Public Comment Summary Report

Project Title: Effective Availability and Utilization of Home Dialysis Modalities

Dates:

The Call for Public Comment ran from March 1, 2022 to March 30, 2022.

Project Overview:
The Centers for Medicare & Medicaid Services (CMS) has contracted with the University of Michigan Kidney Epidemiology and Cost Center (UM-KECC) to develop facility-level measures in the area of modality education for dialysis patients. The contract name is Kidney Disease Quality Measure Development, Maintenance, and Support. The contract number is 75FCMC18D0041, task order number 75FCMC18F0001. As part of its measure development process, UM-KECC requested interested parties to submit comments on the candidate or concept measures that may be suitable for this project. UM-KECC has been tasked by CMS to develop dialysis facility quality measures that allow measurement of differences across U.S. dialysis facilities' effectiveness of education of patients about dialysis modality options (i.e. In-center vs. home dialysis) and/or effective utilization of home dialysis modalities in the treatment of chronic kidney failure.

Information About the Comments Received:

The measure developer solicited public comments by email.

We received 4 responses on this particular topic

General Stakeholder Comments:

N/A

Measure-Specific Stakeholder Comments:

One commenter writes that the home dialysis access domain should also include patient-reported assessments of whether the individual was given a choice of modality, meaningful education on those choices and whether they are being treated with the modality they prefer.

Commenters expressed concern that 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. With the exclusion of this population, the measure misses a significant opportunity to drive performance improvement. Specifically, since 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.

Response:

With respect to including a measure or component of a measure about whether patient was given a choice of their modality or meaningful education, such assessments risk becoming a check-box item. Additionally, the CMS regulations already require dialysis facilities provide education on modality choice therefore we assume this is happening. 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. Moreover, studies have reported that around a third of patients felt like modality selection was not really their choice, e.g., deferred to their physician, or felt they were not given sufficient education to make an informed choice. Similar experiences were shared by several TEP members, citing that they received poor education or that modality education was biased toward in-center hemodialysis. There are currently no validated PRO metrics that assess patients made an informed choice, or similarly that they received meaningful education. We agree it is important to determine if modality decisions were really the express choice of the patient. Such a PRO would require development and validation testing in order to go beyond being simply a "check-box" measure.

The opinion that this metric would do little to move the marker on home dialysis utilization was not expressed by TEP members during our meetings. We specifically focused on incident patients who switched from in-center to home dialysis 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 switch to peritoneal/home dialysis. 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, not amenable to a facility-level metric, although noted to be important for future measure development work (see above response on patient reported education measure).

Given that about 90% of incident patients start with in-center HD, TEP members felt there was ample opportunity for improvement in the current state without undue concern about facilities trying to game the measure. In addition, we presented the option to risk adjust for facilities that have higher rates of incident patients who start on home dialysis, as a way of encouraging better pre-dialysis care and avoiding potential unintended consequences of the measure, but the TEP members did not want to put up "guard rails" for the small number of facilities that would be impacted. This sentiment of TEP members is also well documented in the TEP summary report.

A minority of patients change from In-center HD to Home HD after the first year of In-center dialysis. This reflects a small number of patients overall and therefore the current measure captures most of the opportunity to drive performance improvement. Furthermore, home HD accounts for ~10% of home dialysis patients. 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. In other words, the decision to switch is driven by the nursing home as an alternative to transporting patient to a facility for In-center HD. Given the reliability issues with prevalent

patients noted above, the fact that most patients who switch, do so in their first year of dialysis 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 the TEP Summary Report.

Comment

One commenter noted 5 domains of home dialysis quality that should be the focus of measure development going forward:

- Home dialysis access (including patient education about modality options)
- Clinical care (accounting for residual kidney function)
- Safety (peritonitis)
- Retention
- Quality of Life

Response:

We thank the commenter. Several of these suggestions came up at the 2021 TEP. These are potential consideration for future measure development dependent on data availability. In addition, we note that current NKF-approved measures of PD adequacy take residual renal function into account for the calculation of Kt/V in PD patients. This suggests that more granular data collection strategies for this population should make assessment of longitudinal trends in residual renal function while on PD possible.

Comment

Commenters expressed concern about the concept of 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 and training the patient received in preparation for a modality switch, and the measure may even infringe on the patient-physician relationship. 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. 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 inadvertently pressured or even coerced into selecting a home modality.

Response:

The SMoSR is not intended to be a proxy of the quality of patient engagement or quality of education about modality options. Given the low rates of home dialysis uptake in the U.S. relative to Canada and many western European nations, this measure is meant to provide additional opportunities for facilities (including the nephrologists who practice in the dialysis setting and are required members of the Interdisciplinary Care Team for each patient) to encourage consideration of home dialysis among patients in their first year of dialysis. Relatedly,

the CMS regulations already require dialysis facilities provide education on modality choice therefore we assume this is happening. 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.

We recognize the concern about unintended consequences. We assume that physicians respect the patient – physician relationship and adhere to ethics and therefore would not pressure or coerce patients into a specific treatment modality. In addition, the concept of Informed Consent is a fundamental ethical principle of clinical medicine. We believe that increased patient switches to home dialysis modalities after initiating dialysis using In-center HD very likely reflects an informed decision by a better-educated patient, compared to the initial modality decision. Assessment of the quality of education and informed consent would also require separate metrics that would be patient reported. These are potential consideration for future measure development dependent on data availability.

C**omment**

A commenter expresses concerns about how transfers among organizations are accounted for. They believe that the Hospital Referral Region approach is fairer, and 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.

Response:

Switches to home dialysis that occur within 30 days of a transfer to a new facility are attributed to the prior facility.

With respect to measurement at the Hospital Referral Region (HRR), we are not aware of empirical evidence that shows measuring home dialysis at the HRR level is fairer in terms of performance scores. Measurement at the Hospital Referral Region through aggregation of facilities by their parent organization presents several challenges:

(1) 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.

Comment

One comment is concerned about reliability data for small providers.

Response: 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.

Comment

One commenter was concerned about the "less than thirty days" exclusion in this measure because 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, they shared concerns regarding the reliability of the proposed metric for most dialysis facilities.

Response:

We thank the commenter, and agree that outcomes in the first 30 days of starting dialysis may not reflect the care of the facility as they are still establishing the patient.

Comment

One commenter stated that 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 patients for home dialysis prior to dialysis initiation. This puts the facility at risk for doing poorly with the metric, despite providing high quality care.

Response:

This issue was discussed by the TEP. The TEP members were presented with the option of including an adjustment for facilities that already have a high percentage of incident patients on home dialysis. However the TEP decided against this in order to "remove the guard rails" and allow for improvement of home dialysis uptake across many more facilities. In addition, our own

analyses demonstrate that facilities with established home dialysis programs tend to perform better on the SMoSr measure than those without. Furthermore, those programs with larger home dialysis programs tend to perform better than those with smaller pre-existing home programs, suggesting that the commenter's concern may not be present, or at least, that there are other factors (e.g. facility expertise and comfort with home modalities) that are stronger determinants of a facility's performance on the measure.

Comment

One commenter stated they 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"). They 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. They 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.

Response:

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. 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. In contrast, the KCQA measure uses Hospital Referral Regions 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) HRR 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.

Preliminary Recommendations

Based on the comments made, no changes were made to the measure specifications. However the measure will undergo regular maintenance where further changes can be considered and made if they are warranted.

Overall Analysis of the Comments and Recommendations

We appreciate the breadth and thoughtfulness of the comments provided. Home Dialysis is clearly an important area of measure development for the dialysis community, and the comments presented here draw attention to particular areas of interest (sch as patient education about modality choice).

Public Comment Verbatim Report

You may attach this table as a separate file. Upon request from the Contracting Officer's Representative (COR), the measure developer may delete optional fields.

Comment Number*	Date Posted/ Received	Name, Credentials, and Organization of Commenter	Type of Organization*	Email Address*	Measure Set or Measure	Text of Comments	Response*
1	March 30, 2022	Kidney Care Partners Akebia Therapeutics, Inc. American Kidney Fund, Inc. American Nephrology Nurses Association American Society of Nephrology American Society of Pediatric Nephrology Ardelyx AstraZeneca Atlantic Dialysis Management Services, LLC Baxter International, Inc. Cara Therapeutics, Inc. Centers for Dialysis Care CorMedix Inc. DaVita, Inc.	Professional Organization	Lisa McGonigal MD, MPH Healthcare Quality Consultant Kidney Care Partners, lisa@limacmd.com	Standardized Modality Switch Ratio (SmoSR)	See appendix	We thank you for your feedback. Stakeholder comments will be reviewed by measure developers and taken under consideration. Responses to comment themes are provided above.

Comment Number*	Date Posted/ Received	Name, Credentials, and Organization of Commenter	Type of Organization*	Email Address*	Measure Set or Measure	Text of Comments	Response*
1 (cont.)	(cont.)	Dialysis Patient Citizens, Inc. Dialysis Vascular Access Coalition DialyzeDirect Fresenius Medical Care North America Greenfield Health Systems Kidney Care Council North American Transplant Coordinators Organization Nephrology Nursing Certification Commission Otsuka America Pharmaceutical, Inc. Renal Healthcare Association (formerly NRAA) Renal Physicians Association Renal Support Network Rockwell Medical Rogosin Institute Satellite Healthcare, Inc. U.S. Renal Care, Inc. Vertex Pharmaceuticals Vifor Pharma Ltd.	(cont.)	(cont.)	(cont.)	(cont.)	(cont.)

Comment Number*	Date Posted/ Received	Name, Credentials, and Organization of Commenter	Type of Organization*	Email Address*	Measure Set or Measure	Text of Comments	Response*
2	March 30, 2022	Kevin Longino, CEO and Transplant Patient Paul M. Palevsky, MD, President, National Kidney Foundation	Patient Advocacy Organization	Morgan Reid, Director of Transplant Policy and Strategy, morgan.reid@kidney.org Miriam Godwin, miriam.godwin@kidney.org	Standardized Modality Switch Ratio (SmoSR)	See appendix	We thank you for your feedback. Stakeholder comments will be reviewed by measure developers and taken under consideration. Responses to comment themes are provided above.
3	March 30, 2022	Susan E. Quaggin, MD, FASN President, American Society of Nephrology (ASN)	Professional Organization	ASN Regulatory and Quality Officer David L. White, dwhite@asn-online.org	Standardized Modality Switch Ratio (SmoSR)	See appendix	We thank you for your feedback. Stakeholder comments will be reviewed by measure developers and taken under consideration. Responses to comment themes are provided above.
4	March 30, 2022	Timothy Pflederer, MD President, Renal Physicians Association (RPA)	Professional Organization	rpa@renalmd.org	Standardized Modality Switch Ratio (SmoSR)	See appendix	We thank you for your feedback. Stakeholder comments will be reviewed by measure developers and taken under consideration. Responses to comment themes are provided above.

*Optional

Note: Measure developers may enter the text of comments verbatim without edits for spelling, punctuation, grammar, or any other reason and should ask their COR for specific guidance.