Memorandum

June 9, 2023

To: Renal Standing Committee, Fall 2022

From: Battelle staff

Re: Post-comment web meeting to discuss public comments received

Background

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.

For the fall cycle of the renal project, the standing committee evaluated three newly submitted measures against standard measure evaluation criteria.[3] The committee failed to recommend all three measures for initial endorsement.

The standing committee did not recommend the following measures:

- #3719 Prevalent Standardized Waitlist Ratio (PSWR) (Centers for Medicare & Medicaid Services [CMS]/University of Michigan-Kidney Epidemiology Cost Center [UM-KECC])
- #3722 Home Dialysis Rate (Kidney Care Quality Alliance [KCQA])
- #3725 Home Dialysis Retention (KCQA)

Standing Committee Actions in Advance of the Meeting

1. Review this briefing memo and meeting summary.
2. Review and consider the full text of all comments received and the proposed responses to the post-evaluation comments.
3. Be prepared to provide feedback and input on proposed post-evaluation comment responses.

Comments Received

Following the standing committee's measure evaluation meeting on February 10, 2023, the committee endorsement recommendations were posted on the Partnership for Quality Measurement (PQM)™ website for public comment. The commenting period opened on March

[1] Kovesdy CP. Epidemiology of chronic kidney disease: an update 2022. Kidney Int Suppl. 2022;12(1):7-11

[2] Merrill JP. Dialysis versus transplantation in the treatment of end-stage renal disease. Annu Rev Med. 1978;29:343-358.

[3] National Quality Forum. Measure Evaluation Criteria and Guidance. 2021.

28, 2023 and closed on May 5, 2023. The committee received two comments in total from two organizations pertaining to the three measures under review and the committee endorsement recommendations. This memo focuses on comments received after the standing committee's evaluation.

All comments that have been received are posted on the respective committee post-comment webpage.

Battelle staff have included all post-evaluation comments that were received in the Post-comment Response Excel file. Measure stewards/developers were asked to respond to comments where appropriate, which have also been included in the Excel file. Please review this memo, agenda, and the Post-comment Response Excel file in advance of the meeting and consider whether you have any concerns with comments received and the responses for each comment.

In order to facilitate the discussion, Battelle staff will spend the majority of the time considering comments that disagree with the measure and/or the standing committee recommendations. However, the standing committee can pull any comment for discussion.

Comments and Their Disposition

Measure Specific Comments

#3722 Home Dialysis Rate (KCQA) and #3725 Home Dialysis Retention (KCQA)

One comment was submitted by Kidney Care Partners (KCP) that addressed CBE #3722 and CBE #3725. The commenter, KCP, expressed disagreement with the standing committee's recommendations to not endorse the measures. Battelle staff have categorized major issues identified in the comment along with proposed responses that address each issue below:

1. Clarification that the measures did not pass on evidence
2. Patient choice and evaluation of paired measures
3. Use of observational studies
4. Assessing measure importance with a nine-member panel (#3722)
5. 90-day justification (#3725)

1. Clarification that the measures did not pass on evidence

The commenter noted that the standing committee failed to pass the measure on Evidence, not Validity; the measure thus did not progress to a vote on Validity.

Measure Steward/Developer Response:
N/A

Proposed Standing Committee Response:
Thank you for your comment.

Battelle Response:
Thank you for your comment. We have updated the meeting summaries to reflect that CBE #3722 and CBE #3725 did not pass on evidence.

Action Item:

Discuss and finalize standing committee response.

2. *Patient choice and evaluation of paired measures*

The developer attests that home dialysis utilization remains remarkably low in the U.S., and that “despite little agreement in the U.S. as to how many patients should dialyze at home, most members of the kidney community acknowledge that home dialysis rates could increase substantially without infringing on patient choice.” This was taken into account during the decision of KCQA's Home Dialysis Workgroup and Steering Committee to not incorporate a specific exclusion for patient preference into the measure specifications.

To more effectively address this concern, our Workgroup and Steering Committee recommend that the Home Dialysis Rate Measure be paired with the accompanying KCQA Home Dialysis Retention Measure (NQF 3725). However, we note with dismay that despite the fact that the measures were submitted as a paired set, an option provided by NQF, we learned during the measure review meeting that the Standing Committee was instructed to consider each measure in a vacuum; they were prohibited from discussing that the measures were designed to counterbalance each other to address this and similar concerns.”

Measure Steward/Developer Response:
N/A

Proposed Standing Committee Response:
Thank you for your comment. The committee discussed this in length during the February 10 evaluation meeting and determined that the current unilateral focus on home growth will certainly lead to increased technique failure rates, may subject many patients to a treatment modality for which they have not received adequate education or training, and may even inadvertently infringe on patient choice. Therefore, the decision not to endorse this measure will stand.

Battelle Response:
Thank you for your comment. According to NQF criteria, measures should be evaluated against a standard set of criteria, which is an individual measures assessment, rather than a set. Developers can indicate if a measure should be or is paired with another measure to help address concerns with respect to unintended consequences from the measure’s use.

Action Item:
Discuss and finalize standing committee response.

3. *Use of observational studies*

The commenter noted that the observational studies supporting the measure “provide considerable evidence that home therapies are at least equivalent to in-center dialysis in terms of clinical outcomes, and superior in terms of patient-reported outcomes on physical and mental health-related QOL.” The commenter continues to state that “NQF’s own Evidence Algorithm does not require RCTs for a measure to pass the Evidence Criterion; the application of such academic, controlled studies is often simply not feasible—or ethical—in real-world clinical settings. We thus believe that in reversing its initial position, the

Committee did not adhere to the Evidence Algorithm in its final review of the measures, succumbing to the unfeasible, extraordinary, and inappropriate RCT standard promoted by one Committee member."

Measure Steward/Developer Response:
N/A

Proposed Standing Committee Response:
Thank you for your comment. During the February 10 evaluation meeting, the committee focused on determining whether there is strong enough evidence that home modalities provide better outcomes than in-center dialysis treatments. The committee also pointed out that home dialysis outcomes may be worse than in-center outcomes for some patient subgroups, such as diabetic patients. The committee further acknowledged that there are dialysis studies that are prospective randomized trials and that the current observational studies have significant vulnerabilities.

Action Item:
Discuss and finalize standing committee response

4. *Assessing measure importance with a nine-member panel*

For CBE #3722, the commenter noted that "KCQA did not rely on a nine-member panel to assess the measure's importance. Rather, the KCQA Home Dialysis Measures were conceptualized, researched (including the required systematic assessment of importance), and developed by an eight-member Technical Expert Home Dialysis Workgroup and a broad-based fifteen-member Steering Committee, both consisting of nephrologists, nurses, patients/advocates, epidemiologists, dialysis facility administrators, and researchers. Both measures also enjoy the strong support of the renal community, with near-unanimous endorsement from KCQA's thirty Member Organizations and overwhelming approval from an unaffiliated (i.e., no affiliation with KCQA or involvement in the measures' development) 35-member Face Validity Panel—of which nearly half, notably, were ESRD patients (in-center and home dialysis and post-transplant)."

Measure Steward/Developer Response:
N/A

Proposed Standing Committee Response:
Thank you for your comment. During the February 10 evaluation meeting, the committee ultimately determined that the true benefits of home dialysis over in-center dialysis are not currently demonstrated in the literature and that there is no empirical evidence to suggest the benefits of home modalities lead to better outcomes that outweigh undesirable effects for all patients. Therefore, the committee's decision not to recommend endorsement for both measures will stand.

Action Item:
Discuss and finalize standing committee response

5. *90-day justification*

For CBE #3725, the commenter noted that "90 days was identified by our Expert Workgroup and Steering Committee as an appropriate retention goal that will serve to foster proper

investment in patient support and preparation for the transition home, but is not so formidable a time requirement that it will discourage home trials in all but the most ideal candidates. It must be noted that the KCQA measure more precisely identifies clinically appropriate patients for inclusion in the denominator population than the current ETC metric by excluding patients discharged from the facility less than 90 days after meeting a 30-day eligibility criterion for transplant, death, discontinuation of dialysis, recovery of function, admission to hospice, and/or admission to nursing home or other LTCF. Moreover, the measure accounts for the requisite home dialysis training period (up to 4 weeks for home hemodialysis), wherein a certain proportion of patients can be expected to drop out before completion. Patients are thus not eligible for inclusion in the Retention Measure denominator until Day 30 following their first home dialysis treatment, at which time the consecutive time count towards the numerator criterion commences. The rationale for both the 30-day "eligibility criterion" and the 90-day discharge exclusion is to avoid creating a disincentive for a home dialysis trial by penalizing providers for events beyond their control and treatment failures - including those for biological reasons such as infection or a decrease in renal function."

Measure Steward/Developer Response:
N/A

Proposed Standing Committee Response:
Thank you for your comment. During the February 10 evaluation meeting, the committee discussed the 90-day home dialysis period and the 30-day escape mechanism. However, the committee also raised concern that the evidence provided was based on empirical studies and opinions from a technical expert panel (TEP) convened by the developer. Due to this evidence concern, the committee did not recommend the measure.

Action Item:
Discuss and finalize standing committee response

#3719 Prevalent Standardized Waitlist Ratio (PSWR)

1. The American Medication Association (AMA) submitted one comment in agreement with the standing committee's concerns around the validity of the measure as specified. The AMA supported the current recommendation to not endorse this measure.

Measure Steward/Developer Response:
Thank you for your comment. Most of the concerns about validity raised by the Standing Committee pertained to attribution of waitlisting practices to dialysis practitioners. As noted above in our response to the KCQA, we argue that dialysis practitioners are crucially important for successful waitlisting of patients and are therefore the appropriate targets for this quality measure.

Proposed Standing Committee Response:
Thank you for your comment.

Action Item:
Discuss and finalize standing committee response.

2. The single comment submitted by KCP also addressed #3719 and supported the committee's recommendation due to three main issues

- Attribution
- Variation in Transplant Center Eligibility Criteria
- Measure Reliability

Attribution

The commenter strongly objects to successful/unsuccessful placement on a transplant waitlist to individual clinicians or group practices and believes this is a fatal structural flaw with the measure. The commenter expresses that the transplant center decides whether a patient is placed on a waitlist, not the practitioner or group practice.

Variation in Transplant Center Eligibility Criteria

The commenter states that "criteria indicating a patient is not eligible' for transplantation can differ by geographic 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.

Measure Reliability

The commenter states that "the overall IUR of the PSWR is 0.56, interpreted as 'questionable' reliability by statistical convention. Thus, nearly half of the observed variation in the measure could be attributed to random noise rather than true performance differences between providers."

Measure Steward/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 choose to refer.

We agree that there is variation across transplant centers in eligibility criteria and that underlying patient comorbidities may affect their candidacy. The PSWR measure accordingly includes adjustment for a wide range of comorbidities, and furthermore includes adjustment for transplant center characteristics. An example is waitlist mortality, which can be viewed as a proxy for stringency of center waitlisting criteria.

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.

Proposed Standing Committee Response:
Thank you for your comment. The committee determined that the measure did not pass validity, a must-pass criterion. Therefore, no further action is needed.

Action Item:
Discuss and finalize standing committee response.