

Renal Standing Committee Fall 2022 Post-Comment Web Meeting

Battelle convened the Renal standing committee for the Fall 2022 <u>post-comment web meeting</u> on Friday, June 9th, 2023 from 2:30 p.m. – 4:30 p.m. (ET).

Welcome, Review of Meeting Objectives, and Attendance

Katie Goodwin, deputy endorsement and maintenance technical lead, welcomed participants to the web meeting. The standing committee co-chairs, Lorien Dalrymple and Renee Garrick, thanked committee members for attending. Brenna Rabel, deputy director of the consensus-based entity work, gave opening remarks and expressed gratitude for the standing committee's continued participation.

Ms. Goodwin then provided an overview of the meeting's objectives:

- Review the <u>post-comment memo</u> and the <u>meeting summary</u> from the Fall 2022 measure evaluation meeting.
- Provide feedback and input on the full text of all comments received and the proposed responses to the post-evaluation comments.

Ms. Goodwin reminded the committee that during the Fall 2022 cycle, the Renal standing committee reviewed three measures during the measure evaluation meeting on February 10th, 2023:

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

The standing committee did not recommend the three measures for endorsement. The <u>meeting summary</u> was posted on the Partnership for Quality Measurement (PQM)[™] website for public comment from March 28th, 2023 to May 5th, 2023. During this commenting period, the committee received two comments in total from two organizations pertaining to the three measures under review and the committee endorsement recommendations. One comment agreed with the standing committee's recommendation to not endorse measure CBE #3725 and one comment addressed multiple measures (CBE #3719, CBE #3722, and CBE #3725), raising concern and disagreement with the standing committee's recommendations.

Review and Discuss Post-Evaluation Comments Received

CBE #3719 Prevalent Standardized Waitlist Ratio (PSWR) (UM-KECC/CMS)

Ms. Goodwin presented the public comments received for each measure as well as the developer's responses and/or proposed responses. Dr. Matthew Pickering, endorsement and maintenance technical lead, facilitated the standing committee discussion of comments and garnered input on proposed committee responses.



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Two comments were received related to CBE #3719. The first comment was in support of the standing committee's recommendation to not endorse the measure. The second comment was also in agreement with the standing committee's recommendation, citing similar concerns around attribution, variation in transplant center eligibility, and measure's reliability. Ms. Goodwin noted that the developer of CBE #3719 responded to the comments, noting that dialysis practitioners are crucially important for successful waitlisting of patients and are therefore the appropriate targets for this quality measure. Additionally, being waitlisted for kidney transplantation is the culmination of a variety of preceding preparatory activities. The developer added that it agrees that there is variation across transplant centers in eligibility criteria and that underlying patient comorbidities may affect their candidacy. The PSWR measure includes adjustment for a wide range of comorbidities, and furthermore includes adjustment for transplant center characteristics. Lastly, the developer noted that given the established effect of sample size on inter-unit reliability (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.

Ms. Goodwin noted that the proposed committee response to the first comment drafted by Battelle staff was to thank the commenters, and that the committee determined the measure did not pass on validity, a must-pass criterion. The committee agreed with the response and therefore, no further action is needed.

Dr. Pickering then facilitated discussion of the proposed standing committee response to the second comment to confirm if the committee agreed with the proposed response. The standing committee recommended that the proposed response emphasizes on the need for creative approaches to measuring kidney care across the care journey but otherwise agreed with the response. The standing committee also emphasized the need to incentivize multi-practitioner collaboration and think more deeply about the type of metrics and methodologies that could capture that collaboration. In addition, the committee recognized the role nephrologists play in patient education, advocacy, and care-coordination.

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

Ms. Goodwin then summarized the comment received from Kidney Care Partners that focused on several issues related to the committee's review of CBE #3722 and CBE #3725. She also noted that the developer submitted similar comments in its response to the committee's deliberations, which were provided in the <u>developer's response document</u>. The comment was themed into several topic areas to help facilitate the discussion.

For the first topic, Ms. Goodwin reviewed the commenter's concern that the measure evaluation meeting summary incorrectly stated that both measures did not pass the validity criterion. Ms. Goodwin clarified that the meeting summary has been updated to accurately reflect that the measures did not pass the evidence criterion. The standing committee had no additional discussion for this topic.

The next topic focused on patient choice exclusion and the process for evaluating paired measure submissions. The comment provided justification to not incorporate a specific exclusion for patient preference into the measure specifications. The comment also noted that both measures were submitted as a pair to help address patient choice concerns but were evaluated by the standing committee independently. Ms. Goodwin clarified that according to the

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National Quality Forum (NQF) criteria, measures should be evaluated individually against a standard set of criteria rather than as a paired set. Standing committee members supported the proposed response, which noted the current unilateral focus on home dialysis will certainly lead to increased technique failure rates and may subject many patients to a treatment modality for which they have not received adequate education or training and may inadvertently infringe on patient choice. The standing committee suggested revising the response to indicate that during review of the measure it focused on determining whether there is adequate evidence that home modalities provide better outcomes than in-center dialysis treatments. The standing committee also pointed out that home dialysis outcomes may be worse than in-center outcomes for some patient subgroups, such as diabetic patients.

The next topic focused on concerns that the evidence algorithm was not appropriately applied during the review of these measures, which were developed utilizing data from observational studies. The comment further stated that the committee was inappropriately treating randomized-controlled trials as the evidence standard, which is (1) not the standard as described in the CBE evaluation criteria and (2) infeasible, extraordinary, and inappropriate in this context. During the discussion of this topic, standing committee members emphasized that their evaluation of the measures followed the evidence algorithm and that evidentiary concerns were based on methodological concerns in the evidence provided, not the lack of a randomized study design. During the February evaluation meeting, standing committee members agreed that it did not have high certainty that benefits clearly outweigh undesirable effects, and it did not find that the evidence was high-to-moderate quality. Additionally, the lack of evidence supporting the superiority of home versus in-center dialysis led standing committee members to not pass the measure on evidence. In considering the proposed standing committee response to this comment, the standing committee suggested including additional characterization of the concerns around the evidence provided as well as suggestions for methodological ways to strengthen the evidence. This may include future collaboration with a study methodologist and exploration of analytic techniques for non-randomized study designs to mitigate potential bias, such as propensity scoring and stratification.

Lastly, Ms. Goodwin reviewed comments for the remaining two topics, which clarified how measure importance was assessed with expert input and provided justification for the 90-day timeframe in measure CBE #3725. The standing committee agreed these issues were discussed at length during the measure evaluation meeting, and there was agreement with the proposed standing committee responses to these aspects of the comment received.

Before concluding the discussion, Dr. Pickering asked the standing committee if there were any further recommendations for the measure developer, beyond what has been shared thus far, recognizing the importance of measurement within this area of dialysis care. The standing committee recommended adding a qualitative component addressing patient motivations for selecting in-home versus in-center care and involving patient voice more prominently in the design of future research. This may be a patient-reported outcome component. Lastly, a standing committee member shared that End-Stage Renal Disease (ESRD) Treatment Choices (ETC) trial data is forthcoming and could provide more support for measures in this area.

Opportunity for Public Comment

Ms. Goodwin opened the web meeting to allow for public comment. No public comments were provided during this time.



Next Steps

Ms. Goodwin reviewed the next steps. She informed attendees that the Consensus Standards Approval Committee (CSAC) will consider the standing committee's recommendations during its meeting on July 24th. Following the CSAC meeting, the 30-day appeals period will be held from August 1st through August 30th, 2023. Ms. Goodwin then thanked the committee and shared opportunities for further Partnership for Quality Measurement involvement and information about the upcoming informational webinar on June 30th. The co-chairs expressed gratitude to the members of the standing committee for their contributions and the meeting was adjourned.