Effective Availability and Utilization of Home Dialysis Technical Expert Panel Summary Report

June, 2021

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Effective Availability and Utilization of Home Dialysis Measure Development

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, the University of Michigan Kidney Epidemiology and Cost Center convenes groups of stakeholders who contribute direction and thoughtful input to the measure developer during measure development and maintenance.

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 patient education about dialysis modality options, specifically, the uptake of a home dialysis modality (peritoneal dialysis, home hemodialysis versus in-center hemodialysis) and/or effective utilization of home dialysis modalities in the treatment of chronic kidney failure.

Technical Expert Panel Objectives

The Technical Expert Panel (TEP) was asked to review existing data and provide their expert opinion and experience to make recommendations to UM-KECC regarding the development of a draft measure that addresses potentially important quality gaps in utilization of home dialysis. Specifically, the TEP was asked to evaluate the construct validity of a prototype home dialysis utilization quality measure developed by UM-KECC in 2020. TEP input was also sought regarding appropriate risk adjustment strategies for the measure and the usability of the measure from both patients' and providers' perspectives. Additionally, the TEP was advised that recommended measures should be evidence based, scientifically acceptable (reliable and valid), feasible, and usable by CMS, providers, and the public.

Technical Expert Panel Composition

A public call for nominations opened on November 15, 2019 and closed on December 16th 2020. Nominations were sought from individuals with the following areas of expertise or experiential perspectives:

- Nephrologists, nephrology nurses, nephrology trained social workers, and dialysis facility nursing staff
- Consumer/Patient/Family (caregiver) perspective
- Performance measurement experts
- Quality improvement experts
- Purchaser Perspective
- Healthcare disparities experts

The following individuals were selected to serve on the TEP:

Name and Credentials	Organizational Affiliation, City, State	Conflicts of Interest Disclosed
Derek Forfang *(TEP Co-chair)* Patient Advocate	San Pablo, CA	None
Brigitte Schiller MD *(TEP Co-chair)* Nephrologist	Satellite Healthcare. San Jose, CA	Speakers Bureau Astra Zeneca
Michelle Cassin RN, CPDN Home Dialysis Nurse	DaVita Kidney Care. Nashua, NH	None
Glenn Chertow MD, MPH Nephrologist	Stanford University, Stanford, CA	Serves on the board of directors at Satellite Healthcare as well as an advisor to Baxter and Outset Medical
Paul T. Conway BA Chair, Policy and Global Affairs	American Association of Kidney Patients. Falls Church, VA	None
Richard Knight MBA President	American Association of Kidney Patients	None

Name and Credentials	Organizational Affiliation, City, State	Conflicts of Interest Disclosed
April McGraw BSN,RN,CNN Dialysis Nurse	DaVita. Williamsburg, VA	None
Rajnish Mehrotra MD Nephrologist	University of Washington. Seattle, WA	Honorarium Baxter Healthcare
Matthew Oliver MD, MHS, FRCPC Nephrologist	University of Toronto. Toronto, Canada	Received honorarium for speaking at a Baxter Healthcare event
Amber Pettis BS,MBA Patient Advocate	Memphis, TN	None
Cheri Rodriques Jones Patient Advocate	Holyoke, Massachusetts	None
Martin Schreiber MD Nephrologist	DaVita Kidney Care. Aurora, OH	Modalities DaVita
Stacy Cigliana RN, CNN VP of Clinical Services	US Renal Care. Wentzville, MO	Actively employed at US Renal Care
Isaac Teitelbaum MD Nephrologist	Anschutz Medical Campus University of Colorado. Aurora, CO	None
Eric Weinhandl PhD Epidemiologist	Chronic Disease Research Group. Minneapolis, Minnesota	Consultant to Fresenius Medical Care North America
Contractor Staff		
Jonathan Segal, MD, MS	*Professor of Internal Medicine*, Division of Nephrology, University of Michigan, Kidney Epidemiology and Cost Center	None
Claudia Dahlerus, PhD	*Assistant Research Scientist,* Internal Medicine, Division of Nephrology, University of Michigan, Kidney Epidemiology and Cost Center	None
Joseph Messana, MD,	*Professor of Internal Medicine*, Division of Nephrology Research Professor, Health Management and Policy,	None

Name and Credentials	Organizational Affiliation, City, State	Conflicts of Interest Disclosed
	University of Michigan, Kidney Epidemiology and Cost Center.	
Ananda Sen, PhD	*Professor of Biostatistics and Research Professor,* University of Michigan, School of Public Health	None
Peter Song, PhD	*Professor of Biostatistics,* Dept. of Biostatistics, University of Michigan, School of Public Health	None
Tao Xu, PhD	*Senior Analyst,* University of Michigan, Kidney Epidemiology and Cost Center	None
Kathy Sleeman, MA	*Senior Programmer*, University of Michigan, Kidney Epidemiology and Cost Center	None
Juan Du, MS	*Senior Programmer,* University of Michigan, Kidney Epidemiology and Cost Center	None
Xi Wang, MPH	*Senior Analyst,* University of Michigan, Kidney Epidemiology and Cost Center	None
Casey Parrotte, BA, PMP	*Senior Project Manager,* University of Michigan, Kidney Epidemiology and Cost Center	None
Wen Wang, MS	*PhD Student- Biostatistics,* University of Michigan, Kidney Epidemiology and Cost Center	None
Jaclyn George	*Project Intermediate Manager,* University of Michigan, Kidney Epidemiology and Cost Center	None

1. Introduction

This report summarizes the discussions and recommendations of the Effective Availability and Utilization of Home Dialysis TEP meetings convened on March 24th 2021, April 14th 2021, April 22nd 2021, and May 13th 2021. All meetings were public and held virtually via zoom video-conference. The TEP provided advice and expert input on a prototype quality measure assessing uptake of a home dialysis modality among end-stage renal disease (ESRD) patients in their first year of dialysis. The discussions were informed by an annotated bibliography of relevant literature compiled by UM-KECC, and data provided by UM-KECC.

2. Preliminary Activities

2.1 Information Gathering

Prior to the in-person TEP meeting, UM-KECC provided TEP members with an annotated bibliography of published literature (Appendix B) related to home dialysis modalities (peritoneal dialysis and home hemodialysis).

The Annotated Bibliography was organized into three subject categories:

- Epidemiology and characteristics of home dialysis modality uptake
- Education, decision making and home dialysis uptake
- Outcomes by type of modality (in-center hemodialysis, peritoneal dialysis, home hemodialysis)

2.2 TEP Charter

The Effective Availability and Utilization of Home Dialysis TEP Charter (Appendix A) was distributed to the TEP members for review prior to the first meeting and was approved by the TEP members. At the first TEP meeting, key elements of the charter were highlighted and the aspects of developing a quality measure for home dialysis uptake were emphasized.

Key elements highlighted included expectations of TEP members to use existing literature and their expert opinion and experience to provide feedback and recommendations to UM-KECC regarding the prototype home dialysis uptake measure.

The role of the TEP was outlined and the following responsibilities were highlighted:

- Provide input on construct validity of a prototype home dialysis utilization quality measure developed in 2020
- Consider appropriate risk adjustment strategies for the measure and input regarding the usability of the measure from both patient's and providers perspectives
- Provide feedback on draft measure specifications
- As needed, provide input to support submission of the measure to CMS for review, and to the NQF for endorsement consideration
- As needed, TEP members may be asked to provide input to UM-KECC as they prepare responses to NQF and public comments

3. Background for a Home Dialysis Metric

An overview of the proposed home dialysis metric was provided by the TEP co-chair, Dr. Schiller. Dr. Schiller explained that the goal of the new quality measure is to compare the effectiveness of modality education and/or the effective utilization of home dialysis modalities. She explained this will be a patient-centered facility metric for comparison across the United States, including longitudinal monitoring.

3.1 Review of Evidence on Home Dialysis Modalities

To frame the discussion of the prototype home dialysis metric, Dr. Schiller presented a summary of the literature review results (see Appendix B), highlighting key findings from studies that focused on the epidemiology and characteristics of home modality uptake, the role of education and decision making in home dialysis uptake, and outcomes by type of dialysis modality (in-center hemodialysis,

peritoneal dialysis, home hemodialysis). The summary of literature presented was intended to inform the subsequent discussion on home modality uptake and the prototype measure.

Dr. Schiller highlighted some of the key patient and facility level characteristics associated with lower uptake of home dialysis, including sex, race, comorbidities, and facility size and nephrologist and nurse experience. Several barriers to home dialysis were identified based on specific studies, such as clinical (health status), operational, economic, and patient level barriers. There was some discussion among TEP members on the extent to which rural location may be related to uptake, but there was recognition that unpacking the specific association is complex as rural locations can vary in how proximate or not they are to dialysis facilities.

Next, Mr. Forfang (co-chair) summarized results from studies that examined the role and impact of education on home modality uptake. He explained that studies show that about 30% of patients have reported their modality selection was not really their choice or did not feel as though they made an informed choice, and that this percentage is higher among in-center hemodialysis (ICHD) patients. He continued to describe work demonstrating a mismatch between stated preference for a modality and actual modality at dialysis start as well as studies indicating that decision-making efficacy and satisfaction were greater among people on peritoneal dialysis (PD) vs in-center hemodialysis. Overall, Mr. Forfang stated that proper education and shared decision making would increase the number of people who choose a home dialysis modality.

Next, Dr. Schiller provided a summary of outcomes studies, noting the lack of randomized control trials, and overall mixed evidence about longer term outcomes for home versus in-center dialysis. It was noted that some evidence suggests that physical and mental quality of life may differ in some domains between PD and ICHD. Additionally, a few studies were highlighted that reported when nephrologists and nephrology nurses were surveyed about which modality they themselves would prefer if they had to do dialysis, most selected a home modality over in center hemodialysis.

Based on the presented evidence, the following summary points were provided for the TEP to consider and to generate discussion.

- Persistently low rates of home dialysis use is associated with both patient and facility level factors
- Education and shared decision making interventions suggest an opportunity to improve uptake of home dialysis
- Outcomes of in-center and home dialysis appear similar

TEP members acknowledged the barriers to uptake of home dialysis modalities, and recognized that overall uptake is low. Some members noted there are multiple factors that can influence uptake, including the nephrologist, other providers, and the dialysis facility staff. It was also recognized that a home dialysis metric should not have the unintended effect of people being “forced” to go on a home modality. While this is a facility level metric, it was noted that less than 50% of facilities in the United States have a home dialysis program, so an assessment of quality in this domain needs to be

fair and should stimulate greater uptake of a home modality. Overall, much of the discussion at the first two meetings centered on the role of education and shared decision making.

3.2 Discussion and the role of modality education and decision-making

The discussion overall focused on the importance of effective dialysis modality education and support for decision-making with a focus on these key elements: the process of education ideally should begin before dialysis start; physicians need to take an active role in decision support; the quality of education is important and consideration should be given to standardization of content; the timing of education matters as it relates to planned or unplanned start of dialysis; peer-to-peer education is valuable; and the education process needs to be matched to patient goals. The main challenge noted was that data are not available to measure if education was effective or if an informed decision was made. Specific comments from TEP members on these elements are provided in the rest of this section.

- Physicians play a critical role in providing dialysis education. If physicians are knowledgeable about home dialysis, then they are more likely to provide balanced education to the patient while considering co-morbidities that may impact a modality selection. Some patient TEP members described bias (toward in-center HD) in the education they experienced, where the risks of home dialysis were highlighted and over-emphasized and those of in-center dialysis downplayed.
- 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 facility. Modality education should be an iterative process since patients new to dialysis may not be ready to absorb information or make a modality decision immediately after starting ICHD.
- Peer-to-peer education that focuses on the perspective and direct experience of those doing home dialysis is needed as there are limits to which education from a clinician resonates.
- Educational content about modality options and the delivery of this material could be standardized, similar to as is done in Canada. This transparency may help avoid bias in the education process and standardization could help ensure that education is achieving the intended goal of helping empower patients to make an informed decision. Ultimately, the education needs to be tailored to support patients in making a modality decision that works best for their lives.

Collectively, the opinions of TEP members focused on these critical components that allow for assessing the quality and effectiveness of modality education and decision-making: the timing (e.g., pre-dialysis), the quality of content, how it is done and who is providing the education. A measure should also account for pre-dialysis decision making (e.g., people who start on a home modality). In addition, a measure should reflect successful use of home dialysis not just the total number of people at the facility who are on a home therapy, and a measure should avoid unintended consequences.

Dr. Dahlerus (UM-KECC) presented a patient centered paradigm illustrating that modality education begins at the pre-dialysis stage and continues throughout the care continuum to best tailor education and seek opportunities for shared decision making. UM-KECC recognized that there is consensus among the TEP members about the importance of pre-dialysis education and shared decision-making. UM-KECC noted a pre-dialysis education measure is outside the scope of this TEP but could be considered for future measure development.

4. Overview of data and supporting analyses on modality uptake and characteristics

Dr. Dahlerus began her discussion by introducing the data sources used in this measure. National data available to support home dialysis are found in two major sources:

- CMS Consolidated Renal Operations in a Web- enabled Network (CROWNWeb) – which includes Medical Evidence Form CMS 2728
- CMS Medicare Claims- includes Part A claims (e.g. inpatient admissions) and Part B claims (e.g. outpatient claims including dialysis claims)

Dr. Dahlerus presented results from UM-KECC analyses (see appendix C) that showed a small increase in home dialysis (PD and home hemodialysis (HHD)) as the incident modality relative to ICHD between 2016-2018. During that time period, 43% facilities offered in center dialysis only, 52% facilities offered both home and in center dialysis, and just under 5% offered only home dialysis. Of the over 850,000 patients (over four years) who started dialysis, there were 53,000 switches to home dialysis, and over 790,000 patients did not switch, with 65% of the switches occurring in the first year. Among incident ICHD patients, 4% switched within the first year, and 2% of all incident ICHD patients switched after the first year. Of the patients who switch from ICHD to home dialysis, 50% do so by day 90 and 75% do so by 6 months from dialysis start (see slide 10 in TEP Meeting 2).

4.1 Discussion

A TEP member asked why prevalent patients are not included in the measure. Dr. Dahlerus answered by saying that since most switches occur during the first year, this time period allows for the best opportunity to determine differences in facility performance. A TEP member noted that a majority of switches to HHD occur after the first year of dialysis, and therefore these switches would not be captured by this measure. Another TEP member commented about whether the switch rate is different for facilities that offer both ICHD and home dialysis compared to facilities that only offer ICHD. UM-KECC noted that the average switch rates are in fact different based on the modalities offered at the facility with slightly higher switch rates at facilities that offer both. A TEP member commented that if there is better pre-dialysis modality education, then the switch rate may be lower and we need to account for facilities with a high number of patients who start directly on a home therapy.

Other considerations mentioned in the discussion were to account for patients who have an abrupt start with no pre-dialysis nephrology care, and whether a facility is in an urban or rural community in terms of equal access to home dialysis.

5. Overview of Standardized Modality Switch Ratio (SMoSR) Measure

5.1 Measure Construct

The focus of the measure is on the proportion of in-center hemodialysis patients in their first year of treatment who switch to a home dialysis modality. Switches in the first year reflect robust education, effective presentation of modality educational materials, and facilitation by the dialysis unit. The basic premise of the measure is that patients consented to switch to a home modality as a result of effective decision support by the dialysis facility. Also, one can infer patients consented to switch to a home modality as a result of shared decision-making between patient and provider. The measure is a standardized ratio so the numerator is the observed number of switches and the denominator is the expected number of switches for a facility, adjusted for the national rate of patients switching in-center to home dialysis during the first year of dialysis. The proposed measure is based on 3 years of data plus one year of follow-up to capture switches. The multiyear time period is needed for adequate reliability given the low event rate.

Next UM-KECC presented the measure denominator and definition of the eligible population. The starting population (based on CROWNWeb data) includes 700,000 incident and prevalent patients on in-center hemodialysis. After restricting to in-center HD patients in the first year, the denominator population is 320,000. The numerator is the number of patients from the denominator with an eligible switch to home dialysis over the four year period. An eligible switch is considered as an in-center HD patient that switches to home dialysis within 365 days of ESRD onset, and the home dialysis modality is maintained for >= 60 days. Only the first switch is included if patients have multiple switches. Patients who start on a home modality are excluded.

After the initial overview, TEP member comments included the following:

- Facility attribution needs discussion to determine the time period needed when a patient switches modality and changes facilities at the same time.
- Facility type (in-center only vs. in-center and home dialysis) may need to be considered in the model.
- Facilities with a high percentage of incident patients on a home modality and early switches both may reflect pre-dialysis education.
- Facility location (urban/rural)
- Facilities that only treat nursing home patients and modality changes associated with being in a nursing home
- Risk Adjustment and Exclusion Criteria (comorbidities, and exclusion criteria)

UM-KECC presented basic model results from the SMoSR in order to set-up further discussion on risk adjustment and the measure details. The model was adapted from the Standardized Mortality Ratio (SMR) model. The initial model results that were presented to the TEP included sociodemographic factors such as race, ethnicity, sex, age, as well as incident comorbidities.

5.2 Race, Ethnicity, model risk covariates discussion

The TEP was asked to provide their initial thoughts on the draft model results. Several TEP members commented on the inclusions of race and ethnicity in the model and expressed concern that adjusting for these could inadvertently exacerbate existing disparities in care since black patients are already less likely to select a home dialysis modality. UM-KECC clarified that we included these factors initially to inform the discussion, and because we are required by the NQF to perform sociodemographic and socioeconomic testing to assess the impact of social risk on a quality measure. However, UM-KECC went on to explain that it is not our intention to include these factors in the final model because of the known potential to reinforce disparities. CMS also clarified that race and ethnicity adjustment factors would not be included as a matter of general policy because it has implications for any measures that would be used in a Federal payment program.

There was additional discussion about what data are available on socioeconomic status. UM-KECC explained the two indicators are dual-eligible status (patient-level) and an area level indicator, the Area Deprivation Index, which is a composite score based on several different indicators of SES (e.g., percentage of residents in the zip-code that own their home; percentage of single-parent households).

One TEP member noted the different impact of predictors when looking at switches from in-center hemodialysis to peritoneal dialysis versus a switch to home hemodialysis and raised the question of whether consideration should be given for separate modality switch measures, one for switching to PD and one for switching to HHD. Due to the low switch rate for HHD, two separate measures did not seem feasible.

5.3 Summary of conceptual support of measure

After the introduction and overview of the basic measure construct underlying the SMoSR. UM-KECC asked whether the TEP was comfortable with the basic construct of the prototype measure before moving forward to discuss the measure details related to risk adjustment and measure exclusions, and other considerations. There was discussion about the important role that nephrologists play in providing education about home dialysis, and the need to clarify some of the issues such as facility type, durability of switch, and facility attribution. A few TEP members raised a concern about facilities that already have a high percentage of incident patients on a home dialysis, since they will have fewer eligible patients that would “switch” to a home modality. The facility would potentially not score as well on the measure. Further discussion about this issue took place when discussing possible risk adjustment to account for patients that start on a home modality.

Dr. Schiller posed the question to the TEP if there was agreement that it is valuable to have this metric which looks at switches in the first year of dialysis recognizing additional details need to be ironed out. There was overall TEP support for the measure construct of the proposed SMoSR.

6. Attribution and Durability of Switches

6.1 Attribution for transfers

UM-KECC presented the algorithm for attributing switches. Thirty days was used as the period to determine giving credit to the sending facility for the switch to a home modality if it happens within 30 days of transferring to the receiving facility. As an illustration, if a patient switches from facility A to B, and the patient is on in-center hemodialysis, but switches to home dialysis within 30 days of arriving at facility B, facility A would get credit for the switch. Facility A has invested the time and successfully educated the patient. After 30 days, the switch would be attributed to the receiving facility which would have had time to dedicate educational efforts on home dialysis.

UM-KECC presented information about facilities that only offer in-center hemodialysis and the referral patterns that we can determine when a patient changes to a home modality and therefore changes clinics. About 30% of in-center only facilities refer all home dialysis patients to one single receiving facility. Overall, the majority of in center dialysis centers are sending/referring patients to a relatively small group of facilities that have home dialysis programs.

UM-KECC asked for feedback on attribution when a patient changes modality and a facility. Specifically, UM-KECC wanted to discern if there was support from the TEP for the "sending" facility getting credit for patients switching to home dialysis if that switch occurs <30 days after changing facilities, and if "receiving" facilities should get the credit for switches that occur >30 days after the patient changes facilities. Dr. Schiller confirmed the 30 days cut-point sounds reasonable and the TEP supported this.

A TEP member commented that if patients are starting with home dialysis, then that success goes to the nephrology practice and not the facility. The facility should not be penalized for good pre-dialysis care and decisions being made before the patient starts treatment. Similarly, if the patient wanted to do PD, but started with in-center dialysis due to poor planning, the facility could get credit for the modality switch and mask poor pre-dialysis care. We have to be careful to not design a measure where there are delays in modality selection or switches in an effort to game the system.

A TEP member suggested that we consider the aggregation unit from the ESRD Treatment Choices model. They explained that in that model, if a patient transfers from one facility to another to support home dialysis and stays in the same aggregation unit, that unit would get credit. This approach would simplify attribution for switched to home dialysis.

6.2 Durability of Switches

UM-KECC initially presented a definition of a successful switch which would be a switch to a home dialysis modality that is then maintained for at least 60 days. Data presented showed that approximately 89% of patients have a switch that lasts for 30 days or more and that 80% have a switch that lasts for 60 days or longer. There was extensive discussion about the time period (days) for defining a durable switch. Opinion on time periods was markedly distinct between patient TEP members that favored shorter time periods 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.

- Shorter time periods: Comments made that support a shorter time period to define durability included: This would reward the education and access to home dialysis even if there is a subsequent failure that precludes longer term home therapy. This would encourage the use of home dialysis as a bridge to scheduled living donor transplant. Most treatment failures where a patient goes back to in-center are not a failure of shared decision making about selecting home dialysis. The patient members of the TEP made it clear that any amount of time at home, even a few weeks, was worthwhile and strongly advocated that we use a shorter definition to define a durable switch. The unintended consequences for a shorter time period that was discussed could be an increase in referrals to home dialysis for patients where this may not be an appropriate modality or in the patients best interest.
- Longer time periods: Comments made that support a longer time period to define durability included: before 90 days there can be a struggle to establish a patient on home dialysis and someone who only dialyzes at home for 30-60 days would not be considered a success. The unintended consequences of a longer time period related to an increased risk to a referring in-center program due to failure of the home program to keep a patient on a home modality. If a longer time to define success is required, then providers may remain cautious about whom to offer home dialysis to and will not change the current practice pattern, ultimately limiting the growth of home therapy.

6.3 Additional Discussion

A TEP member commented that if a patient is on home dialysis but does not meet the minimum time required for a durable switch due to a kidney transplant, then the facility should still receive credit in the measure.

It was again pointed out that while the dialysis facility staff can educate and encourage home dialysis, it is critical for the nephrologist and patients to be the driver in this process.

A TEP member asked if the training days would count towards the total number of days for a durable switch. UM-KECC confirmed that training days were included in the total number of days that were counted.

Concern was raised by TEP members that not only is education important, but so too is access to home dialysis. In addition, there must be adequate facility resources to support the education and training for an increased number of patients to choose home therapies. This may require a change in current business models.

Lastly, a TEP member commented that how long a patient has been on dialysis at the time of a modality change is important. Some data suggests that durability of a switch to PD is longer for incident patients than it is for prevalent patients. Durability of a change to HHD may have a different relationship with dialysis vintage.

Ultimately, a consensus was not reached as to a specific number of days to be used to define the durability of a modality switch.

7. Risk Adjustment

Incident Comorbidities: Since this measure includes all patients at the facility, we are limited in availability of comorbidity information to those that are listed in the CMS Form 2728. A TEP member raised the issue of not having information about disease severity and that some comorbidities may actually be an indication for home dialysis. Another TEP member noted that by accounting for comorbidities, it may help provide more opportunity for home dialysis to be offered to all patients. Since modality decisions are not a "one size fits all", adjusting for comorbidities may help the nephrologist and patient make the best choice in shared decision making.

Pre-Dialysis Nephrology Care: Dr. Dahlerus presented data showing both the number of incident patients, as well as a percentage, of patients that has pre-dialysis care, and then presented two options for addressing pre-dialysis care and modality education. One option is to use information from the 2728 for nephrology care prior to dialysis initiation and the other option is to adjust for the proportion of patients at the facility who started with a home modality. Since the measure uses direct standardization for risk adjustment, facilities that have higher proportions of patients who start with a home modality would have a higher standard to achieve and so this would need to be accounted for in the measure. By adjusting for the number of patients who start on home dialysis, we would lower the expectations for a facility with a high rate of patients with home dialysis starts, and would have a bar that is worth jumping over for facilities with low rates. A TEP member raised the question of how this would work for facilities that do not offer home dialysis. Dr. Segal indicated that it would be possible to add an indicator in the model for these facilities since their proportion of home dialysis patients starting at the facility will always be zero. Another TEP member expressed concern that interpreting switch rates for facilities who have a high proportion of home dialysis starts when those rates are above or below the expected rate may be challenging. Dr. Segal noted that preliminary analyses indicated that facilities that have a high proportion of patients who start on home dialysis tend to have higher home dialysis switch rates. There was acknowledgement

by TEP members that effective pre-dialysis care, even if a patient starts with in-center HD, may influence the subsequent switch rate. One TEP member pointed out that this metric needs to look after the relatively large group of patients who "crash" into dialysis and clearly had no modality education. Another TEP member agreed that the measure needs to address this group and align with the national policy to promote home dialysis, specifically, they were uncomfortable about the potential lack of concordance in risk adjustment of home dialysis measures across federal programs (e.g., CMS programs and current Centers for Medicare and Medicare Innovation (CMMI)) models like the ESRD Treatment Choices Model). The group further discussed that even those who did have modality education should still have the opportunity to do home dialysis and so the two groups need not be mutually exclusive. The Canadian experience was highlighted since there is a very high percentage of patients who start on home dialysis, leaving less in-center HD patients who are eligible to switch. The dynamic in the US would be expected to change over time as more patients start on home dialysis and less in-center patients are eligible to switch. A TEP member pointed out that while this will be a facility metric, it will require that the nephrologists are supportive of the effort and participate in the education. Adding to the complexity, most dialysis facilities have more than one physician practice, so some of the facility rates will be a blend of the different physician's efforts. In addition, modality education at the facility will need to be different for different patient populations and caution will be needed to avoid the unintended consequence of patients being pushed into home dialysis that do not want to do it. The group went on to note that the onus is on the facility and the nephrologist to create a patient centric system that supports patient's going to home dialysis, but that system will be different for different programs and different patient populations. Ultimately, a TEP member noted, the metric needs to support the established Federal policy stemming from the 2019 Executive Order on Advancing American Kidney Care that more patients should have the opportunity to do home dialysis, measure progress over time, and account for variations in patient characteristics between facilities. Several TEP members agreed that there needed to be recognition of facilities that already had high uptake of home dialysis patients at the start of therapy so as not to penalize practices that are already doing a good job. Yet, as another TEP member pointed out, there are very few facilities that have such high rates and so we should not put up such tight guardrails to protect them at the expense of not helping the majority of other facilities make progress in providing more home dialysis.

Age: Age may be a marker for other factors that impact uptake of home dialysis or the ability to perform dialysis at home, such as dementia. There was discussion about not wanting to disadvantage patients or facilities that have a higher percentage of older or younger patients. Some TEP members suggested that we not adjust for age and were concerned that by doing so, we could limit home dialysis being offered to older patients. UM-KECC clarified that by risk adjusting for age, we could help level the playing field across facilities that have differences in their age distribution. A question was raised about stratification by age as an alternative to risk adjustment with age, and Dr. Segal noted that this is difficult to do at the facility level due to small numbers of patients in some of the age strata. A comment was made that the new ETC payment model does not adjust for age, and so having inconsistencies between different government programs can be confusing. One TEP member noted that it is important to consider age since there is a difference between

programs who are good at promoting home dialysis among younger patients and ones that is successful at doing so with older patients. After initial discussion, TEP members were hesitant to adjust for age in the model, expressing a preference for a more simple model upfront, and then learning from that initial experience.

Geography: Data on urban and rural facilities were presented to set the context for discussion about differences in home dialysis in different geographic areas and if that merited an adjustment for rural/urban location. The small difference in percentages of home dialysis between rural and urban locations may suggest there is no clear bias in home dialysis utilization based on location. A TEP member indicated that some urban areas have unique challenges in offering home dialysis and may need special consideration. Another TEP member expressed concern about smaller facilities not being able to be scored on the measure and questioned whether there could be aggregation of these clinics in a geographic area.

A TEP member asked if there will be threshold that is necessary to be met for this metric (ex: 10 people per year). Dr. Dahlerus said we would not adjust for the number of patients in the unit but eligibility of the facility would require a certain minimum number of patient months at risk, and most likely 11 or more incident patients at the unit. There would also need to be a minimum number of expected switches to qualify.

8. Exclusion Criteria

The TEP were presented with a list of potential facility and patient level exclusions for the measure and asked to comment on these.

- Facility exclusions
  - Home only facilities
  - Home only facilities that only serve NHs
- Patient level exclusions
  - Nursing home patients on home hemodialysis (patient months)
  - Pediatric patients
  - Hospice
  - AKI patients – exclude all with no 2728

A TEP member noted that nursing home patients receiving home hemodialysis in the nursing home are often doing so because it was the decision of the nursing home to provide dialysis on-site. This was not thought to represent true shared decision making about the modality option. UM-KECC indicated that we can look at modality for nursing home patients on a month-by-month basis and a TEP member suggested that these patient months be excluded. Other TEP members agreed.

TEP members supported an exclusion for pediatric patients noting that this is a complex population with a number of different demands on the family structure and often move to transplant relatively quickly.

TEP members also agreed that AKI patients should be excluded from the measure. The emphasis in this group of patients should be monitoring for kidney recovery, but if AKI patients do not recover function and are considered to have ESKD, then they should be eligible to be included in the measure if they later switch to a home modality.

The group also agreed that patients enrolled in hospice should also be excluded from the measure. It was noted that hospice status is determined from Medicare claims and so this will be missing for non-Medicare patients who are enrolled in hospice. This issue occurs in other quality measures that include all patients and is not necessarily a barrier to exclusion.

9. Measure Specifications

Denominator: All Incident patients on in-center hemodialysis at the facility during the reporting period

Numerator: Proportion of patients from denominator (incident patients on in-center hemodialysis) that switched to a home modality within one year of starting dialysis- includes only first durable switch.

Model Details: A two-stage Cox model is used with the first stage being a patient model stratified by facility to avoid bias caused by different covariate distributions across facilities.

Risk adjustment: Comorbidities at ESRD incidence, calendar year, body mass index, age, cause of ESRD.

Exclude: Pediatric patients, patients in hospice, AKI (patients with no 2728), patient months with a nursing home stay

Reporting period: 4 years

9.1 Additional Discussion

A TEP member commented that non- English speaking patients may be at a disadvantage and that we need to create an appropriate system for those patients to be able to have similar education opportunities to choose their modality.

Several TEP members had asked about tracking changes to home dialysis uptake over time. Dr. Segal said that although we have four years of information we have not fully examined looking at changes over time. This is something we can look at to see how the rates of home dialysis have changed over time.

10. Summary and Conclusion

TEP Recommendations

The following are TEP recommendations based on the series of discussions and where there was general consensus.

- There was broad consensus that home dialysis is underutilized and that a quality measure to monitor facility performance would be useful to patients, providers, and other stakeholders (also see page 9 summarizing data on switches to home dialysis).
- The TEP supported the basic construct of the Standardized Modality Switch Ratio (SMoSR) Measure. The TEP further also agreed the proposed measure should be considered for modification over time taking into account new information.
- Effective pre-dialysis education and shared decision making are future areas that should be considered in assessing uptake of home dialysis. There was agreement such measure development was outside the scope of this current TEP
- Attribution for patients who change modality and facilities: If there is modality change within 30 days of transferring facilities, the sending facility will receive credit. Otherwise, modality changes after 30 days will be attributed to the new facility.
- Risk Adjustment
    - Include incident comorbidities that are listed on the CMS Form 2728
    - Do not include race, ethnicity, sex, or age
    - No risk adjustment for pre-dialysis nephrology care or for the proportion of patients that start on home dialysis.
- Facility level exclusions
    - Home only facilities, and facilities that only serve nursing homes will be excluded.
- Patient level exclusions
    - Patient months where the patient is in a nursing home on home hemodialysis will be excluded.
    - Hospice patients
    - Pediatric patients (less than 18 years of age)
    - Patients with no 2728 (AKI patients)

There was no consensus on defining the time period for a durable switch. Opinions generally ranged from 30-90 days. However several patient TEP members expressed support for an even shorter time period because for many people on dialysis, any time, even one day or a few weeks, spent doing dialysis at home is preferred to receiving in-center dialysis. Clinical providers generally favored longer time periods to ensure the clinical stability of patients. The TEP did not express strong support for adjusting for evidence of pre-dialysis care. Additionally there was no clear support for or against adjusting for geography, and there was recognition that geography may function as a surrogate for other demographics.

Future Areas for Consideration

The following topic areas were discussed at the end of the meeting and the TEP recommended these be considered for future measure development to address current gaps in care.

1. Effective pre-dialysis education: There was wide-spread agreement among TEP members that pre-dialysis modality education is critical to ensuring that the type of dialysis is aligned with the patient's goals for care. In the short term, measuring the number of patients who start on a home modality would be a reasonable surrogate for this process.
2. Develop Peer-reviewed Education: Provider's comfort level with home dialysis can bias how modality education is presented, so ensuring standardized content and quality of education is critical to supporting patient's modality decision. Developing an objective fact-based educational program that is transparent, free from bias and presents positives and negatives of each modality could help standardize the decision support process
3. Measure retention of home dialysis patients in their modality: while measuring how many patients start a home modality is a reflection of the education and opportunity offered to patients, considering how long patients are able to remain on a home modality will evaluate the programs ability to keep patients in the home setting. There was robust discussion during the TEP meeting at how best to define a durable switch to home dialysis, so considering the number of months on home therapy would be one way to measure success of a home dialysis program's patient retention.
4. Measure complications related to home dialysis: There is an NHSN measure for bloodstream infections for hemodialysis, but there is no equivalent measure for home dialysis. Measuring peritonitis rates would be a useful next step.
5. Develop a measure for home patients similar to ICH-CAHPS. One of the TEP members has been working on validating a survey for this purpose, but assessment of patients' perception of their home dialysis care is needed.
6. Create a Provider-level metric for home dialysis switches in the first year: this TEP, and others, have underscored the importance of aligning metrics between dialysis facilities and dialysis providers so that there is better cooperation in reaching goals.
7. Measuring changes to home dialysis after the first year of dialysis: although the number of conversion from in-center to home dialysis is lower after the first year, home hemodialysis switches can potentially occur in this later time frame. In addition, one unintended consequence of a first year switch measure could be that less emphasis is placed on modality education after the first year.

At the end of the meeting UM-KECC said there would be a follow-up call to present results from the draft SMoSR reflecting some of the key recommendations discussed by the TEP. That follow-up call was held July 14, 2021.

11. Feedback on draft measure: SMoSR

On July 14, 2021, the TEP met (virtually) to provide feedback on the final model for the proposed switch measure (SMoSR). There was TEP discussion about risk adjustment for age (whether or not

to adjust) and UM-KECC provided results that include a measure with and without adjustment for age. UM-KECC noted there were little overall differences in the model results.

Dr. Dahlerus presented a flowchart to show how the population is defined and calculation steps for the SMoSR. The starting population is the full ESRD patient population, then walked through how inclusion/exclusion criteria and risk adjustment were applied. The calculated score is the total number of observed over expected modality switches for each facility. It was noted this is a four year model, and based on a two-stage cox model.

The results of the model were also discussed. A TEP member asked what the cut off for age would be in this particular model? Dr. Segal explained that the variable is defined by multiple age categories. Another TEP member asked if the first day of training established any of the first 30 days for a durable switch, or is it the first day at home that establishes the switch? The measure includes training days in the 30 days used to determine a durable switch.

Dr. Segal presented results showing the baseline patient characteristics then went through the results. Higher BMI was associated with a slightly higher rate of patients switching to home dialysis while younger patients have higher rates of switching than the older patients; and there is a slightly lower rate of switching for patients with diabetes versus those without diabetes.

Dr. Segal presented the model results noting that those in the younger age groups have about twice the risk of switching to when adjusted for other covariates in this model. In the model without age, individuals who are either overweight or obese had about 20% higher risk of switching to home dialysis and the impact was attenuated when we account for age in the model. When we look at the cause of kidney failure, those were not statistically significant, so there was no impact on the cause of kidney disease in terms of switching.

The TEP reviewed an additional slide listing the incident comorbidities that are listed on the CMS form 2728, organized by their hazard ratio from highest to lowest. (See 16-fifth presentation below). Dr. Segal showed the models with and without adjusting for age and noted that the two models are highly correlated.

Dr. Segal presented another slide comparing how facilities would score- better than expected, as expected or worse than expected. It was noted that only a small percentage of facilities will change performance categories based on whether or not there is an adjustment for age in the model.

The TEP reviewed the measure's C-Statistic that is slightly higher at 0.634 with age included in the model compared to 0.594 when age is not included in the model. IUR with age in the model is 0.604 and without age it is 0.596.

Initially there was concern from TEP members that the C-Statistic was low. A TEP member asked UM-KECC how this C-Statistic compares to other measures that are being used currently by CMS. Dr. Segal explained that for a C-Statistic it is in the range of other measures that have been NQF endorsed that are being used by CMS for public reporting. Another TEP member commented that this model is predicting what is actually occurring in terms of switches and there was discussion that

the goal of the quality measure is not to predict current behavior, but rather to change it. UM-KECC noted that while the C-statistic is part of the NQF submission, this is not a focal point of the model or explaining how it works in terms of capturing the outcome of interest. In addition, the model parameters are reviewed as part of the measure maintenance process, so if there are changes over time, there are opportunities for revisions to provide the best model fit.

A TEP member made a comment noting that there is a big component of subjectivity, and judgment on the part of the team and the patient in modality decisions. They added that it is not surprising that the model does not have a high C-statistic because of the underlying components that are not measureable. After this comment was made, one TEP member said that the C-Statistic (for this measure model) gives them hope that we can move the needle in the United States in terms of increasing home dialysis uptake. Ultimately, the TEP members indicated that the C-statistic was reasonable for this measure.

A TEP member asked if we adjust for dual eligible, and if we adjust for this whether it would increase the C-Statistic. Dr. Segal added that as part of the NQF submission we do examine socioeconomic factors and the impact it has on the modeling and determine whether it should or should not be included. That information was not available during the time of this call.

UM-KECC thanked the TEP members for their participation and engagement during the meetings.

12. Public Comments

There was one public comment from the March 24th 2021 meeting:

“Hi this is Lisa McGonigal from Kidney Care Partners. I just had a quick question. I just wanted to clarify or to verify rather that a little more well delineated specifications will be shared on the next measure. I think that is what you said, but I just wanted to confirm. So, things would include perhaps the exclusions if or not there is a risk adjustment and so on?”

Dr. Segal confirmed it will be share at future meetings and the TEP will be weighing in on all of those issues.

There was one public comment from the April 22nd, 2021 meeting:

“Hello, you know I am going to make a comment. While I work as the quality improvement director, I’m basically here as a nurse who has in interest to what is going on. There’s only a couple of things that I’d like you all to think about. When you’re talking about transferring a unit to reach a therapy that might not be offered in your clinic, I have not heard anybody mention anything about the transitional care unit model and how that would be calculated in terms of time for success, when you’re talking about how, and I know Fresenius has really been advocating and spreading transitional care units to transition both incident and prevalent patients. The other thing is that I’ve not heard people mentioning about the issue of language barriers and literacy. Being someone who speaks Russian, I’ve been asked to translate for patients but having a conversation at the dinner

table is very different than teaching health procedures and protocols so that's just another thing I was thinking about in terms of language barriers and literacy, learning disabilities, the issue of some of the concerns in the Indian health system and the issue of the TCU. How is that considered in this model? And I apologize for my phone." Elena K Balovlenkov, RN MS

There was one public comment from the April 14th 2021 meeting verbalized by Elena K Balovlenkov, RN MS

"One of the things that I want to point out, that we have been talking about, the new work moving forward talking a lot about increasing the percent of patients in home therapies over the next 5 years by 20% and looks significantly at patients who legal address is a nursing home so that is a major consideration and just looking at New York we've had an impact of one particular company that have gone from just the beginning of the year from having 12 facilities in long term care offering home therapies to 19. So there is a push for that and so I think when we look at our population, it is something that needs to be considered however you factor it in. The other thing, I've heard a lot from nephrologists about the shortage of people to do the training to support the physician because you have to have been a nurse for at least one year before you're allowed to be educated yourself to teach home therapies whether it be home hemo or PD because you have to have a certain level of proficiency. So while you look at attribution to the physician versus the facility, I think we have to develop a realistic view point when we are looking at that of the support that is out there to support physicians in doing this education. So that is one consideration. I think I had one other thing, oh, we talk a lot about primary care and this, I can't even tell you why this is coming to my head, but it's been bugging me a lot these past couple of weeks you know we talk about primary care physicians referring to nephrologists and I really think we need to include endocrinologists also referring to nephrologists because a lot of our diabetic patients might not see their primary care doctors but they will go see their endocrinologist and you never hear anybody talking about the endocrinologist referring to renal so those are just some things to think about. "

13. Appendices

A. TEP Charter
B. Literature Review
C. TEP meeting slide presentations