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Renal, Spring 2022 Cycle CDP Report

TECHNICAL REPORT
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Executive Summary

Chronic kidney disease (CKD) has emerged as one of the most prominent causes of morbidity and mortality in the 21st century.[1] Without timely and effective treatment, CKD can progress to severe renal dysfunction and eventually end-stage renal disease (ESRD). Renal transplantation and dialysis are the most accessed treatment modalities among ESRD patients.[2] The selection of ESRD treatment and the education that accompanies the treatment are critical factors for the overall cost and quality of patient outcomes.[3] The National Quality Forum (NQF) Renal Standing Committee oversees NQF's portfolio of endorsed renal measures, including those associated with CKD. NQF-endorsed kidney care measures are used in several quality and performance improvement programs administered by the Centers for Medicare & Medicaid Services (CMS), such as Dialysis Facility Compare and the ESRD Quality Incentive Program (ESRD QIP).

For this cycle, the Standing Committee evaluated five newly submitted measures and one measure undergoing maintenance review against NQF's standard evaluation criteria. The Standing Committee recommended two measures for endorsement but did not recommend the remaining four measures for endorsement. The Consensus Standards Approval Committee (CSAC) upheld the Standing Committee's recommendations.

The endorsed measures are listed below:

- NQF #2594 Optimal End-Stage Renal Disease (ESRD) Starts (The Permanente Foundation/Kaiser Permanente Southern California)
- NQF #3695 Percentage of Prevalent Patients Waitlisted (PPPW) (University of Michigan Kidney and Epidemiology Cost Center [UM-KECC]/Centers for Medicare & Medicaid Services [CMS])

The measures that did not receive endorsement are listed below:

- NQF #3659 Standardized Fistula Rate (UM-KECC/CMS)
- NQF #3689 First Year Standardized Waitlist Ratio (FYSWR) (UM-KECC/CMS)
- NQF #3694 Percentage of Prevalent Patients Waitlisted in Active Status (aPPPW) (UM-KECC/CMS)
- NQF #3696 Standardized Modality Switch Ratio for Incident Dialysis Patients (SMoSR) (UM-KECC/CMS)

Brief summaries of the measures and their evaluations are included in the body of the report; detailed summaries of the Standing Committee's discussion and ratings of the criteria for each measure are in Appendix A.

Introduction

Worldwide, kidney disease has increased in prevalence and rose from the 13th leading cause of death to the 10th.[4] It has been the 10th leading cause of death in the United States (U.S.) from 2015 to 2020.[5] It is estimated that 37 million adults in the U.S. have CKD.[6] If CKD is not treated, it can progress to ESRD, which is treated via dialysis or a kidney transplant. The Centers for Disease Control and Prevention (CDC) estimates that "every 24 hours, 360 people begin dialysis treatment."[6] Treating kidney disease has also led to increased Medicare expenditures, as treating those with CKD costs $87.2 billion and those with ESRD costing $37.3 billion in 2019. The Renal Standing Committee reviewed six measures during the spring 2022 cycle, which focused on the use of fistulas, switches from in-center dialysis to home dialysis, measuring planned starts of renal replacement therapy, and tracking patients on the kidney or kidney-pancreas transplant waitlist.

Fistulas

There are three main types of vascular access: native arteriovenous fistula (AVF), arteriovenous graft (AVG), and central venous catheter (CVC) to treat kidney failure patients on dialysis. Effective kidney failure treatment is dependent on reliable vascular access so that patients can receive long-term therapy. Dialysis improvements have allowed renal patients to live longer and have an increased quality of life; as such, a patient's vascular access must be able to provide long-term patency for dialysis access and low complication rates.[7] The Standing Committee evaluated a measure this cycle that assesses fistula rates (NQF #3659).

Home Dialysis

Effective healthcare allows patients to make their own informed choices regarding their dialysis modality selection; however, home dialysis rates remain low in the U.S.[8] In 2017, only 10.8 percent of U.S. incidents and only 11.8 percent of prevalent patients were on home dialysis.[8] There are many barriers to the uptake of home dialysis, including economic barriers, clinical training, lack of physician competency in prescribing home dialysis modalities, lack of sufficient housing or storage space for dialysis supplies, and adequate education.[8] Patient education plays an important role in home dialysis modality uptake and allows patients to make informed choices regarding their dialysis modality to improve their quality of care. The Standing Committee evaluated a measure this cycle that assesses dialysis switch rates (NQF #3696).

End-Stage Renal Disease Treatment

ESRD defines the loss of kidney function. The kidney's role is to clean the circulating blood of toxins that are in the body and then rid the body of that waste in the form of urine. If the kidneys are unable to perform their role, toxins can build up in the body, which can lead to death. Dialysis and transplantation are the two forms of treatment for ESRD.[9] The Standing Committee evaluated a measure this cycle that assesses the initiation of dialysis or a kidney transplant (NQF #2594).

Renal Transplant Waitlisting

Kidney transplants help patients live longer and have an improved quality of life.[9] Dialysis practitioners can assist in improving a patient's health status and address barriers to being waitlisted for a kidney transplant.[10] Providing optional patient education on the transplant process, assistance in communication with the transplant center, and timely referrals to transplant centers for evaluation also

helps to ensure patients are ready to be waitlisted.[10] The Standing Committee evaluated three measures this cycle that assess transplant waitlisting status (NQF #3689, NQF #3694, and NQF #3695).

NQF Portfolio of Performance Measures for Renal Conditions

The Renal Standing Committee (Appendix C) oversees NQF's portfolio of renal measures (Appendix B), which includes measures for hemodialysis, standardized mortality and transfusion ratios, phosphorus concentration, hypercalcemia, pediatric hemodialysis, Angiotensin Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) therapy, optimal ESRD starts, and bloodstream infections in hemodialysis patients. This portfolio contains 18 measures: six process measures, six intermediate clinical outcome measures, and six outcome measures.

Renal Measure Evaluation

On June 29 and 30, 2022, the Renal Standing Committee evaluated five new measures and one measure undergoing maintenance review against NQF's standard measure evaluation criteria.

Table 1. Renal Measure Evaluation Summary

Measure	Maintenance	New	Total
Measures under review for endorsement	1	5	6
Measures endorsed	1	1	2
Measures not endorsed	0	4	4
Reasons for not endorsing	Importance – 0 Scientific Acceptability – 0 Use – 0 Overall Suitability – 0 Competing Measure – 0	Importance – 1 Scientific Acceptability – 3 Overall Suitability – 0 Competing Measure – 0	4

Scientific Methods Panel Measure Evaluation

Prior to the Standing Committee's review, the Scientific Methods Panel (SMP) reviewed eight complex measures in this topic area. The SMP passed three measures, did not reach consensus on validity for three measures, did not pass two measures on both reliability and validity, and did not pass one measure on reliability. Measures that passed the SMP's review or for which the SMP did not reach consensus were reviewed by the Standing Committee. Measures that did not pass the SMP's review may or may not be eligible for a revote and full evaluation conducted by the Standing Committee. A measure is not eligible for a revote if it did not pass the SMP's review for one or more of the following reasons:

1. An inappropriate methodology or testing approach was applied to demonstrate reliability or validity.
2. Incorrect calculations or formulas were used for testing.
3. The description of specifications, testing approach, results, or data is insufficient for the SMP to apply the criteria.

4. Appropriate levels of testing were not provided or otherwise did not meet NQF's minimum evaluation requirements.

The following three measures were not eligible for a revote conducted by the Standing Committee, nor were they pulled for discussion by the Standing Committee:

- NQF #1460 Bloodstream Infection in Hemodialysis Outpatients (Centers for Disease Control and Prevention)
- NQF #3679 Home Dialysis Rate (Kidney Care Quality Alliance)
- NQF #3697 Home Dialysis Retention (Kidney Care Quality Alliance)

A meeting summary detailing the SMP's measure evaluation for the spring 2022 cycle is available on the SMP webpage.

Comments Received Prior to Standing Committee Evaluation

NQF accepts comments on endorsed measures on an ongoing basis through the Quality Positioning System (QPS). In addition, NQF solicits comments for a continuous period during each evaluation cycle via an online tool located on the project webpage. For this evaluation cycle, the commenting period opened on May 10, 2022, and pre-meeting commenting closed on June 7, 2022. Prior to June 7, 2022, 11 comments were submitted and shared with the Standing Committee prior to the measure evaluation meeting(s) (Appendix F).

Comments Received After Standing Committee Evaluation

The continuous public commenting period with NQF member support closed on September 6, 2022. Following the Standing Committee's evaluation of the measures under review, NQF received 21 comments from four organizations (including two NQF member organizations) and individuals pertaining to the draft report and to the measures under review (Appendix G). All comments for each measure under review have also been summarized in Appendix A.

NQF members had the opportunity to express their support ("support" or "do not support") for each measure submitted for endorsement consideration to inform the Standing Committee's recommendations during the commenting period. One NQF member expressed "do not support" for NQF #3659, NQF #3689, NQF #3694, NQF #3695, and NQF #3696.

Summary of Measure Evaluation

The following brief summaries of the measure evaluation highlight the major issues that the Standing Committee considered. Details of the Standing Committee's discussion and ratings of the criteria for each measure are included in Appendix A.

End-Stage Renal Disease Treatment

NQF #2594 Optimal End-Stage Renal Disease (ESRD) Starts (The Permanente Federation/Kaiser Permanente Southern California): Endorsed

Description: Optimal End Stage Renal Disease (ESRD) Starts is the percentage of new adult ESRD patients during the measurement period who experience a planned start of renal replacement therapy

by receiving a preemptive kidney transplant, by initiating home dialysis (peritoneal dialysis or home hemodialysis), or by initiating outpatient in-center hemodialysis via arteriovenous fistula or arteriovenous graft; **Measure Type**: Process; **Level of Analysis**: Population: Regional and State, Clinician: Group/Practice, Facility, Health Plan, Integrated Delivery System; **Setting of Care**: Ambulatory Care, Inpatient/Hospital, Outpatient Services; **Data Source**: Registry Data, Claims, Other, Electronic Health Records

This facility-level measure was originally endorsed in 2015. Although it is not yet implemented in a federal program, this measure is utilized internally by the Kaiser Permanente Federation and is reported across eight regions within the Kaiser Permanente network. Components of the measure, such as rate of preemptive transplantation, rate of functioning vascular access, and incidence and prevalence of home dialysis modalities (peritoneal dialysis [PD] and home hemodialysis [HHD]), are publicly reported, and the developer's team has applied for consideration in federal programming, specifically the CMS Merit-Based Incentive Payment System (MIPS) Program.

The Standing Committee sought clarity from the developer on the measure's level of analysis (LOA) after observing what they identified as multiple LOAs in the submission. The developer confirmed that the LOA is best identified as an integrated delivery system. The Standing Committee then agreed that it would proceed with a review of the measure under the LOA designation of "integrated delivery system." The Standing Committee agreed that the updated evidence further supports the measure and passed the measure on the evidence criterion. The Standing Committee also noted a clear performance gap, as well as variation in performance, as indicated by the disparities data, and passed the measure on the performance gap criterion.

The Standing Committee inquired about the rationale behind the requirement of a minimum of 50 new ESRD patients in the denominator. The developer explained that statistically, 50 optimal starts is necessary to deem the measurement statistically meaningful. The developer also attested that additional reliability testing was not conducted and that the measure specifications have not changed significantly. The Standing Committee agreed that further discussion and a formal vote were not needed and accepted the previous Standing Committee's vote on reliability with a unanimous verbal confirmation. The developer also attested that additional validity testing was not conducted. Likewise, the Standing Committee agreed that further discussion and a formal vote were not needed and accepted the prior Standing Committee's vote on validity with a unanimous verbal confirmation.

The Standing Committee agreed that the measure is feasible; it also acknowledged that the measure is not currently publicly reported but is used for internal and regional quality assessment across the Kaiser Permanente network. The developer stated that the Kidney Care Choices model within the Center for Medicare *&* Medicaid Innovation (CMMI) Center started reporting optimal starts in 2022, and additional data will likely be seen in 2023. The developer also advised that they have applied for use in the CMS MIPS Program. Ultimately, the Standing Committee passed the measure on feasibility and use. The Standing Committee also agreed that the measure data demonstrated continuous improvement and noted that there is continued opportunity for improvement; however, it expressed concerns with potential unintended consequences, including the misrepresentation of an optimal start. The developer addressed the Standing Committee's concern with the misrepresentation of optimal starts by explaining

that optimal starts capture the first day of outpatient dialysis treatment, not the first day of the designated modality of treatment, and that there is no penalty for failure on the initial modality. The developer also explained that patients who switch from one dialysis modality to another are not included in this measure. The Standing Committee accepted the developer's clarifications on optimal starts and passed the measure on usability and overall suitability for endorsement.

During the post-evaluation commenting period, two comments were received for this measure. The first comment came from the developer, clarifying that the measure is applicable 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. The developer also noted that 12 rolling months is the most meaningful reporting period. The second comment was supportive of the measure but did offer suggestions for improvement, namely, that all patients should be considered home patients until they are ruled out for some reason, supportive care or conservative management should be taken into consideration, and a shared decision-making measure to accompany this measure is needed to ensure that the patient is included in deciding what is truly optimal for them. The developer responded to the comment, stating that the measure is based on shared decision making from patients and caregivers with the efforts of a multidisciplinary care team. The developer also stated that the measure incorporates all kidney care options, and while they support wider use of home dialysis, there are clinical and social issues that drive a patient's choice of therapy. They noted that patients who choose conservative therapy are not included in the optimal ESRD start numerator or denominator, so this measure fully supports patients who choose not to start dialysis. The Standing Committee did not raise any concerns with the comment, nor did it raise any concerns with the developer's response and maintained its decision to recommend the measure for endorsement. During the CSAC meeting on December 9, 2022, the CSAC upheld the Standing Committee's decision to recommend the measure for endorsement. No appeals were received.

Fistulas

NQF #3659 Standardized Fistula Rate for Incident Patients (Centers for Medicare & Medicaid Services [CMS]/University of Michigan Kidney and Epidemiology Cost Center [UM-KECC]): Not Endorsed

Description: Adjusted percentage of adult incident hemodialysis patient-months using an autogenous arteriovenous fistula (AVF) as the sole means of vascular access. The Standardized Fistula Rate (SFR) for Incident Patients is based on the prior SFR (NQF #2977) that included both incident and prevalent patients. This measure was initially endorsed in 2016, but as part of measure maintenance review by the NQF Standing Committee in 2020, concerns were raised about the strength of evidence supporting the prior measure. Namely, recent updates to the Kidney Disease Outcomes Quality Initiative (KDOQI) guidelines downgraded the evidence supporting fistula as the preferred access type and instead focus on catheter avoidance and developing an individualized ESKD Lifeplan. However, the 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. Given that over 80% of incident dialysis patients begin treatment with a tunneled catheter, and that 12 months after dialysis initiation AV fistula rates exceed 60%, the incident SFR was developed to focus on the subset of dialysis patients that the evidence suggests may benefit the most during a time of intense vascular access creation. Specifically, blood stream infection rates are the lowest in incident patients with AV fistula compared to long-term

catheters. Therefore the goal of this new measure is to evaluate facility performance in increasing fistula use in the incident population in order to reduce the heightened risks patients face due to bacteremia and infection related hospitalizations; **Measure Type**: Outcome: Intermediate Clinical Outcome; **Level of Analysis**: Facility; **Setting of Care**: Outpatient Services; **Data Source**: Registry Data, Claims

This facility-level measure was newly submitted for endorsement and is not yet implemented in an accountability program. The Standing Committee expressed concerns about the evidence, noting that it did not demonstrate a significant difference between assessing incident and prevalent patients. Additionally, the Standing Committee discussed the absence of a definitive recommendation on the superiority of fistulas versus grafts, regarding infection rates, per the National Kidney Foundation Kidney Disease Outcomes Quality Initiative (NKF KDOQI). It also highlighted two pre-evaluation comments, which asserted that the proposed measure is inherently unchanged from the previous measure and long-term catheter rate measurement is preferred over the currently proposed measure. The Standing Committee inquired about a correlation between low fistula rates and facility size. The developer stated that they did not parse the data out by facility size and explained that they cannot say for certain that the small facility size is a direct correlation to low fistula rates. The Standing Committee shared no additional concerns and did not reach consensus on the evidence criterion.

The Standing Committee noted that the developer cited an increase from 20 percent to greater than 60 percent in AVFs in the first year of dialysis and deemed this an indication of an opportunity for improvement. The Standing Committee questioned whether the data were a true reflection of a gap or indicative of other factors, such as the starting of dialysis in which a change in the use of AVFs and catheters is seen. The Standing Committee also questioned whether further improvement was feasible or appropriate, noting that it might not be appropriate for some subpopulations based on their stage of care. The Standing Committee did not pass the measure on performance gap, a must-pass criterion. Therefore, the Standing Committee did not discuss or vote on any proceeding criteria and did not recommend the measure for initial endorsement.

During the post-evaluation commenting period, two comments were received. Both comments agreed with the Standing Committee's recommendation to not endorse the measure. During the CSAC meeting on December 9, 2022, the CSAC upheld the Standing Committee's decision to not recommend the measure for endorsement.

Home Dialysis

NQF #3696 Standardized Modality Switch Ratio for Incident Dialysis Patients (SMoSR) (CMS/UM-KECC): Not Endorsed

Description: The standardized modality switch ratio (SMoSR) is defined to be the ratio of the number of observed modality switches (from in-center to home dialysis—peritoneal or home hemodialysis) that occur for adult incident ESRD dialysis patients treated at a particular facility, to the number of modality switches (from in-center to home dialysis—peritoneal or home hemodialysis) that would be expected given the characteristics of the dialysis facility's patients and the national norm for dialysis facilities. The measure includes only the first durable switch that is defined as lasting 30 continuous days or longer. The SMoSR estimates the relative switch rate (from in-center to home dialysis) for a facility, as compared to the national switch rate. Qualitatively, the degree to which the facility's SMoSR varies from

1.00 is the degree to which it exceeds (> 1.00) or is below (< 1.00) the national modality switch rates for patients with the same characteristics as those in the facility. Ratios greater than 1.00 indicate better than expected performance while ratios <1.00 indicate worse than expected performance. When used for public reporting, the measure calculation will be restricted to facilities with at least one expected modality switch in the reporting year. This restriction is required to ensure patients cannot be identified due to small cell size; **Measure Type**: Outcome; **Level of Analysis**: Facility; **Setting of Care**: Outpatient Services; **Data Source**: Claims, Registry Data

This facility-level measure was newly submitted for endorsement and is not yet implemented in an accountability program. 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. The Standing Committee did not reach consensus on evidence.

The Standing Committee agreed that a performance gap exists but asked the developer to clarify how the expected modality switch rates are determined. The developer stated that the expected home modality switch rates are based on the national rate of home modality switches across facilities, which was adjusted for case mix. The Standing Committee accepted the developer's response and passed the measure on performance gap.

The SMP reviewed this measure prior to the Standing Committee's review and passed it on reliability and validity. The Standing Committee voted to accept the SMP's rating for reliability. In addition, the Standing Committee discussed several topics related to the validity of the measure. Specifically, it 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 compared to those that only offer

in-center dialysis; they noted 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 and did not recommend the measure for initial endorsement.

During the post-evaluation commenting period, three comments were received for this measure, one of which detailed a reconsideration request from the developer. The other two comments expressed support for the Standing Committee's recommendation to not endorse this measure. During the post-comment meeting, the Standing Committee discussed the reconsideration request, in which the developer posited that NQF's measure evaluation criteria were not applied properly. In particular, a clear reason for overturning the SMP's validity decision was not articulated. The developer also expressed that the Standing Committee's focus on measuring patient choice was inappropriate, considering that patient choice is not necessarily a factor, given the numerator and denominator details. The Standing Committee voted not to reconsider the measure, citing the validity concerns raised during the measure evaluation meeting as the reason for overturning the SMP's decision. The Standing Committee noted that in addition to the concerns regarding the measure's exclusions and risk adjustment, the Standing Committee raised concern with the weak correlations between this measure and others included in the analysis. Furthermore, the Standing Committee stated that many factors determine whether a patient chooses and maintains home dialysis, which often does not have to do with a facility's quality of care, suggesting that this measure cannot accurately assess a facility's quality of care. During the CSAC meeting on December 9, 2022, the CSAC upheld the Standing Committee's decision to not recommend the measure for endorsement, as they agreed that all NQF criteria were applied appropriately.

Renal Transplant Waitlisting

NQF #3689 First-Year Standardized Waitlist Ratio (FYSWR) (CMS/UM-KECC): Not Endorsed

Description: The FYSWR measure tracks the number of incident patients in a practitioner (inclusive of physicians and advanced practice providers) group who are under the age of 75 and were listed on the kidney or kidney-pancreas transplant waitlist or received a living donor transplant within the first year of initiating dialysis. For each practitioner group, the First Year Standardized Waitlist Ratio (FYSWR) is calculated to compare the observed number of waitlist events in a practitioner group to its expected number of waitlist events. The FYSWR uses the expected waitlist events calculated from a Cox model, adjusted for age and patient comorbidities at incidence of dialysis. For this measure, patients are assigned to the practitioner group based on the National Provider Identifier (NPI)/Unique Physician Identifier Number (UPIN) information entered on the CMS Medical Evidence 2728 form; **Measure Type**: Outcome; **Level of Analysis**: Clinician: Group/Practice; **Setting of Care**: Outpatient Services; **Data Source**: Registry Data, Claims

This clinician group/practice-level measure was newly submitted for endorsement and is not yet implemented in an accountability program. The Standing Committee expressed concern that the evidence does not show a link between a nephrologist's care influencing a patient being waitlisted for a

transplant because the decision to waitlist a patient is made by the transplant facility. However, other Standing Committee members supported the attribution of the measure to the nephrologist, noting that if transplant centers are not responsive to a nephrologist's referrals, the nephrologist may change where they refer patients to. The developer stated that there is empirical evidence demonstrating the nephrologist's ability to impact the measure's outcome. The Standing Committee also questioned why the developer did not create a measure to track referral rates rather than waitlisting. The developer noted that referral rates are data points that are not currently collected. Ultimately, the Standing Committee did not reach on consensus on evidence. The Standing Committee also agreed that a performance gap and inequities regarding waitlisting exist. Therefore, it passed the measure on performance gap.

The SMP reviewed this measure prior to the Standing Committee's review and passed it on reliability and validity. The Standing Committee voted to accept the SMP's rating for reliability. However, the Standing Committee raised several concerns with the validity of the measure, particularly regarding exclusions and attribution. The Standing Committee expressed concern that patients who are waitlisted, prior to starting dialysis, are excluded. The developer noted that most patients arrive to dialysis without being waitlisted, and this measure addresses those patients. The Standing Committee also expressed concern that patients who choose not to have a transplant are included in the measure and that this may incentivize providers to put patients on a waitlist to achieve a higher score. The developer noted that the measure should not reflect a waitlist rate of 100 percent but that the measure's objective is to compare practitioner groups and identify those who are outlying in their performance. The Standing Committee also raised a concern with attribution, specifically the developer's use of CMS form 2728, as the physician who fills out this form may not be the physician who cares for the patient in the facility. The developers stated that although the physicians may differ, the measure is at the group-practice level, and approximately 90 percent of the time, the physicians are part of the same practice. 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 and did not recommend the measure for initial endorsement.

During the post-evaluation commenting period, three comments were received. All comments agreed with the Standing Committee's recommendation to not endorse the measure. During the CSAC meeting on December 9, 2022, the CSAC upheld the Standing Committee's decision to not recommend the measure for endorsement.

NQF #3694 Percentage of Prevalent Patients Waitlisted in Active Status (aPPPW) (CMS/UM-KECC): Not Endorsed

Description: This measure tracks the percentage of patients in each dialysis practitioner group practice who were on the kidney or kidney-pancreas transplant waitlist in active status. Results are averaged across patients prevalent on the last day of each month during the reporting year. The proposed measure is a directly standardized percentage, which is adjusted for covariates (e.g. age and risk factors); **Measure Type**: Outcome; **Level of Analysis**: Clinician: Group/Practice; **Setting of Care**: Outpatient Services; **Data Source**: Claims, Registry Data

This group/practice-level measure was newly submitted for endorsement and is not yet implemented in an accountability program. The Standing 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. Conversely, the Standing Committee agreed that substantial gaps and disparities were present and passed the measure on performance gap.

The SMP reviewed this measure prior to the Standing Committee's review and passed the measure on reliability but did not reach consensus on validity. The Standing Committee voted to accept the SMP's rating for reliability. In addition, it discussed several topics related to the validity of the measure. 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 and did not recommend the measure for initial endorsement.

During the post-evaluation commenting period, six comments were received for this measure, one of which detailed the reconsideration request from the developer. The other five comments expressed support for the Standing Committee's recommendation to not endorse this measure. During the post-comment meeting, the Standing Committee discussed the reconsideration request, in which the developer posited that NQF's measure evaluation criteria were not applied properly, given that this measure, NQF #3694, did not pass, while a similar measure, NQF #3695, did pass. The Standing Committee voted to not reconsider the measure because although NQF #3694 and NQF #3695 are both similar measures, they do have differences, including different numerators. The Standing Committee also noted that NQF #3694 is a measure that addresses transplant waitlisting in active status and that while nephrologists have a role in optimizing and referring the patients for transplantation, they have nothing to do with the activation of patients on the waitlist. This suggests that the measure is not an accurate reflection of the quality of care provided by nephrologists. The Standing Committee further cited concern with the testing data, which showed extreme variation in transplant center practice. The Standing Committee stated that the decision to not recommend NQF #3694 was made based on these subtle differences between the two measures. During the CSAC meeting on December 9, 2022, the CSAC upheld the Standing Committee's decision to not recommend the measure for endorsement, as they agreed that all NQF criteria were applied appropriately.

NQF #3695 Percentage of Prevalent Patients Waitlisted (PPPW) (CMS/UM-KECC): Endorsed

Description: This measure tracks the percentage of patients in each dialysis practitioner group practice who were on the kidney or kidney-pancreas transplant waitlist. Results are averaged across patients prevalent on the last day of each month during the reporting year. The proposed measure is a directly standardized percentage, which is adjusted for covariates (e.g., age and risk factors); **Measure Type**: Outcome; **Level of Analysis**: Clinician: Group/Practice; **Setting of Care**: Outpatient Services; **Data Source**: Registry Data, Claims

This group/practice-level measure was newly submitted for endorsement and is not yet implemented in an accountability program. The Standing Committee stated that evidence exists to support the measure and passed the measure on this criterion. Likewise, the Standing Committee agreed that disparities and variation are both present, the latter being meaningful across practices. The Standing Committee requested further details on the attribution of disparities, considering that transplant centers determine which patients are waitlisted; however, the measure is attributed to individual clinicians. The developer noted that the variation is derived from the risk model, which includes adjustment for transplant center effects. Variations persist after adjusting for both patient and transplant center characteristics; thus, this indicates that the variation is attributed to the group/practice. The Standing Committee accepted this explanation and passed the measure on performance gap.

The SMP reviewed this measure prior to the Standing Committee's review and passed it on reliability but did not reach consensus on validity. The Standing Committee voted to accept the SMP's rating for reliability. In addition, it discussed several topics related to the validity of the measure, such as how a patient's comorbidities are established. A CMS 2728 form is completed when the patient first enrolls in dialysis; however, it is not updated as the patient's comorbidities change. Additionally, claims data are not an ideal way to obtain patient comorbidity data. The developer advised that the risk model utilizes transplant centers' rate of transplants and organ availability, along with waitlist mortality rates, which accounts for the variability across centers. The developer also advised that several models are based on Medicare claims data and a considerable amount of research utilizes comorbidities identified through claims. Their TEP believed strongly that SDOH were utilized in the measure's risk adjustment, considering that patient finances and social support are used by transplant centers to make waitlist decisions. Thus, the developer advised that SDOH needs to be accounted for as the measure holds the dialysis practitioners accountable. The Standing Committee accepted this explanation and passed the measure on validity.

The Standing Committee agreed that the measure is feasible; it also acknowledged that the measure is new but not currently publicly reported, nor is it utilized in an accountability or quality program. The Standing passed the measure on feasibility and use. In addition, the Standing Committee expressed concern regarding a potential unintended consequence: A practitioner may direct patients towards a center that is likely to waitlist them. This would potentially improve the practitioner's rate on the measure and could impact a patient's choice regarding which transplant center they choose to be waitlisted for their transplant. The developer advised that patient choice is accounted for in the modeling, as patients are tracked based on the ZIP code where they reside. Thus, if a patient goes to a transplant center outside of their ZIP code, this will be accounted for in the modeling. The Standing

Committee accepted this explanation and passed the measure on usability and overall suitability for endorsement.

During the post-evaluation commenting period, four comments were received for this measure. All four comments disagreed with the Standing Committee's recommendation to recommend the measure for endorsement. During the post-comment meeting, the Standing Committee thanked the commenters and determined that the concerns raised were discussed during the measure evaluation meeting and that the measure met all of NQF's criteria for endorsement. During the CSAC meeting on December 9, 2022, the CSAC upheld the Standing Committee's decision to recommend the measure for endorsement. No appeals were received.

Measures Withdrawn From Consideration

Three measures previously endorsed by NQF either have not been resubmitted for maintenance of endorsement or were withdrawn during the endorsement evaluation process. Endorsement for these measures has been removed.

Table 2. Measures Withdrawn From Consideration

Measure	Reason for withdrawal
NQF #0256 Hemodialysis Vascular Access – Minimizing Use of Catheters as Chronic Dialysis Access	This measure was retired by the developer.
NQF #0257 Maximizing Placement of Arterial Venous Fistula (AVF)	This measure was retired by the developer.
NQF #1667 Pediatric Kidney Disease: ESRD Patients Receiving Dialysis: Hemoglobin Level < 10g/dL	This measure was retired by the developer because it is not currently in use and the developer does not believe a performance gap exists.

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Appendix A: Details of Measure Evaluation

Rating Scale: H=High; **M**=Moderate; **L**=Low; **I**=Insufficient; **NA**=Not Applicable

NQF ensures that quorum is maintained for all live voting. Quorum is 66 percent of active Standing Committee members minus any recused Standing Committee members. Due to the exclusion of recused Standing Committee members from the quorum calculation, the required quorum for live voting may vary among measures. Quorum (16 out of 24 Standing Committee members for all measures) was reached and maintained throughout the measure evaluation meetings on June 29–30, 2022. For the post-comment call on October 6, 2022, quorum was reached and maintained throughout the meeting. Vote totals may differ between measure criteria and between measures because Standing Committee members may have joined the meeting late, stepped away for a portion of the meeting, or had to leave the meeting before voting was complete. The vote totals listed below reflect Standing Committee members present and eligible to vote at the time of the vote. Voting results are provided below.

A measure is recommended for endorsement by the Standing Committee when greater than 60 percent of voting members select a passing vote option (i.e., Pass, High and Moderate, or Yes) on all must-pass criteria and overall suitability for endorsement. A measure is not recommended for endorsement when less than 40 percent of voting members select a passing vote option on any must-pass criterion or overall suitability for endorsement.

Measures Endorsed

NQF #2594 Optimal End-Stage Disease (ESRD) Starts

Measure Worksheet | Specifications

Description: Optimal End Stage Renal Disease (ESRD) Starts is the percentage of new adult ESRD patients during the measurement period who experience a planned start of renal replacement therapy by receiving a preemptive kidney transplant, by initiating home dialysis (peritoneal dialysis or home hemodialysis), or by initiating outpatient in-center hemodialysis via arteriovenous fistula or arteriovenous graft.

Numerator Statement: The number of new ESRD patients age 18 and over who initiate outpatient renal replacement therapy in the twelve-month measurement period with an optimal ESRD therapy, which includes preemptive kidney transplant, home dialysis (peritoneal dialysis or home hemodialysis), or outpatient in-center hemodialysis via arteriovenous fistula or arteriovenous graft.

Denominator Statement: The number of patients age 18 and over who receive a preemptive kidney transplant or initiate long-term dialysis therapy (do not recover kidney function by 90 days) for the first time in the twelve-month measurement period

Exclusions: None

Adjustment/Stratification: No additional risk adjustment analysis included; No risk adjustment or stratification

Level of Analysis: Population: Regional and State, Health Plan, Clinician: Group/Practice, Facility, Integrated Delivery System

Setting of Care: Ambulatory Care, Outpatient Services, Inpatient/Hospital

Type of Measure: Process

Data Source: Claims, Other, Registry Data, Electronic Health Records

Measure Steward: The Permanente Federation

STANDING COMMITTEE MEETING [June 29-30, 2022]

1. Importance to Measure and Report:

(1a. Evidence, 1b. Performance Gap)

1a. Evidence: **Total votes-17; H-4; M-13; L-0; I-0**; 1b. Performance Gap: **Total votes- 18; H-0; M-18; L-0; I-0**

Rationale:

- The Standing Committee sought clarity from the developer on the measure's LOA after observing what they identified as multiple LOAs in the submission. The developer confirmed that the LOA is best identified as "integrated delivery system." The Standing Committee accepted this designation and proceeded with review of the measure.
- The Standing Committee noted the updated evidence, which posits that use of optimal starts (i.e., initial therapy of hemodialysis via an arteriovenous fistula or graft, peritoneal dialysis, or pre-emptive transplant) reduces treatment costs and complications associated with kidney disease.
- The Standing Committee noted correlative effects of optimal starts, noting the developer's assertion that optimal starts improve patient outcomes because it decreases mortality and cardiovascular risk, reduces hospitalizations, and increases the likelihood for higher quality of quality of life.
- The Standing Committee agreed that the evidence remains strong from the initial submission in 2015 and that no new information disputes the notability of the evidence.
- The Standing Committee noted improvement, as indicated by the developer's performance data over six consecutive annual measurement periods. Kaiser Permanente's national mean annual performance rate improved from 57.1 percent in December 2015 to 58.3 percent in December 2020.
- The Standing Committee also observed that Asian/Pacific Islanders consistently had the highest percent of optimal starts (63–69 percent), Black patients had the lowest performance (51–61 percent), and White (56–59 percent) and Hispanic patients (55–57 percent) performed in the middle range.
- The Standing Committee noted a clear performance gap, as well as variation in performance, as indicated by disparities data, and passed the measure on performance gap.

2. Scientific Acceptability of Measure Properties:
(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)
2a. Reliability: **Accepted Previous Evaluation** 2b. Validity: **Accepted Previous Evaluation**
Rationale:

- The SMP did not review this measure.
- The Standing Committee noted that the measure specifications are clear, precise, and slightly updated. The Standing Committee highlighted the updates, which include a removal of the 10 percent patient limit for new hemodialysis patients receiving an AVG and the inclusion of patients with failing kidney transplants who are starting or returning to dialysis. The Standing Committee noted that the developer assessed the impact of removing this criterion and found that the percent AVG in 2016 (before the removal of the 10 percent limit) and 2021 (after the removal of the 10 percent limit) remained below the 10 percent AVG limit previously set in place. The developer explained that this change did not alter the way the data elements were collected, nor did it impact the measurement. The Standing Committee agreed with the developer's assertion that the percent AVG has not experienced significant impact due to the removal of this limiting criterion.
- The Standing Committee also noted that the developer included patients with failing kidney transplants starting or returning to dialysis and assessed the impact of including these patients as inconsequential, more specifically noting a small difference of 3.3 percent in the denominator with the criterion versus the denominator without the criterion. The Standing Committee agreed with the developer's assertion that this change did not have significant impact on the reported measurement rate.
- The Standing Committee questioned why there is a minimum of 50 new ESRD patients in the denominator. The developer explained that the statistics become very difficult to quantify and that a minimum of 50 optimal starts is required to deem the measurement meaningful.

- The Standing Committee expressed interest in understanding how modality switches are accounted. The developer noted that the modality switch is not tracked and that the first outpatient day of ESRD treatment is what is measured. The developer further explained that modality switch is only applicable to new dialysis, as well as the patients with a failed transplant who are starting dialysis.
- The Standing Committee observed that the developer conducted validity testing at the patient/encounter level and opted to use this testing as a representation of data element reliability testing. According to NQF evaluation criteria guidance, data element validity testing can satisfy data element reliability testing requirements. The developer conducted empirical validity testing on all critical patient/encounter-level data elements; therefore, additional reliability testing was not required.
- The developer attested that additional reliability testing was not conducted and the measure specifications have not changed significantly. The Standing Committee agreed that further discussion and a formal vote were not needed. Therefore, the Standing Committee accepted the previous endorsement vote on reliability with a unanimous verbal confirmation.
- The Standing Committee noted that validity testing was conducted at the patient/encounter level using 2015 data-element testing data, and the developer tested the accuracy of the regional data compared to the authoritative source. Specifically, the renal replacement therapy information submitted by the regional care coordinator was compared to that provided by the renal replacement therapy provider on record.
- Among the data elements, the Standing Committee noted 96 percent accuracy among denominator data elements, 87 percent accuracy among numerator data elements, and an overall data element accuracy of 83 percent.
- The Standing Committee agreed with the developer's affirmation of the measure's predictive value because it observed a positive predictive value of 0.94 to identify a true optimal ESRD start and a negative predictive value of 0.79 to identify a nonoptimal start.
- The Standing Committee noted that the exclusion criterion related to the 10 percent hemodialysis patient limit for AVG was removed (in 2017) in advance of the spring 2022 measure review. The Standing Committee noted that the developer attested no significant change to the measure results as a result of this change.
- The Standing Committee noted meaningful differences in performance, as demonstrated by the developer's comparison of regional performance for the measure. The Standing Committee agreed that the data indicate variation in optimal ESRD starts by region and between the region and the all-regions group mean.
- The developer attested that additional validity testing was not conducted.
- The Standing Committee agreed that further discussion and a formal vote were not needed. Therefore, the Standing Committee accepted the prior endorsement vote on validity with a unanimous verbal confirmation.

3. Feasibility: Total votes-18; H-4; M-14; L-0; I-0

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c. Susceptibility to inaccuracies/ unintended consequences identified; 3d. Data collection strategy can be implemented)

Rationale:

- The Standing Committee noted that all data elements are in defined fields in electronic health records (EHRs) and data are abstracted from a record by someone other than the person obtaining original information.

- The Standing Committee highlighted that the renal care coordinators are designated to rectify any inconsistencies in data, and it accepted the developer's recognition that this process has proven to be feasible when carried out by a data analyst with proper training and program support.
- The Standing Committee agreed with the developer's attestation that missing denominator patients has not been an issue largely because authorization for dialysis or kidney transplant is required to receive payment.
- The Standing Committee accepted the developer's acknowledgement of its concern and passed the measure on feasibility.

4. Usability and Use:

(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences)

4a. Use**: Total votes-19; Pass-17; No Pass-2**; 4b. Usability: **Total votes-19; H-3; M-15; L-1; I-0**

Rationale:

- The Standing Committee acknowledged that although the measure is not publicly reported in its entirety, its internal and regional use is a qualified function of accountability.
- The Standing Committee noted that the measure is currently utilized by the Permanente Federation to track the performance of eight Kaiser Permanente Regions (i.e., Northern California, Southern California, Northwest/Oregon, Southern Washington State, Hawaii, Colorado, Georgia, and the Mid-Atlantic States).
- Furthermore, the Standing Committee highlighted that the measure has been utilized successfully to improve outcomes in Kaiser Permanente Southern California for 10 years and in the national Kaiser Permanente program for three years.
- The Standing Committee acknowledged that the developer submitted the measure for potential use in the Centers for Medicare & Medicaid Services' (CMS) MIPS and the Kidney Care Choices Model within the Center for Medicare & Medicaid Innovation (CMMI) Center.
- The Standing Committee accepted the developer's internal and regional use of the measure and plan for use in a federal program and passed the measure on use.
- The Standing Committee noted performance improvement in the variation of Optimal ESRD Starts rates from 2017 (57.5 percent) to 2019 (60.7 percent). Additionally, the Standing Committee noted the slight drop in performance in 2021 (56.5 percent) but expressed understanding in the developer's attribution of the downward performance to impacts of the coronavirus disease 2019 (COVID-19) pandemic.
- The Standing Committee expressed concern with potential unintended consequences, including misrepresentation of an optimal start. The developer advised that optimal starts capture the first day of outpatient dialysis treatment, not the first day of the designated modality of treatment, and there is no penalty for failure on the initial modality. The developer also explained that patients who switch from one dialysis modality to another are not included in this measure.
- The Standing Committee accepted the developer's clarifications and passed the measure on usability.

5. Related and Competing Measures

- No related or competing measures were identified.

6. Standing Committee Recommendation for Endorsement: Total votes- 19; Yes-19; No-0

7. Public and Member Comment

- Two post-evaluation comments were received.

- The first comment came from the developer, clarifying that the measure is applicable 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. The developer also noted that 12 rolling months is the most meaningful reporting period.
- The second comment was supportive of the measure but did note that all patients should be considered home patients until they are ruled out for some reason. Additionally, the commenter stated that supportive care or conservative management should be taken into consideration. Lastly, the commenter noted that a shared decision-making measure to accompany this measure is needed to ensure that the patient is included in deciding what is truly optimal for them.
    - The developer responded to the comment, stating that the measure is based on shared decision making from patients and caregivers with the efforts of a multidisciplinary care team. Additionally, the developer stated that the measure incorporates all kidney care options, and while they support wider use of home dialysis, there are clinical and social issues that drive a patient's choice of therapy. The developer also noted that patients who choose conservative therapy are not included into the optimal ESRD start numerator or denominator, so this measure fully supports patients who choose not to start dialysis. The Standing Committee did not raise any concerns with the comment, nor did it raise concerns with the developer's response and maintained its decision to recommend the measure for endorsement.

8. Consensus Standards Approval Committee (CSAC) Endorsement Decision: Total votes- 15; Yes-15; No-0 December 9, 2022: Endorsed

- The CSAC upheld the Standing Committee's decision to recommend the measure for endorsement.

9. Appeals

- No appeals were received.

NQF #3695 Percentage of Prevalent Patients Waitlisted (PPPW)

Measure Worksheet | Specifications

Description: This measure tracks the percentage of patients in each dialysis practitioner group practice who were on the kidney or kidney-pancreas transplant waitlist. Results are averaged across patients prevalent on the last day of each month during the reporting year. The proposed measure is a directly standardized percentage, which is adjusted for covariates (e.g., age and risk factors).

Numerator Statement: The numerator is the adjusted count of patient months in which the patient at the dialysis practitioner group practice is on the kidney or kidney-pancreas transplant waitlist as of the last day of each month during the reporting year.

Denominator Statement: All patient-months for patients who are under the age of 75 in the reporting month and who are assigned to a dialysis practitioner group practice according to each patient's treatment history during a given month during the reporting year.

Exclusions: Exclusion that are implicit in the denominator include:

* Patients who were at age 75 or older in the reporting month

* Patients who were admitted to a skilled nursing facility (SNF) during the month of evaluation were excluded from that month;

* Patients who were admitted to a skilled nursing facility (SNF) within one year of dialysis initiation according to form CMS-2728

* Patients determined to be in hospice were excluded from month of evaluation and the remainder of reporting period

* Patients with dementia

The noted exclusions represent conditions for which transplant waitlist candidacy is highly unlikely, and which can be identified readily with available data.

Patients who were attributed to dialysis practitioner groups with fewer than 11 patients are not excluded from the measure. All patients who meet the denominator inclusion criteria are included and used to model a given dialysis practitioner group's expected waitlist rate. If a dialysis practitioner group has fewer than 11 patients, then the dialysis practitioner group is excluded from reporting outcomes.

Adjustment/Stratification: Statistical risk model with risk factors

Level of Analysis: Clinician: Group/Practice

Setting of Care: Outpatient Services

Type of Measure: Outcome

Data Source: Registry Data, Claims

Measure Steward: CMS

STANDING COMMITTEE MEETING [June 29 and 30, 2022]

1. Importance to Measure and Report:

(1a. Evidence, 1b. Performance Gap)

1a. Evidence: **Total Votes-18; Pass-13; No Pass-5**; 1b. Performance Gap: **Total Votes-18; H-1; M-14; L-3; I-0**

Rationale:

- The Standing Committee considered the evidence presented for the measure, which included several studies that noted empirical patient support on the value of waitlisting, strong support for the association between processes under dialysis practitioner control and waitlisting, and feedback from two convened TEPs that supported the importance of waitlisting and were in favor of a measure that targeted waitlisting.
- The Standing Committee did not identify any concerns with the presented evidence and passed the measure on the evidence criteria.
- The Standing Committee considered the performance gap data presented for the measure and noted the mean performance was 19.1 percent for practitioner group practices with at least 11 patients.
- The Standing Committee considered the disparities data presented for the measure. The mean waitlisting performance was lowest for Native American/Alaskan natives (12.3 percent). Non-Hispanics had a lower waitlisting percentage on average (18.6 percent) than Hispanics (21.9 percent). Females had a mean waitlisting percentage of 17.2 percent, and males had a mean of 20.5 percent.
- The Standing Committee agreed that sufficient variation exists in performance across practices and disparities are present. However, the Standing Committee requested further details regarding the attribution of disparities, considering this is a group/practice measure.
- The developer noted that the variation is derived from the risk model, which includes adjustment for transplant center effects, and that variations persist after adjustment for patient characteristics and transplant center characteristics. Therefore, the developer indicated that the variation is attributed to the clinician group/practice.
- The Standing Committee accepted this explanation and passed the measure on performance gap.

2. Scientific Acceptability of Measure Properties:

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)

2a. Reliability: **Total Votes-18; Yes-18; No-0**; 2b. Validity: **Total Votes-17; H-0; M-12; L-5; I-0**

Rationale:

- The SMP reviewed this measure.

- The SMP passed the measure on reliability **(Total Votes-10; H-4; M-4; L-0; I-2)** but did not reach consensus on validity **(Total Votes-9; H-0; M-5; L-4; I-0)**.
- The Standing Committee acknowledged that the reliability testing was conducted at the accountable-entity level using an inter-unit reliability (IUR) with a bootstrapping approach. The IUR value was 0.9409. Based on these data, the Standing Committee voted to accept the SMP's rating for reliability.
- The Standing Committee considered the accountable entity-level validity testing for the measure and noted that the results showed that higher measure performance correlated with higher transplant rates and a lower mortality rate.
- The Standing Committee noted that the risk adjustment model used a mixed-effects logistic regression model, in which dialysis practitioner groups are modeled as fixed effects and transplant centers are modeled as random effects.
- The Standing Committee questioned how a patient's comorbidities are established when claims data are not an ideal way to obtain patient comorbidity data.
- The developer advised that several models exist based on Medicare claims data, and a considerable amount of research utilizes comorbidities identified through claims.
- The developer also expressed that their TEP believed strongly that SDOH were utilized in the measure's risk adjustment. Medicare-Medicaid dual eligibility and ADI were risk factors significantly associated with the outcome of waitlisting; therefore, they were included in the final risk adjustment model.
- The Standing Committee accepted this explanation and passed the measure on validity.

3. Feasibility: Total Votes-18; H-10; M-8; L-0; I-0

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c. Susceptibility to inaccuracies/ unintended consequences identified; 3d. Data collection strategy can be implemented)

Rationale:

- The measure data elements are generated or collected and used by healthcare personnel during the provision of care.
- Furthermore, the data elements are coded by someone other than the person obtaining the original information and the measure relies on data elements that are defined in a combination of electronic sources.
- The Standing Committee agreed that the measure is feasible and passed it on feasibility.

4. Usability and Use:

(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences)

4a. Use**: Total Votes-18; Pass-17; No Pass-1**; 4b. Usability: **Total Votes-18; H-3; M-10; L-5; I-0**

Rationale:

- The Standing Committee agreed that the measure is not currently publicly reported, nor is it utilized in an accountability or quality program.
- However, the Standing Committee acknowledged that the developer plans to use the measure in public reporting and a quality payment program. Therefore, the Standing Committee passed the measure on use.
- The Standing Committee expressed concern regarding a potential unintended consequence: A practitioner may direct patients towards a center that is likely to waitlist them. This could improve the practitioner's rate but could also impact a patient's choice regarding which transplant center they choose.
- The developer advised that patient choice is accounted for in the modeling, as patients are tracked based on the ZIP code where they reside. Thus, if a patient goes to a transplant center outside of their ZIP code,

this will be accounted for. The Standing Committee accepted this explanation and passed the measure on usability.

5. Related and Competing Measures

- No related or competing measures were noted.

6. Standing Committee Recommendation for Endorsement: **Total Votes-18; Yes-13; No-5**

- The Standing Committee recommended the measure for endorsement.

7. Public and Member Comment

- Two pre-evaluation comments were submitted. One comment was not in favor of the measure due to the attribution of successful or unsuccessful waitlisting to dialysis facilities, individual practitioners, or group practices.
- Additionally, another comment did not support the measure due to a 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 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.
- Four post-evaluation comments were received for this measure:
    - One commenter noted that they had several issues with the measure: (1) the attribution of the measure; (2) the model did not validly account for variation in transplant center eligibility criteria; and (3) the developer did not provide stratification of reliability scores by provider size for the measures.
        - The measure developer responded to all three issues raised in the comment:
            - The developer stated that being waitlisted for kidney transplantation is the culmination of a variety of preceding preparatory activities. They explained that these efforts heavily depend on dialysis practitioner groups. However, the developer stated that aspects that are not entirely dependent on dialysis practitioner groups can still be influenced by dialysis practitioner groups, such as the actual waitlisting decision made by transplant centers or a patient's choice about the transplantation option.
            - The developer agreed that variation exists across transplant centers in eligibility criteria and that underlying patient comorbidities may affect their candidacy. However, the waitlisting measures adjust for a wide range of comorbidities and transplant center characteristics.
            - The developer also stated with regard to the reliability for small providers that 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. Furthermore, 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.

        - The Standing Committee thanked the commenter but noted that this measure met all NQF criteria for endorsement, and therefore, it maintained its decision to recommend the measure for endorsement.
    - The second commenter noted concern for how the percentage of prevalent patients waitlisted (PPPW) could have a negative impact on smaller transplant centers.
        - The developer agreed that variation exists across transplant centers in eligibility criteria and that underlying patient comorbidities may affect their candidacy; however, the waitlisting measures adjust for a wide range of comorbidities and transplant center characteristics, such as random effect and center waitlist mortality.
        - The Standing Committee thanked the commenters but noted that this measure met all NQF criteria for endorsement, and therefore, it maintained its decision to recommend the measure for endorsement.

8. Consensus Standards Approval Committee (CSAC) Endorsement Decision: Total votes- 15; Yes-14; No-1
December 9, 2022: Endorsed

- The CSAC upheld the Standing Committee's decision to recommend the measure for endorsement.

9. Appeals

- No appeals were received.

Measures Not Endorsed

NQF #3659 Standardized Fistula Rate for Incident Patients

Measure Worksheet

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

The Standardized Fistula Rate (SFR) for Incident Patients is based on the prior SFR (NQF #2977) that included both incident and prevalent patients. This measure was initially endorsed in 2016, but as part of measure maintenance review by the NQF Standing Committee in 2020, concerns were raised about the strength of evidence supporting the prior measure. Namely, recent updates to the KDOQI guidelines downgraded the evidence supporting fistula as the preferred access type and instead focus on catheter avoidance and developing an individualized ESKD Lifeplan. However, the 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. Given that over 80% of incident dialysis patients begin treatment with a tunneled catheter, and that 12 months after dialysis initiation AV fistula rates exceed 60%, the incident SFR was developed to focus on the subset of dialysis patients that the evidence suggests may benefit the most during a time of intense vascular access creation. Specifically, blood stream infection rates are the lowest in incident patients with AV fistula compared to long-term catheters. Therefore, the goal of this new measure is to evaluate facility performance in increasing fistula use in the incident population in order to reduce the heightened risks patients face due to bacteremia and infection related hospitalizations.

Numerator Statement: The numerator is the adjusted count of adult incident patient-months using an AVF as the sole means of vascular access as of the last hemodialysis treatment session of the month.

Denominator Statement: All patient-months for patients at least 18 years old as of the first day of the reporting month who are determined to be maintenance hemodialysis patients (in-center and home HD) and became ESRD within the prior 12 months for the entire reporting month at the same facility.

Exclusions: Exclusions that are implicit in the denominator definition include:

* Patient-months after 12 months of starting ESRD
* Pediatric patients (<18 years old)
* Patients-months on Peritoneal Dialysis

* Patient-months with in-center or home hemodialysis for less than a complete reporting month at the same facility

In addition, the following exclusions are applied to the denominator:

Patients with a catheter that have limited life expectancy:

* Patients under hospice care in the current reporting month

* Patients with metastatic cancer in the past 12 months

* Patients with end stage liver disease in the past 12 months

* Patients with coma or anoxic brain injury in the past 12 months

The denominator is defined at the patient level not facility level. The reason this rule is applied is to comport with how measures are implemented for public reporting. Due to small cell size and potentially identifiable data, facilities with <11 patients do not receive a score.

As stated in the measure description and rationale, this is a measure of incident patients only. Dialysis patients in their first 12 months of ESRD are more likely to be using a catheter for vascular access and in turn are at higher risk for CVC related infections. The measure focus is on the first 12 months of dialysis since this is the most active time of vascular access creation and where the potential benefit is greatest relative to treatment with a CVC.

Patient attribution to facilities is already described – see SP15: "Patients are required to have been treated by the same facility for the complete month in order to be assigned to that facility for the reporting month."

When a patient is not treated in a single facility for a span of 30 days (for instance, if there were two facility transfers within 30 days of each other), we do not attribute that patient to any facility for that month. Therefore, transient treatment at a facility due to either travel or a temporary clinical condition do not impact the fistula rate of that facility.

Patients with a catheter (of any duration) AND one or more of the limited life expectancy exclusions are excluded from the denominator.

Adjustment/Stratification: Statistical risk model with risk factors

Level of Analysis: Facility

Setting of Care: Outpatient Services

Type of Measure: Outcome: Intermediate Clinical Outcome

Data Source: Registry Data, Claims

Measure Steward: CMS

STANDING COMMITTEE MEETING [June 29-30, 2022]

1. Importance to Measure and Report:

(1a. Evidence, 1b. Performance Gap)

1a. Evidence: **Total votes-17; H-0; M-7; L-10; I-0** 1b. Performance Gap: **Total votes-16; H-0; M-6; L-10; I-0**

Rationale:

- The Standing Committee agreed with the evidence's recommendation of AVFs as the preferred access method for most dialysis patients according to a 2015 TEP.
- The Standing Committee noted a 1.78 increased odds of starting dialysis with an AVF and a 0.51 odds of starting dialysis with a central venous catheter (CVC) in instances when education was provided to kidney patients. The Standing Committee noted the additional impact of patient education via data that showed decreased rates of CVCs (45 percent to 8 percent) with the creation of a vascular access coordinator program.
- The Standing Committee acknowledged these sources as credible evidence that education on treatment modality plays a role in decreased catheter use, but it still expressed some uncertainty about the strength of the evidence (noting that about half of the sources do not examine incident patients) and the true value it adds to the existing CVC measures.
- The developer added that this measure is intended to be jointly reported with the *Hemodialysis Vascular Access: Long-Term Catheter Rate* measure and further explained that these two vascular access quality

measures, when used together, consider AVF use as a positive outcome and prolonged use of a tunneled catheter as a negative outcome.

- Additionally, the developer referenced The National Kidney Foundation (NKF) KDOQI Vascular Access Guidelines to support the suggestion that a functioning AVF is preferred to an AVG due to fewer long-term vascular access events, such as thrombosis and loss of primary patency; they also noted that most patients starting dialysis with a CVC should convert to either an AVF or AVG.
- The Standing Committee discussed the absence of a definitive recommendation on the superiority of fistulas versus grafts, regarding infection rates, per the NKF KDOQI; it also noted that updates to the KDOQI guidelines downgraded evidence supporting fistula as the preferred access type.
- The Standing Committee also highlighted two pre-evaluation comments, which asserted that the proposed measure is inherently unchanged from the previous measure and long-term catheter rate measurement is preferred over the currently proposed measure.
- Ultimately, the Standing Committee did not reach consensus on evidence.
- The Standing Committee observed the SFR data from 2018–2019 and noted that in 2019, the mean value was 41.4 percent, the interquartile range was 17 percentage points (49.9 percent – 75th, 32.9 percent – 25th), the bottom quartile of dialysis group practices had 19.7 percent of incident patients using an AVF, and the top quartile of dialysis group practices had 16.32 percent of incident patients using an AVF.
- The Standing Committee also observed what they considered evident disparities in AVF use among the incident ESRD dialysis population. The data demonstrated that the mean SFR was higher for males (46.2 percent) than females (35.1 percent), higher for those who identify as White (43.4 percent) than those who identify as Black (36.4 percent), and slightly higher for non–dual-eligible persons (41.9 percent) than dual-eligible persons (40.8 percent).
- Although the Standing Committee noted variation and opportunity for improvement in the measure's performance statistics and disparities data, it still questioned whether the data were a true reflection of a gap or an indication of other factors, such as the starting of dialysis, during which a change in the use of AV fistulas and catheters is seen.
- Furthermore, the Standing Committee questioned whether further improvement was feasible or appropriate, noting that it might not be appropriate for some subpopulations based on their stage of care. The developer explained that the fistula measure adjusts for patient factors in which fistula placement may be either more difficult or not an appropriate choice.
- The Standing Committee also inquired about demonstrating a correlation between low fistula rates and facility size. The developer stated that they did not parse the data out by facility size but explained that they cannot say for certain that the small facility size is a direct correlation to low fistula rates. The Standing Committee expressed a desire to see performance data parsed out by facility size in the future.
- Ultimately, the Standing Committee did not pass the measure on performance gap, a must-pass criterion, based on these concerns. Therefore, the Standing Committee did not discuss or vote on any proceeding criteria.

2. Scientific Acceptability of Measure Properties: Vote Not Taken

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)

2a. Reliability: **Vote Not Taken**; 2b. Validity: **Vote Not Taken**

3. Feasibility: Vote Not Taken

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c. Susceptibility to inaccuracies/ unintended consequences identified; 3d. Data collection strategy can be implemented)

4. Usability and Use: Vote Not Taken

(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences)

4a. Use**: Vote Not Taken**; 4b. Usability: **Vote Not Taken**

5. Related and Competing Measures

- No related or competing measures were noted.

6. Standing Committee Recommendation for Endorsement: Vote Not Taken

7. Public and Member Comment

- Two pre-evaluation public comments were submitted, one of which included an expression of non-support. One public commenter expressed concern with the classification of incident dialysis patients and questioned the appropriateness of such specification. Additionally, the commenter argued that the proposed fistula measure remains unchanged from the previous measure (SFR #2977) and misdirects the focus to dialysis facilities. The other public commenter expressed concern, similarly, with the narrowed target population of incident patients. Additionally, the commenter took issue with the unavailability of stratified reliability scores by facility size and further expressed that catheter avoidance is a more appropriate focus for vascular access in both the incident and prevalent dialysis populations.
- Two post-evaluation comments were received for this measure. Both commenters agreed with the Standing Committee's recommendation to not endorse the measure.
    - The first commenter stated that KDOQI guidelines focus on catheter reduction and that they take no stance on the superiority of fistulas over grafts. The commenter further stated that a true performance gap for the measure does not exist. Lastly, the commenter raised concerns that the reliability for small facilities might be substantially lower than the overall IUR; however, because the developer did not present the range of reliability scores, it is unclear whether reliability is sufficient for small facilities.
        - The measure developer responded to the first commenter, disagreeing with the concerns raised. The developer noted that a performance gap remains between providers in AVF use at the facility level; KDOQI guidelines for vascular access continue to support AV fistula creation in incident patients; and 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.
        - The Standing Committee did not raise any concerns with the comment, nor did it raise any concerns with the developer's response and maintained its decision to not recommend the measure for endorsement.
    - The second commenter stated their opposition to the measure and believes that the fistula first focus has led to many patients being poorly served by the nephrology community. The commenter noted that they 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."
        - The measure developer responded to the comment, stating that while they recognize the importance of patient choice when creating a vascular access plan, there are no standard criteria for how to validate an informed decision. The developer continued,

noting that a check-box attestation would likely be an insufficient test for accurately determining whether an informed choice was made by a patient. The developer also stated that some patients who decline creation of an AVF do so after one or more previous attempts at creating a surgical access.

- The Standing Committee did not raise any concerns with the comment, nor did it raise any concerns with the developer's response and maintained its decision to not recommend the measure for endorsement.

8. Consensus Standards Approval Committee (CSAC) Endorsement Decision: Total votes- 15; Yes-15; No-0 December 9, 2022: Not endorsed

- The CSAC upheld the Standing Committee's decision to not recommend the measure for endorsement.

NQF #3689 First Year Standardized Waitlist Ratio (FYSWR)

Measure Worksheet

Description: The FYSWR measure tracks the number of incident patients in a practitioner (inclusive of physicians and advanced practice providers) group who are under the age of 75 and were listed on the kidney or kidney-pancreas transplant waitlist or received a living donor transplant within the first year of initiating dialysis. For each practitioner group, the First Year Standardized Waitlist Ratio (FYSWR) is calculated to compare the observed number of waitlist events in a practitioner group to its expected number of waitlist events. The FYSWR uses the expected waitlist events calculated from a Cox model, adjusted for age and patient comorbidities at incidence of dialysis. For this measure, patients are assigned to the practitioner group based on the National Provider Identifier (NPI)/Unique Physician Identifier Number (UPIN) information entered on the CMS Medical Evidence 2728 form.

Numerator Statement: Number of patients in the practitioner group listed on the kidney or kidney-pancreas transplant waitlist or who received living donor transplants within the first year following initiation of dialysis.

Denominator Statement: The denominator for the FYSWR is the expected number of waitlist or living donor transplant events in the practitioner group according to each patient's treatment history for patients within the first year following initiation of dialysis, adjusted for age, incident comorbidities, dual Medicare-Medicaid eligibility, Area Deprivation Index (from patient's residence zip code) and transplant center characteristics, among patients under 75 years of age who were not already waitlisted and did not have kidney transplantation prior to the initiation of ESRD dialysis.

Exclusions: Patients who were at age 75 or older on their initiation of dialysis date are excluded. Patients who were admitted to a skilled nursing home facility (SNF) or a hospice during the month of evaluation were excluded. These exclusions represent conditions for which transplant waitlist candidacy is highly unlikely, and which can be identified readily with available data. Patients were also excluded if waitlisted or transplanted prior to initiation of first dialysis. Patients who were attributed to dialysis practitioner groups with fewer than 11 patients or 2 expected events are not excluded from the measure. All patients who meet the denominator inclusion criteria are included and used to model a given dialysis practitioner group's expected waitlist rate. If a dialysis practitioner group has fewer than 11 patients or 2 expected events, then the dialysis practitioner group is excluded from reporting outcomes.

Adjustment/Stratification: Statistical risk model with risk factors

Level of Analysis: Clinician: Group/Practice

Setting of Care: Outpatient Services

Type of Measure: Outcome

Data Source: Registry Data, Claims

Measure Steward: CMS

STANDING COMMITTEE MEETING [June 29-30, 2022]

1. Importance to Measure and Report:

(1a. Evidence, 1b. Performance Gap)

1a. Evidence: **Total votes-18**; **Pass-10**; **No Pass-8**; 1b. Performance Gap: **Total votes- 19; H-4**; **M-14**; **L-1**; **I-0**

Rationale:

- The Standing Committee noted the evidence connected to the convening of two TEPs, both of which were in favor of the development of measures that targeted waitlisting, to improve access to kidney transplantation.
- The Standing Committee also referred to an *American Journal of Transplantation* study cited by the developer which showed that patients were most likely to rank waitlisting characteristics as the most important feature when choosing a transplant center.
- Furthermore, the Standing Committee highlighted four studies that showed an association between processes under dialysis practitioner control and waitlisting.
- The Standing Committee noted that it is clear a link exists between waitlisting and transplant rates. However, the Standing Committee questioned whether a link exists between a nephrologist's care and a patient being waitlisted for a transplant, as transplant centers determine who is waitlisted.
- The developer noted that there is empirical evidence that the nephrologist can impact the outcome of waitlisting.
- The Standing Committee asked the developer why the measure is at the provider level rather than the transplant facility level. The Standing Committee noted that the measure being at the provider level implies that nephrology providers can do more for individuals who are eligible for the waitlist than a patient who is not eligible.
- The developer noted that the nephrologist plays a role in waitlisting and can impact the outcome of a decision to waitlist or not based on the care provided.
- The Standing Committee further questioned why the developer did not create a measure based on referral rates. The developer noted that, at this time, there is no national data source for referral rates.
- While some Standing Committee members questioned the evidence, other members supported the attribution of the measure to the nephrologist, noting that if transplant centers are not responsive to referrals, those patterns can shift. Additionally, Standing Committee members noted that transplant centers hold the nephrologist responsible for their patients and not having a measure for providers would be a miss.
- The Standing Committee did not reach consensus on evidence for this measure.
- The Standing Committee noted that the bottom quartile of practitioners had 46 percent lower waitlisting rates among new dialysis patients than the national average and the top quartile had 33 percent higher waitlisting rates among new dialysis patients than the national average.
- Additionally, the Standing Committee recognized the disparities data, which showed that the mean first year standardized waitlist ratio was highest for the categories of Other (2.88) and Asian/Pacific Islander (2.04) and lowest for Black (1.05). The Standing Committee further noted large inequities exist in renal disease, particularly in waitlisting.
- The Standing Committee passed the measure on performance gap.

2. Scientific Acceptability of Measure Properties:
(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)
2a. Reliability: **Total votes-19**; **Yes-18**; **No-1**; 2b. Validity: **Total votes-18**; **H-0**; **M-6**; **L-10**; **I-2**
Rationale:

- The SMP reviewed this measure. The measure passed with a rating of moderate on reliability **(Total votes-10; H-0, M-10, L-0, I-0)** and validity **(Total votes-10; H-0, M-8, L-2, I-0)**.
- The Standing Committee noted reliability testing at the accountable-entity level using an IUR with a bootstrapping approach.

- The Standing Committee noted that the developer calculated an IUR value of 0.64, which indicates that 64 percent of the variation in the measure can be attributed to the between-facility differences and 36 percent to the within-facility variation.
- The Standing Committee had no concerns regarding the reliability testing and accepted the SMP's vote for reliability.
- The Standing Committee highlighted the validity testing at the accountable-entity level, which evaluated the association between the dialysis practitioner group-level measure performance, subsequent mortality, and overall transplant rates among all patients attributed to the practitioner groups.
- The Standing Committee expressed several concerns regarding exclusions, particularly that the current exclusion criteria are based on a logical construct; however, there could be undermeasured confounders that impact a patient's ability to be waitlisted, such as mental health issues or lack of support.
- The Standing Committee was also concerned that patients who are waitlisted prior to starting dialysis, or preemptively waitlisted, are excluded from the measure. The developer noted that the majority of patients arrive to dialysis without waitlisting, and this measure captures those patients.
- Additionally, the Standing Committee questioned why patients who choose not to undergo transplants are included in the measure, considering that including them can potentially create unintended consequences, such as patients being pressured or coerced to do something they do not want to do.
- The developer noted the measure is not intended to expect all patients to waitlist; rather, the objective is to compare practitioner groups and identify those who are outlying in their performance.
- The Standing Committee asked the developer how they adjusted for the large amount of heterogeneity at the transplant center level, to which the developer noted that within the adjustment model, transplant rates at the center and transplant waitlist mortality were both used to adjust for heterogeneity.
- The Standing Committee expressed concern regarding the measure's use of CMS form 2728 rather than the Monthly Capitation Payment (MCP) form, as this can result in misclassifying the provider because the provider who fills out the form may not be the provider who cares for the patient in the facility.
- The developer noted that they chose CMS form 2728 because the measure is an all-patient, incident measure.
- The developers further explained that they looked at a subset of the data of patients who have Medicare to examine the differences between the MCP and 2728 claims. The developers found that while a different provider may sign the form, they are looking at the group practice, and approximately 90 percent of the time, the providers are part of the same practice.
- The Standing Committee asked whether the developers examined how much attribution changed over time, to which the developer noted that it remained consistent at 70 to 80 percent of providers being a part of the same practice.
- The Standing Committee voted to not accept the SMP's validity vote (Total Votes – 18; Yes–7; No–11). The Standing Committee ultimately did not pass the measure on validity based on the above concerns.

3. Feasibility: Vote Not Taken

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c. Susceptibility to inaccuracies/ unintended consequences identified; 3d. Data collection strategy can be implemented)

4. Usability and Use:

(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences)

4a. Use**: Vote Not Taken**; 4b. Usability: **Vote Not Taken**

5. Related and Competing Measures

- No related or competing measures were noted.

6. Standing Committee Recommendation for Endorsement: Vote Not Taken

7. Public and Member Comment

- Two public comments were submitted; neither were in favor of the measure. One commenter had concerns with the measure's attribution to the group practice, the variation in transplant center eligibility criteria, and the stratification of the reliability results by group size being absent from the testing.
- The other commenter had concerns regarding the measure's focus on maintenance dialysis populations, reliance on CMS form 2728, the attribution of the measures to facilities, lack of adjustment for variables that are critical for patient equity, and the focus on dialysis unit-specific measures without consideration of advance CKD care and nephrologist-led care.
- Three post-evaluation comments from two commenters were received for this measure. Both commenters opposed the measure and did not disagree with the Standing Committee's decision to not endorse the measure.
    - One commenter noted that they had several issues with the measure: (1) the attribution of the measure; (2) the model did not validly account for variation in transplant center eligibility criteria; and (3) the developer did not provide stratification of reliability scores by provider size for the measures.
        - The developer responded to all three issues raised in the comment above:
            - The developer stated that being waitlisted for kidney transplantation is the culmination of a variety of preceding preparatory activities. The developer explained that these activities heavily depend on the dialysis practitioner groups. However, the developer stated that aspects that are not entirely dependent on dialysis practitioner groups can still be influenced by dialysis practitioner groups, such as the actual waitlisting decision made by transplant centers or a patient's choice about the transplantation option.
            - The developer agreed that variation exists across transplant centers in eligibility criteria and that underlying patient comorbidities may affect their candidacy. However, the waitlisting measures adjust for a wide range of comorbidities and transplant center characteristics.
            - The developer also stated with regard to the reliability for small providers that 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. Furthermore, 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.
        - The Standing Committee did not raise any concerns with the comment, nor did it raise any concerns with the developer's response and maintained its decision to not recommend the measure for endorsement.

- The second commenter stated their opposition to the measure and highlighted some concerns, which included 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; and including patients in the measure who choose not to undergo a transplant.
    - The developer responded, stating that being waitlisted for kidney transplantation is the culmination of a variety of preceding preparatory activities. The developer explained that these activities heavily depend on the dialysis practitioner groups. However, the developer stated that aspects that are not entirely dependent on dialysis practitioner groups can still be influenced by dialysis practitioner groups, such as the actual waitlisting decision made by transplant centers or a patient's choice about the transplantation option. The developer further stated that the scope of this measure development effort was focused on the performance of dialysis practitioner groups.
    - The Standing Committee did not raise any concerns with the comment, nor did it raise any concerns with the developer's response and maintained its decision to not recommend the measure for endorsement.

8. Consensus Standards Approval Committee (CSAC) Endorsement Decision: Total votes- 15; Yes-14; No-1

December 9, 2022: Not endorsed

- The CSAC upheld the Standing Committee's decision to not recommend the measure for endorsement.

NQF #3694 Percentage of Prevalent Patients Waitlisted in Active Status (aPPPW)

Measure Worksheet

Description: This measure tracks the percentage of patients in each dialysis practitioner group practice who were on the kidney or kidney-pancreas transplant waitlist in active status. Results are averaged across patients prevalent on the last day of each month during the reporting year. The proposed measure is a directly standardized percentage, which is adjusted for covariates (e.g., age and risk factors).

Numerator Statement: The numerator is the adjusted count of patient months in which the patient at the dialysis practitioner group practice is on the kidney or kidney-pancreas transplant waitlist in an active status as of the last day of each month during the reporting year.

Denominator Statement: All patient-months for patients who are under the age of 75 in the reporting month and who are assigned to a dialysis practitioner group practice according to each patient's treatment history during a given month during the reporting year.

Exclusions:

* Patients who were at age 75 or older in the reporting month

* Patients who were admitted to a skilled nursing facility (SNF) during the month of evaluation were excluded from that month;

* Patients who were admitted to a skilled nursing facility (SNF) within one year of dialysis initiation according to form CMS-2728

* Patients determined to be in hospice were excluded from month of evaluation and remainder of reporting period

* Patients with dementia

The noted exclusions represent conditions for which transplant waitlist candidacy is highly unlikely, and which can be identified readily with available data.

Patients who were attributed to dialysis practitioner groups with fewer than 11 patients are not excluded from the measure. All patients who meet the denominator inclusion criteria are included and used to model a given dialysis practitioner group's expected waitlist rate. If a dialysis practitioner group has fewer than 11 patients, then the dialysis practitioner group is excluded from reporting outcomes.

Adjustment/Stratification: Statistical risk model with risk factors

Level of Analysis: Clinician: Group/Practice

Setting of Care: Outpatient Services
Type of Measure: Outcome
Data Source: Claims, Registry Data
Measure Steward: CMS

STANDING COMMITTEE MEETING [June 29 and 30, 2022]

1. Importance to Measure and Report:

(1a. Evidence, 1b. Performance Gap)

1a. Evidence: **Total Votes-17; Pass-9; No Pass-8**; 1b. Performance Gap: **Total Votes-19; H-2; M-17; L-0; I-0**

Rationale:

- The Standing Committee highlighted a portion of evidence presented for the measure, which included several studies that noted empirical patient support on the value of waitlisting, strong support for the association between processes under dialysis practitioner control and waitlisting, and feedback from two convened TEPs that supported the importance of waitlisting and favor for a measure that targeted waitlisting. The Standing Committee did not identify any concerns with the presented evidence and passed the measure on the evidence criteria.
- The Standing Committee observed the measure range in 2019 was 0.0 to 70.4, with a mean of 12.3 percent for dialysis practitioner group practices with at least 11 patients.
- The Standing Committee considered disparities data with a mean waitlisting performance being the lowest for Native American/Alaskan natives (6.9 percent). Non-Hispanics had a lower waitlisting percentage on average (11.8 percent) than Hispanics (14.5 percent). Females had a mean waitlisting percentage of 10.9 percent, and males had a mean of 13.3 percent.
- The Standing Committee agreed that substantial gaps and disparities were both present and passed the measure on performance gap.

2. Scientific Acceptability of Measure Properties:

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)

2a. Reliability: **Total Votes-18; Yes-18; No-0**; 2b. Validity: **Total Votes-18; H-0; M-7; L-9; I-2**

Rationale:

- The SMP reviewed this measure.
- The SMP passed the measure on reliability **(Total Votes-10; H-5; M-3; L-0; I-2)** and did not reach consensus on validity **(Total Votes-10; H-0; M-6; L-4; I-0)**.
- The Standing Committee noted reliability testing at the accountable-entity level and IUR with a bootstrapping approach. The developer reported an IUR value of 0.93, which indicates that 93 percent of the variation in the measure can be attributed to the between-facility differences and 7 percent to the within-facility variation.
- The Standing Committee voted to accept the SMP's rating for reliability.
- The Standing Committee considered the accountable entity-level validity testing for the measure. The results showed that a higher measure performance was correlated with higher transplant rates and a lower mortality rate.
- The Standing Committee questioned whether transplant center characteristics are accounted for in the risk model and expressed concern with the use of SDOH.
- The developer advised that the variables in the risk model are based on a conceptual rationale that included theoretical/clinical considerations and existing literature for factors affecting kidney transplant waitlisting, transplant centers' waitlist mortality, and transplant rates that are accounted for.

- Three risk categories were chosen for the model: social risk, functional risk, and medical/clinical risk. The use of SDOH was informed by the measure's TEP.
- The Standing Committee continued to express discomfort with the use of SDOH in the risk model and did not pass the measure on validity.

3. Feasibility: Vote Not Taken

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c. Susceptibility to inaccuracies/ unintended consequences identified; 3d. Data collection strategy can be implemented)

4. Usability and Use: Vote Not Taken

(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences)

5. Related and Competing Measures

- No related or competing measures were noted.

6. Standing Committee Recommendation for Endorsement: **Vote Not Taken**

7. Public and Member Comment

- Two pre-evaluation comments were received; neither were in favor of the measure due to the attribution of successful or unsuccessful waitlisting to dialysis facilities, individual practitioners, or group practices.
- Additionally, both comments did not support the measure due to the following: 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.
- Six post-evaluation comments were received for this measure from three commenters. Five comments opposed the measure, and one comment from the developer requested the Standing Committee to reconsider its decision.
    - One commenter stated that a patient's status on the waitlist (i.e., active or inactive) can change frequently within the transplant centers and can be notoriously difficult to track, which would seriously compromise the measure's validity and render the information it provides flawed. Additionally, this commenter noted concerns with the attribution of successful or unsuccessful waitlisting to individual practitioners or group practices and thus cannot support the measure. The commenter also expressed concern with the variation in transplant centers' eligibility criteria. Lastly, the commenter was also concerned that the reliability for small providers might be substantially lower than the overall IURs.
        - The developer responded to all the issues raised in the comments above:
            - The developer stated that they 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. The developer continued noting that practitioners play a substantial role in addressing the issues that can allow a patient to return to active status. The developer concluded that while a

waitlisting measure directed at the transplant center may also be potentially appropriate, the scope of this measure development effort was focused on dialysis facilities.

- The developer further stated that being waitlisted for kidney transplantation is the culmination of a variety of preceding preparatory activities. The developer explained that these activities heavily depend on the dialysis practitioner groups. However, the developer stated that aspects that are not entirely dependent on dialysis practitioner groups can still be influenced by dialysis practitioner groups, such as the actual waitlisting decision made by transplant centers or a patient's choice about the transplantation option.
- The developer agreed that variation exists across transplant centers in eligibility criteria and that underlying patient comorbidities may affect their candidacy. However, the waitlisting measures adjust for a wide range of comorbidities and transplant center characteristics.
- The developer also stated with regard to the reliability for small providers that 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. Furthermore, 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.

    - The Standing Committee did not raise any concerns with the comments, nor did it raise any concerns with the developer's response and maintained its decision to not recommend the measure for endorsement.

- Another commenter agreed with the comments raised by the Standing Committee, particularly regarding attribution, a focus on incident maintenance dialysis populations, reliance on CMS-2728 for risk adjustment, a lack of variables that are critical for patient equity in the model, and a focus on dialysis unity-specific measures without consideration of CKD care and nephrologist-led care.
    - The developer responded to the comments, stating that being waitlisted for kidney transplantation is the culmination of a variety of preceding preparatory activities. The developer explained that these activities heavily depend on the dialysis practitioner groups. The developer further stated the scope of this particular measure development effort was focused on the much larger group of patients who start dialysis without being transplanted. The developer continued that this measure uses Medicare claims for the prevalent comorbidities in addition to comorbidities listed on the form CMS-2728. For SDOH factors, the developer does include variables to adjust for social risk, including the Area Deprivation Index and Medicare-Medicaid dual eligibility.
    - The Standing Committee did not raise any concerns with the comment, nor did it raise any concerns with the developer's response and maintained its decision to not recommend the measure for endorsement.
- The developer requested a reconsideration of the measure on the basis that the measure evaluation criteria were not applied appropriately., The developer stated that the evidence

presented as well as the results from the validity testing are sufficient for achieving a passing score on evidence as well as a moderate score on validity because NQF #3694 is similar to NQF #3695, which did pass these criteria.

- The Standing Committee voted to not reconsider the measure (Total Votes - 20; Yes–3; No–17) because although NQF #3694 and NQF #3695 are similar measures, they do have differences, including different numerators. The Standing Committee also noted that NQF #3694 is a measure that addresses transplant waitlisting in active status and that while nephrologists have a role in optimizing and referring the patients for transplantation, they have nothing to do with the activation of patients on the waitlist, suggesting that the measure is not an accurate reflection of the quality of care provided by nephrologists. The Standing Committee further cited concern with the testing data because they showed extreme variation in transplant center practice. The Standing Committee stated that the decision to not recommend NQF #3694 was made based on these subtle differences between the two measures.

8. Consensus Standards Approval Committee (CSAC) Endorsement Decision: Total votes- 15; Yes-14; No-1 December 9, 2022: Not endorsed

- The CSAC upheld the Standing Committee's decision to not recommend the measure for endorsement.

NQF #3696 Standardized Modality Switch Ratio for Incident Dialysis Patients (SMoSR)

Measure Worksheet

Description: The standardized modality switch ratio (SMoSR) is defined to be the ratio of the number of observed modality switches (from in-center to home dialysis—peritoneal or home hemodialysis) that occur for adult incident ESRD dialysis patients treated at a particular facility, to the number of modality switches (from in-center to home dialysis—peritoneal or home hemodialysis) that would be expected given the characteristics of the dialysis facility's patients and the national norm for dialysis facilities. The measure includes only the first durable switch that is defined as lasting 30 continuous days or longer.

The SMoSR estimates the relative switch rate (from in-center to home dialysis) for a facility, as compared to the national switch rate. Qualitatively, the degree to which the facility's SMoSR varies from 1.00 is the degree to which it exceeds (> 1.00) or is below (< 1.00) the national modality switch rates for patients with the same characteristics as those in the facility. Ratios greater than 1.00 indicate better than expected performance while ratios <1.00 indicate worse than expected performance.

When used for public reporting, the measure calculation will be restricted to facilities with at least one expected modality switch in the reporting year. This restriction is required to ensure patients cannot be identified due to small cell size

Numerator Statement: Observed number of switches from in-center hemodialysis to a home dialysis modality (peritoneal dialysis or home hemodialysis) among eligible patients at the facility during the time period.

Denominator Statement: Expected number of switches from in-center hemodialysis to a home dialysis modality (peritoneal dialysis or home hemodialysis) among eligible patients at the facility during the time period, given the national average of modality switches, and patient case-mix at the facility.

Exclusions: The following exclusions are applied to the denominator:

* Patient's time at risk under hospice care

* Patient's time at risk when in a nursing home and on home hemodialysis

* Pediatric patients (less than 18 years of age)

* Patients with no CMS-2728 Medical Evidence Form (i.e., AKI patients on dialysis but not designated as ESRD)

Patients who are attributed to clinics with fewer than 1 expected modality switch are not excluded from the measure. All patients who meet the denominator inclusion criteria are included and used to model a given facilities expected switch rate to home dialysis. If that switch rate is <1, then the facility is excluded from reporting outcomes

Adjustment/Stratification:
Statistical risk model with risk factors
Level of Analysis: Facility
Setting of Care: Outpatient Services
Type of Measure: Outcome
Data Source: Claims, Registry Data
Measure Steward: Centers for Medicare & Medicaid Services

STANDING COMMITTEE MEETING [June 29-30, 2022]
1. Importance to Measure and Report:
(1a. Evidence, 1b. Performance Gap)
1a. Evidence: **Total votes-17**; **Pass-7; No Pass-10**; 1b. Performance Gap: **Total votes- 17; H-1**; **M-14**; **L-2**; **I-0**
Rationale:

- The Standing Committee noted the rationale behind the measure, which states that switches to home dialysis in the first year are reflective of a robust education, an effective presentation of modality educational materials, and the facilitation of the discussion regarding patients.
- The Standing Committee also highlighted the studies submitted by the developer, which did not include any formal randomized control trials but *did* include observational studies, an accepted form of evidence, that observed the epidemiology and characteristics of home dialysis uptake.
- The Standing Committee generally agreed with the premise that education can affect the outcome of a patient switching to a home modality; however, it noted that it is not clear that the evidence supporting modality switch, as a marker of education, is substantiated. The Standing Committee also noted that the measure does not track ongoing educational activities or what the activities might be.
- The developer emphasized that the measure is a measure of switches, not education.
- The Standing Committee noted that in this context, education is a proxy for the switch. The developer noted that the focus on education is due to published literature, which shows that it is very unlikely or rare that someone ends up switching to a home modality if they are not aware of their options.
- The Standing Committee further questioned the evidence, stating that education can result in several outcomes, such as not choosing a home modality or choosing it and access not being available due to the facility infrastructure. In the case of a patient who chooses to stay on an in-center modality after receiving education, facilities could be penalized even though they did provide education.
- The Standing Committee questioned why the developer did not report a rate of home dialysis rather than a measure of switches. The developer noted that if they did report a rate, 40 percent of dialysis facilities would have been excluded because they do not offer home dialysis. The developers argued that this would result in less useful information to patients who are deciding on which facility to choose.
- The Standing Committee questioned why the developer did not use more recent data. The developer noted that there were more recent studies from 2019 that were included in the submission.
- The Standing Committee questioned why the measure was at the facility level when education should start prior to the patient arriving at the facility. The developer stated that early education may not be possible, as dialysis initiation can happen abruptly.
- Some Standing Committee members noted that because the measure focuses on switches after dialysis initiation, there are potential unintended consequences of this focus, such as encouraging practitioners to not initiate home dialysis and recommend in-facility dialysis so that the dialysis facilities could then increase their switch rates. The developer further noted that pre-dialysis education is outside the scope of

the measure, considering the measure foci on incident patients and modality switches likely reflect robust education, effective presentation, and facilitation by the dialysis unit.

- The Standing Committee did not reach consensus on evidence.
- The Standing Committee noted that the mean SMoSR was 1.07, the first quartile performance was 0.37, and the third quartile performance was 1.52, demonstrating a wide range of provider performance on this measure.
- The Standing Committee also acknowledged the disparities data, noting that Black, Native American, and Asian /Pacific Islanders had a lower hazard of modality switch compared to White patients.
- The Standing Committee asked the developer to clarify whether the data presented for performance gap were people who switched modalities or whether they were people on each kind of modalities. The developer stated that the data are showing a switch to a home modality.
- The Standing Committee also asked how the expected modality switches were determined, to which the developer stated the expected value is based on the national rate of switches across facilities adjusting for case mix.
- Ultimately, the Standing Committee passed the measure on performance gap.

2. Scientific Acceptability of Measure Properties:

(2a. Reliability – precise specifications, testing; 2b. Validity – testing, threats to validity)

2a. Reliability: **Total votes-17**; **Yes-17**; **No-0**; 2b. Validity: **Total votes-19**; **H-0**; **M-7**; **L-12**; **I-0**

Rationale:

- The SMP reviewed this measure.
- The SMP passed the measure on reliability **(Total votes-8; H-0, M-6, L-2, I-0)** and validity **(Total votes-8; H-1, M-5, L-2, I-0)**.
- The Standing Committee noted accountable-entity level reliability testing and observed that the IUR was 0.605, indicating that over 60 percent of the variation in the measure can be attributed to the between-facility variation and less than 40 percent to the within-facility variation; the PIUR was 0.606.
- The Standing Committee questioned whether a patient is still attributed to the facility if they reside in a dialysis facility but only receive one treatment in a month due to issues such as hospitalization. The developer explained that if the patient is still assigned to the facility during the 30-day period, then they are still attributed to the facility. If the patient is discharged from the facility, then they are not attributed to the facility.
- The Standing Committee questioned which facility a patient would be attributed to if they had initiated a switch within 30 days and were then moved to another facility for training and treatment. The developer noted that if the switch occurs before 30 days, it would be attributed to the initial facility; conversely, if it occurred after the 30 days, it would be attributed to the receiving facility.
- The Standing Committee also questioned whether training days are included in the 30 days. The developer noted that training days are included.
- The Standing Committee further questioned the developer's choice of 30 days as the marker for durability. The developer noted that they originally showed the TEP 60 days due to an assumption that was made that the patient would need enough time to be clinically stable. However, patients on the TEP disagreed with the 60 days because they noted that any days at home are better than no days at home; conversely, the providers on the TEP felt the durability marker should be longer (i.e., between 60 and 90 days).
- The TEP ultimately agreed that 30 days would be sufficient time for a patient to be stable and the switch to be considered durable.

- The Standing Committee accepted the SMP's rating for reliability.
- The Standing Committee noted validity testing at the accountable-entity level, noting that the developer reported Spearman's Rho correlation, Gamma coefficients, Pearson's correlation coefficient, and logistic regression relationships with several other measures (i.e., *Standardized Mortality Ratio*, *First-Year Standardized Mortality Ratio*, *Standardized Waitlist Ratio-Incident Dialysis Patients*, ICH-CAHPS *Providing Information to Patients*, and the *Percentage of Home Dialysis Patients at the Facility*).
- The Standing Committee stated that the correlation results between waitlisting and this measure (NQF #3696) were significant (i.e., Spearman's Rho equals 0.12) but not as significant as would be expected, given that waitlisting is also a function of education. Additionally, some Standing Committee members were surprised by the weak correlation between risk of hospitalizations and this measure (Spearman's Rho equals -0.060) because hospitalizations can be prevented through education.
- Some Standing Committee members were troubled by how facilities that do not offer home modalities will be perceived statistically as they are included in the calculation; however, since they do not offer a home modality option, they may not be perceived as doing well on a switch measure. The developer noted that facilities that offer both modality types tend to do better in switches than those that only offer in-center dialysis. There is not a specific reason for why this may be other than the lower performance of facilities that only offer in-center dialysis could be due to less familiarity with home modalities.
- The Standing Committee noted it is not clear whether all the chosen comorbidities in the risk adjustment model influence the choice of modality; further, it is unclear whether the use of CMS form 2728 is problematic because the form captures patients' health state at the beginning of care, not how their medical conditions can change.
- The developer noted that the population is incident patients, and this measure was adjusted for comorbidities that are not the result of facility care. The developer further stated that because this is an all-patient measure, they are not looking at what comorbidities are developed during the year.
- 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, calling into question the exclusions and risk adjustment.
- The developer noted that CMS is implementing screening for SDOH, which will help in identifying patients for certain therapies.
- Many Standing Committee members expressed that the exclusions were not sufficient, specifically questioning the developer's decision to include patients who live alone and those who choose to not to go on a home modality.
- The Standing Committee also asked for clarification on whether nursing home residents are included in the measure. The developer noted that nursing home patients are excluded from the denominator and numerator irrespective of the modality type. However, some of those patients will be in the model once they are out of the nursing home or before they were in it.
- The Standing Committee voted to not accept the SMP's validity vote (Total Votes – 19; Yes–9; No–10). The Standing Committee ultimately did not pass the measure on validity based on the above concerns.

3. Feasibility: Vote Not Taken

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c. Susceptibility to inaccuracies/ unintended consequences identified; 3d. Data collection strategy can be implemented)

4. Usability and Use:

(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences)
4a. Use**: Vote Not Taken**; 4b. Usability: **Vote Not Taken**

5. Related and Competing Measures

- No related or competing measures were noted.

6. Standing Committee Recommendation for Endorsement: **Vote Not Taken**

7. Public and Member Comment

- Two public comments were submitted; neither were in favor of the measure. Both commenters expressed concern that modality switch rates were being used as a proxy for patient engagement and education.
- One commenter noted that the measure results in a high risk for conflict between informed patient preferences, pre-existing decisions, and dialysis facility incentives.
- Three post-evaluation comments were received from three commenters for this measure, with two comments opposing the measure and one comment from the developer requesting the Standing Committee to reconsider its decision.
    - The first commenter stated that while the measure will incentivize switching in-center patients to home dialysis, 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. Additionally, the commenter stated that the measure offers no insight into the degree or quality of education and training the patient received in preparation for the switch and may even inadvertently infringe on patient choice.
        - The developer responded, stating that 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 is 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. The developer continued, noting that the assertion that this measure would encourage practitioners to start all patients on in-center hemodialysis 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 hemodialysis, 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.
        - The Standing Committee did not raise any concerns with the comment, nor did it raise any concerns with the developer's response and maintained its decision to not recommend the measure for endorsement.
    - Another commenter expressed concern that the measure could lead to practitioners being encouraged to initiate patients in-center to gain credit for changing the patient to home-based therapy later.
        - The developer responded, stating that 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 is 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. The developer continued, noting that the assertion that this measure would encourage practitioners to start all patients on in-center hemodialysis 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 hemodialysis, 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.

        - The Standing Committee did not raise any concerns with the comment, nor did it raise any concerns with the developer's response and maintained its decision to not recommend the measure for endorsement.
    - The developer requested reconsideration of the measure on the basis that NQF's measure evaluation criteria were not applied properly. In addition, the developer posited that a clear reason for overturning the SMP's validity decision was not articulated and that the Standing Committee's focus on measuring patient choice was inappropriate because patient choice is not necessarily a factor, given the numerator and denominator details.
        - The Standing Committee voted not to reconsider the measure (Total Votes - 19; Yes–1; No–18), citing the validity concerns raised during the measure evaluation meeting as the reason for overturning the SMP's decision. The Standing Committee noted that in addition to the concerns regarding the measure's exclusions and risk adjustment, the Standing Committee raised concern with the weak correlations between this measure and others included in the analysis. Furthermore, the Standing Committee stated that many factors determine whether a patient chooses and maintains home dialysis, which often do not have to do with a facility's quality of care, suggesting that this measure cannot accurately assess a facility's quality of care.

8. Consensus Standards Approval Committee (CSAC) Endorsement Decision: Total votes- 15; Yes-15; No-0 December 9, 2022: Not endorsed

- The CSAC upheld the Standing Committee's decision to not recommend the measure for endorsement.

Appendix B: Renal Portfolio—Use in Federal Programs*

NQF#	Title	Federal Programs (Finalized or Implemented)
0249	Delivered Dose of Hemodialysis Above Minimum	Dialysis Facility Compare
0255	Measurement of Phosphorus Concentration	None
0318	Peritoneal Dialysis Adequacy Clinical Performance Measure III - Delivered Dose of Peritoneal Dialysis Above Minimum	Dialysis Facility Compare
0323	Adult Kidney Disease: Hemodialysis Adequacy: Solute	None
0369	Dialysis Facility Risk-Adjusted Standardized Mortality Ratio	Dialysis Facility Compare
1423	Minimum spKt/V for Pediatric Hemodialysis Patients	Dialysis Facility Compare
1424	Monthly Hemoglobin Measurement for Pediatric Patients	None
1425	Measurement of nPCR for Pediatric Hemodialysis Patients	Dialysis Facility Compare
1454	Proportion of Patients With Hypercalcemia	None
1460	Bloodstream Infection in Hemodialysis Outpatients	None
1463	Standardized Hospitalization Ratio for Dialysis Facilities (SHR)	Dialysis Facility Compare
1662	Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy	None
2594	Optimal End-Stage Renal Disease (ESRD) Starts	None
2701	Avoidance of Utilization of High Ultrafiltration Rate (>=13 ml/kg/hour)	None
2706	Pediatric Peritoneal Dialysis Adequacy: Achievement of Target Kt/V	None
2978	Hemodialysis Vascular Access: Long-Term Catheter Rate	Dialysis Facility Compare End-Stage Renal Disease Quality Incentive Program
2979	Standardized Transfusion Ratio for Dialysis Facilities	Dialysis Facility Compare End-Stage Renal Disease Quality Incentive Program
3695	Percentage of Prevalent Patients Waitlisted (PPPW)	Dialysis Facility Compare

*Adapted from the CMS Measures Inventory Tool. Last Accessed on January 3, 2023.

Appendix C: Renal Standing Committee and NQF Staff

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Appendix D: Measure Specifications

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

STEWARD

The Permanente Federation

DESCRIPTION

Optimal End Stage Renal Disease (ESRD) Starts is the percentage of new adult ESRD patients during the measurement period who experience a planned start of renal replacement therapy by receiving a preemptive kidney transplant, by initiating home dialysis (peritoneal dialysis or home hemodialysis), or by initiating outpatient in-center hemodialysis via arteriovenous fistula or arteriovenous graft.

TYPE

Process

DATA SOURCE

Claims, Other, Registry Data, Electronic Health Records

The data collection instrument is in Question 1 of the Additional section. It can be completed from records maintained by the renal care team as patients reach ESRD, and submitted to the measure analyst every 3 months. CMS 2728 Form: Within KP we do not have access to this data, but all the essential data elements are available on the CMS 2728 Form which is submitted for every new ESRD patient in the US (whether they have Medicare coverage or not). The only missing data is the date of stopping dialysis if recover from acute renal failure by 90 days, and in most cases, a 2728 Form is not submitted for these patients. Patients who recover kidney function and stop dialysis by 90 days are not included in the denominator or numerator. We anticipate that this will be the source of data for organizations outside of KP in the future.

LEVEL

Population: Regional and State, Health Plan, Clinician: Group/Practice, Facility, Integrated Delivery System

SETTING

Ambulatory Care, Outpatient Services, Inpatient/Hospital

NUMERATOR STATEMENT

The number of new ESRD patients age 18 and over who initiate outpatient renal replacement therapy in the twelve month measurement period with an optimal ESRD therapy, which includes preemptive kidney transplant, home dialysis (peritoneal dialysis or home hemodialysis), or outpatient in-center hemodialysis via arteriovenous fistula or arteriovenous graft.

NUMERATOR DETAILS

New Information

The Optimal ESRD Starts numerator is the total number of new patients age 18 and over who initiate renal replacement therapy for the first time and do not come off dialysis by 90 days, with one of the following:

• A preemptive kidney transplant or simultaneous pancreas-kidney transplant (SPK). Preemptive means that the patient has never experienced out-patient dialysis, OR

• Initial home or self-dialysis modality, including planned and "successful urgent start" peritoneal dialysis (PD) and home hemodialysis (HHD) via an arteriovenous fistula or arteriovenous graft. ”Successful urgent start” peritoneal dialysis means that the patient never

experienced outpatient hemodialysis via a hemodialysis catheter before starting outpatient peritoneal dialysis, OR

• Initial outpatient hemodialysis (HD), including self-hemodialysis (SHD), via arteriovenous fistula (AVF) prepared surgically without use of artificial materials. The patient may have a hemodialysis catheter in place if it is not used. Do not count patient with a single needle in AVF with blood return via catheter, OR

• Initial outpatient hemodialysis (HD), including self-hemodialysis (SHD), via arteriovenous graft (AVG). The patient may have a hemodialysis catheter if it is not used. Do not count patient with a single needle in AVG with blood return via catheter.

From Old Submission

The item underlined in this sentence was removed from the new submission:

• Initial outpatient hemodialysis (HD), including self-hemodialysis (SHD), via arteriovenous graft (AVG), limited to no more than 10% of all patients starting in-center hemodialysis#.

#Arteriovenous fistula (AVF) is highly preferred for hemodialysis over an arteriovenous graft (AVG). AVF are associated with many fewer follow-up encounters with vascular surgery and interventional radiology to remove clots, dilate and replace. CMS has recognized AVF superiority in its Fistula First Quality Initiative, which continues to collect data and promote practice improvement methods.

DENOMINATOR STATEMENT

The number of patients age 18 and over who receive a preemptive kidney transplant or initiate long-term dialysis therapy (do not recover kidney function by 90 days) for the first time in the twelve month measurement period

DENOMINATOR DETAILS

New Information

The population being measured are patients age 18 and over who 1) receive a preemptive kidney transplant (having never received outpatient dialysis), including simultaneous pancreas and kidney transplant, plus 2) patients age 18 and over initiating long-term maintenance dialysis who do not recover kidney function by 90 days.

The population includes patients who start renal replacement therapy and then are lost to follow up (lose insurance, move away) and/or die.

The denominator is the number of the above patients within the measured entity during the 12-month measurement period.

Clarifications based on the above definition (not exclusions):

1. The denominator does not include patients who initiate outpatient dialysis but then recover GFR to the point where they can stop dialysis treatments by 90 days after the first outpatient dialysis.

2. The denominator does not include patients who previously reached ESRD, such as

• Patients who previously were on dialysis 90 days or more who then recovered kidney function for a while, but then restarted dialysis

• Patients who switch from one dialysis modality to another, for example switching from in-center hemodialysis to home dialysis.

3. The denominator does not include patients who died without experiencing outpatient dialysis or a kidney transplant.

From Old Submission

The item underlined in this sentence was removed from the new submission:

2. The denominator does not include patients who previously reached ESRD, such as

• Patients who previously were on dialysis 90 days or more who then recovered kidney function for a while, but then restarted dialysis

• Patients who switch from one dialysis modality to another, for example switching from in-center hemodialysis to home dialysis.

• Patients with failing kidney transplants starting or returning to dialysis.

EXCLUSIONS

None

EXCLUSION DETAILS

None

RISK ADJUSTMENT

No additional risk adjustment analysis included

No risk adjustment or stratification

not applicable

STRATIFICATION

As there is no patient sampling (all patients who reach ESRD are included), there is no stratified sampling.

For comparative purposes and tracking within Kaiser Permanente, the metric has been calculated (stratified) by geographic medical regions or areas. Results by geographic regions/areas are shown here.

Table 1. Table shows % optimal ESRD starts by geographic markets as of 2021 Q3

Geographic Markets	# of New ESRD Patients	# of KP New Patients With Optimal ESRD Starts	% Optimal ESRD Starts
Market 1	103	64	62.1%
Market 2	162	85	52.5%
Market 3	201	117	58.2%
Market 4	128	82	64.1%

Geographic Markets	# of New ESRD Patients	# of KP New Patients With Optimal ESRD Starts	% Optimal ESRD Starts
Market 5	132	48	36.4%
Market 6	139	79	56.8%
Market 7	1,806	970	53.7%
Market 8	1,331	815	61.2%
Kaiser Permanente	4,002	2,260	56.5%

Table 1. Table shows % optimal ESRD starts by geographic markets as of 2021 Q3

TYPE SCORE

Rate/proportion

Better quality = Higher score

ALGORITHM

New Information

1. The target population is all new ESRD patients as described in sp.15. Data is validated by each market via chart review, compiled and submitted on standardized spreadsheets for quality reporting.

2. Determine denominator:

• Eliminate patients who do not meet the denominator definition sp.15.

a. Eliminate patients who recovered kidney function by day 90

b. Eliminate patients who previously were on dialysis 90 days or more who then recovered kidney function then later restarted dialysis

c. Eliminate patients changing dialysis modality

d. Eliminate patients who died without experiencing outpatient dialysis or a kidney transplant

• Eliminate patients with incomplete data if unavailable

3. Count patients in each category. Each denominator patient must be assigned to one and only one of the groups below per numerator criteria in sp.13.

Group A: Preemptive kidney transplant

Group B: Peritoneal Dialysis (Home)

Group C: Home Hemodialysis

Group D: In-center HD with AVF

Group E: In-center HD with AVG

Group F: In-center HD with Catheter

4. Note: Denominator = A + B + C + D + E + F

5. Calculate Optimal ESRD Starts = ((A + B + C + D + E'))/Denominator) x 100%

6. Calculate Modality Sub-metrics

• Preemptive Kidney Transplant Starts + (A/Denominator) x 100%

• Home Dialysis Starts = ((B + C))/Denominator) x 100%

• Optimal AVF & AVG Starts = ((D + E'))/Denominator) x 100%

• Non-Optimal ESRD Starts = 100% - Optimal ESRD Starts

From Old Submission

Remove underlined item from sentence below since this item is no longer excluded in the measure specification.

2. Determine denominator:

....

c. Eliminate patients starting dialysis after failed transplant

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N/A

NQF #3695 Percentage of Prevalent Patients Waitlisted (PPPW)

STEWARD

Centers for Medicare & Medicaid Services

DESCRIPTION

This measure tracks the percentage of patients in each dialysis practitioner group practice who were on the kidney or kidney-pancreas transplant waitlist. Results are averaged across patients prevalent on the last day of each month during the reporting year. The proposed measure is a directly standardized percentage, which is adjusted for covariates (e.g. age and risk factors).

TYPE

Outcome

DATA SOURCE

Registry Data, Claims

EQRS (formerly CROWNWeb), Medicare Claims, and the CMS Medical Evidence Form 2728 were used as the data sources for establishing the denominator. EQRS was used for the age risk adjustment and exclusion of patients aged 75 or older. Organ Procurement and Transplant Network (OPTN) is the data source for the numerator (waitlisting in active status). Medicare

claims from the year prior to the reporting period were used for comorbidity condition adjustments. Medicare claims during the reporting period were used for the hospice exclusion criteria. The Nursing Home Minimum Dataset and Questions 17u and 22 on the CMS Medical Evidence Form were used to identify SNF patients. Additionally, Medicare claims during the reporting period and a payment history file were used to determine dual eligibility status. The Medicare Provider Files from the CMS Integrated Data Repository (IDR) were used to identify dialysis practitioner's group practice. Area Deprivation Index (ADI) was obtained from Census data (2011-2015) based on patient zip code. In order to assess the transplant center characteristics, Scientific Registry of Transplant Recipients (SRTR) data was used.

LEVEL

Clinician: Group/Practice

SETTING

Outpatient Services

NUMERATOR STATEMENT

The numerator is the adjusted count of patient months in which the patient at the dialysis practitioner group practice is on the kidney or kidney-pancreas transplant waitlist as of the last day of each month during the reporting year.

NUMERATOR DETAILS

The adjusted count of patient months in which the patient at the dialysis practitioner group practice is on the kidney or kidney-pancreas transplant waitlist, adjusted for patient-mix. To be included in the numerator for a particular month, the patient must be on the kidney or kidney-pancreas transplant waitlist as of the last day of the month during the reporting year.

DENOMINATOR STATEMENT

All patient-months for patients who are under the age of 75 in the reporting month and who are assigned to a dialysis practitioner group practice according to each patient's treatment history during a given month during the reporting year.

DENOMINATOR DETAILS

During the target reporting months for eligible Medicare ESRD dialysis patients, Medicare physician claims were used to identify 1) the individual dialysis practitioner that received the monthly capitation payment (MCP) and 2) the dialysis group practice identifier to which that practitioner belongs. Tax identification numbers (TINs) are used to identify the dialysis practitioner group practices on Medicare physician claims. For each month, the patient was assigned to the practitioner, and in turn to that dialysis practitioner's group practice, which as a whole provided dialysis services with the most face-to-face interaction, according to the Healthcare Common Procedure Coding System (HCPCS) codes. Monthly capitation payment HCPCS codes included are the following: 90951, 90952, 90953, 90954, 90955, 90956, 90957, 90958, 90959, 90960, 90961, 90962, 90963, 90964, 90965, 90966. Information regarding first ESRD service date, modality, death, waitlist status, and transplant are obtained from Medicare claims, EQRS, Organ Procurement and Transplant Network (OPTN), and the Social Security Death Master File.

EXCLUSIONS

Exclusion that are implicit in the denominator include:

* Patients who were at age 75 or older in the reporting month

* Patients who were admitted to a skilled nursing facility (SNF) during the month of evaluation were excluded from that month;

* Patients who were admitted to a skilled nursing facility (SNF) within one year of dialysis initiation according to form CMS-2728

* Patients determined to be in hospice were excluded from month of evaluation and the remainder of reporting period

* Patients with dementia

The noted exclusions represent conditions for which transplant waitlist candidacy is highly unlikely, and which can be identified readily with available data.

Patients who were attributed to dialysis practitioner groups with fewer than 11 patients are not excluded from the measure. All patients who meet the denominator inclusion criteria are included and used to model a given dialysis practitioner group's expected waitlist rate. If a dialysis practitioner group has fewer than 11 patients, then the dialysis practitioner group is excluded from reporting outcomes.

EXCLUSION DETAILS

The Nursing Home Minimum Dataset and the Questions 17u and 22 on CMS Medical Evidence Form were used to identify patients in skilled nursing facilities. For hospice patients, a separate CMS file that contains final action claims submitted by hospice providers was used to determine the hospice status. Nursing home status from the CMS-2728 form is only used for incident patients, i.e. patients in which the start of ESRD is within one year of the month of evaluation. Once a patient is determined to be on hospice, the patient is excluded from the measure in the month of evaluation and the remainder of the reporting period. In addition, we used Agency for Healthcare Research and Quality (AHRQ) Clinical Classifications Software (CCS) diagnosis categories for prevalent comorbidity selection, including dementia. Patients with evidence of dementia in the prior year were excluded from analysis.

RISK ADJUSTMENT

Statistical risk model with risk factors (specify number of risk factors)

Covariates in the model are listed below:

- Age
  Age is included as continuous variable as well as age spline with knots at 15, 55, and 70
- ADI
- Dual eligibility
  Dual Eligible
  Not Dual Eligible
- Diabetes, primary cause of ESRD
- Comorbidities at ESRD incidence:
  Congestive heart failure
  Atherosclerotic heart disease and other cardiac disease
  Cerebrovascular disease, CVA, TIA
  Peripheral vascular disease
  Diabetes other than as primary cause of ESRD (all types including diabetic retinopathy)
  Chronic obstructive pulmonary disease
  Inability to ambulate
  Inability to transfer
  Malignant neoplasm, cancer
  Tobacco use (current smoker)
  Drug dependence
  No Medical Evidence (CMS-2728) Form
  At least one of the comorbidities listed
- A set of prevalent comorbidities based on either Medicare inpatient or outpatient claims (individual comorbidities categorized into 64 categories – see below)
- Transplant center fixed characteristics and random effect

To estimate the probability that a prevalent patient is waitlisted, we use a mixed-effects logistic regression model, in which dialysis practitioner groups are modeled as fixed effects and transplant centers are modeled as random effects. The expected number of prevalent patients waitlisted for the dialysis practitioner group under evaluation is estimated as the sum of the probabilities of prevalent patients waitlisted across all dialysis practitioner groups and assuming their effects are the same as the dialysis practitioner group under evaluation.

Consider patient *k* at dialysis practitioner group practice *i* and transplant center *j* during calendar month *l*; we set the response variate to Y_{ijkl} =1 if the patient is on the wait list and Y_{ijkl} =0 if not. The model and methods are described in some additional detail below:

- To estimate the probability that a prevalent patient is waitlisted, we use a mixed-effects logistic regression model:

$$\log\left(\frac{p_{ijkl}}{1-p_{ijkl}}\right) = \gamma_i + \alpha_j + \beta^T Z_{ijkl}, \quad (1)$$

Probability that a prevalent patient is wait listed using a mixed-effects logistic regression model

where p_{ijkl} represents the probability that patient *k* at dialysis practitioner group practice *i* and transplant center *j* during calendar month *l* is waitlisted, and Z_{ijkl} represents the set of patient-level characteristics, including age (coded as a linear spline with empirically determined knots at ages 15, 55 and 70), incident comorbidities, prevalent comorbidities, ADI, and dual eligibility and *i* and the dialysis practitioner group practice indicators. In this mixed-effect model, γ_i is the fixed effect for dialysis practitioner groups and α_j is the random effect for transplant center *j.* It is assumed that the α_js arise as independent normal variables (i.e., α_j ~ N(0,σ^2)).

- We then compute $PPPW_m$ for each dialysis practitioner group practice *m* as follows:

$$PPPW_m = \sum_i \sum_j \sum_k \sum_l exp(\gamma_m + \alpha_j + \beta^T Z_{ijkl}) \Big/ \{1 + exp(\gamma_m + \alpha_j + \beta^T Z_{ijkl})\} \Big/ n,$$

Compute $PPPW_m$ for each dialysis practitioner group practice *m*

where *n* = total number of patient-months included in the overall study sample.

STRATIFICATION

N/A

TYPE SCORE

Rate/proportion
Better quality = Higher score

ALGORITHM

See attached flowchart.

Appendix E: Related and Competing Measures

No related or competing measures were identified.

Appendix F: Pre-Evaluation Comments

Comments received as of June 7, 2022.

#3659 Standardized Fistula Rate for Incident Patients

Comment 1 by: David White, American Society of Nephrology; Submitted by David White

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.

Comment 2 by: Lisa McGonigal, Kidney Care Partners; Submitted by Lisa McGonigal, Kidney Care Partners

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.

#3689 First Year Standardized Waitlist Ratio (FYSWR)

Comment 1 by: Lisa McGonigal, Kidney Care Partners; Submitted by Lisa McGonigal, Kidney Care Partners

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.

Comment 2 by: Submitted by David White, American Society of Nephrology

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

#3694 Percentage of Prevalent Patients Waitlisted in Active Status (aPPPW)

Comment 1 by: Lisa McGonigal, Kidney Care Partners; Submitted by Lisa McGonigal, Kidney Care Partners

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.

Comment 2 by: Lisa McGonigal, Kidney Care Partners; Submitted by Lisa McGonigal, Kidney Care Partners

Percentage 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.

Comment 3 by: Submitted by David White, American Society of Nephrology

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.

#3695 Percentage of Prevalent Patients Waitlisted (PPPW)

Comment 1 by: Lisa McGonigal, Kidney Care Partners; Submitted by Lisa McGonigal, Kidney Care Partners

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.

Comment 2 by: Submitted by David White, American Society of Nephrology

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.

#3696 Standardized Modality Switch Ratio for Incident Dialysis Patients (SMoSR)

Comment 1 by: David White, American Society of Nephrology; Submitted by David White

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 care partners 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 care partners. 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.

Comment 2 by: Lisa McGonigal, Kidney Care Partners; Submitted by Lisa McGonigal, Kidney Care Partners

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

Appendix G: Post-Evaluation Comments

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

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 (Endorsed)

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)

NATIONAL QUALITY FORUM

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 Endorsed)

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

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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 Endorsed)

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

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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

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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#: 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

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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

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) (Endorsed)

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.

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.

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 Endorsed)

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

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