size and Performance Scores Absent. We also note that CMS has provided no stratification of reliability scores by provider size for the measures; we are thus unable to discern how widely reliability varies across the spectrum of practitioner/group practice sizes. We are concerned that the reliability for small providers 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 FYSWR, for which empiric testing has yielded an overall IUR of only 0.64—interpreted as “moderate” reliability by statistical convention. 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 concerned that FYSWR reliability is similarly lower for small groups, effectively rendering the metric meaningless for use in performance measurement in this subset of providers. KCP believes it is incumbent on CMS to demonstrate reliability for all providers by stratifying data by practice size.

Developer Response

Being waitlisted for kidney transplantation is the culmination of a variety of preceding preparatory activities. These include, but are not limited to, education of patients about the option of transplantation, 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 practitioner groups. Although some aspects of the waitlisting process may not entirely depend on dialysis practitioner groups, 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 practitioner groups. For example, through coordination of care, strong communication with transplant centers, and advocacy for patients by dialysis practitioner groups, as well as comprehensive education, encouragement, and support of patients during their decision-making about the transplantation option. The practitioner level access to transplant waitlisting measures were therefore proposed in the spirit of shared accountability, with the recognition that success requires substantial effort by dialysis practitioner groups. In this respect, the measures represent an explicit acknowledgment of the tremendous contribution dialysis practitioner groups can be, and are already, making towards access to transplantation, to the benefit of the patients under their care. Although waitlisting measures directed at the transplant center may also be potentially appropriate, the scope of this particular measure development effort was focused on performance of dialysis practitioner groups. The developer agrees that measures directed at referral and transplant education would be potentially valuable, but limitations in national data availability on referral and appropriate tools to capture quality of transplant education pose practical hurdles to development of such measures. We agree with KCQA that referral is an important metric to report at the dialysis facility level, and we have done a lot of work over the years (including holding two TEPs) in support of development of a

measure/collection of referral data. Although we agree that information on referral can be valuable for incorporation into access to transplantation measures, there is currently no mechanism to capture data on referral on a national scale. Further, in light of known ongoing disparities in access to transplantation, and in the spirit of ensuring fair access to kidney transplantation, we believe a denominator including all dialysis patients is still appropriate, rather than only those the dialysis facilities chooses to refer We agree that there is variation across transplant centers in eligibility criteria and that underlying patient comorbidities may affect their candidacy. All three waitlisting measures accordingly include adjustment for a wide range of comorbidities, and furthermore include adjustment for transplant center characteristics. An example is waitlist mortality, which can be viewed as a proxy for stringency of center waitlisting criteria. Further, the prevalent waitlisting measures include adjustment for transplant center random effects, capturing broad aspects of each transplant center's tendency to waitlist patients. Given the established effect of sample size on IUR calculations, it is expected that large facilities will have higher IUR values and small facilities will have lower IUR values for any given measure. Using the empirical null method, facilities are flagged if they have outcomes that are extreme when compared to the variation in outcomes for other facilities of a similar size. That is, smaller facilities have to have more extreme outcomes compared to other smaller facilities to be flagged.

NQF Response

Thank you for your comment. It has been shared with the Standing Committee and measure developer.

NQF Committee Response

N/A

Dr. Lisa McGonigal, MD, MPH, Kidney Care Partners

Comment ID#: 8125 (Submitted: 08/22/2022)

Council / Public: QMRI

Level of Support: Member Does NOT Support

Comment

KCP recognizes the tremendous importance of improving transplantation rates for patients with ESRD, but does not support the attribution of successful or unsuccessful waitlisting to individual practitioners or group practices and thus cannot support these measures. KCP believes that while referral to a transplant center and initiation or even completion of the waitlist evaluation process might be appropriate measures for these levels of analysis that could be used in CMS's quality programs, the newly proposed practitioner/group level Percentage of Prevalent Patients Waitlisted (PPPW), Percentage of Prevalent Patients Waitlisted in Active Status (aPPPW), and First Year Standardized Waitlist Ratio (FYSWR) measures are not. Waitlisting per se is a decision made by the transplant center and is beyond the locus of control of any of the providers targeted in these measures. In reviewing these measures, we offer the following comments: I. Overarching Concerns.

Several of KCP's concerns apply to all three proposed transplant access measures: a. Attribution. As above, we strongly object to attributing successful/unsuccessful placement on a transplant waitlist to individual clinicians or practitioner group practices and believe this is a fatal structural flaw with these measures. The transplant center decides whether a patient is placed on a waitlist, not the practitioner or group practice. KCP patient members who are transplant recipients have noted there are many obstacles and delays in the evaluation process with multiple parties that have nothing to do with the facility or practitioner—e.g., one patient noted their private pay insurance changed the locations where they could be evaluated for transplant eligibility on multiple occasions, repeatedly interrupting the process mid-stream. Penalizing a practitioner/group practice each month through the PPPW, aPPPW, and FYSWR for these or other delays is inappropriate; such misattribution is fundamentally misaligned with NQF's first "Attribution Model Guiding Principle," which states that measures' attribution models should fairly and accurately assign accountability. KCP emphasizes our commitment to improving transplantation access, but we believe other measures with an appropriate sphere of control should be pursued. For instance, our sister organization, the Kidney Care Quality Alliance (KCQA), has developed a dialysis facility-level Transplant Access Measure Set that will be submitted to NQF for endorsement consideration later this year. The set pairs a referral rate metric with a measure assessing the waitlisting rate specifically among those patients who were referred by the facility within the preceding three years. Because the KCQA waitlisting measure denominator is limited to those patients specifically identified as appropriate transplant candidates and deliberately referred by the dialysis facility within a defined time period, facilities have considerably more agency over the measure than less precise metrics like the PPPW; this construct will also provide a counterbalance to the referral measure, curbing the tendency to indiscriminately refer patients who are not appropriate transplant candidates, preventing unnecessary patient and transplant center burden. The same approach could be applied at the practitioner/group level. b. Variation in Transplant Center Eligibility Criteria. We also note that criteria indicating a patient is "not eligible" for transplantation can differ by location. For instance, one center might require evidence of an absence of chronic osteomyelitis, infection, heart failure, etc., while another may apply eligibility exclusions differently or have additional or 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. c. Stratification of Reliability Results by Group Size and Performance Scores Absent. We also note that CMS has provided no stratification of reliability scores by provider size for the measures; we are thus unable to discern how widely reliability varies across the spectrum of practitioner/group practice sizes. We are concerned that the reliability for small providers 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 FYSWR, for which empiric testing has yielded an overall IUR of only 0.64—interpreted as "moderate" reliability by statistical convention. 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 concerned that FYSWR reliability is similarly lower for small groups, effectively rendering the metric meaningless for use in performance measurement in this subset of providers. KCP believes it is incumbent on CMS to demonstrate reliability for all providers by stratifying data by practice size.

Developer Response

Being waitlisted for kidney transplantation is the culmination of a variety of preceding preparatory activities. These include, but are not limited to, education of patients about the option of transplantation, 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 practitioner groups. Although some aspects of the waitlisting process may not entirely depend on dialysis practitioner groups, 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 practitioner groups. For example, through coordination of care, strong communication with transplant centers, and advocacy for patients by dialysis practitioner groups, as well as comprehensive education, encouragement, and support of patients during their decision-making about the transplantation option. The practitioner level access to transplant waitlisting measures were therefore proposed in the spirit of shared accountability, with the recognition that success requires substantial effort by dialysis practitioner groups. In this respect, the measures represent an explicit acknowledgment of the tremendous contribution dialysis practitioner groups can be, and are already, making towards access to transplantation, to the benefit of the patients under their care. Although waitlisting measures directed at the transplant center may also be potentially appropriate, the scope of this particular measure development effort was focused on performance of dialysis practitioner groups. The developer agrees that measures directed at referral and transplant education would be potentially valuable, but limitations in national data availability on referral and appropriate tools to capture quality of transplant education pose practical hurdles to development of such measures. We agree with KCQA that referral is an important metric to report at the dialysis facility level, and we have done a lot of work over the years (including holding two TEPs) in support of development of a measure/collection of referral data. Although we agree that information on referral can be valuable for incorporation into access to transplantation measures, there is currently no mechanism to capture data on referral on a national scale. Further, in light of known ongoing disparities in access to transplantation, and in the spirit of ensuring fair access to kidney transplantation, we believe a denominator including all dialysis patients is still appropriate, rather than only those the dialysis facilities chooses to refer We agree that there is variation across transplant centers in eligibility criteria and that underlying patient comorbidities may affect their candidacy. All three waitlisting measures accordingly include adjustment for a wide range of comorbidities, and furthermore include adjustment for transplant center characteristics. An example is waitlist mortality, which can be viewed as a proxy for stringency of center waitlisting criteria. Further, the prevalent waitlisting measures include adjustment for transplant center random effects, capturing broad aspects of each transplant center's tendency to waitlist patients. Given the established effect of sample size on IUR calculations, it is expected that large facilities will have higher IUR values and small facilities will have lower IUR values for any given measure. Using the empirical null method, facilities are flagged if they have outcomes that are extreme when compared to the variation in outcomes for other facilities of a similar size. That is, smaller facilities have to have more extreme outcomes compared to other smaller facilities to be flagged.

NQF Response

Thank you for your comment. It has been shared with the Standing Committee and measure developer.

NQF Committee Response

N/A

Dr. Lisa McGonigal, MD, MPH, Kidney Care Partners

Comment ID#: 8134 (Submitted: 08/22/2022)

Council / Public: QMRI

Level of Support: Member Does NOT Support

Comment

Of concern with this particular metric, KCP notes that a patient's status on the waitlist (active/inactive) can change frequently within the transplant centers and can be notoriously difficult to track. We believe this reality would seriously compromise the measure's validity and render the information it provides flawed, at best—and potentially harmful, should patients and providers act on the assumption of accuracy.

Developer Response

We recognize the significant role of the transplant center in making waitlist decisions. However, inactive status on the waitlist is usually the result of changes in medical condition, pending testing or changes in the social situation of the patient. Dialysis practitioners play a substantial role, even a primary role in many cases, to address the issues that can allow the patient to return to active status. Further, 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." (42, C.F.R. § 482.94). 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.

NQF Response

Thank you for your comment. It has been shared with the Standing Committee and measure developer.

NQF Committee Response

N/A

Dr. Lisa McGonigal, MD, MPH, Kidney Care Partners

Comment ID#: 8131 (Submitted: 08/22/2022)

Council / Public: QMRI

Level of Support: Member Does NOT Support

Comment

KCP agrees with the Standing Committee's recommendation against the aPPPW. We recognize the tremendous importance of improving transplantation rates for patients with ESRD, but we do not support the attribution of successful or unsuccessful waitlisting to individual practitioners or group practices and thus cannot support these measures. KCP believes that while referral to a transplant center and initiation or even completion of the waitlist evaluation process might be appropriate measures for these levels of analysis that could be used in CMS's quality programs, the newly proposed practitioner/group level Percentage of Prevalent Patients Waitlisted (PPPW), Percentage of Prevalent Patients Waitlisted in Active Status (aPPPW), and First Year Standardized Waitlist Ratio (FYSWR) measures are not. Waitlisting per se is a decision made by the transplant center and is beyond the locus of control of any of the providers targeted in these measures. In reviewing these measures, we offer the following comments: I. Overarching Concerns. Several of KCP's concerns apply to all three proposed transplant access measures: a. Attribution. As above, we strongly object to attributing successful/unsuccessful placement on a transplant waitlist to individual clinicians or practitioner group practices and believe this is a fatal structural flaw with these measures. The transplant center decides whether a patient is placed on a waitlist, not the practitioner or group practice. KCP patient members who are transplant recipients have noted there are many obstacles and delays in the evaluation process with multiple parties that have nothing to do with the facility or practitioner—e.g., one patient noted their private pay insurance changed the locations where they could be evaluated for transplant eligibility on multiple occasions, repeatedly interrupting the process mid-stream. Penalizing a practitioner/group practice each month through the PPPW, aPPPW, and FYSWR for these or other delays is inappropriate; such misattribution is fundamentally misaligned with NQF's first "Attribution Model Guiding Principle," which states that measures' attribution models should fairly and accurately assign accountability. KCP emphasizes our commitment to improving transplantation access, but we believe other measures with an appropriate sphere of control should be pursued. For instance, our sister organization, the Kidney Care Quality Alliance (KCQA), has developed a dialysis facility-level Transplant Access Measure Set that will be submitted to NQF for endorsement consideration later this year. The set pairs a referral rate metric with a measure assessing the waitlisting rate specifically among those patients who were referred by the facility within the preceding three years. Because the KCQA waitlisting measure denominator is limited to those patients specifically identified as appropriate transplant candidates and deliberately referred by the dialysis facility within a defined time period, facilities have considerably more agency over the measure than less precise metrics like the PPPW; this construct will also provide a counterbalance to the referral measure, curbing the tendency to

indiscriminately refer patients who are not appropriate transplant candidates, preventing unnecessary patient and transplant center burden. The same approach could be applied at the practitioner/group level. b. Variation in Transplant Center Eligibility Criteria. We also note that criteria indicating a patient is “not eligible” for transplantation can differ by location. For instance, one center might require evidence of an absence of chronic osteomyelitis, infection, heart failure, etc., while another may apply eligibility exclusions differently or have additional or 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. c. Stratification of Reliability Results by Group Size and Performance Scores Absent. We also note that CMS has provided no stratification of reliability scores by provider size for the measures; we are thus unable to discern how widely reliability varies across the spectrum of practitioner/group practice sizes. We are concerned that the reliability for small providers 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 FYSWR, for which empiric testing has yielded an overall IUR of only 0.64—interpreted as “moderate” reliability by statistical convention. 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 concerned that FYSWR reliability is similarly lower for small groups, effectively rendering the metric meaningless for use in performance measurement in this subset of providers. KCP believes it is incumbent on CMS to demonstrate reliability for all providers by stratifying data by practice size. Of concern with this particular metric, we note that a patient’s status on the waitlist (active/inactive) can change frequently within the transplant centers and can be notoriously difficult to track. We believe this reality would seriously compromise the measure’s validity and render the information it provides flawed, at best—and potentially harmful, should patients and providers act on the assumption of accuracy.

Developer Response

Being waitlisted for kidney transplantation is the culmination of a variety of preceding preparatory activities. These include, but are not limited to, education of patients about the option of transplantation, 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 practitioner groups. Although some aspects of the waitlisting process may not entirely depend on dialysis practitioner groups, 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 practitioner groups. For example, through coordination of care, strong communication with transplant centers, and advocacy for patients by dialysis practitioner groups, as well as comprehensive education, encouragement, and support of patients during their decision-making about the transplantation option. The practitioner level access to transplant waitlisting measures were therefore proposed in the spirit of shared accountability, with the recognition that success requires substantial effort by dialysis practitioner groups. In this respect, the measures represent an explicit acknowledgment of the tremendous contribution dialysis practitioner groups can be, and are already, making towards access to transplantation, to the benefit of the patients under their care. Although waitlisting measures

directed at the transplant center may also be potentially appropriate, the scope of this particular measure development effort was focused on performance of dialysis practitioner groups. The developer agrees that measures directed at referral and transplant education would be potentially valuable, but limitations in national data availability on referral and appropriate tools to capture quality of transplant education pose practical hurdles to development of such measures. We agree with KCQA that referral is an important metric to report at the dialysis facility level, and we have done a lot of work over the years (including holding two TEPs) in support of development of a measure/collection of referral data. Although we agree that information on referral can be valuable for incorporation into access to transplantation measures, there is currently no mechanism to capture data on referral on a national scale. Further, in light of known ongoing disparities in access to transplantation, and in the spirit of ensuring fair access to kidney transplantation, we believe a denominator including all dialysis patients is still appropriate, rather than only those the dialysis facilities chooses to refer We agree that there is variation across transplant centers in eligibility criteria and that underlying patient comorbidities may affect their candidacy. All three waitlisting measures accordingly include adjustment for a wide range of comorbidities, and furthermore include adjustment for transplant center characteristics. An example is waitlist mortality, which can be viewed as a proxy for stringency of center waitlisting criteria. Further, the prevalent waitlisting measures include adjustment for transplant center random effects, capturing broad aspects of each transplant center's tendency to waitlist patients. Given the established effect of sample size on IUR calculations, it is expected that large facilities will have higher IUR values and small facilities will have lower IUR values for any given measure. Using the empirical null method, facilities are flagged if they have outcomes that are extreme when compared to the variation in outcomes for other facilities of a similar size. That is, smaller facilities have to have more extreme outcomes compared to other smaller facilities to be flagged.

NQF Response

Thank you for your comment. It has been shared with the Standing Committee and measure developer.

NQF Committee Response

N/A

Ms. Jennifer Sardone, UM-KECC

Comment ID#: 8173 (Submitted: 09/06/2022)

Council / Public: PRO

Level of Support: N/A

Comment

We are requesting reconsideration of the Active Percentage of Prevalent Patients Waitlisted (aPPPW) on the basis that the measure evaluation criteria were not applied appropriately. As described below, the Renal Standing Committee voted Consensus Not Reached on Evidence as well

as Validity. The latter criteria requires must-pass, thus the committee did not recommend the measure for initial endorsement. We contend that the evidence presented as well as the results from validity testing are sufficient for achieving a passing score on evidence as well as a moderate score on validity. We base this argument on the committee's review of a very similar measure, NQF #3695 Percentage of Prevalent Patients Waitlist (PPPW), that received passing votes on both of these criteria during the same session. Ultimately, we respectfully request reconsideration from the committee on this criterion. Background – Scientific Methods Panel Review The aPPPW was reviewed by the Scientific Methods Panel (SMP) in March 2022. The validity discussion was described as follows in the summary of the SMP review meeting : "In its preliminary analyses, the SMP passed the measure on reliability but did not reach consensus on validity. The SMP discussed the risk adjustment model, specifically, concurrent risk factors; transplant center characteristics; and the use of sociodemographic status (SDS) factors, such as ADI. The SMP noted the potential for adjusting away some of the transplant center effects by including transplant center characteristics in the risk adjustment model. However, the developer explained that their TEP advised that adjustment was warranted so that providers disproportionately caring for socially vulnerable patients are not unfairly penalized. The SMP also noted the lack of validation using an external data set of the risk adjustment model." In addition to concerns noted above, the SMP also had a question about how the issue of non-independence of patient-months was handled in the risk model. The developer responded directly to all concerns, as follows. First, the developer clarified that the choice to adjust for transplant center characteristics and SDS factors was based on the notion of controlling for factors affecting transplant waitlisting that would be beyond the control of dialysis practitioner groups, in order to validly capture quality of dialysis practitioner performance. The developer described the conceptual basis of the social risk adjustment, as transplant centers take the availability of social support and financial resources into account in order to ensure good patient outcomes post-transplant. The Technical Expert Panel consensus was to include these adjustments to ensure the measure does not penalize providers that were disproportionally caring for socially vulnerable populations. Similarly, the adjustment for transplant center characteristics captures factors occurring at the transplant center level, such as factors related to organ availability, and variations in transplant center criteria for waitlist candidacy. Second, with respect to the question about validating the risk adjustment model with an external dataset, the developer noted that the model already includes national data inclusive of the universe of patients to which the measure is directed; thus a completely independent dataset for external validation is not possible. Finally, a biostatistician from the developer team responded to the concern regarding non-independence of patient-months, explaining that the empirical null method used in the modeling approach does handle this. The empirical null method aims to separate underlying intrinsic variation, or over-dispersion due to correlations among patient-months in dialysis practitioner group outcomes from variation that might be attributed to poor or excellent care. The developer provided written explanation with citations to the methods in the Developer Response to the Scientific Methods Panel's Preliminary Analysis, prior to the March meeting. Review of Evidence At the Renal Standing Committee meeting, the committee reviewed the evidence provided in support of the aPPPW. As described in the meeting summary, "The committee questioned the evidence and whether the nephrologist is truly the driver for a patient to be added to the transplant list when the transplant center has control over this matter. Ultimately, the Standing Committee did not reach consensus on evidence." In this request for reconsideration, the developer draws the committee's attention to the inconsistency between the vote on evidence for

this measure and the vote for the Percentage of Prevalent Patients Waitlisted (PPPW, NQF # 3695). The evidence base and risk model characteristics of aPPPW and PPPW are nearly identical; in fact, the aPPPW uses the same denominator and a numerator that is a subset of the PPPW. Further, during the evidence discussion of the aPPPW committee members specifically clarified that the evidence base used to support the PPPW was identical to that of the aPPPW. However, the Standing Committee voting result on evidence was not consistent between the two measures, with the PPPW passing (13 votes to pass, out of 18 votes) and the aPPPW not reaching consensus (only 9 votes to pass, out of 17 votes). Finally, NQF staff clarified that for an outcome measure such as the aPPPW, a vote to pass on evidence only requires that the target of the measure, in this case dialysis practitioner groups, can take some action that can help lead to the outcome. For example, dialysis practitioners play an important role in referring patients for transplant evaluation, as discussed during the committee meeting. Since referral is a necessary step on the road to active waitlisting, the evidence provided sufficient rationale for passing the measure. Review of Validity During the measure evaluation meeting, the Renal Standing Committee discussed several topics related to the validity of the measure, several of which were addressed during the SMP review (see Background section above). As described in the meeting summary, “Specifically, the Standing Committee discussed the potential of patients being removed from the transplant waitlist by the transplant team and thus reflecting poorly on the dialysis practitioner. Additionally, the Standing Committee questioned the use of SDOH in the measure’s risk adjustment model, stating that adjusting for social risk can lead to reinforcing or sustaining disparities. The developer advised that area deprivation index (ADI) and dual eligibility are the two SDOH that are included in the risk model. The developer noted that the inclusion of SDOH in the risk model was informed by the measure’s technical expert panel (TEP), considering that economic support needs to be accounted for regarding patients who are waitlisted. The Standing Committee questioned whether transplant center characteristics are accounted for in the risk model. In response, the developer confirmed that the transplant centers’ waitlist mortality and transplant rates are accounted for in the model to account for variability among transplant centers. The Standing Committee continued to express discomfort with the use of SDOH in the risk model and did not pass the measure on validity, a must-pass criterion; therefore, the Standing Committee did not discuss or vote on any proceeding criteria.” Again, we would draw the committee’s attention to the discordance between the review of the aPPPW validity testing and risk model as well as the discussion around the PPPW. Based on the meeting summary, there are inconsistencies between the review of the aPPPW and PPPW measures. The choices for risk adjustment for both models are identical. As an example, the Standing Committee accepted our explanation for including SDOH in PPPW, but the summary of the discussion of the same adjustment in aPPPW noted a “discomfort” with the adjustment. The active waitlisting criteria in the numerator is the only specification differentiating the two measures, which was not discussed or acknowledged by the committee. We also note our particular concerns about the committee’s discussion of patient choice. At one point during the discussion, the committee focused on the lack of an exclusion for patient choice (i.e., an exclusion for patients who elected against receiving a transplant and therefore were not referred for waitlisting). Conceptually, we agree that patient choice is an important component of ethical care. We agree that practitioners should respect patient choice in all clinical decisions. Our assumption is that most important clinical outcomes are driven predominantly by patient choice as part of the principle of informed consent (or informed withholding of consent). However, measuring patient choice in practice is highly problematic for a number of reasons, including: patient choice is

influenced by patient understanding of the clinical decision, a function of adequate and accurate education by the provider and dialysis team; additionally, a lack of a validated, low-burden tool for measurement of patient choice and, more importantly, the underlying understanding of the patient for the choices being considered. Indeed, if patient choice exclusions are to be required of all quality measures in the absence of a practical mechanism to measure patient understanding and associated clinical care choices, few if any quality measures would be available in any care setting. Summary As outlined above, we believe the evidence and validity testing information provided in the measure submission for the aPPPW are sufficient for a moderate rating, as supported by Standing Committee's favorable review of the very closely related PPPW measure. We respectfully request reconsideration from the committee on this criterion.

Developer Response

N/A

NQF Response

N/A

NQF Committee Response

The Standing Committee voted to not reconsider this measure at the October 6th Post-Comment meeting. Additional details are provided in the meeting summary which can be found on the Renal project page on the NQF website.

Ms. Kelly Brooks, MPA, The National Forum of ESRD Networks

Comment ID#: 8168 (Submitted: 09/05/2022)

Council / Public: QMRI

Level of Support: N/A

Comment

The National Forum of ESRD Networks ("the Forum") is appreciative of the opportunity to comment on the National Quality Forum ("NQF") on the specific measures evaluated by its Renal Standing Committee. With the input of our Medical Advisory Council (MAC) and Kidney Patient Advisory Council (KPAC), we would respectfully submit our following comments and recommendations with regard to NQF #3694 Percentage of Prevalent Patients Waitlisted in Active Status (aPPPW): The Forum noted in NQF comments for this proposal multiple concerns that led to the NQF declining to recommend this measure. Some of these comments raised concerns regarding "the attribution of successful or unsuccessful waitlisting to dialysis facilities, individual practitioners, or group practices" as well as "a focus on incident maintenance dialysis populations with "stand alone" measures independent of measures targeting patients in other stages of kidney diseases, such as non-dialysis advanced CKD and prevalent dialysis; reliance on CMS-2728 data for any risk adjustment, including transplant measures; lack of adjustment for variables that are critical for patient equity, such as SDOH; and a focus on dialysis unit-specific measures without consideration of advanced CKD care and nephrologist-led care." The Forum agrees with many of

these concerns. Recommendation: The Forum agrees with the NQF in not supporting the aPPPW measure. We thank you once again for your time and consideration. Respectfully submitted, David Henner, DO, President, Forum of ESRD Networks; Daniel Landry, DO, Chair, Medical Advisory Council; Derek Forfang, Co-Chair, Kidney Patient Advisory Council; Dawn Edwards, Co-Chair, Kidney Patient Advisory Council

Developer Response

Being waitlisted for kidney transplantation is the culmination of a variety of preceding preparatory activities. These include, but are not limited to, education of patients about the option of transplantation, 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 practitioner groups. Although some aspects of the waitlisting process may not entirely depend on dialysis practitioner groups, 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 practitioner groups. For example, through coordination of care, strong communication with transplant centers, and advocacy for patients by dialysis practitioner groups, as well as comprehensive education, encouragement, and support of patients during their decision-making about the transplantation option. The practitioner level access to transplant waitlisting measures were therefore proposed in the spirit of shared accountability, with the recognition that success requires substantial effort by dialysis practitioner groups. In this respect, the measures represent an explicit acknowledgment of the tremendous contribution dialysis practitioner groups can be, and are already, making towards access to transplantation, to the benefit of the patients under their care. With respect to the population focus of this measure, it is directed at prevalent dialysis patients. Although waitlisting measures directed at the advanced CKD population, prior to initiation of dialysis may also be potentially appropriate, the scope of this particular measure development effort was focused on the much larger group of patients who start dialysis without being transplanted. Patients who were waitlisted prior to dialysis, and who maintain their waitlisting following dialysis initiation, will be captured in this measure. With respect to comorbidity assessment, this measure uses Medicare claims for the prevalent comorbidities in addition to comorbidities listed on the form CMS-2728. With respect to SDOH, the developer does include variables to adjust for social risk, including the Area Deprivation Index and Medicare-Medicaid dual eligibility. The choice to adjust for transplant center characteristics and SDS factors was based on the notion of controlling for factors affecting transplant waitlisting that would be beyond the control of dialysis practitioner groups, in order to validly capture quality of dialysis practitioner performance. We did not take our decision to include these factors lightly, and certainly are very aware of existing disparities in access to the transplant waitlist; our decision to propose this measure is in large part motivated by a desire to reduce such disparities. For this reason, we did not adjust for race, as it may serve to sustain known racial disparities and structural racism. However, the factors we chose (ADI, dual eligibility) do have a conceptual basis in that they are proxies for financial and social resources that can affect success following transplantation.

NQF Response

Thank you for your comment. It has been shared with the Standing Committee and measure developer.

NQF Committee Response

N/A

NQF #3695 Percentage of Prevalent Patients Waitlisted (PPPW) (Recommended)

Dr. Lisa McGonigal, MD, MPH, Kidney Care Partners

Comment ID#: 8130 (Submitted: 08/22/2022)

Council / Public: QMRI

Level of Support: Member Does NOT Support

Comment

KCP does not concur with the Standing Committee's support of this measure. We recognize the tremendous importance of improving transplantation rates for patients with ESRD, but we do not support the attribution of successful or unsuccessful waitlisting to individual practitioners or group practices and thus cannot support these measures. KCP believes that while referral to a transplant center and initiation or even completion of the waitlist evaluation process might be appropriate measures for these levels of analysis that could be used in CMS's quality programs, the newly proposed practitioner/group level Percentage of Prevalent Patients Waitlisted (PPPW), Percentage of Prevalent Patients Waitlisted in Active Status (aPPPW), and First Year Standardized Waitlist Ratio (FYSWR) measures are not. Waitlisting per se is a decision made by the transplant center and is beyond the locus of control of any of the providers targeted in these measures. In reviewing these measures, we offer the following comments: I. Overarching Concerns. Several of KCP's concerns apply to all three proposed transplant access measures: a. Attribution. As above, we strongly object to attributing successful/unsuccessful placement on a transplant waitlist to individual clinicians or practitioner group practices and believe this is a fatal structural flaw with these measures. The transplant center decides whether a patient is placed on a waitlist, not the practitioner or group practice. KCP patient members who are transplant recipients have noted there are many obstacles and delays in the evaluation process with multiple parties that have nothing to do with the facility or practitioner—e.g., one patient noted their private pay insurance changed the locations where they could be evaluated for transplant eligibility on multiple occasions, repeatedly interrupting the process mid-stream. Penalizing a practitioner/group practice each month through the PPPW, aPPPW, and FYSWR for these or other delays is inappropriate; such misattribution is fundamentally misaligned with NQF's first "Attribution Model Guiding Principle," which states that measures' attribution models should fairly and accurately assign accountability. KCP emphasizes our commitment to improving transplantation access, but we believe other measures with an appropriate sphere of control should be pursued. For instance, our sister organization, the Kidney Care Quality Alliance (KCQA), has developed a dialysis facility-level Transplant Access Measure Set that will be submitted to NQF for endorsement consideration later this year. The set pairs a referral rate metric with a measure assessing the waitlisting rate specifically among those patients who

were referred by the facility within the preceding three years. Because the KCQA waitlisting measure denominator is limited to those patients specifically identified as appropriate transplant candidates and deliberately referred by the dialysis facility within a defined time period, facilities have considerably more agency over the measure than less precise metrics like the PPPW; this construct will also provide a counterbalance to the referral measure, curbing the tendency to indiscriminately refer patients who are not appropriate transplant candidates, preventing unnecessary patient and transplant center burden. The same approach could be applied at the practitioner/group level. b. Variation in Transplant Center Eligibility Criteria. We also note that criteria indicating a patient is "not eligible" for transplantation can differ by location. For instance, one center might require evidence of an absence of chronic osteomyelitis, infection, heart failure, etc., while another may apply eligibility exclusions differently or have additional or 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. c. Stratification of Reliability Results by Group Size and Performance Scores Absent. We also note that CMS has provided no stratification of reliability scores by provider size for the measures; we are thus unable to discern how widely reliability varies across the spectrum of practitioner/group practice sizes. We are concerned that the reliability for small providers 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 FYSWR, for which empiric testing has yielded an overall IUR of only 0.64—interpreted as "moderate" reliability by statistical convention. 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 concerned that FYSWR reliability is similarly lower for small groups, effectively rendering the metric meaningless for use in performance measurement in this subset of providers. KCP believes it is incumbent on CMS to demonstrate reliability for all providers by stratifying data by practice size.

Developer Response

Being waitlisted for kidney transplantation is the culmination of a variety of preceding preparatory activities. These include, but are not limited to, education of patients about the option of transplantation, 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 practitioner groups. Although some aspects of the waitlisting process may not entirely depend on dialysis practitioner groups, 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 practitioner groups. For example, through coordination of care, strong communication with transplant centers, and advocacy for patients by dialysis practitioner groups, as well as comprehensive education, encouragement, and support of patients during their decision-making about the transplantation option. The practitioner level access to transplant waitlisting measures were therefore proposed in the spirit of shared accountability, with the recognition that success requires substantial effort by dialysis practitioner groups. In this respect, the measures represent an explicit acknowledgment of the tremendous contribution dialysis practitioner groups can be, and are already, making towards access to

transplantation, to the benefit of the patients under their care. Although waitlisting measures directed at the transplant center may also be potentially appropriate, the scope of this particular measure development effort was focused on performance of dialysis practitioner groups. The developer agrees that measures directed at referral and transplant education would be potentially valuable, but limitations in national data availability on referral and appropriate tools to capture quality of transplant education pose practical hurdles to development of such measures. We agree with KCQA that referral is an important metric to report at the dialysis facility level, and we have done a lot of work over the years (including holding two TEPs) in support of development of a measure/collection of referral data. Although we agree that information on referral can be valuable for incorporation into access to transplantation measures, there is currently no mechanism to capture data on referral on a national scale. Further, in light of known ongoing disparities in access to transplantation, and in the spirit of ensuring fair access to kidney transplantation, we believe a denominator including all dialysis patients is still appropriate, rather than only those the dialysis facilities chooses to refer We agree that there is variation across transplant centers in eligibility criteria and that underlying patient comorbidities may affect their candidacy. All three waitlisting measures accordingly include adjustment for a wide range of comorbidities, and furthermore include adjustment for transplant center characteristics. An example is waitlist mortality, which can be viewed as a proxy for stringency of center waitlisting criteria. Further, the prevalent waitlisting measures include adjustment for transplant center random effects, capturing broad aspects of each transplant center's tendency to waitlist patients. Given the established effect of sample size on IUR calculations, it is expected that large facilities will have higher IUR values and small facilities will have lower IUR values for any given measure. Using the empirical null method, facilities are flagged if they have outcomes that are extreme when compared to the variation in outcomes for other facilities of a similar size. That is, smaller facilities have to have more extreme outcomes compared to other smaller facilities to be flagged.

NQF Response

N/A

NQF Committee Response

Thank you for your comment. The Standing Committee determined that this measure met all NQF criteria for endorsement and therefore, recommended the measure for endorsement.

Dr. Lisa McGonigal, MD, MPH, Kidney Care Partners

Comment ID#: 8126 (Submitted: 08/22/2022)

Council / Public: QMRI

Level of Support: Member Does NOT Support

Comment

KCP recognizes the tremendous importance of improving transplantation rates for patients with ESRD, but does not support the attribution of successful or unsuccessful waitlisting to individual practitioners or group practices and thus cannot support these measures. KCP believes that while referral to a transplant center and initiation or even completion of the waitlist evaluation process

might be appropriate measures for these levels of analysis that could be used in CMS's quality programs, the newly proposed practitioner/group level Percentage of Prevalent Patients Waitlisted (PPPW), Percentage of Prevalent Patients Waitlisted in Active Status (aPPPW), and First Year Standardized Waitlist Ratio (FYSWR) measures are not. Waitlisting per se is a decision made by the transplant center and is beyond the locus of control of any of the providers targeted in these measures. In reviewing these measures, we offer the following comments: I. Overarching Concerns. Several of KCP's concerns apply to all three proposed transplant access measures: a. Attribution. As above, we strongly object to attributing successful/unsuccessful placement on a transplant waitlist to individual clinicians or practitioner group practices and believe this is a fatal structural flaw with these measures. The transplant center decides whether a patient is placed on a waitlist, not the practitioner or group practice. KCP patient members who are transplant recipients have noted there are many obstacles and delays in the evaluation process with multiple parties that have nothing to do with the facility or practitioner—e.g., one patient noted their private pay insurance changed the locations where they could be evaluated for transplant eligibility on multiple occasions, repeatedly interrupting the process mid-stream. Penalizing a practitioner/group practice each month through the PPPW, aPPPW, and FYSWR for these or other delays is inappropriate; such misattribution is fundamentally misaligned with NQF's first "Attribution Model Guiding Principle," which states that measures' attribution models should fairly and accurately assign accountability. KCP emphasizes our commitment to improving transplantation access, but we believe other measures with an appropriate sphere of control should be pursued. For instance, our sister organization, the Kidney Care Quality Alliance (KCQA), has developed a dialysis facility-level Transplant Access Measure Set that will be submitted to NQF for endorsement consideration later this year. The set pairs a referral rate metric with a measure assessing the waitlisting rate specifically among those patients who were referred by the facility within the preceding three years. Because the KCQA waitlisting measure denominator is limited to those patients specifically identified as appropriate transplant candidates and deliberately referred by the dialysis facility within a defined time period, facilities have considerably more agency over the measure than less precise metrics like the PPPW; this construct will also provide a counterbalance to the referral measure, curbing the tendency to indiscriminately refer patients who are not appropriate transplant candidates, preventing unnecessary patient and transplant center burden. The same approach could be applied at the practitioner/group level. b. Variation in Transplant Center Eligibility Criteria. We also note that criteria indicating a patient is "not eligible" for transplantation can differ by location. For instance, one center might require evidence of an absence of chronic osteomyelitis, infection, heart failure, etc., while another may apply eligibility exclusions differently or have additional or 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. c. Stratification of Reliability Results by Group Size and Performance Scores Absent. We also note that CMS has provided no stratification of reliability scores by provider size for the measures; we are thus unable to discern how widely reliability varies across the spectrum of practitioner/group practice sizes. We are concerned that the reliability for small providers 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 FYSWR, for which empiric testing has yielded an overall IUR of only 0.64—interpreted as "moderate" reliability by statistical convention. 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 concerned that FYSWR reliability is similarly lower for small groups, effectively rendering the metric meaningless for use in performance measurement in this subset of providers. KCP believes it is incumbent on CMS to demonstrate reliability for all providers by stratifying data by practice size.

Developer Response

Being waitlisted for kidney transplantation is the culmination of a variety of preceding preparatory activities. These include, but are not limited to, education of patients about the option of transplantation, 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 practitioner groups. Although some aspects of the waitlisting process may not entirely depend on dialysis practitioner groups, 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 practitioner groups. For example, through coordination of care, strong communication with transplant centers, and advocacy for patients by dialysis practitioner groups, as well as comprehensive education, encouragement, and support of patients during their decision-making about the transplantation option. The practitioner level access to transplant waitlisting measures were therefore proposed in the spirit of shared accountability, with the recognition that success requires substantial effort by dialysis practitioner groups. In this respect, the measures represent an explicit acknowledgment of the tremendous contribution dialysis practitioner groups can be, and are already, making towards access to transplantation, to the benefit of the patients under their care. Although waitlisting measures directed at the transplant center may also be potentially appropriate, the scope of this particular measure development effort was focused on performance of dialysis practitioner groups. The developer agrees that measures directed at referral and transplant education would be potentially valuable, but limitations in national data availability on referral and appropriate tools to capture quality of transplant education pose practical hurdles to development of such measures. We agree with KCQA that referral is an important metric to report at the dialysis facility level, and we have done a lot of work over the years (including holding two TEPs) in support of development of a measure/collection of referral data. Although we agree that information on referral can be valuable for incorporation into access to transplantation measures, there is currently no mechanism to capture data on referral on a national scale. Further, in light of known ongoing disparities in access to transplantation, and in the spirit of ensuring fair access to kidney transplantation, we believe a denominator including all dialysis patients is still appropriate, rather than only those the dialysis facilities chooses to refer We agree that there is variation across transplant centers in eligibility criteria and that underlying patient comorbidities may affect their candidacy. All three waitlisting measures accordingly include adjustment for a wide range of comorbidities, and furthermore include adjustment for transplant center characteristics. An example is waitlist mortality, which can be viewed as a proxy for stringency of center waitlisting criteria. Further, the prevalent waitlisting measures include adjustment for transplant center random effects, capturing broad aspects of each transplant center’s tendency to waitlist patients. Given the established effect of sample size on IUR calculations, it is expected that large facilities will have higher IUR values and small facilities will have lower IUR values for any given measure. Using the empirical null method, facilities are

flagged if they have outcomes that are extreme when compared to the variation in outcomes for other facilities of a similar size. That is, smaller facilities have to have more extreme outcomes compared to other smaller facilities to be flagged.

NQF Response

N/A

NQF Committee Response

Thank you for your comment. The Standing Committee determined that this measure met all NQF criteria for endorsement and therefore, recommended the measure for endorsement.

Dr. Lisa McGonigal, MD, MPH, Kidney Care Partners

Comment ID#: 8129 (Submitted: 08/22/2022)

Council / Public: QMRI

Level of Support: Member Does NOT Support

Comment

KCP recognizes the tremendous importance of improving transplantation rates for patients with ESRD, but does not support the attribution of successful or unsuccessful waitlisting to individual practitioners or group practices and thus cannot support these measures. KCP believes that while referral to a transplant center and initiation or even completion of the waitlist evaluation process might be appropriate measures for these levels of analysis that could be used in CMS's quality programs, the newly proposed practitioner/group level Percentage of Prevalent Patients Waitlisted (PPPW), Percentage of Prevalent Patients Waitlisted in Active Status (aPPPW), and First Year Standardized Waitlist Ratio (FYSWR) measures are not. Waitlisting per se is a decision made by the transplant center and is beyond the locus of control of any of the providers targeted in these measures. In reviewing these measures, we offer the following comments: I. Overarching Concerns. Several of KCP's concerns apply to all three proposed transplant access measures: a. Attribution. As above, we strongly object to attributing successful/unsuccessful placement on a transplant waitlist to individual clinicians or practitioner group practices and believe this is a fatal structural flaw with these measures. The transplant center decides whether a patient is placed on a waitlist, not the practitioner or group practice. KCP patient members who are transplant recipients have noted there are many obstacles and delays in the evaluation process with multiple parties that have nothing to do with the facility or practitioner—e.g., one patient noted their private pay insurance changed the locations where they could be evaluated for transplant eligibility on multiple occasions, repeatedly interrupting the process mid-stream. Penalizing a practitioner/group practice each month through the PPPW, aPPPW, and FYSWR for these or other delays is inappropriate; such misattribution is fundamentally misaligned with NQF's first "Attribution Model Guiding Principle," which states that measures' attribution models should fairly and accurately assign accountability. KCP emphasizes our commitment to improving transplantation access, but we believe other measures with an appropriate sphere of control should be pursued. For instance, our sister organization, the Kidney Care Quality Alliance (KCQA), has developed a dialysis facility-level Transplant Access Measure Set that will be submitted to NQF for endorsement consideration later

this year. The set pairs a referral rate metric with a measure assessing the waitlisting rate specifically among those patients who were referred by the facility within the preceding three years. Because the KCQA waitlisting measure denominator is limited to those patients specifically identified as appropriate transplant candidates and deliberately referred by the dialysis facility within a defined time period, facilities have considerably more agency over the measure than less precise metrics like the PPPW; this construct will also provide a counterbalance to the referral measure, curbing the tendency to indiscriminately refer patients who are not appropriate transplant candidates, preventing unnecessary patient and transplant center burden. The same approach could be applied at the practitioner/group level. b. Variation in Transplant Center Eligibility Criteria. We also note that criteria indicating a patient is "not eligible" for transplantation can differ by location. For instance, one center might require evidence of an absence of chronic osteomyelitis, infection, heart failure, etc., while another may apply eligibility exclusions differently or have additional or 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. c. Stratification of Reliability Results by Group Size and Performance Scores Absent. We also note that CMS has provided no stratification of reliability scores by provider size for the measures; we are thus unable to discern how widely reliability varies across the spectrum of practitioner/group practice sizes. We are concerned that the reliability for small providers 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 FYSWR, for which empiric testing has yielded an overall IUR of only 0.64—interpreted as "moderate" reliability by statistical convention. 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 concerned that FYSWR reliability is similarly lower for small groups, effectively rendering the metric meaningless for use in performance measurement in this subset of providers. KCP believes it is incumbent on CMS to demonstrate reliability for all providers by stratifying data by practice size.

Developer Response

Being waitlisted for kidney transplantation is the culmination of a variety of preceding preparatory activities. These include, but are not limited to, education of patients about the option of transplantation, 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 practitioner groups. Although some aspects of the waitlisting process may not entirely depend on dialysis practitioner groups, 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 practitioner groups. For example, through coordination of care, strong communication with transplant centers, and advocacy for patients by dialysis practitioner groups, as well as comprehensive education, encouragement, and support of patients during their decision-making about the transplantation option. The practitioner level access to transplant waitlisting measures were therefore proposed in the spirit of shared accountability, with the recognition that success requires substantial effort by dialysis practitioner groups. In this respect, the measures represent an explicit acknowledgment of the tremendous

contribution dialysis practitioner groups can be, and are already, making towards access to transplantation, to the benefit of the patients under their care. Although waitlisting measures directed at the transplant center may also be potentially appropriate, the scope of this particular measure development effort was focused on performance of dialysis practitioner groups. The developer agrees that measures directed at referral and transplant education would be potentially valuable, but limitations in national data availability on referral and appropriate tools to capture quality of transplant education pose practical hurdles to development of such measures. We agree with KCQA that referral is an important metric to report at the dialysis facility level, and we have done a lot of work over the years (including holding two TEPs) in support of development of a measure/collection of referral data. Although we agree that information on referral can be valuable for incorporation into access to transplantation measures, there is currently no mechanism to capture data on referral on a national scale. Further, in light of known ongoing disparities in access to transplantation, and in the spirit of ensuring fair access to kidney transplantation, we believe a denominator including all dialysis patients is still appropriate, rather than only those the dialysis facilities chooses to refer We agree that there is variation across transplant centers in eligibility criteria and that underlying patient comorbidities may affect their candidacy. All three waitlisting measures accordingly include adjustment for a wide range of comorbidities, and furthermore include adjustment for transplant center characteristics. An example is waitlist mortality, which can be viewed as a proxy for stringency of center waitlisting criteria. Further, the prevalent waitlisting measures include adjustment for transplant center random effects, capturing broad aspects of each transplant center's tendency to waitlist patients. Given the established effect of sample size on IUR calculations, it is expected that large facilities will have higher IUR values and small facilities will have lower IUR values for any given measure. Using the empirical null method, facilities are flagged if they have outcomes that are extreme when compared to the variation in outcomes for other facilities of a similar size. That is, smaller facilities have to have more extreme outcomes compared to other smaller facilities to be flagged.

NQF Response

N/A

NQF Committee Response

Thank you for your comment. The Standing Committee determined that this measure met all NQF criteria for endorsement and therefore, recommended the measure for endorsement.

Ms. Kelly Brooks, MPA, The National Forum of ESRD Networks

Comment ID#: 8165 (Submitted: 09/05/2022)

Council / Public: QMRI

Level of Support: N/A

Comment

The National Forum of ESRD Networks ("the Forum") is appreciative of the opportunity to comment on the National Quality Forum ("NQF") on the specific measures evaluated by its Renal Standing Committee. With the input of our Medical Advisory Council (MAC) and Kidney Patient

Advisory Council (KPAC), we would respectfully submit our following comments and recommendations with regard to NQF #3695 Percentage of Prevalent Patients Waitlisted (PPPW): The Forum did receive a positive comment from its KPAC regarding this measure ("No one should receive credit for anything related to transplant for patients until they have been placed "active" on the waitlist"), members of our MAC were concerned that nephrology practices may not have a lot of control over this measure, given the recent implementation of the "waitlist mortality measure" for transplant centers. This latter measure attributes any mortality for a waitlisted patient towards the transplant center's waitlist mortality for up to 2 years after they have been taken off the list. One unintended consequence of the PPPW could be that small transplant centers will be more cautious about waitlisting patients due to the new transplant mortality measure. Because of this, and other concerns we mentioned back in spring, I do not think NQF should endorse this measure. Recommendation: Out of concern for how the PPPW could have a negative impact on smaller transplant centers, the Forum would recommend against endorsing the PPPW measure. We thank you once again for your time and consideration. Respectfully submitted, David Henner, DO, President, Forum of ESRD Networks; Daniel Landry, DO, Chair, Medical Advisory Council; Derek Forfang, Co-Chair, Kidney Patient Advisory Council; Dawn Edwards, Co-Chair, Kidney Patient Advisory Council

Developer Response

We agree that there is variation across transplant centers in eligibility criteria for waitlisting and that implementation of waitlist mortality measures directed at transplant centers may further affect this. To adjust for this, we have included transplant center effects (both a random effect, and adjustment for transplant center waitlist mortality) in the model for this measure.

NQF Response

N/A

NQF Committee Response

Thank you for your comment. The Standing Committee considers measures independently of others that have been recently implemented. The Standing Committee determined that this measure met all NQF criteria for endorsement and therefore, recommended the measure for endorsement.

NQF #3696 Standardized Modality Switch Ratio for Incident Dialysis Patients (SMoSR) (Not Recommended)

Dr. Lisa McGonigal, MD, MPH, Kidney Care Partners

Comment ID#: 8133 (Submitted: 08/22/2022)

Council / Public: QMRI

Level of Support: Member Does NOT Support

Comment

KCP supports the Standing Committee's recommendation against the Standardized Modality Switch Ratio (SMoSR) Measure. CMS indicates the basic premise of the measure is that patients who consent to changing their treatment modality from in-center to home do so as a result of iterative education efforts and effective decision support by the dialysis facility, which can help patients select a modality that is best aligned with their personal goals and values. It was also noted that the Technical Expert Panel (TEP) that convened in Spring 2021 to offer feedback on a draft modality switch measure had broad consensus that: 1) home dialysis rates are very low in the US; 2) a quality measure to monitor facility performance on home dialysis would be useful to patients, providers, and other stakeholders; and 3) there must be greater emphasis on effective and on-going education by both nephrologists and the facility care team to allow more patients to make a more informed modality choice. The TEP also recognized that a majority of switches to home dialysis occur within the first year of beginning chronic dialysis. While KCP agrees with all of the TEP's above conclusions, we remain unsure how the developer arrived at modality switch rates as a valid proxy for proper patient education. If, as stated, the goal is to incentivize improved modality education, this measure misses the mark. Certainly the measure will incentivize switching in-center patients to home dialysis, but there is no mechanism for the measure to discern whether such conversions are the result of the "iterative education efforts and effective decision support" that the developer envisions. Indeed, the measure offers no insight whatsoever into degree or quality of education and training the patient received in preparation for the switch and may even inadvertently infringe on patient choice; any home dialysis-related measure, particularly when tied to financial incentives, must be approached with considerable caution to ensure that patients who should not or do not want to receive home dialysis are not pressured or even coerced into selecting a home modality. We note that KCQA is developing a home dialysis measure set for consideration for National Quality Forum (NQF) endorsement later this year. The paired measure set is developed and designed to promote steady, deliberate performance improvement over time by addressing both sides of the home dialysis utilization equation—uptake and retention. The set pairs a "core" Home Dialysis Rate Measure with a "guardrail" Home Dialysis Retention Measure to counterbalance unopposed incentivization of home prescription and minimize risk of unchecked home dialysis growth. The retention measure will also allow providers to more readily assess the success of their efforts to create a sustainable home program through appropriate patient education, preparation, and support, and to apply targeted quality improvement interventions as needed. We are also concerned that the SMoSR requires use of a complicated and rather confusing two-part regression model connected through an estimated "mixture structure" to account for the many facilities that do not offer home dialysis ("zero-patient facilities"). We believe this issue is more effectively addressed in the KCQA measures, which have adopted the approach deployed in CMS's ESRD Treatment Choices (ETC) Model, wherein the home dialysis rate is aggregated across dialysis facilities under the same legal entity/parent organization within the same Hospital Referral Region. We believe that this HRR approach is fair and respects the existing business structure many organizations have developed around home dialysis, and is more easily deciphered by both patients and providers. Finally, we note that while CMS reports that the TEP supported the basic construct of the SMoSR, KCP staff attended the TEP calls and made note of considerable reservations expressed by TEP members: • The measure addresses only a small subset of patients—incident patients who switched from in-center to home dialysis within the first year of treatment; the TEP voiced concern that the measure would thus ultimately do little to "move the marker" on overall

home dialysis utilization within facilities and across dialysis organizations. • Likewise, TEP members argued that as there is significant room for improvement in home dialysis utilization in established patients, the measure should also address prevalent patients. With the exclusion of this population, the measure misses a significant opportunity to drive performance improvement. • Because the measure only gives "credit" for incident patients specifically who switch from in-center to a home modality, there was considerable concern that implementation of the SMoSR in a penalty-based program would create a perverse incentive to, paradoxically, start new patients on in-center dialysis so as to allow for a subsequent modality "switch" to home, for which credit could be received.

Developer Response

Education/Patient Choice The goal of the SMoSR is to incentivize patient access to home dialysis modalities. The commenter fails to acknowledge the literature evidence that clearly demonstrates the role of patient education, along with several other resources provided by the dialysis facility, that are required for a patient to successfully switch from in-center dialysis to a home modality, particularly early after initiating in-center dialysis for the first time. Patient education is a key component of ensuring that dialysis patients are aware of home modalities and the relative risks and potential benefits of their use. The dialysis facility and nephrology practitioner must be involved in ongoing evaluation of dialysis modality and discussions regarding home options on a regular basis for all patients as a required function of the Interdisciplinary Care Team (IDT) as stated in the CfC494 Medicare Dialysis Facility regulations. Specifically, V458 is under Patient Rights in the CMS Conditions for Coverage regulation, and outlines the Interdisciplinary Care Team's responsibilities for education and facilitation of patient choice in different modalities, including home dialysis. This measure construct highlights the importance of ongoing discussions over time and the critical role HD facilities play in influencing patients' modality selection. As noted in the measure submission, modality education and decision making ideally should occur in the pre-dialysis stages. However, since many patients start dialysis abruptly, and may have had little or no pre-dialysis education, this process should continue in the dialysis facility after initiating chronic dialysis. This point was clearly agreed to by the TEP held during development of this measure. Modality education is often an iterative process since patients new to dialysis may not be ready to absorb the vast quantity of information or make a modality decision immediately after starting in-center HD and their priorities may change as they understand dialysis and their own needs more fully. This measure construct highlights the importance of ongoing discussions over time and the critical role HD facilities play in influencing patients' modality selection. Modality switch or transfer requires patient consent at several steps, including, but not limited to consent for placement of PD catheter (for home PD), and implied consent and cooperation with the extensive home dialysis training required for patients to successfully initiate and maintain home dialysis. Successful modality switch, particularly the durable modality switch definition used in this measure, should reasonably be considered to be primarily driven by patient choice. Any suggestion that it is primarily driven by facility or nephrologist financial considerations is an insult to the great majority of providers who practice ethical care in the dialysis community. We reject the commenter's suggestion that these financial considerations might play a significant role in home dialysis choice after implementation of this measure. In addition, the assertion that this measure would encourage practitioners to start all patients on in-center HD and then change to home dialysis in

order to “game” the measure is problematic because well over 80% of ESRD patients already begin on in-center HD, including a subset of patients whose pre-dialysis preference was for treatment at home. This assertion is concerning because it suggests providers would force a treatment option on patients, potentially including a surgical procedure for vascular access. Finally, it is very unlikely that dialysis facility staff would be willing to attempt to coerce treating and referring nephrologists to provide unethical care to pre-dialysis patients just so the facility could improve their score on one quality measure. Accounting for dialysis facilities that do not offer home dialysis While conceptually the SMoSR and the KCQA Measure are similar in that both are designed to measure the use of home dialysis, operationally there are significant differences in how the uptake of home dialysis is considered. One of the primary challenges in measuring home dialysis utilization is that approximately 40% of US dialysis facilities only offer in-center hemodialysis. However, these dialysis facilities are still required to fulfill the patient modality education and facilitation requirements delineated in the Conditions for Coverage (CfC494). The SMoSR addresses this issue by accounting for referrals from an in-center only dialysis facility to a facility that offers home dialysis so that the referring clinic can still receive credit for promoting home dialysis even if that service is not offered at the facility originating the transfer. In contrast, the KCQA measure uses Hospital Referral Regions (HRRs) to aggregate facilities by their parent organization which presents several challenges: (1) Under KCQA’s approach, accurate facility-level information about home dialysis modality availability and use would not be available to the public users of Care Compare’s dialysis information and ESRD QIP programs for nearly 3000 US dialysis facilities. (2) It will be difficult to differentiate attribution between physician provider groups who promote home dialysis for CKD patients such that they start directly on a home modality and facilities that educate hemodialysis patients about home modalities and facilitate a change after the patient has started dialysis. (3) HRRs can be geographically large and often cross state lines such that reporting outcomes at the State or Renal Network region would be problematic. In addition, there can be significant variation in home dialysis use at the facility level within an HRR that would be difficult to detect. The commenter’s statement criticism of this measures statistical basis is inaccurate. The sophisticated model used for risk adjustment is methodologically very similar to statistical models used for other NQF-endorsed quality measures, particularly the Standardized Mortality Ratio (NQF #0369) which is currently endorsed. This statistical approach allows for multiple patient-level risk adjusters while allowing calculation of individual facility-level results that can be easily compared to the national rate. The decision to use modality switch/transfer as the dependent variable is entirely justified by the facts stated in items 1-3 of our response immediately above. To briefly summarize, a dialysis facility quality measure that unnecessarily combines individual facility results into arbitrary regional groupings does not adequately serve the goals of the ESRD program, particularly with respect to public reporting and facilitation of dialysis consumer informed decision-making. Range of TEP Opinions for SMoSR The commenter’s opinion that this metric would do little to move the marker on home dialysis utilization was not expressed by TEP members during our meetings. SMoSR specifically focused on incident patients who switched from in-center to home in the first year of dialysis since that is when most patients who start in-center HD are considering modality options and are most likely to change to peritoneal dialysis. Moreover, our initial exploratory analyses which included prevalent patients had reliability that was too low for NQF or QIP (IUR 0.4). This was discussed with TEP members during our meetings. TEP members also discussed the value of pre-dialysis modality education as a way to improve home dialysis utilization, but this was outside of the scope of our charter, and not amenable to a facility-level metric although noted to

be important for future measure development work. Additionally, one TEP member expressed an opinion focused specifically on including prevalent patients because many patients who change from in-center HD to Home HD do so after the first year of in-center dialysis. However, this is a relatively small number of patients overall and so we are in fact not missing a "big opportunity" to drive performance improvement. Furthermore, home HD accounts for ~10% of home patients and approximately 40-50% of the patients who switch from In-center to HHD do so when they are admitted to a nursing home that offers "home" HD. Given the reliability issues with prevalent patients noted above, as well as the marked differences between nursing home "home HD" (which TEP members uniformly agreed should be excluded from the measure) and self-care at home HHD, we decided to focus on incident patients. The TEP advocated for future measure development to consider home dialysis among prevalent patients and this is noted in our Summary Report.

NQF Response

Thank you for your comment. It has been shared with the Standing Committee and measure developer.

NQF Committee Response

N/A

Ms. Jennifer Sardone, UM-KECC

Comment ID#: 8172 (Submitted: 09/06/2022)

Council / Public: PRO

Level of Support: N/A

Comment

(Part 2 of 2) The discussion about the risk adjustment model was also concerning, particularly surrounding comorbidity adjustment. The measure population is incident patients in their first year of dialysis. The developer contends that, for this incident population, adjustment based on comorbidities at ESRD incidence is appropriate. The committee did not discuss the differences between risk-adjustment approaches for incident versus prevalent patients and why the suggested approach is most appropriate. The measure submission provided evidence and a clear rationale for why the measure was not adjusted for social risk factors (in the testing for social risk section). Despite this, the committee members called for adjustment for social risk factors which seems inconsistent with NQF's current recommendations. Summary As outlined above, we believe the evidence and validity testing results provided for the measure are sufficient for a moderate rating. In our opinion, the committee discussion was not reflective of the NQF evaluation guidance, resulting in the Renal Standing Committee overriding the SMP recommendation without adequate justification. Because of these irregularities in the SC review of SMoSR, we request reconsideration of this measure.

Developer Response

N/A

NQF Response

N/A

NQF Committee Response

The Standing Committee voted to not reconsider this measure at the October 6th Post-Comment meeting. Additional details are provided in the meeting summary which can be found on the Renal project page on the NQF website.

Ms. Jennifer Sardone, UM-KECC

Comment ID#: 8171 (Submitted: 09/06/2022)

Council / Public: PRO

Level of Support: N/A

Comment

(Part 1 of 2) We are requesting reconsideration of the Standardized Modality Switch Ratio for Incident Dialysis Patients (SMoSR) on the basis that the measure evaluation criteria were not applied appropriately. The measure was deemed consensus not reached on evidence and did not pass validity. We contend that the information provided in the measure submission for both of these criteria were sufficient for moderate ratings, based on the NQF evaluation criteria. Evidence The Renal Standing Committee discussed the evidence in support of this outcome measure, but did not reach consensus. The Committee's discussion summarized by NQF staff: "The Standing Committee expressed concern with the evidence, noting that it is not clear that the evidence supporting modality switch as a marker of education is substantiated. The Standing Committee noted that a facility may provide education; however, if the patient chooses to stay on an in-center modality versus transitioning to home dialysis, that facility could be penalized, even though patient education was provided, due to patient choice. The Standing Committee discussed that dialysis modality education should occur prior to dialysis initiation and that this measure could encourage practitioners not to initiate home dialysis and recommend in-facility dialysis so that the dialysis facilities could then increase their switch rates. The developer advised that pre-dialysis education is outside of the scope of this measure but that the measure foci on incident patients and modality changes likely reflect robust education, effective presentation, and facilitation conducted by the dialysis unit." Per the evaluation guidance for outcome measures, the developer needs to prove that "empirical data demonstrate a relationship between the outcome to at least one healthcare structure, process, intervention, or service." The measures submission cited several studies that demonstrate how educational interventions facilitated shared-decision making and are associated with greater home dialysis uptake, thus fulfilling the above evidence criteria. The dialysis facility should be involved in ongoing evaluation of dialysis modality and discussions regarding home options on a regular basis for all patients. As noted in the measure submission, modality education and decision making ideally should occur in the pre-dialysis stages. However, since many patients start dialysis abruptly, and may have had little or no pre-dialysis education, this process should

continue in the dialysis facility after initiating chronic dialysis. Modality education is often an iterative process since patients new to dialysis may not be ready to absorb the vast quantity of information or make a modality decision immediately after starting in-center HD and their priorities may change as they understand dialysis and their own needs more fully. Moreover, the CMS Conditions for Coverage require facilities to provide modality education in order to facilitate patient selection of a modality. The committee's focus on the role of pre-dialysis education underestimates the importance of ongoing discussions over time and the critical role HD facilities play in influencing patients' modality selection. The assertion that this measure would encourage practitioners to start all patients on in-center HD and then change to home dialysis in order to "game" the measure is problematic because well over 80% of ESRD patients already begin on in-center HD, including a subset of patients whose pre-dialysis preference was for treatment at home. In addition, this assertion was raised repeatedly during the discussion. It is concerning because it suggests providers would force a treatment option on patients, potentially including a surgical procedure for vascular access. Finally, it is very unlikely that dialysis facility staff would be willing to attempt to coerce treating and referring nephrologists to provide unethical care to pre-dialysis patients just so the facility could improve their score on one quality measure. Validity The SMoSR was reviewed by the Scientific Methods Panel (SMP) in early 2022, and was given moderate ratings for both reliability and validity based on that review. The Renal Standing Committee, during their discussion of the measure, voted to not accept the SMP rating for validity. The validity discussion was described as follows in the summary of the Renal Standing Committee meeting: "In addition, the Standing Committee discussed several topics related to the validity of the measure. Specifically, the Standing Committee discussed the risk adjustment model and questioned whether the comorbidities included in the model influence the choice of dialysis modality. The Standing Committee also noted that capturing comorbidities from the Centers for Medicare & Medicaid Services (CMS) 2728 form is problematic because this form captures patients' health state at the beginning of care, not how their medical condition changes over time. The developer advised that the measure captures incident patients and adjusts for comorbidities when the patient initiates dialysis; thus, the comorbidities in the risk model should be those that are not the result of the dialysis facilities' care and should not reflect changes in the patient's medical condition over time. The Standing Committee emphasized that many factors are used to determine whether patients are appropriate for a home modality, many of which are not represented in the model, further calling into question the risk adjustment and exclusions. The developer noted that CMS is implementing screening for social determinants of health (SDOH), which will help in identifying patients for certain therapies. The Standing Committee questioned how dialysis facilities that do not offer home modalities will be perceived statistically. The developer noted that facilities that offer both modality types tend to do better in switches, as compared to those that only offer in-center dialysis, and that this may be due to less familiarity with home modalities. Lastly, the Standing Committee asked whether nursing home residents are included in the measure. The developer noted that patients currently residing in a nursing home are excluded from the measure. Due to the above concerns regarding validity, the Standing Committee did not accept the SMP's vote and did not pass the measure on validity, a must-pass criterion; therefore, the Standing Committee did not discuss or vote on any proceeding criteria." The overall discussion of validity was unfocussed. While the committee rejected the SMPs recommendation for SMoSR on validity, the SC did not clearly articulate why the SMPs decision was flawed or why members felt the need to re-adjudicate the validity decision. Finally, many of the SC member comments during the

discussion suggest they believed that the measure was designed to encourage 100% performance across all facilities, which is not correct. For example, at one point during the discussion, the committee focused on the lack of an exclusion for patient choice (i.e., an exclusion for patients who elected against home dialysis). This concept is problematic in the context of dialysis facilities for a number of reasons, the least of which is that there is not an existing mechanism for measuring patient choice that could be incorporated in any quality measure in this setting. The burden associated with collecting this information, along with the difficultly in determining how patient choice could be accurately documented (in a way that accounts for dialysis facility behavior that could influence a patient's choice, like the education provided to the patient) means that it is likely to be years before such a measure of patient choice is developed and NQF-endorsed, given the consensus endorsement's rigorous scientific acceptability standards. Another limitation in measuring patient choice is that it would be nearly impossible to accurately measure the construct of patient choice as separate and distinct from informed decision. Therefore, we do not use patient choice as an exclusion because we could not justify any currently developed approach to the Methodology Panel as being valid and being able to demonstrate the construct validity of patient choice. However, we re-state that SMoSR does not have an absolute performance threshold. As constructed the measure is intended to identify outliers relative to all US dialysis facilities. Since facilities are being compared to their peers' performance, SMoSR identifies extreme variance from average performance, after adjustment for multiple patient demographics and other risk adjusters specific to the facility level setting. As a result individual patient choice will not typically influence facility performance. However, if many or most of the facility's patients choose not to accept standard practice recommendations, the facility may well then be identified as an outlier performer. If that is the case then it would be appropriate to ask why so many of a facility's patients would choose a clinical path that diverges from the national norm.

Developer Response

N/A

NQF Response

N/A

NQF Committee Response

The Standing Committee voted to not reconsider this measure at the October 6th Post-Comment meeting. Additional details are provided in the meeting summary which can be found on the Renal project page on the NQF website.

Ms. Kelly Brooks, MPA, The National Forum of ESRD Networks

Comment ID#: 8169 (Submitted: 09/05/2022)

Council / Public: QMRI

Level of Support: N/A

Comment

The National Forum of ESRD Networks ("the Forum") is appreciative of the opportunity to comment on the National Quality Forum ("NQF") on the specific measures evaluated by its Renal Standing Committee. With the input of our Medical Advisory Council (MAC) and Kidney Patient Advisory Council (KPAC), we would respectfully submit our following comments and recommendations with regard to NQF #3696 Standardized Modality Switch Ratio for Incident Dialysis Patients (SMoSR): The Forum strongly supports efforts to encourage home dialysis through education and informed decision-making. The Forum, however, is concerned that the SMoSR measure could lead to practitioners being encouraged to initiate patients in-center in order to gain "credit" for changing the patient to home-based therapy later on. Sometimes this may need to be done if the home training is delayed due to training dates or staff shortages, but otherwise the in-center start would be more likely to let the undecided patient become complacent and decline to switch to home. One of our KPAC members also commented as follows: "While the measure is important, I believe the credit for the switch should be longer than 30 days (e.g., 90 days or longer). To incentivize switching for a short period could actually harm patients. We want patients to benefit from home for the longest time possible. The failure rate of home is somewhere around 40 percent after one year and 70 percent after two years. The focus of the measure should be to improve those statistics in my thinking. Another issue of concern is that once patients are in an in-center setting it is difficult to get us to change. Even the best programs may only get 9-12 percent of patients to switch. We need to have a physician level measure to start patients at home before they ever go in-center. The problems of physicians and dialysis centers not being well trained and comfortable with home dialysis, and also the social determinants of health affecting not only the patients, but also the location of the dialysis units, are challenging, and must be attributed very well if the measures are to be truly applicable." Recommendation: The Forum agrees with the NQF in not supporting the SMoSR measure. We thank you once again for your time and consideration. Respectfully submitted, David Henner, DO, President, Forum of ESRD Networks; Daniel Landry, DO, Chair, Medical Advisory Council; Derek Forfang, Co-Chair, Kidney Patient Advisory Council; Dawn Edwards, Co-Chair, Kidney Patient Advisory Council

Developer Response

Education/Patient Choice The goal of the SMoSR is to incentivize patient access to home dialysis modalities. The commenter fails to acknowledge the literature evidence that clearly demonstrates the role of patient education, along with several other resources provided by the dialysis facility, that are required for a patient to successfully switch from in-center dialysis to a home modality, particularly early after initiating in-center dialysis for the first time. Patient education is a key component of ensuring that dialysis patients are aware of home modalities and the relative risks and potential benefits of their use. The dialysis facility and nephrology practitioner must be involved in ongoing evaluation of dialysis modality and discussions regarding home options on a regular basis for all patients as a required function of the Interdisciplinary Care Team (IDT) as stated in the CfC494 Medicare Dialysis Facility regulations. Specifically, V458 is under Patient Rights in the CMS Conditions for Coverage regulation, and outlines the Interdisciplinary Care Team's responsibilities for education and facilitation of patient choice in different modalities, including home dialysis. This measure construct highlights the importance of ongoing discussions over time and the critical role HD facilities play in influencing patients' modality selection. As noted in the

measure submission, modality education and decision-making ideally should occur in the pre-dialysis stages. However, since many patients start dialysis abruptly, and may have had little or no pre-dialysis education, this process should continue in the dialysis facility after initiating chronic dialysis. This point was clearly agreed to by the TEP held during development of this measure. Modality education is often an iterative process since patients new to dialysis may not be ready to absorb the vast quantity of information or make a modality decision immediately after starting in-center HD and their priorities may change as they understand dialysis and their own needs more fully. This measure construct highlights the importance of ongoing discussions over time and the critical role HD facilities play in influencing patients' modality selection. Modality switch or transfer requires patient consent at several steps, including, but not limited to consent for placement of PD catheter (for home PD), and implied consent and cooperation with the extensive home dialysis training required for patients to successfully initiate and maintain home dialysis. Successful modality switch, particularly the durable modality switch definition used in this measure, should reasonably be considered to be primarily driven by patient choice. Any suggestion that it is primarily driven by facility or nephrologist financial considerations is an insult to the majority of providers who practice ethical care in the dialysis community. We reject the commenter's suggestion that these financial considerations might play a significant role in home dialysis choice after implementation of this measure. In addition, the assertion that this measure might encourage practitioners to start all patients on in-center HD and then change to home dialysis in order to "game" the measure is problematic because well over 80% of ESRD patients already begin on in-center HD, including a subset of patients whose pre-dialysis preference was for treatment at home. This assertion is concerning because it suggests providers would force a treatment option on patients, potentially including a surgical procedure for vascular access. Finally, it is very unlikely that dialysis facility staff would be willing to attempt to coerce treating and referring nephrologists to provide unethical care to pre-dialysis patients just so the facility could improve their score on one quality measure. Thirty-day time period for defining a switch This issue was discussed extensively at the TEP and there was no consensus on defining the time period for a durable switch. Opinion on time periods was markedly distinct between patient TEP members that favored shorter time periods (some less than 30 days) and clinical providers that supported longer time periods for defining what counts as a durable (or "successful") switch. Specifically, patient TEP members advocated for a shorter definition as any time at home (e.g., days, a week) was thought to be valuable, whereas providers endorsed longer time periods, such as 60 or 90 days. As a result UM-KECC proposed the 30-day time-period as a practical compromise. As with other features of the measure, this time period can be re-evaluated in future iterations of the measure.

NQF Response

Thank you for your comment. It has been shared with the Standing Committee and measure developer.

NQF Committee Response

N/A

Public Comments on Renal Spring 2022 Draft Report

Draft Report Comment #1

David White, American Society of Nephrology ; Submitted by Mr. David White

Comment ID#: 8089 (Submitted: 06/07/2022)

Council / Public: Public

Level of Support: N/A

Comment

TO: NQF Renal Standing Committee FR: Tod Ibrahim, Executive Vice President, the American Society of Nephrology Members of the National Quality Forum Renal Standing Committee The more than 37,000,000 Americans living with kidney diseases and the 21,000 nephrologists, scientists, and other kidney health care professionals who are members of the American Society of Nephrology (ASN), thank you for the opportunity to comment on the 5 proposed transplantation, vascular access, and modality education measures under consideration: • Facility-Level Standardized Modality Switch Ratio for Incident Dialysis Patients (SMoSR) • Facility-Level Standardized Fistula Rate for Incident Patients (ISFR) • Practitioner/Group-Level First Year Standard Waitlist Ratio (FYSWR) • Practitioner/Group-Level Percentage of Prevalent Patients Waitlisted (PPPW) • Practitioner/Group-Level Percentage of Prevalent Patients Waitlisted in Active Status (aPPPW) Based on our review, ASN is concerned by several aspects of the measures and offers comment on all five measures submitted to NQF: • Focus on incident maintenance dialysis populations with “stand alone” measures that are independent of measures targeting patients in other stages of kidney diseases such as non-dialysis advanced chronic kidney disease and prevalent dialysis. • Reliance on CMS-2728 data (End Stage Renal Disease Medical Evidence Report Medicare Entitlement and/or Patient Registration) for any risk adjustment including transplant measures • Attribution of measures to dialysis facilities • Lack of adjustment for variables that are critical for patient equity, such as social determinants of health • Focus on dialysis unit-specific measures, without consideration of advanced CKD care and nephrologist-led care Facility-Level Standardized Modality Switch Ratio for Incident Dialysis Patients (SMoSR) The stated goal of the SMoSR measure is to incentivize high quality modality education. However, ASN does not understand how or why the developer arrived at the modality switch rates as a valid proxy for high quality patient engagement and education about modality options. The measure does not indicate the degree or quality of education or the training the patient received in preparation for a modality switch, and the measure may even infringe on the patient-physician relationship. If a dialysis facility or organization is responsible for a metric around dialysis modality switch, that may place the facility inappropriately at odds with conversations and achieved decisions between the patient, the patient’s carepartners and the nephrology clinician. ASN feels strongly that a nephrologist-led care team working with the patient must be at the core of deciding dialysis modality. ASN notes that this measure discounts any prior conversations and education that may have occurred among the nephrology clinician, the patient, and the patient’s carepartners. This is extraordinarily non-patient centered and, bizarrely, incentivizes initiation with hemodialysis prior to a modality change. A measure that focuses on modality switches as opposed to receipt of proper patient education and that is attributed to the facility results in a high risk for conflict between informed patient

preferences, pre-existing decisions, and dialysis facility incentives. ASN generally supports CMS's ETC Model handling of modality switches, wherein the home dialysis rate is aggregated across dialysis facilities under the same legal entity/parent organization within the same Hospital Referral Region. We believe that this HRR approach is fairer and aligns with the existing business structure that many larger organizations have around home dialysis, and is more easily deciphered by patients, physicians, and providers. Ironically, the proposed measure will actually penalize facilities that have a higher incident home dialysis rate. If a facility serves a population that already has a high home dialysis rate (e.g., 20% Home Dialysis in the service area), then more patients who are likely to desire home dialysis are already performing home dialysis as their initial dialysis modality than facility service areas where fewer (e.g., 10%) maintenance dialysis patients are performing home dialysis. Often times, facilities are involved in preparing patient for home dialysis prior to dialysis initiation. This puts the facility at risk for doing poorly with the metric, despite providing high quality care. The "less than 30 days" exclusion in this measure also concerns ASN, since some patients may decide to transition at less than 30 days for valid reasons, although understandably a facility may less often be responsible for home dialysis transitions during the first weeks a patient is receiving in-center dialysis. Additionally, given that individual facilities are relatively small, ASN has concerns regarding the reliability of the proposed metric for most dialysis facilities. We feel strongly that this proposed metric should be completely reconsidered. Facility-Level Standardized Fistula Rate for Incident Patients (ISFR) ASN agrees that vascular access is an important clinical consideration for patients and supports that hypothesis that some facilities are better than other facilities at optimizing the longevity of hemodialysis fistulas and grafts as well as at facilitating creation of fistulas and grafts. ASN also continues its support of CMS's Long-Term Catheter Rate Measure (NQF #2978) in the ESRD QIP to maintain prevalent central venous catheter use at a small portion of the dialysis population. However, ASN does not believe that narrowing the target population of the prior, all-patient iteration of the Standardized Fistula Rate Measure (SFR, previously NQF #2977) to incident dialysis patients makes for an appropriate metric or that this change addresses the issues that led to its loss of NQF endorsement in 2020. Inherently, the proposed fistula measure is unchanged from the prevalent measure, applying the existing measure to an incident population. ASN does believe attributing performance on this measure to the dialysis facility is appropriate. As a nephrologists' society, ASN considers optimizing vascular access among incident dialysis patients an appropriate focus for a measure for physicians and physician groups, but the proposed measure is misdirected at dialysis facilities. A well-thought-out vascular access plan is patient-centered, and clinician led. Dialysis facilities who meet patients for the first time should not be primarily responsible for vascular access plans. Rather, this should be done under the direction of the patient's whole kidney care team, in which the patient and their nephrologist work closely with the providers placing access, such as the surgeon or interventionalist. Of note, there are patients for whom timely AVF placement is not feasible and AV graft (AVG) is a reasonable, safer alternative to a catheter. AVG placement should be considered in the numerator -- also, this measure encourages dialysis facilities to cherry pick patients with existing arteriovenous fistulas. This is not patient-centered. Practitioner/Group-Level First Year Standard Waitlist Ratio (FYSWR) Practitioner/Group-Level Percentage of Prevalent Patients Waitlisted (PPPW) Practitioner/Group-Level Percentage of Prevalent Patients Waitlisted in Active Status (aPPPW) While ASN is supportive of these measures for ensuring and promoting equitable access to kidney transplantation, it is important to recognize that the actual waitlisting of patients -- active or inactive -- on the waitlist is beyond the control of dialysis units or individual nephrologists as currently structured. While

dialysis facilities and managing nephrologists may be able to exert some influence over several of these factors, this influence is dwarfed by the role of the transplant centers, rendering the attribution misdirected. In order to improve these measures, albeit leaving these still without the proper attribution, it is imperative that the following information be easily and readily accessible to referring physicians and dialysis units: 1. Waitlisting criteria at transplant centers including absolute AND relative contraindications. 2. Clear information on the reasons for declining a patient for listing by transplant centers so that nephrologists can determine if patients would benefit from referral to a different transplant center. 3. Active status on the waitlist needs to be made clearly available to nephrologists and dialysis facilities so that centers and dialysis facilities are immediately aware of when (and why) patients are inactivated on the list. If physicians are going to be held accountable for this, they need to be aware of the status and what needs to be done to be re-activate those patients on the waitlist. 4. “Internal holds” placed on a patient by the transplant center while leaving the patient as active on the waitlist. Differences in how transplant centers use this practice can adversely impact the measure and access to transplant for patients who are on extended periods of internal hold unbeknownst to them. The implementation of these measures should be accompanied by easy and timely access to the status of the patient in the evaluation process and waitlist status. A way to shed light on whether transplant centers are inappropriately using “internal hold” for patients is to share organ offer data with nephrologists and dialysis facilities which would help identify patients who are on internal hold instead of being inactivated. The Health Resources and Services Administration (HRSA) and the Organ Procurement and Transplantation Network (OPTN) need to provide access to waitlist data, information on steps to transplantation from centers, and organ offer data in a manner that is timely, easily accessible, and actionable. Please contact ASN Regulatory and Quality Officer David L. White at dwhite@asn-online.org or call (202) 640-4635.

Developer Response

N/A

NQF Response

Thank you for your comment. It has been shared with the Standing Committee and measure developer.

NQF Committee Response

N/A

Lisa McGonigal, Kidney Care Partners ; Submitted by Dr. Lisa McGonigal, MD, MPH

Comment ID#: 8071 (Submitted: 05/17/2022)

Council / Public: QMRI

Level of Support: Member Does NOT Support

Comment

Kidney Care Partners (KCP) is a non-profit coalition of more than thirty organizations comprising the full spectrum of stakeholders related to dialysis care—patients and advocates, dialysis professionals, physicians, nurses, researchers, therapeutic innovators, transplant coordinators, and manufacturers. KCP is committed to advancing policies that improve the quality of care and life for individuals at every stage along the chronic kidney and end stage renal disease care continuum, from prevention to dialysis, transplant, and post-transplant care. We commend NQF for undertaking this important work and offer comment on the five new measures under review: • Facility-Level Standardized Fistula Rate for Incident Patients (NQF 3659) • Practitioner/Group-Level First Year Standard Waitlist Ratio (NQF 3689) • Practitioner/Group-Level Percentage of Prevalent Patients Waitlisted in Active Status (NQF 3694) • Practitioner/Group-Level Percentage of Prevalent Patients Waitlisted (NQF 3695) • Facility-Level Standardized Modality Switch Ratio for Incident Dialysis Patients (NQF 3696) KCP thanks you for the opportunity to provide early comments on this these measures. If you have any questions after reviewing the comments, please do not hesitate to contact Lisa McGonigal, MD, MPH (lmcgon@msn.com). Sincerely, Kidney Care Partners Akebia Therapeutics, Inc. American Kidney Fund, Inc. American Nephrology Nurses Association American Society of Nephrology American Society of Pediatric Nephrology Ardelyx AstraZeneca Atlantic Dialysis Management Services, LLC Baxter International, Inc. Cara Therapeutics, Inc. Centers for Dialysis Care CorMedix Inc. DaVita, Inc. Dialysis Patient Citizens, Inc. Dialysis Vascular Access Coalition DialyzeDirect Fresenius Medical Care North America Greenfield Health Systems Kidney Care Council North American Transplant Coordinators Organization Nephrology Nursing Certification Commission Otsuka America Pharmaceutical, Inc. Renal Healthcare Association (formerly NRAA) Renal Physicians Association Renal Support Network Rockwell Medical Rogosin Institute Satellite Healthcare, Inc. U.S. Renal Care, Inc. Vertex Pharmaceuticals Vifor Pharma Ltd.

Developer Response

N/A

NQF Response

Thank you for your comment. It has been shared with the Standing Committee and measure developer.

NQF Committee Response

N/A

Lisa McGonigal, Kidney Care Partners ; Submitted by Dr. Lisa McGonigal, MD, MPH

Comment ID#: 8123 (Submitted: 08/22/2022)

Council / Public: QMRI

Level of Support: Member Does NOT Support

Comment

Kidney Care Partners (KCP) is a non-profit coalition of more than thirty organizations comprising the full spectrum of stakeholders related to dialysis care—patients and advocates, dialysis professionals, physicians, nurses, researchers, therapeutic innovators, transplant coordinators, and manufacturers. KCP is committed to advancing policies that improve the quality of care and life for individuals at every stage along the chronic kidney and end stage renal disease care continuum, from prevention to dialysis, transplant, and post-transplant care. We commend NQF for undertaking this important work and offer comment on the six measures under review: • Practitioner/Group-Level First Year Standard Waitlist Ratio (NQF 3689) • Practitioner/Group-Level Percentage of Prevalent Patients Waitlisted in Active Status (NQF 3694) • Practitioner/Group-Level Percentage of Prevalent Patients Waitlisted (NQF 3695) • Facility-Level Standardized Fistula Rate for Incident Patients (NQF 3659) • Facility-Level Standardized Modality Switch Ratio for Incident Dialysis Patients (NQF 3696) • Optimal ESRD Started (NQF 2594)

Developer Response

N/A

NQF Response

Thank you for your comment. It has been shared with the Standing Committee and measure developer.

NQF Committee Response

N/A

Pre-Evaluation Measure-Specific Comments on Renal Spring 2022 Submissions

NQF #3659 Standardized Fistula Rate for Incident Patients (Not Recommended)

David White, American Society of Nephrology ; Submitted by Mr. David White

Comment ID#: 8091 (Submitted: 06/07/2022)

Council / Public: Public

Level of Support: N/A

Comment

TO: National Quality Forum Renal Standing Committee FR: Tod Ibrahim, Executive Vice President, the American Society of Nephrology DA: June 7, 2022 RE: Public Comment: Spring 2022 Renal Measures Dear Members of the National Quality Forum Renal Standing Committee On behalf of the more than 37,000,000 Americans living with kidney diseases and the 21,000 nephrologists, scientists, and other kidney health care professionals who are members of the American Society of Nephrology (ASN), thank you for the opportunity to offer commentary on the five proposed transplantation, vascular access, and modality education measures put forth by the Centers for Medicare and Medicaid Services (CMS)/University of Michigan Kidney Epidemiology and Cost Center (UM-KECC): • Facility-Level Standardized Modality Switch Ratio for Incident Dialysis Patients (SMoSR) • Facility-Level Standardized Fistula Rate for Incident Patients (ISFR) • Practitioner/Group-Level First Year Standard Waitlist Ratio (FYSWR) • Practitioner/Group-Level Percentage of Prevalent Patients Waitlisted (PPPW) • Practitioner/Group-Level Percentage of Prevalent Patients Waitlisted in Active Status (aPPPW) Based on our review, ASN is concerned by several aspects of the measures and offers comment on all five measures submitted to NQF: • Focus on incident maintenance dialysis populations with “stand alone” measures that are independent of measures targeting patients in other stages of kidney diseases such as non-dialysis advanced chronic kidney disease and prevalent dialysis. This siloed focus disadvantages kidney care providers who have provided high quality care for people with advanced CKD, including referral for home dialysis and pre-emptive transplantation and penalizes dialysis providers who assume care of individuals with insufficient care prior to dialysis initiation • Reliance on CMS-2728 data (End Stage Renal Disease Medical Evidence Report Medicare Entitlement and/or Patient Registration) for any risk adjustment including transplant measures • Attribution of measures to dialysis facilities • Lack of adjustment for variables that are critical for patient equity, such as social determinants of health • Focus on dialysis unit-specific measures, without consideration of advanced CKD care and nephrologist-led care Below are comments about the specific measures: Facility-Level Standardized Fistula Rate for Incident Patients (ISFR) ASN agrees that vascular access is an important clinical consideration for patients and supports that hypothesis that some facilities are better than other facilities at optimizing the longevity of hemodialysis fistulas and grafts as well as at facilitating creation of fistulas and grafts. ASN also continues its support of CMS’s Long-Term Catheter Rate Measure (NQF #2978) in the ESRD QIP to maintain prevalent central venous catheter use at a small portion of the dialysis population. However, ASN does not believe that narrowing the target population of the prior, all-patient iteration of the Standardized Fistula Rate Measure (SFR, previously NQF #2977) to incident dialysis patients makes for an appropriate metric or that this change addresses the issues that led to its loss of NQF endorsement in 2020. Inherently, the proposed fistula measure is

unchanged from the prevalent measure, applying the existing measure to an incident population. ASN does believe attributing performance on this measure to the dialysis facility is appropriate. As a nephrologists' society, ASN considers optimizing vascular access among incident dialysis patients an appropriate focus for a measure for physicians and physician groups, but the proposed measure is misdirected at dialysis facilities. A well-thought-out vascular access plan is patient-centered, and clinician led. Dialysis facilities who meet patients for the first time should not be primarily responsible for vascular access plans. Rather, this should be done under the direction of the patient's whole kidney care team, in which the patient and their nephrologist work closely with the providers placing access, such as the surgeon or interventionalist. Of note, there are patients for whom timely AVF placement is not feasible and AV graft (AVG) is a reasonable, safer alternative to a catheter. AVG placement should be considered in the numerator. Finally, this measure encourages dialysis facilities to cherry pick patients with existing arteriovenous fistulas, potentially marginalizing patients with other types of access. This is not patient-centered and is not equitable. ASN appreciates the opportunity to provide comments on the five proposed transplantation, vascular access, and modality education measures under consideration. To discuss the contents of this memorandum, please contact ASN Regulatory and Quality Officer David L. White at dwhite@asn-online.org or call (202) 640-4635.

NQF Response

Thank you for your comment. It has been shared with the Standing Committee and measure developer.

Lisa McGonigal, Kidney Care Partners ; Submitted by Dr. Lisa McGonigal, MD, MPH

Comment ID#: 8072 (Submitted: 05/17/2022)

Council / Public: QMRI

Level of Support: Member Does NOT Support

Comment

Facility-Level Standardized Fistula Rate for Incident Patients (NQF 3659, CMS): KCP does not support the Standardized Fistula Rate for Incident Patients (Incident SFR) Measure. KCP maintains that vascular access is one of the most important clinical considerations for patients making decisions about dialysis facilities, and we continue our strong support of CMS's Long-Term Catheter Rate Measure (NQF 2978) in the ESRD QIP to reduce catheter use. However, we do not believe that merely narrowing the target population of the prior, all-patient iteration of the Standardized Fistula Rate Measure (SFR, previously NQF 2977) effectively addresses the issues that led to its loss of NQF endorsement in 2020. We note that the SFR's loss of NQF endorsement was precipitated by KDOQI's then-recent downgrading of the evidence supporting fistulas as the preferred access type, in favor of catheter avoidance and individualized ESKD Lifeplans. To support the premise for this new, incident-only measure, CMS now counters that the same guidelines do suggest that under favorable circumstances an AV fistula is preferred to an AV graft in incident patients due to fewer long-term vascular access events (e.g., thrombosis, loss of primary patency, interventions) and because "blood stream infection rates are the lowest in incident patients with AV fistula compared to long-term catheters." We note, however, that the KDOQI guideline explicitly indicates there is inadequate evidence to make a recommendation on choice of AV fistula vs AV graft for incident

vascular access based on associations with infections; thus, here again, the KDOQI statement focuses on catheter reduction and takes no stance on the superiority of fistulas over grafts in this regard. CMS also indicates that the Incident SFR was developed to focus on the subset of dialysis patients that evidence suggests may benefit the most during a time of intense vascular access creation, noting that while greater than 80% of incident dialysis patients begin treatment with a tunneled catheter, AV fistula rates exceed 60% by twelve months after dialysis initiation. Here we note that NQF's Renal Standing Committee also rejected the prior SFR because they believed the measures was effectively "topped out" at 64% for all patients for whom an AV fistula is clinically appropriate. As the new measure defines an incident patient as one who began maintenance hemodialysis within the prior twelve months, we believe CMS's logic here is flawed. Rather than supporting the premise of the measure, fistula rates climbing from less than 20% at dialysis initiation to greater than 60% within twelve months supports that dialysis facilities are already placing fistulas in nearly all clinically appropriate new patients, once under their care, such that by the end of the first year of dialysis the population approaches that "topped out" AV fistula rate identified by NQF. We also note that stratification of reliability scores by facility size was not detailed; 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 IUR, as has often been the case with other CMS standardized measures. Without evidence to the contrary, KCP is thus concerned the Incident SFR reliability may be unacceptably low 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. Taking all of the above into consideration, we do not believe limiting the SFR population to incident patients effectively addresses the previously identified issues with the original measure. We maintain that catheter avoidance is the appropriate focus for vascular access in both the incident and prevalent dialysis populations, and we believe the Standardized Fistula Rate for Incident Patients is an unnecessary solution to a problem already being effectively addressed by the existing vascular access measure.

NQF Response

Thank you for your comment. It has been shared with the Standing Committee and measure developer.

NQF #3689 First Year Standardized Waitlist Ratio (FYSWR) (Not Recommended)

Lisa McGonigal, Kidney Care Partners ; Submitted by Dr. Lisa McGonigal, MD, MPH

Comment ID#: 8073 (Submitted: 05/17/2022)

Council / Public: QMRI

Level of Support: Member Does NOT Support

Comment

Practitioner/Group-Level First Year Standard Waitlist Ratio (NQF 3689, CMS) Practitioner/Group-Level Percentage of Prevalent Patients Waitlisted in Active Status (NQF 3694, CMS) Practitioner/Group-Level Percentage Of Prevalent Patients Waitlisted (NQF 3695, CMS) KCP recognizes the tremendous importance of improving transplantation rates for patients with ESRD, but does not support the attribution of successful or unsuccessful waitlisting to dialysis facilities,

individual practitioners, or group practices and thus cannot support these measures. KCP believes that while a referral to a transplant center and initiation or even completion of the waitlist evaluation process might be appropriate measures for these levels of analysis that could be used in CMS's quality programs, the newly proposed practitioner/group level Percentage of Prevalent Patients Waitlisted (PPPW), Percentage of Prevalent Patients Waitlisted in Active Status (aPPPW), and First Year Standardized Waitlist Ratio (FYSWR) measures are not. Waitlisting per se is a decision made by the transplant center and is beyond the locus of control of any of the providers targeted in these measures. In reviewing these measures, we offer the following comments: I. Overarching Concerns Several of KCP's concerns apply to all three proposed transplant access measures: a. Attribution. As above, we strongly object to attributing successful/unsuccessful placement on a transplant waitlist to dialysis facilities, individual clinicians, or practitioner group practices and believe this is a fatal structural flaw with these measures. The transplant center decides whether a patient is placed on a waitlist, not the facility, practitioner, or group practice. KCP patient members who are transplant recipients have noted there are many obstacles and delays in the evaluation process with multiple parties that have nothing to do with the facility or practitioner—e.g., one patient noted their private pay insurance changed the locations where they could be evaluated for transplant eligibility on multiple occasions, repeatedly interrupting the process mid-stream. Penalizing a practitioner/group practice each month through the PPPW, aPPPW, and FYSWR for these or other delays is inappropriate; such misattribution is fundamentally misaligned with NQF's first "Attribution Model Guiding Principle," which states that measures' attribution models should fairly and accurately assign accountability. KCP emphasizes our commitment to improving transplantation access, but we believe other measures with an appropriate sphere of control should be pursued. For instance, our sister organization, the Kidney Care Quality Alliance (KCQA), has developed a dialysis facility-level Transplant Access Measure Set that will be submitted to NQF for endorsement consideration later this year. The set pairs a referral rate metric with a measure assessing the waitlisting rate specifically among those patients who were referred by the facility within the preceding three years. Because the KCQA waitlisting measure denominator is limited to those patients who were deliberately referred by the dialysis facility within a defined time period, facilities have considerably more agency over the measure than metrics such as the PPPW; this construct will also provide a counterbalance to the referral measure, curbing the tendency to indiscriminately refer patients who are not appropriate transplant candidates, preventing unnecessary patient and transplant center burden. The same approach could be applied at the practitioner/group level. b. Variation in Transplant Center Eligibility Criteria. We also note that criteria indicating a patient is "not eligible" for transplantation can differ by location. For instance, one center might require evidence of an absence of chronic osteomyelitis, infection, heart failure, etc., while another may apply eligibility exclusions differently or have additional or 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. c. Stratification of Reliability Results by Group Size and Performance Scores Absent. We also note that CMS has provided no stratification of reliability scores by provider size for the measures; we are thus unable to discern how widely reliability varies across the spectrum of practitioner/group practice sizes. We are concerned that the reliability for small providers 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 FYSWR, for which empiric testing has yielded an overall IUR of only 0.64—interpreted as "moderate" reliability by statistical convention. 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 concerned that FYSWR reliability is similarly lower for small groups, effectively rendering the metric meaningless for use in performance measurement in this subset of providers. KCP believes it is incumbent on CMS to demonstrate reliability for all providers by stratifying data by practice size.

NQF Response

Thank you for your comment. It has been shared with the Standing Committee and measure developer.

Mr. David White, American Society of Nephrology

Comment ID#: 8098 (Submitted: 06/07/2022)

Council / Public: Public

Level of Support: N/A

Comment

TO: NQF Renal Standing Committee FR: Tod Ibrahim, Executive Vice President, the American Society of Nephrology Members of the National Quality Forum Renal Standing Committee The more than 37,000,000 Americans living with kidney diseases and the 21,000 nephrologists, scientists, and other kidney health care professionals who are members of the American Society of Nephrology (ASN), thank you for the opportunity to comment on the 5 proposed transplantation, vascular access, and modality education measures under consideration: • Facility-Level Standardized Modality Switch Ratio for Incident Dialysis Patients (SMoSR) • Facility-Level Standardized Fistula Rate for Incident Patients (ISFR) • Practitioner/Group-Level First Year Standard Waitlist Ratio (FYSWR) • Practitioner/Group-Level Percentage of Prevalent Patients Waitlisted (PPPW) • Practitioner/Group-Level Percentage of Prevalent Patients Waitlisted in Active Status (aPPPW) Based on our review, ASN is concerned by several aspects of the measures and offers comment on all five measures submitted to NQF: • Focus on incident maintenance dialysis populations with "stand alone" measures that are independent of measures targeting patients in other stages of kidney diseases such as non-dialysis advanced chronic kidney disease and prevalent dialysis. • Reliance on CMS-2728 data (End Stage Renal Disease Medical Evidence Report Medicare Entitlement and/or Patient Registration) for any risk adjustment including transplant measures • Attribution of measures to dialysis facilities • Lack of adjustment for variables that are critical for patient equity, such as social determinants of health • Focus on dialysis unit-specific measures, without consideration of advanced CKD care and nephrologist-led care

NQF Response

Thank you for your comment. It has been shared with the Standing Committee and measure developer.

NQF #3694 Percentage of Prevalent Patients Waitlisted in Active Status (aPPPW) (Not Recommended)

Lisa McGonigal, Kidney Care Partners ; Submitted by Dr. Lisa McGonigal, MD, MPH

Comment ID#: 8076 (Submitted: 05/17/2022)

Council / Public: QMRI

Level of Support: Member Does NOT Support

Comment

IPercentage of Prevalent Patients Waitlisted In Active Status (NQF 3694, CMS) KCP has identified two concerns specific to the aPPPW measure: a. Rate vs. Ratio. Notwithstanding our concerns described above, 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. b. Active Status Data. We also note that a patient's status on the waitlist (active/inactive) can change frequently within the transplant centers and can be notoriously difficult to track. We believe this reality will seriously compromise the measure's validity and render the information it provides flawed, at best—and potentially harmful, should patients and providers act on the assumption of accuracy.

NQF Response

Thank you for your comment. It has been shared with the Standing Committee and measure developer.

Lisa McGonigal, Kidney Care Partners ; Submitted by Dr. Lisa McGonigal, MD, MPH

Comment ID#: 8074 (Submitted: 05/17/2022)

Council / Public: QMRI

Level of Support: Member Does NOT Support

Comment

Practitioner/Group-Level First Year Standard Waitlist Ratio (NQF 3689, CMS) Practitioner/Group-Level Percentage of Prevalent Patients Waitlisted in Active Status (NQF 3694, CMS) Practitioner/Group-Level Percentage Of Prevalent Patients Waitlisted (NQF 3695, CMS) KCP recognizes the tremendous importance of improving transplantation rates for patients with ESRD, but does not support the attribution of successful or unsuccessful waitlisting to dialysis facilities, individual practitioners, or group practices and thus cannot support these measures. KCP believes that while a referral to a transplant center and initiation or even completion of the waitlist evaluation process might be appropriate measures for these levels of analysis that could be used in CMS's quality programs, the newly proposed practitioner/group level Percentage of Prevalent Patients Waitlisted (PPPW), Percentage of Prevalent Patients Waitlisted in Active Status (aPPPW), and First Year Standardized Waitlist Ratio (FYSWR) measures are not. Waitlisting per se is a decision made by the transplant center and is beyond the locus of control of any of the providers targeted in these measures. In reviewing these measures, we offer the following comments: I. Overarching Concerns Several of KCP's concerns apply to all three proposed transplant access measures: a.

Attribution. As above, we strongly object to attributing successful/unsuccessful placement on a transplant waitlist to dialysis facilities, individual clinicians, or practitioner group practices and believe this is a fatal structural flaw with these measures. The transplant center decides whether a patient is placed on a waitlist, not the facility, practitioner, or group practice. KCP patient members who are transplant recipients have noted there are many obstacles and delays in the evaluation process with multiple parties that have nothing to do with the facility or practitioner—e.g., one patient noted their private pay insurance changed the locations where they could be evaluated for transplant eligibility on multiple occasions, repeatedly interrupting the process mid-stream. Penalizing a practitioner/group practice each month through the PPPW, aPPPW, and FYSWR for these or other delays is inappropriate; such misattribution is fundamentally misaligned with NQF's first "Attribution Model Guiding Principle," which states that measures' attribution models should fairly and accurately assign accountability. KCP emphasizes our commitment to improving transplantation access, but we believe other measures with an appropriate sphere of control should be pursued. For instance, our sister organization, the Kidney Care Quality Alliance (KCQA), has developed a dialysis facility-level Transplant Access Measure Set that will be submitted to NQF for endorsement consideration later this year. The set pairs a referral rate metric with a measure assessing the waitlisting rate specifically among those patients who were referred by the facility within the preceding three years. Because the KCQA waitlisting measure denominator is limited to those patients who were deliberately referred by the dialysis facility within a defined time period, facilities have considerably more agency over the measure than metrics such as the PPPW; this construct will also provide a counterbalance to the referral measure, curbing the tendency to indiscriminately refer patients who are not appropriate transplant candidates, preventing unnecessary patient and transplant center burden. The same approach could be applied at the practitioner/group level. b. Variation in Transplant Center Eligibility Criteria. We also note that criteria indicating a patient is "not eligible" for transplantation can differ by location. For instance, one center might require evidence of an absence of chronic osteomyelitis, infection, heart failure, etc., while another may apply eligibility exclusions differently or have additional or 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. c. Stratification of Reliability Results by Group Size and Performance Scores Absent. We also note that CMS has provided no stratification of reliability scores by provider size for the measures; we are thus unable to discern how widely reliability varies across the spectrum of practitioner/group practice sizes. We are concerned that the reliability for small providers 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 FYSWR, for which empiric testing has yielded an overall IUR of only 0.64—interpreted as "moderate" reliability by statistical convention. 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 concerned that FYSWR reliability is similarly lower for small groups, effectively rendering the metric meaningless for use in performance measurement in this subset of providers. KCP believes it is incumbent on CMS to demonstrate reliability for all providers by stratifying data by practice size.

NQF Response

Thank you for your comment. It has been shared with the Standing Committee and measure developer.

Mr. David White, American Society of Nephrology

Comment ID#: 8099 (Submitted: 06/07/2022)

Council / Public: Public

Level of Support: N/A

Comment

TO: NQF Renal Standing Committee FR: Tod Ibrahim, Executive Vice President, the American Society of Nephrology Members of the National Quality Forum Renal Standing Committee The more than 37,000,000 Americans living with kidney diseases and the 21,000 nephrologists, scientists, and other kidney health care professionals who are members of the American Society of Nephrology (ASN), thank you for the opportunity to comment on the 5 proposed transplantation, vascular access, and modality education measures under consideration: • Facility-Level Standardized Modality Switch Ratio for Incident Dialysis Patients (SMoSR) • Facility-Level Standardized Fistula Rate for Incident Patients (ISFR) • Practitioner/Group-Level First Year Standard Waitlist Ratio (FYSWR) • Practitioner/Group-Level Percentage of Prevalent Patients Waitlisted (PPPW) • Practitioner/Group-Level Percentage of Prevalent Patients Waitlisted in Active Status (aPPPW) Based on our review, ASN is concerned by several aspects of the measures and offers comment on all five measures submitted to NQF: • Focus on incident maintenance dialysis populations with “stand alone” measures that are independent of measures targeting patients in other stages of kidney diseases such as non-dialysis advanced chronic kidney disease and prevalent dialysis. • Reliance on CMS-2728 data (End Stage Renal Disease Medical Evidence Report Medicare Entitlement and/or Patient Registration) for any risk adjustment including transplant measures • Attribution of measures to dialysis facilities • Lack of adjustment for variables that are critical for patient equity, such as social determinants of health • Focus on dialysis unit-specific measures, without consideration of advanced CKD care and nephrologist-led care Practitioner /Group-Level First Year Standard Waitlist Ratio (FYSWR) Practitioner/Group-Level Percentage of Prevalent Patients Waitlisted (PPPW) Practitioner/Group-Level Percentage of Prevalent Patients Waitlisted in Active Status (aPPPW) While ASN is supportive of these measures for ensuring and promoting equitable access to kidney transplantation, it is important to recognize that the actual waitlisting of patients -- active or inactive -- on the waitlist is beyond the control of dialysis units or individual nephrologists as currently structured. While dialysis facilities and managing nephrologists may be able to exert some influence over several of these factors, this influence is dwarfed by the role of the transplant centers, rendering the attribution misdirected. In order to improve these measures, albeit leaving these still without the proper attribution, it is imperative that the following information be easily and readily accessible to referring physicians and dialysis units: 1. Waitlisting criteria at transplant centers including absolute AND relative contraindications. 2. Clear information on the reasons for declining a patient for listing by transplant centers so that nephrologists can determine if patients would benefit from referral to a different transplant center. 3. Active status on the waitlist needs to be made clearly available to nephrologists and dialysis facilities so that

centers and dialysis facilities are immediately aware of when (and why) patients are inactivated on the list. If physicians are going to be held accountable for this, they need to be aware of the status and what needs to be done to be re-activate those patients on the waitlist. 4. “Internal holds” placed on a patient by the transplant center while leaving the patient as active on the waitlist. Differences in how transplant centers use this practice can adversely impact the measure and access to transplant for patients who are on extended periods of internal hold unbeknownst to them. The implementation of these measures should be accompanied by easy and timely access to the status of the patient in the evaluation process and waitlist status. A way to shed light on whether transplant centers are inappropriately using “internal hold” for patients is to share organ offer data with nephrologists and dialysis facilities which would help identify patients who are on internal hold instead of being inactivated. The Health Resources and Services Administration (HRSA) and the Organ Procurement and Transplantation Network (OPTN) need to provide access to waitlist data, information on steps to transplantation from centers, and organ offer data in a manner that is timely, easily accessible, and actionable.

NQF Response

Thank you for your comment. It has been shared with the Standing Committee and measure developer.

NQF #3695 Percentage of Prevalent Patients Waitlisted (PPPW) (Recommended)

Lisa McGonigal, Kidney Care Partners ; Submitted by Dr. Lisa McGonigal, MD, MPH

Comment ID#: 8075 (Submitted: 05/17/2022)

Council / Public: QMRI

Level of Support: Member Does NOT Support

Comment

Practitioner/Group-Level First Year Standard Waitlist Ratio (NQF 3689, CMS) Practitioner/Group-Level Percentage of Prevalent Patients Waitlisted in Active Status (NQF 3694, CMS) Practitioner/Group-Level Percentage Of Prevalent Patients Waitlisted (NQF 3695, CMS) KCP recognizes the tremendous importance of improving transplantation rates for patients with ESRD, but does not support the attribution of successful or unsuccessful waitlisting to dialysis facilities, individual practitioners, or group practices and thus cannot support these measures. KCP believes that while a referral to a transplant center and initiation or even completion of the waitlist evaluation process might be appropriate measures for these levels of analysis that could be used in CMS’s quality programs, the newly proposed practitioner/group level Percentage of Prevalent Patients Waitlisted (PPPW), Percentage of Prevalent Patients Waitlisted in Active Status (aPPPW), and First Year Standardized Waitlist Ratio (FYSWR) measures are not. Waitlisting per se is a decision made by the transplant center and is beyond the locus of control of any of the providers targeted in these measures. In reviewing these measures, we offer the following comments: I. Overarching Concerns Several of KCP’s concerns apply to all three proposed transplant access measures: a. Attribution. As above, we strongly object to attributing successful/unsuccessful placement on a transplant waitlist to dialysis facilities, individual clinicians, or practitioner group practices and believe this is a fatal structural flaw with these measures. The transplant center decides whether a patient is placed on a waitlist, not the facility, practitioner, or group practice. KCP patient members

who are transplant recipients have noted there are many obstacles and delays in the evaluation process with multiple parties that have nothing to do with the facility or practitioner—e.g., one patient noted their private pay insurance changed the locations where they could be evaluated for transplant eligibility on multiple occasions, repeatedly interrupting the process mid-stream. Penalizing a practitioner/group practice each month through the PPPW, aPPPW, and FYSWR for these or other delays is inappropriate; such misattribution is fundamentally misaligned with NQF's first "Attribution Model Guiding Principle," which states that measures' attribution models should fairly and accurately assign accountability. KCP emphasizes our commitment to improving transplantation access, but we believe other measures with an appropriate sphere of control should be pursued. For instance, our sister organization, the Kidney Care Quality Alliance (KCQA), has developed a dialysis facility-level Transplant Access Measure Set that will be submitted to NQF for endorsement consideration later this year. The set pairs a referral rate metric with a measure assessing the waitlisting rate specifically among those patients who were referred by the facility within the preceding three years. Because the KCQA waitlisting measure denominator is limited to those patients who were deliberately referred by the dialysis facility within a defined time period, facilities have considerably more agency over the measure than metrics such as the PPPW; this construct will also provide a counterbalance to the referral measure, curbing the tendency to indiscriminately refer patients who are not appropriate transplant candidates, preventing unnecessary patient and transplant center burden. The same approach could be applied at the practitioner/group level. b. Variation in Transplant Center Eligibility Criteria. We also note that criteria indicating a patient is "not eligible" for transplantation can differ by location. For instance, one center might require evidence of an absence of chronic osteomyelitis, infection, heart failure, etc., while another may apply eligibility exclusions differently or have additional or 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. c. Stratification of Reliability Results by Group Size and Performance Scores Absent. We also note that CMS has provided no stratification of reliability scores by provider size for the measures; we are thus unable to discern how widely reliability varies across the spectrum of practitioner/group practice sizes. We are concerned that the reliability for small providers 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 FYSWR, for which empiric testing has yielded an overall IUR of only 0.64—interpreted as "moderate" reliability by statistical convention. 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 concerned that FYSWR reliability is similarly lower for small groups, effectively rendering the metric meaningless for use in performance measurement in this subset of providers. KCP believes it is incumbent on CMS to demonstrate reliability for all providers by stratifying data by practice size.

NQF Response

Thank you for your comment. It has been shared with the Standing Committee and measure developer.

Mr. David White, American Society of Nephrology
Comment ID#: 8100 (Submitted: 06/07/2022)

Council / Public: Public

Level of Support: N/A

Comment

TO: NQF Renal Standing Committee FR: Tod Ibrahim, Executive Vice President, the American Society of Nephrology Members of the National Quality Forum Renal Standing Committee The more than 37,000,000 Americans living with kidney diseases and the 21,000 nephrologists, scientists, and other kidney health care professionals who are members of the American Society of Nephrology (ASN), thank you for the opportunity to comment on the 5 proposed transplantation, vascular access, and modality education measures under consideration: • Facility-Level Standardized Modality Switch Ratio for Incident Dialysis Patients (SMoSR) • Facility-Level Standardized Fistula Rate for Incident Patients (ISFR) • Practitioner/Group-Level First Year Standard Waitlist Ratio (FYSWR) • Practitioner/Group-Level Percentage of Prevalent Patients Waitlisted (PPPW) • Practitioner/Group-Level Percentage of Prevalent Patients Waitlisted in Active Status (aPPPW) Based on our review, ASN is concerned by several aspects of the measures and offers comment on all five measures submitted to NQF: • Focus on incident maintenance dialysis populations with “stand alone” measures that are independent of measures targeting patients in other stages of kidney diseases such as non-dialysis advanced chronic kidney disease and prevalent dialysis. • Reliance on CMS-2728 data (End Stage Renal Disease Medical Evidence Report Medicare Entitlement and/or Patient Registration) for any risk adjustment including transplant measures • Attribution of measures to dialysis facilities • Lack of adjustment for variables that are critical for patient equity, such as social determinants of health • Focus on dialysis unit-specific measures, without consideration of advanced CKD care and nephrologist-led care Practitioner/Group-Level First Year Standard Waitlist Ratio (FYSWR) Practitioner/Group-Level Percentage of Prevalent Patients Waitlisted (PPPW) Practitioner/Group-Level Percentage of Prevalent Patients Waitlisted in Active Status (aPPPW) While ASN is supportive of these measures for ensuring and promoting equitable access to kidney transplantation, it is important to recognize that the actual waitlisting of patients -- active or inactive -- on the waitlist is beyond the control of dialysis units or individual nephrologists as currently structured. While dialysis facilities and managing nephrologists may be able to exert some influence over several of these factors, this influence is dwarfed by the role of the transplant centers, rendering the attribution misdirected. In order to improve these measures, albeit leaving these still without the proper attribution, it is imperative that the following information be easily and readily accessible to referring physicians and dialysis units: 1. Waitlisting criteria at transplant centers including absolute AND relative contraindications. 2. Clear information on the reasons for declining a patient for listing by transplant centers so that nephrologists can determine if patients would benefit from referral to a different transplant center. 3. Active status on the waitlist needs to be made clearly available to nephrologists and dialysis facilities so that centers and dialysis facilities are immediately aware of when (and why) patients are inactivated on the list. If physicians are going to be held accountable for this, they need to be aware of the status and what needs to be done to be re-activate those patients on the waitlist. 4. “Internal holds” placed on a patient by the transplant center while leaving the patient as active on the waitlist. Differences in how transplant centers use this practice can adversely impact the measure and

access to transplant for patients who are on extended periods of internal hold unbeknownst to them. The implementation of these measures should be accompanied by easy and timely access to the status of the patient in the evaluation process and waitlist status. A way to shed light on whether transplant centers are inappropriately using “internal hold” for patients is to share organ offer data with nephrologists and dialysis facilities which would help identify patients who are on internal hold instead of being inactivated. The Health Resources and Services Administration (HRSA) and the Organ Procurement and Transplantation Network (OPTN) need to provide access to waitlist data, information on steps to transplantation from centers, and organ offer data in a manner that is timely, easily accessible, and actionable.

NQF Response

Thank you for your comment. It has been shared with the Standing Committee and measure developer.

NQF #3696 Standardized Modality Switch Ratio for Incident Dialysis Patients (SMoSR) (Not Recommended)

David White, American Society of Nephrology ; Submitted by Mr. David White

Comment ID#: 8090 (Submitted: 06/07/2022)

Council / Public: Public

Level of Support: N/A

Comment

TO: National Quality Forum Renal Standing Committee FR: Tod Ibrahim, Executive Vice President, the American Society of Nephrology DA: June 7, 2022 RE: Public Comment: Spring 2022 Renal Measures Dear Members of the National Quality Forum Renal Standing Committee On behalf of the more than 37,000,000 Americans living with kidney diseases and the 21,000 nephrologists, scientists, and other kidney health care professionals who are members of the American Society of Nephrology (ASN), thank you for the opportunity to offer commentary on the five proposed transplantation, vascular access, and modality education measures put forth by the Centers for Medicare and Medicaid Services (CMS)/University of Michigan Kidney Epidemiology and Cost Center (UM-KECC): • Facility-Level Standardized Modality Switch Ratio for Incident Dialysis Patients (SMoSR) • Facility-Level Standardized Fistula Rate for Incident Patients (ISFR) • Practitioner/Group-Level First Year Standard Waitlist Ratio (FYSWR) • Practitioner/Group-Level Percentage of Prevalent Patients Waitlisted (PPPW) • Practitioner/Group-Level Percentage of Prevalent Patients Waitlisted in Active Status (aPPPW) Based on our review, ASN is concerned by several aspects of the measures and offers comment on all five measures submitted to NQF: • Focus on incident maintenance dialysis populations with “stand alone” measures that are independent of measures targeting patients in other stages of kidney diseases such as non-dialysis advanced chronic kidney disease and prevalent dialysis. This siloed focus disadvantages kidney care providers who have provided high quality care for people with advanced CKD, including referral for home dialysis and pre-emptive transplantation and penalizes dialysis providers who assume care of individuals with insufficient care prior to dialysis initiation • Reliance on CMS-2728 data (End Stage Renal Disease Medical Evidence Report Medicare Entitlement and/or Patient Registration) for any risk adjustment

including transplant measures • Attribution of measures to dialysis facilities • Lack of adjustment for variables that are critical for patient equity, such as social determinants of health • Focus on dialysis unit-specific measures, without consideration of advanced CKD care and nephrologist-led care Below are comments about the specific measures: Facility-Level Standardized Modality Switch Ratio for Incident Dialysis Patients (SMoSR) The stated goal of the SMoSR measure is to incentivize high quality modality education. However, ASN does not understand how or why the developer arrived at the modality switch rates as a valid proxy for high quality patient engagement and education about modality options. The measure does not indicate the degree or quality of education or the training the patient received in preparation for a modality switch, and the measure may even infringe on the patient-physician relationship. If a dialysis facility or organization is responsible for a metric around dialysis modality switch, that may place the facility inappropriately at odds with conversations and achieved decisions between the patient, the patient's carepartners and the nephrology clinician. While ASN acknowledges that education can be improved for many individuals with advanced chronic kidney disease, we feel strongly that a nephrologist-led care team working with the patient must be at the core of deciding dialysis modality. ASN notes that this measure discounts any prior conversations and education that may have occurred among the nephrology clinician, the patient, and the patient's carepartners. This is extraordinarily non-patient centered and, bizarrely, incentivizes initiation with hemodialysis prior to a modality change. A measure that focuses on modality switches as opposed to receipt of proper patient education and that is attributed to the facility results in a high risk for conflict between informed patient preferences, pre-existing decisions, and dialysis facility incentives. This is bad policy. ASN generally supports CMS's ESRD Treatment Choices (ETC) Model handling of modality switches, wherein the home dialysis rate is aggregated across dialysis facilities under the same legal entity/parent organization within the same Hospital Referral Region, although ASN continues to have concerns about how transfers among organizations are accounted for. We believe that this HRR approach is fairer, better acknowledges the existing business structure that many larger organizations have developed around home dialysis, and is more easily deciphered by patients, physicians, and providers. Ironically, the proposed measure will actually penalize facilities that have a higher incident home dialysis rate. If a facility serves a population that already has a high home dialysis rate (e.g., 20% Home Dialysis in the service area), then more patients who are likely to desire home dialysis are already performing home dialysis as their initial dialysis modality than facility service areas where fewer (e.g., 10%) maintenance dialysis patients are performing home dialysis. Often times, facilities are involved in preparing patient for home dialysis prior to dialysis initiation. This puts the facility at risk for doing poorly with the metric, despite providing high quality care. Lastly, the "less than thirty days" exclusion in this measure also concerns ASN, since some patients may decide to transition at less than thirty days for valid reasons, although understandably a facility may less often be responsible for home dialysis transitions during the first weeks a patient is receiving in-center dialysis. Additionally, given that individual facilities are relatively small, ASN has concerns regarding the reliability of the proposed metric for most dialysis facilities. We feel strongly that this proposed metric should be completely reconsidered.

NQF Response

Thank you for your comment. It has been shared with the Standing Committee and measure developer.

Lisa McGonigal, Kidney Care Partners ; Submitted by Dr. Lisa McGonigal, MD, MPH

Comment ID#: 8077 (Submitted: 05/17/2022)

Council / Public: QMRI

Level of Support: Member Does NOT Support

Comment

Facility-Level Standardized Modality Switch Ratio for Incident Dialysis Patients (NQF 3696, CMS)
KCP does not support the Standardized Modality Switch Ratio (SMoSR) Measure. CMS indicates the basic premise of the measure is that patients who consent to changing their treatment modality from in-center to home do so as a result of iterative education efforts and effective decision support by the dialysis facility, which can help patients select a modality that is best aligned with their personal goals and values. It was also noted that the Technical Expert Panel (TEP) that convened in Spring 2021 to offer feedback on a draft modality switch measure had broad consensus that: 1) home dialysis rates are very low in the US; 2) a quality measure to monitor facility performance on home dialysis would be useful to patients, providers, and other stakeholders; and 3) there must be greater emphasis on effective and on-going education by both nephrologists and the facility care team to allow more patients to make a more informed modality choice. The TEP also recognized that a majority of switches to home dialysis occur within the first year of beginning chronic dialysis. While KCP agrees with all of the TEP's above conclusions, we remain unsure how the developer arrived at modality switch rates as a valid proxy for proper patient education. If, as stated, the goal is to incentivize improved modality education, this measure misses the mark. Certainly the measure will incentivize switching in-center patients to home dialysis, but there is no mechanism for the measure to discern whether such conversions are the result of the "iterative education efforts and effective decision support" that the developer envisions. Indeed, the measure offers no insight whatsoever into degree or quality of education and training the patient received in preparation for the switch and may even inadvertently infringe on patient choice; any home dialysis-related measure, particularly when tied to financial incentives, must be approached with considerable caution to ensure that patients who should not or do not want to receive home dialysis are not pressured or even coerced into selecting a home modality.
We note that KCQA is developing a home dialysis measure set for consideration for National Quality Forum (NQF) endorsement later this year. The paired measure set is developed and designed to promote steady, deliberate performance improvement over time by addressing both sides of the home dialysis utilization equation—uptake and retention. The set pairs a "core" Home Dialysis Rate Measure with a "guardrail" Home Dialysis Retention Measure to counterbalance unopposed incentivization of home prescription and minimize risk of unchecked home dialysis growth. The retention measure will also allow providers to more readily assess the success of their efforts to create a sustainable home program through appropriate patient education, preparation, and support, and to apply targeted quality improvement interventions as needed. We are also concerned that the SMoSR requires use of a complicated and rather confusing two-part regression model connected through an estimated "mixture structure" to account for the many facilities that do not offer home dialysis ("zero-patient facilities"). We believe this issue is more effectively addressed in the KCQA measures, which have adopted the approach deployed in CMS's ESRD Treatment Choices (ETC) Model, wherein the home dialysis rate is aggregated across dialysis facilities under the same legal entity/parent organization within the same Hospital Referral Region.

We believe that this HRR approach is fair and respects the existing business structure many organizations have developed around home dialysis, and is more easily deciphered by both patients and providers. Further, we note that while CMS reports that the TEP supported the basic construct of the SMoSR, KCP staff attended the TEP calls and made note of considerable reservations expressed by TEP members: • The measure addresses only a small subset of patients—incident patients who switched from in-center to home dialysis within the first year of treatment; the TEP voiced concern that the measure would thus ultimately do little to “move the marker” on overall home dialysis utilization within facilities and across dialysis organizations. • Likewise, TEP members argued that as there is significant room for improvement in home dialysis utilization in established patients, the measure should also address prevalent patients. With the exclusion of this population, the measure misses a significant opportunity to drive performance improvement. • Because the measure only gives "credit" for incident patients specifically who switch from in-center to a home modality, there was considerable concern that implementation of the SMoSR in a penalty-based program would create a perverse incentive to, paradoxically, start new patients on in-center dialysis so as to allow for a subsequent modality "switch" to home, for which credit could be received. Finally, as a matter of process, we note that stratification of reliability scores by facility size was not detailed; 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 IUR, as has often been the case with other CMS standardized measures. Without evidence to the contrary, KCP is thus concerned the SMoSR reliability may be unacceptably low 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. Similarly, as with CMS’s other standardized ratio measures (e.g., the SMR, SHR, SRR, STrR), KCP again strongly recommends that ratio measures be avoided in favor of risk-adjusted rates or year-over-year normalized rates.

NQF Response

Thank you for your comment. It has been shared with the Standing Committee and measure developer.