Summary of Technical Expert Panel (TEP) Meetings: June 30, 2020; June 29, 2021; July 18, 2022

Kidney Care Choices Model: Delay in Progression of Chronic Kidney Disease (CKD)

September 8, 2022

Prepared by:

Yale New Haven Health Services Corporation – Center for Outcomes Research and Evaluation (CORE)

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Note: For most recent TEP meeting, see <u>Third TEP Meeting</u>.

Background

The Centers for Medicare & Medicaid Services (CMS), through its Center for Medicare and Medicaid Innovation (Innovation Center), has contracted Yale New Haven Health Services Corporation Center for Outcomes Research and Evaluation (CORE) to develop a quality measure related to delay in chronic kidney disease (CKD) progression. The contract name is Quality Measure Development and Analytic Support, Option Year 2. The contract number is HHSM-75FCMC18D0042, Task Order HHSM-75FCMC19F0003. As part of its measure development process, CORE convenes groups of stakeholders and experts who contribute direction and thoughtful input to the measure developer during measure development and maintenance.

The primary goal of this project is to gather expert and stakeholder input to inform quality measure development focusing on Medicare beneficiaries (patients) with CKD, for possible implementation in an Innovation Center Model. This specific quality measure will assess the success of these providers in delaying the progression of patients from Stage 4 CKD to initiation of chronic dialysis according to end-stage renal disease (ESRD) enrollment status.

The CORE measure development team is comprised of clinicians, statisticians, experts in quality outcomes measurement, and measure development. As is standard with all measure development processes, CORE has convened a Technical Expert Panel (TEP) of clinicians, patients and patient advocates, and other stakeholders. Collectively, the TEP members brought expertise in measure development, nephrology, CKD care, kidney transplants, and the patient experience.

This report summarizes the feedback and recommendations received from the TEP during the three meetings held from 2020 to 2022.

Measure Development Team

The measure development team is led by Ms. Nicole Voll, MPH, PMP. Ms. Voll is a certified project management professional with eight years of experience working on CMS contracts on all phases of quality measure development and implementation. She has led and managed the development, timeline, and deliverables of over 20 outcome measures for hospitals and clinicians.

CORE's measure development team is overseen by Dr. Susannah Bernheim, MD, MHS. Dr. Bernheim is Senior Director of Quality Measurement at CORE, Core Faculty in the Robert Wood Johnson Foundation Clinical Scholars Program, and Associate Professor in the Section of General Internal Medicine at the Yale School of Medicine.

Please see Appendix A for the full list of members of the CORE measure development team.

The TEP

In alignment with the CMS Measures Management System (MMS), CORE held a 30-day public call for TEP nominations and convened a TEP for the development of the Quality Measure Assessing Delay in Progression of Chronic Kidney Disease. CORE solicited potential TEP members via emails to individuals and organizations recommended by the measure development team and stakeholder groups, as well as email blasts sent to CMS physician and hospital email listservs, and through a posting on CMS's website. The TEP is composed of 15 members and one former member, listed in Table 1.

The role of the TEP is to provide feedback and recommendations on key methodological and clinical decisions. The first TEP meeting was convened on June 30^{th} , 2020 from 4:00-6:00 PM EST via teleconference. The second TEP meeting was convened June 29^{th} , 2021 from 2:00-4:00 PM EST via teleconference. The third TEP meeting was convened on July 18, 2022 from 4:00-6:00 PM EST via teleconference.

Specific Responsibilities of the TEP Members

- Complete and submit all nomination materials, including the TEP nomination form, letter of interest, disclosure of conflicts of interests, and curriculum vitae;
- Review background materials provided by CORE prior to each TEP meeting;
- Attend and actively participate in the TEP webinar(s);
- Provide input and feedback to CORE on key clinical, methodological, and other decisions;
- Provide feedback to CORE on key policy or other non-technical issues;
- Review the TEP summary report prior to public release; and
- Be available to discuss recommendations and perspectives following group TEP meetings and public release of the TEP summary report.

TEP Members

Table 1. TEP Member Name, Affiliation, and Location

Name, Credentials	Professional Role	Organization, Location
Steven Spencer ³ , MD, MPH	Chief Medical Officer	Onslow Memorial Hospital, University of North Carolina, Jacksonville, NC
Wendy St. Peter, PharmD, FNKF, FASN, FCCP	Professor	University of Minnesota, College of Pharmacy, Minneapolis, MN

Name, Credentials	Professional Role	Organization, Location
Erma Boykin ^{1,2,3} , MSN, MBA-HCM, RN, CNN, CLNC	Renal Clinic Nurse	Atlanta VA Medical Center-Renal Clinic, Decatur, GA
Andrew "Drew" Wall ^{2,3} , MS	Founder and Chief Innovation Officer	HealthMap Solutions, Inc., Tampa, FL
Eric Martinez, MD	Abdominal Transplant Surgeon; Teaching Faculty	Baylor Scott & White Health; Baylor University Medical Center, Dallas/Fort Worth, TX
Adam Weinstein, MD	CMIO (DaVita); Nephrologist (UMSMG)	DaVita; and University of Maryland Shore Medical Group, Annapolis, MD
Lisa Cormack ^{2,3,4}	Caregiver	North Ridgeville, Ohio
Yaakov Liss, MD	Attending Physician Nephrology Department; Dialysis Unit Medical Director; Vice Chair	CareMount Medical Group; DaVita Celia Dill Dialysis Center; Quality Committee RPA, Brewster, NY
Derek Forfang	Patient; Public Policy Committee Chair	National Kidney Foundation, San Pablo, CA
Titte R. Srinivas², MD	FAST; Chief of Nephrology and Hypertension Division; Medical Director Kidney and Pancreas Transplant Programs	University Hospitals Cleveland Medical Center, Cleveland, OH
Jack Lennon, MBA	Patient; Executive Director	Improving Renal Outcomes Collaboratives, Cincinnati, OH
Richard Knight ³ , MBA	Patient; President	American Association of Kidney Patients, Bowie, MD
Daniel E Weiner ³ MD, MS	Associate Professor of Medicine and Nephrologist; Medical Director of Clinical Research	Tufts Medical Center; and Dialysis Clinic Inc, Boston, MA
Jessie Pavlinac ³ MS, RDN-AP, CSR, LD, FAND	Adjunct Senior Instructor	Oregon Health & Science University; School of Medicine, Portland, OR
Scherly Leon ³ MD, MS, MPH	Medical Director; Nephrologist	Atlantic Dialysis, New York, NY

 $^{^{\}rm 1}\,{\rm TEP}$ member did not participate in the June 2020 meeting.

 ² TEP member did not participate in June 2021 meeting.
 ³ TEP member did not participate in July 2022 meeting.

⁴ TEP member dropped from TEP.

Name, Credentials	Professional Role	Organization, Location
Milda Saunders ^{2,3} MD,	Assistant Professor of Medicine;	University of Chicago Medicine,
MPH	General Internist	Chicago, IL

First TEP Meeting

Overview

Prior to the first TEP meeting, TEP members received detailed meeting materials outlining the measure background, measure development process, and proposed measure specifications.

During the first TEP meeting, CORE solicited feedback on the measure intent, the proposed cohort and outcome specifications. Following the meeting, TEP members unable to join the inperson TEP meeting provided additional feedback via email which was incorporated into the summaries. All but one TEP member submitted feedback.

CORE held its first TEP meeting in June 2020. This section of the summary report contains a summary of the June 2020 TEP Meeting, which was a two-hour meeting conducted via teleconference.

This TEP meeting followed a structured format consisting of the presentation of key issues, solicitation of individual member feedback, a brief open discussion, and a short summary and response from CORE staff. Key issues included the measure intent, planned data sources, and initial proposed specifications for the outcome and cohort of the Delay in Progression of CKD Measure. The following bullets represent what was discussed during the first TEP meeting.

Introduction and Background

Introductions

- CORE welcomed participants, introduced CORE team members, and reminded participants of the confidentiality agreement and funding source, and reviewed the meeting agenda.
- The TEP members introduced themselves and mentioned any changes in their affiliations and/or conflict of interests, which were incorporated into the TEP Composition Form where needed.
- Two TEP members noted that they belong to organizations which have applied for the Kidney Care Choices Model. One TEP member noted that they consult with a large dialysis organization.
- Two TEP members disclosed their advocacy work with National Kidney Foundation, the American Society of Nephrology.

Approval of the TEP Charter

• Mr. Jake Miller reviewed the role of the TEP and the TEP Charter, including TEP member responsibilities and TEP objectives. The TEP members approved the TEP Charter.

Kidney Care Choices Model Background

• Ms. Danielle Raso provided a brief overview of the Kidney Care Choices Model, which will test a new structure for payment for kidney care. The model was scheduled to launch in April 2021 and run through 2023, with the potential to be extended through 2025. The model aligns patients through their nephrologists and participation in the model is entirely voluntary. The model has four payment options for participants: one Kidney Care First Option and three Comprehensive Kidney Care Contracting Options. Payment under the model will be adjusted for performance, both relative to other providers and improvement over time. The set of quality measures used to evaluate performance will include the Delay in Progression of CKD Measure (focus of this TEP) and a Standardized Mortality Ratio for Late-Stage CKD and End-Stage Renal Disease (ESRD) Measure (CORE is measure developer), among others.

Measure Intent

Background Information for Measure Intent

- Ms. Nicole Voll reviewed key definitions, including model (refers to the Kidney Care Choices Model), model participant (refers to those nephrologists or Kidney Contracting Entities who have agreed to voluntarily participate in the Kidney Care Choices model), and outcome (refers to the measure outcome, which is progression to ESRD or initiation of chronic dialysis). She added that the conceptual patients represent real people, and decisions made about the measure will impact the care given to real people.
- Ms. Voll stated the Delay in Progression CKD Measure will assess the success of nephrologists in delaying patients' CKD progression from Stage 4 CKD to chronic dialysis initiation (ESRD enrollment excluding for transplantation). The goal of the measure is to incentivize model participants to delay progression to chronic dialysis, while encouraging kidney transplant as a treatment option. This measure is intended to be a low-burden measure for model participants, and to support the quality goals of the Kidney Care Choices Model.

TEP Feedback on Measure Intent

- Mr. Miller called on the TEP members for input on the following: what are your initial thoughts regarding the intent of the Delay in Progression of CKD Measure? Do you think this measure will provide useful information for providers and patients?
 - Three TEP members noted delaying the progression of CKD is an important outcome for both providers and patients and there is a lack of care coordination between providers. They shared their experience with patients who crashed into dialysis, unaware of the severity of their CKD or preventative measures, despite regularly seeing a primary care physician.

- Two TEP members asserted the need for considering equity in kidney care. One noted CKD disproportionately impacts communities of color, and another questioned what we can do to ensure patients who are typically left out of nephrology care receive the care they need.
- Two TEP members stated the importance of making the measure easy to understand for providers. One TEP member added that the measure will give providers a new way of thinking about their CKD patients. Another TEP member opined that the measure would create optimal care processes, especially if patient-centered language should be used to explain the measure results.
- Two TEP members suggested considering slowing progression at earlier stages of CKD. They expressed concern about the measure capturing patients crashing into dialysis instead of working on ensure Stage 3 CKD patients do not reach ESRD or initiate dialysis. They recognized it may be harder to reliably identify these patients since they may not show symptoms. However, even at Stage 4 and 5 CKD, patients and providers can still slow the progression of CKD, such as through lifestyle changes.
- Several members expressed opinions about the measure's potential interactions with other quality measures. One TEP member supported the measure being supported by other quality measures, and another requested not using this measure in isolation to contextualize provider performance.
- One TEP member noted that there is too much of a reliance on laboratory values to identify CKD, and agreed with the need for more care coordination, especially as related to cardiovascular health.
- Three TEP members were concerned about risk adjustment. Specifically, one TEP member expressed concern about penalizing nephrologists who receive many patients with worse Stage 4 CKD. Another agreed, adding that it will be important to adjust for the different causes of ESRD and CKD, which will affect the rate of progression (outcome). Another added that the final measure should incentivize providers to provide high-quality care, rather than hold providers accountable for issues not under their control.

Summary: Measure Intent

 Ms. Voll summarized TEP feedback on measure intent. There was TEP agreement on measure intent. Many TEP members proposed focusing on incentivizing coordination of care between nephrologists and other providers, as well as including patients with an earlier stage of CKD.

Data Sources and Time Periods

Background Information for Data Sources and Time Periods

• Ms. Voll stated the measure will be developed using Medicare fee-for-service claims data and other administrative data. Prior to implementation in the Kidney Care Choices

Model, the measure will be tested and validated against an electronic health record (EHR) dataset that contains laboratory results. Use of claims data only is the lowest burden for providers, though accuracy of staging may be lower in claims data than using actual laboratory values, and possibly lower for non-nephrologists if this measure were to be used among a wider group of providers. Clinical data obtained from the EHR to identify staging would be more accurate by showing a fuller clinical representation, but adds burden to providers who would be required to extract the exact data and submit this to CMS.

- Ms. Voll asked if any of the TEP members had clarifying questions.
 - One TEP member asked whether the staging from nephrologists was accurate in claims.
 - Two TEP members responded that 10th revision of the International Statistical Classification of Diseases and Related Health Problems (ICD-10 codes) for CKD staging are not consistently applied. Patients kidney function may change dramatically from month-to-month based on hydration or other comorbidities.
 - Ms. Voll confirmed this would be assessed during validation.

TEP Feedback

- Mr. Miller presented three questions and called on TEP members for input: Do you agree with using a claims-only approach to support measure development? Do you have other feedback on the data sources? If this measure was adapted for use beyond this Model focused on nephrologists, would you expect other clinical providers to code patients with Stage 4 CKD accurately enough for this measure?
 - Seven TEP members agreed with a claims-only approach.
 - Four members approved of the claims-only approach because it would be low burden for providers. One TEP member stated that data submission burden on providers would make this measure less successful. They expressed concerns about staging coded by non-nephrologists, such as primary care providers. Other members agreed that using EHR data will be difficult, and that there isn't a good alternative to a claims-only measure to implement within the given timeframe
 - Another TEP member stated that using laboratory values may be less accurate than relying claims data solely for indicating the stage of CKD. Two TEP members agreed that nephrologists don't necessarily code CKD staging or ESRD more accurately than other physicians, so their health system engages and educates all physicians on CKD staging and ESRD. Two other members disagreed, and believed claims coding by nephrologists will be the most accurate since they stage CKD every day. All agreed that it will be important to risk-adjust for other clinical conditions because patients with a

- Stage 4 CKD code will not have the same clinical presentations when entering the cohort.
- One TEP member agreed with a claims-only approach to develop the measure quickly; however, additional data sources would increase the accuracy and impact of the measure. They noted it will be easier to adapt this measure for use by other clinical providers with a claims-only approach.
- o Four TEP members disagreed with a claims-only approach.
 - Two TEP members believe laboratory results are necessary for identifying progression. One TEP member noted that laboratory results provide precision in identifying the risk profile for the measure outcome. Since patients need to have Stage 4 CKD to enter the model, including patients with Stage 3 CKD in this measure is not an option. Another stated specifically Estimated Glomerular Filtration Rate (eGFR) and albuminuria would be useful to track progression of CKD.
- Two TEP members supported supplementing claims data with EHR data. They
 suggested not using this measure beyond the Kidney Care Choices Model until there
 is improvement in the EHR and coding processes. They added that slowing the
 progression of CKD is a top priority of patients, but this measure is only one
 indication of a patient's status.
- One TEP member suggested also including patients with the ICD-10 code N18.9 (unspecified).
 - Ms. Voll responded that once the model starts, we expect nephrologists to be incentivized to code more often and accurately. She noted when CORE examined patients who were coded with "Unspecified CKD" (N18.9), their next recorded CKD stage was most often Stage 3 CKD (N18.3).
- Three TEP members provided additional considerations and feedback:
 - One TEP member responded claims-based coding of CKD staging by nephrologists will be the most accurate. However, a claims-only approach would not distinguish whether a patient with Stage 4 CKD who is closer to either Stage 3 or Stage 5, thus not accurately measuring the disease severity for patients newly measured.
 - Another TEP member noted that one challenge is distinguishing between coding for acute kidney injury (AKI) and CKD. They also noted nephrologists don't necessarily code CKD staging more accurately than other physicians. They emphasized this is a heterogenous patient population; some patients may start dialysis, recover kidney function, and may move through CKD stages in reverse, for example from Stage 5 to Stage 3.
- A third TEP member responded that tracking CKD stage and kidney function are not enough – other factors, such as cardiovascular health, also contribute to hospitalizations and costs for CKD patients and should be captured by the measure

 Two TEP members questioned how the outcome is measured, and Dr. Bernheim reiterated that the outcomes of ESRD or initiation of chronic dialysis are measured via Medicare enrollment coverage for ESRD and ESRD with dialysis, which are audited data elements.

Summary

- Dr. Dorsey summarized TEP feedback on the data sources. Progression between CKD stages is not always linear, and there is heterogeneity in risk among patients with the same CKD stage. In general, TEP requested the measure to try to be as inclusive as possible in the cohort definition by including Stage 4 patients broadly, and possibly Stage 3 CKD patients, and use risk adjustment to account for differential distribution of severity of Stage 4 CKD across providers. There was substantial agreement that a claims-only approach is no less problematic than an approach that uses laboratory results from the EHR.
- Dr. Dorsey added when CORE validates the claims data with EHR data, CORE can examine the accuracy of coding by nephrologists and non-nephrologists, which will inform how well the measure can be adapted for use beyond nephrologists.
- Dr. Bernheim noted a TEP suggestion was to consider a hybrid measure, which is a claims-based measure definition that uses supplemental EHR data for risk adjustment.
- Ms. Voll responded Stage 4 CKD patients not on dialysis regardless of transplant are included in the cohort. Dr. Dorsey added that CORE will examine transplant patients using the data (provided there are enough transplant patients) during measure development, and bring this back to the TEP later.
 - One TEP member noted that kidney transplants can fail, so it is important to include these patients in the measure. Another TEP member stated unless a graft fails early, transplant providers are not the best at coding this failure.

Measure Cohort – Inclusion Criteria

Summary of Measure Cohort Inclusion Criteria

- Ms. Voll briefly reviewed measure inclusion criteria, which aligns with the Kidney Care Choices Model. ICD-10 code N18.4 are used to identify patients in the cohort. Enrollment coverage information, which is an audited by Medicare, is used to exclude those who are already on dialysis or have ESRD. This data variable is also used for the measure outcome. Patients with a prior transplant are included if they now have a claim with Stage 4 CKD, or were aligned prior. Patients who are enrolled in hospice at the time of their first Stage 4 CKD claim are not included. She asked TEP members to send any specific feedback on the measure cohort inclusion criteria via email.
- One TEP member noted that although the inclusion criteria of patients 18 years and older aligns with the payment model, consideration should be given to including children and adolescents in the future.

 Dr. Dorsey agreed, explaining that they are often excluded from quality measures or programs because their needs are different and providers are distinct, although often cared for by specialists.

Meeting Wrap-Up

 Mr. Miller thanked the TEP members for their engagement and encouraged them to communicate any questions or additional thoughts via email to CMMIKidneyMeasure@yale.edu. The CORE team will circulate formal meeting minutes and a summary report with the TEP.

Post-Meeting Responses

Due to limited meeting time, the CORE team sent the TEP members the remaining questions outlined in the background materials and PowerPoint presentation via email, which focused on obtaining TEP feedback on the cohort exclusions. Questions, TEP feedback, and CORE responses are summarized below.

Hospice Exclusion from Cohort

Do you agree that patients who enroll in hospice, with Stage 4 CKD (without progression to ESRD) should be excluded from the measure cohort? Can you identify any unintended consequences of this exclusion?

- 13 TEP members (all who responded) agreed that patients who enroll in hospice during the measurement period should be excluded from the measure cohort.
 - Eight TEP members specifically mention not being able to think of unintended consequences.
 - Two respondents support this exclusion to encourage increased appropriate use
 of hospice. They note that without this exclusion, there may be pressure to keep
 patients within the cohort, which would prevent patients from getting hospice
 care that aligns with their end-of-life decisions.
 - Two TEP members agreed that it is often difficult to know if a patient's hospice status is due to their kidney disease progression or another etiology.
 - Two TEP members were open to the possibility of counting hospice enrollment as a "positive outcome" that improves a provider's score, in the case that the provider ordering the hospice care is a nephrologist.
 - One TEP member cautioned that there is a possibility that the data could be affected if a large portion of patients choose hospice once they proceed to ESRD, but mentioned that this is not the usual progression of illness and treatment.
 - One TEP member noted hospice enrollment may be fluid and some people may disenroll. Some people may elect an option separate from hospice, for example comprehensive conservative management without kidney therapy.
- Thank you for your feedback. CORE will work to ensure this exclusion does not unintentionally skew or negatively impact the measure outcome.

Exclusion for Patients Who Die Prior to Progression

Do you agree that patients who die with Stage 4 CKD, without progression to ESRD or chronic dialysis, should be excluded from the cohort?

- Eight TEP members agreed with this exclusion.
 - One TEP member believed these patients should be excluded from the cohort because this measure will be paired with an additional measure for mortality.
 - One TEP member raised concerns that the mortality measure would need to be well-designed so as not to reward providers who have fewer patients progress to dialysis and more patients dying from kidney disease.
 - One respondent stated death should not be treated the same as a transplant;
 including patients in the would distort the number of patients in the cohort.
- Four TEP members disagreed with this exclusion.
 - Two TEP members believe mortality should be included in the measure because death is a competing risk for CKD progression. Progressive kidney disease can make other conditions worse (congestive heart failure, pneumonia and other lung diseases that might be exacerbated by pulmonary edema, etc.); they would not want to exclude patients that die from the cohort unless there were a guarantee that a mortality measure would be implemented simultaneously. They added that it might be reasonable to only exclude cardiovascular and infectious disease-related deaths.
 - One TEP member believes including patients who die in the measure will encourage care coordination for improved quality of life for elderly patients.
 - One TEP member hypothesized that patients who die with stage 4 CKD prior to progressing to ESRD or chronic dialysis will likely be disproportionately from minority and underserved communities, making the remaining cohort an inaccurate representation of the population and eliminate a proportion of patients that are most in need of early, coordinated CKD and primary care.
 - One member added that a potential unintended benefit of including mortality (especially if the measure is implemented beyond nephrology providers to include primary care physicians) is a better collaboration between primary care physicians and nephrology specialists.
- One TEP member would require understanding the impact of risk adjustment on the heterogeneous cohort prior to determining whether mortality should be excluded, and if it is, having a better understanding of the relationship to the mortality measure.
- Thank you for your feedback. CORE will further investigate the impact of removing patients who die prior to progression, taking into consideration the impact of mortality on CKD progression to ESRD or chronic dialysis. We will examine the profiles of patients who die prior to progression, to avoid disproportionally removing patients identifying with underserved groups. We will work to ensure the separate Standardized Mortality Ratio for Late-Stage CKD and ESRD Measure complements this Delay in Progression of

CKD Measure. We will bring the findings from analyses focused on these issues to a future TEP meeting.

Other Survey Responses

- Three respondents emphasized that a better choice would be to develop a hybrid measure (measure using claims data to define the cohort and outcome but incorporating laboratory results). One TEP member explained that this would make it easier to use a time-to-event approach to calculate the outcome rather than a dichotomous outcome definition.
 - CORE will investigate the impact of using laboratory results from the EHR, and subsequent value of proposing a hybrid measure.
- Two TEP members advocated for transparent and organized sharing of information regarding the measure and wanted clarity around how many ICD-10 triggers needed to define a patient as Stage 4 CKD, and how to handle acute kidney injury (AKI). One expressed concern about code "gaming" of Stage 4 CKD diagnoses.
 - CORE continues to test and possibly refine how the measure will identify patients in the cohort and outcome, in collaboration with the Innovation Center, to align with the methods used by the Kidney Care Choices Model. The measure currently requires one Stage 4 CKD claim during the measure performance year to be eligible for this measure cohort, among other inclusion criteria stated in the background materials. We intend to investigate the accuracy of this definition as compared with staging using clinical information such as eGFR and proteinuria. The results of these analyses and a description of the final data variables used for cohort and outcome identification will be brought to a future TEP meeting.

First TEP Conclusion and Next Steps

CORE thanked all TEP members for their participation and feedback. Overall, the majority of TEP members agreed with CORE's approach to measure development and proposed measure specifications. All TEP members agreed on the measure intent, and many TEP members suggested that the measure might incentivize greater coordination of care with clinicians outside of nephrology. The TEP members suggested an inclusive approach to cohort definition and Stage 4 CKD definition specifically, noting concern that patients with the same CKD stage are a heterogeneous cohort with respect to their renal function. CORE will examine the heterogeneity of the cohort, and consider risk variables to adequately adjust for variability in patient risk. Results will be presented at a future TEP meeting. While the majority of TEP members agreed with a claims-only approach, they suggested that CORE investigate the validity of using only claims, the CKD coding practices, compared with a strategy that incorporates laboratory results from the EHR. CORE will validate the data elements against an EHR dataset, and bring results to a future TEP meeting. All TEP members who responded agreed that patients who enroll in hospice during the measurement period should be excluded from the cohort, and the majority of TEP members agreed that patients who die with Stage 4 CKD, without progression to ESRD or chronic dialysis, should be excluded from the measure cohort.

CORE will continue to investigate the impact of patient mortality prior to progression to ESRD or chronic dialysis on the measure cohort and outcome, and will bring measure outcome calculation approach to a future TEP meeting. TEP feedback will inform the development of measure specifications and risk adjustment approach.

Second TEP Meeting

Prior to the second TEP meeting, TEP members received detailed meeting materials outlining the proposed measure specifications and results.

During this TEP meeting, CORE solicited feedback on the cohort exclusions, measure outcome, risk model, measure score performance, reliability testing, and validity testing of claims data elements using EHR data. Following the meeting, TEP members unable to join the in-person TEP meeting were provided the opportunity to submit their feedback via email and were later incorporated into the meeting summary.

CORE held its second TEP meeting on June 29, 2021, which was a two-hour meeting conducted via teleconference.

This TEP meeting followed a structured format consisting of the presentation of all key issues, asking TEP members for clarifying questions, until a round-robin format at the end, where everyone provided feedback, with a short summary and response from CORE.

Introductions

- Ms. Danielle Raso welcomed the participants and introduced the CORE team members.
- Ms. Raso reviewed the confidentially reminder and stated that TEP members represent themselves and not their organizations; she also reviewed the funding source for the team's work and the meeting agenda.
- The TEP members introduced themselves and mentioned changes to their affiliations and/or their conflicts of interest, which were incorporated into the TEP Composition Form.

Kidney Care Choices Model Background

Ms. Danielle Raso briefly reviewed the Kidney Care Choices (KCC) Model, which will test
a new structure for payment for kidney care. The model is scheduled to launch in
January 2022 and will run through 2026. The model aligns patients through
nephrologists and participation in the model is entirely voluntary for participants.

Measure Use, Description, and Cohort

 Ms. Raso gave a brief description of the measure, including its intended use in the KCC Model for beneficiaries receiving care from participating nephrologists. The measure will assess the success of nephrologists in delaying patients' CKD progression from Stage

- 4 CKD to dialysis. Patients who receive a kidney transplant prior to dialysis or within 30 days of ESRD enrollment will not be counted in the outcome.
- Stage 4 CKD diagnoses from all settings and providers are currently considered.

Cohort Exclusion: Mortality

• Based on the TEP feedback and internal discussions, the measure will exclude patients who die prior to the outcome.

Measure Outcome

- Ms. Voll reviewed the measure outcome, which is progression to ESRD requiring chronic dialysis. The outcome does not count patients who have a kidney transplant prior to progression to chronic dialysis, to incentivize kidney transplant.
 - Chronic dialysis is identified using two Medicare enrollment indicators: ESRD and ESRD-Dialysis coverage.
 - There is a 12-month window for which the patients that had a kidney transplant are ineligible for the measure. After that, if the patient is realigned (with Stage 4 CKD, and have nephrologist), they could be eligible for the measure again. In other words, a patient one-year post-transplant with Stage 4 CKD is treated as any other patient with Stage 4 CKD.
 - Because transplants are not a negative outcome, the provider would receive 'credit' for that patient for the rest of the year.
- Ms. Voll discussed patient attribution. For use in the KCC Model, a beneficiary is aligned
 to providers using the KCC Model's alignment methodology. For measure development
 testing, patients were aligned to the nephrologist or nephrology group who gave them
 the most care during the measurement year, with at least two office visits are required
 for alignment.
 - The measure uses a time-to-event outcome calculation which considers the length of time between when patients enter cohort to the outcome.
 - Each patient in the cohort starts at "time zero", which is the date at which a
 patient is diagnosed with Stage 4 CKD and is attributed to a provider. If both
 criteria are satisfied in the previous year, patients begin January 1 (this is the
 most common scenario).
- One TEP member conveyed that GFR is extremely imprecise (high variability), and they
 expressed concern that the measure could be gamed by coding N18.4 (Stage 4 CKD) in
 October through December of the measurement year, then coding N18.5 (Stage 5 CKD)
 in January through March of the next measurement year. Instead, they recommended
 carrying a patient forward into the next performance year if the patient were previously
 aligned.
 - Dr. Dorsey stated that the suggestion to keep Stage 5 CKD patients aligned to providers is an interesting question to explore. Dr. Dorsey noted that the

previous decision to exclude patients with Stage 5 CKD was based on the more limited ability for the nephrologist to have a chance to have a real impact on the patient's outcome, since the condition is more severe at the outset.

Risk Model

- Ms. Voll stated that the measure is risk adjusted to account for patient demographics and clinical characteristics. She described the risk variable selection process, which included bootstrap analysis to determine which variables retained statistical significance (70% threshold), and clinical review by nephrologists.
- Ms. Voll discussed the risk model performance, with a c-statistic of 0.796, which is considered very strong.
- A TEP member asked about how the dialysis status variable fits into the model, and another asked how Stage 3, 4, and 5 CKD were being used as predictors.
 - Ms. Voll clarified that the variable indicates a history of dialysis in years prior, possibly from those patients who had a transplant or temporary dialysis.
- A TEP member asked CORE to share the risk model with the coefficients. Another stated concern over model coefficients in outcome measures that change direction and predictive strength over different performance periods.

Measure Score Performance and Measure Score Expression

- Ms. Voll presented the distribution of measure score performance, which showed a
 wide range between low and high performers. The results are not largely affected by
 having a minimum case count.
- Ms. Voll stated the measure score is a standardized progression ratio, which is the
 predicted number of progression events over the number of expected progression
 events (given case mix, provider/average provider's quality, and the length of time
 patient is in cohort). She asked TEP members to consider options for the expression of
 measure score: either as a ratio or as an incidence rate.

Reliability Testing

• Ms. Voll stated that a Weibull survival model with lognormal frailty was used to calculate a reliability statistic, showing of those providers with at least 25 patients (as an example minimum case count), at least half have a reliability of over 0.8. These results indicate "acceptable" reliability per NQF and the published literature.

Data Element Validity Testing

Ms. Voll stated the goal for validity testing, which was to identify the percentage of
patients with a Stage 4 CKD claim that had a matching eGFR lab value that supported
diagnosis within a reasonable timeframe, being 180 days prior or 30 days after
diagnosis. We did not directly consider race in the matching analysis; we considered a

- match to Stage 4 CKD if either African American or non-African American eGFR values were between 15-29. The match rate was 82%.
- One TEP member stated that for calendar years 2013 to 2019, they believed the team should use the eGFR race coefficient based on the clinical guidance that was most prevalent during that time (meaning 2013-2019), since you may bias the sample less. They suggested this method may have given a false higher match rate.
 - Ms. Voll stated that the Epic EHR system auto-populates both values, so we can't know how providers were using them specifically. Race of the patient was missing in a large number of cases and therefore not used in our analysis.
- A TEP member asked how patients with different stage codes within a year were considered.
 - Ms. Voll responded that claims with only a stage 4 CKD were considered; if they
 had stage 4 and stage 5 on the same claim, neither was considered.
- Several TEP members were wary that the data were from one health system and noted that the results were better than expected.
- A TEP member asserted that including inpatient claims could be problematic for face validity, because patients with acute kidney injury (AKI) could be staged at a higher CKD stage, and ten days after the hospital stay return to a more normal (higher) eGFR.
 - Dr. Li clarified that the validation analyses shown included outpatient claimsonly.
 - Dr. Dorsey agreed that this was an overall consideration. She added that interestingly, the KCC Model does not make that distinction and includes inpatient claims.
- One TEP member communicated (via chat) that he respects CORE's work and the
 conceptual accuracy of the methods approach to validity. He also noted that using the
 race-adjusted variable may give a false match rate, and expressed skepticism of the high
 match rate found.
- Ms. Voll completed presenting the validity analyses, noting that 41-42% of encounters
 within the same year where patients had eGFR 15-29 were missing the CKDS4 diagnosis.
 The issue of underdiagnosis of CKD is systemic, as both the literature and the TEP stated
 last year.

Summary of TEP Feedback (includes messages received in chat format)

- Praise from the TEP. Several TEP members commended CORE on the work done on the measure.
 - One TEP member expressed that the measure development approach represents progress in the right direction.
 - A TEP member noted that CORE did a nice job on a challenging task based on the data that are available, while another reiterated their thanks and pointed out that CORE did a great job incorporating feedback from the previous TEP meeting.

- Confidence level in the measure as currently specified: Confidence in the measure specifications varied widely among the few TEP members who expressed an opinion.
 - One TEP member responded, "moderate to strong confidence";
 - o Two members responded, "moderate confidence", and
 - o Four members indicated, "low to moderate confidence".
 - The reasons for low to moderate confidence given were the use of claims data, limited data availability, and not being convinced that the measure score performance is due to the quality of care.
- Preference on how to report the measure score to providers as a rate or ratio: several TEP members preferred using an incidence rate.
 - o Four members indicated a strong preference for incidence rate; and
 - Several members did not specify or had no preference, and none expressly preferred using a ratio.
- Other considerations:
 - Several TEP members expressed that patients with Stage 3 kidney disease should be included in the measure cohort or be the focus of a separate measure.
 - There was an emphasis on this inclusion as a mechanism for keeping patients away from renal replacement therapies and feeling well for longer.
 - Several members were uncomfortable using the *race adjusted eGFR* for data element validation. A member expressed interest in investigating the differential impact of the risk model on African Americans.
 - Several members were concerned about risk that providers would game the measure given subjectivity in staging patients, fluctuations between stages, and the potential ability to defer dialysis beyond the performance year.
 - One member expressed desire for patients to be measured more longitudinally to circumvent some gaming concerns.
 - One member expressed that smaller practices may be disadvantaged due to lack of administrative structure.
 - A TEP member expressed that inaccurate coding is a persistent issue in the outpatient setting.
 - Several members wanted to better understand the weight of risk variable coefficients in the risk model.
 - A TEP member noted that the availability of transplants can vary by region, and there can be differences in end-of-life care that can be a source of bias.
 - There was some concern about the use of one health system for data element validation.
 - One TEP member voice concern over how the measure addresses disparities and social determinants of health.

Meeting Wrap-Up

 Ms. Raso thanked the TEP members for their engagement and encouraged them to communicate any questions or additional thoughts via email to CMMIKidneyMeasure@yale.edu. The CORE team will circulate a summary report with the TEP.

Second TEP Conclusion

CORE thanks all TEP members for their continued participation and feedback. Overall, the majority of TEP members agreed about the importance of the measure and CORE's rigorous approach to development, although many expressed low to moderate confidence in the measure as it uses only claims. To address TEP concerns, we will consider additional approaches to testing the claims-only approach compared with approaches that use EHR data to further classify CKD severity among patients who have been assigned a Stage 4 diagnosis.

Some TEP members had questions regarding whether the validity testing aimed at demonstrating CKD staging (based on claims data) is valid and adequate for quality measurement. Although the match rate was high, there was concern that the variation in severity of CKD among patients with Stage 4 CKD could not be accounted for using claims alone. As stated above, we will consider additional approaches to testing a measure using only claims.

A few TEP members expressed concerns around potential gaming of the measure, either by inappropriately delaying dialysis to a new calendar year or by manipulating CKD staging in codes. Based on this TEP feedback, CORE is thinking through options, in conjunction with the Innovation Center, to capture a patient's progression to dialysis that may otherwise be lost during attribution each year. This will need to be balanced by not punishing those providers who have patients longer than one year and who may have advanced to Stage 5 CKD.

Some members expressed concern that the measure does not include patients with Stage 3 CKD, as they believe it would be better to incentivize early care and starting at Stage 4 CKD represents a flawed status quo. We agree patients should be referred to nephrologists early, and we believe this measure encourages early referrals. As stated by one TEP member, including patients with Stage 3 CKD was not the goal of the KCC Model, and ways to incorporate earlier stages will be considered in future measures.

Examining the impact of social risk factors is important. Those analyses had not been completed at the time of the TEP meeting. Whether to include an adjustment for social risk factors (and race) is based on both empiric evaluation and is a policy decision by the Innovation Center. Considerations about these adjustments will be addressed in the next phase of development. CORE will systematically investigate the social risk factor impact on measure scores and will make final decisions with stakeholder input.

Overall, the feedback will inform the development of measure specifications and risk adjustment approach. CORE will consider continuing to engage and seek input from the TEP as the measure is developed.

Third TEP Meeting

Prior to the third TEP meeting, TEP members received detailed meeting materials outlining the proposed measure specifications and results.

During this TEP meeting, CORE solicited feedback on the final measure specifications and the additional electronic health record testing for data element validity. Following the meeting, TEP members unable to join the in-person TEP meeting were provided the opportunity to submit their feedback via email and were later incorporated into the Summary of TEP Feedback section.

CORE held its third TEP meeting on July 18, 2022, which was a two-hour meeting conducted via teleconference.

This TEP meeting followed a structured format consisting of the presentation of all key issues, asking TEP members for clarifying questions, two round-robin sessions (where all TEP members present provided feedback) with a short summary and response from CORE.

Introductions

 Mr. Jake Miller welcomed the participants, introduced the CORE team members, reviewed the confidentially reminder and stated that TEP members represent themselves and not their organizations. The TEP members' purpose is to advise CORE, not the Center for Medicare and Medicaid Services (CMS) directly, although CMS Innovation Center personnel attended the call. Mr. Miller also reviewed the funding source for the team's work and the meeting agenda.

TEP Charter

 Mr. Miller reviewed the TEP Charter including the member responsibilities and the TEP members gave their approval.

Kidney Care Choices (KCC) Model Background

Mr. Miller reviewed that the measure is intended for use in the voluntary Kidney Care
Choices Model, but the measure is designed for broader use outside of the model.
Notably, the measure is tested using all providers who provide nephrology services to
Medicare beneficiaries.

Measure Use, Description, and Cohort

- Ms. Voll reviewed the measure description. The measure will assess the success of nephrology practices in delaying patients' CKD progression from Stage 4 CKD to ESRD requiring chronic dialysis.
- Ms. Voll discussed a new measure cohort exclusion: patients with advanced or metastatic cancer, which is defined using specific cancer-related ICD-10 codes from an inpatient encounter. These patients are among the sickest in the cohort, have a high risk of mortality, and dialysis may not be appropriate.
 - A TEP member asked in the chat why the measure excludes only patients who were hospitalized for metastatic cancer rather than all patients with metastatic cancer.
 - Ms. Voll answered that the reason is severity; CORE did not want to remove patients with cancer that are being seen at the hospital for another condition, rather those that are being treated for their advanced cancer. Patients can have metastatic cancer in some cases for a long time, and we were trying to identify only the sickest patients.
 - A TEP member stated that another reason is that metastatic cancer patients would not be eligible for a kidney transplant.
- Ms. Voll described a cohort change: the measure no longer excludes patients who die prior to progressing to ESRD requiring chronic dialysis. This is based on a statistical principle to avoid excluding patients based on future events. The impact of the change on the size of the cohort was minimal.

Measure Outcome

Ms. Voll presented that the measure outcome censors patients who have one of these
events prior to progression to ESRD requiring dialysis: having a kidney transplant, death,
or enrollment in Medicare hospice. Each patient contributes time in the measure until
their censoring event, at which point they are no longer eligible for the outcome.

Risk Model Performance

- Ms. Voll stated that the risk model includes 43 clinical risk factors that account for differences in patient age and clinical characteristics.
- The risk model performance results were re-run with the modified cohort. The c-statistic and the calibration improved slightly since last year. The logistic regression model c-statistic implies strong model discrimination and the calibration is also guite strong.
 - A TEP member asked if it is possible to provide confidence intervals for each of these estimates, since it is good to know where the limits may be.
 - o Dr. Shu-Xia Li stated that it is a very large sample of over 200,000 patients and the confidence intervals are very tight.

- Post-meeting note: C-statistic confidence interval for the risk model Development dataset are 0.800 (0.796, 0.805); Validation dataset is similar at 0.798 (0.793, 0.802).
- A TEP member asked in the chat what happens to patients who switch to a provider who is not in the KCC Model.
 - Ms. Voll responded that the patients are attributed the provider that treated them the most in the measurement year.

Social Risk Factors

- Ms. Voll discussed the social risk factor (SRF) testing. Most of the influence of SRFs are
 mitigated by clinical adjustment and care by kidney care providers. SRFs were
 considered based on their conceptual influence on the measure outcome, data
 feasibility, and impact on risk model performance.
 - The candidate SRFs were dual-eligibility (individual-level variable), the Agency for Healthcare Research and Quality (ARHQ) socioeconomic status (SES) index (zip code-level variable), and the urban resident variable (county-level variable).
- The c-statistic of the risk model did not improve with the inclusion of any of the above SRFs into the full clinical risk model, indicating that the SRFs do not improve the predictability of the model. Medicare-only patients were slightly more likely to progress, lower socioeconomic status was not associated with progression, and non-urban patients were slightly less likely to progress.
- A TEP member asked in the chat what is meant by viable data and whether there is a particular cutoff associated with missing data.
 - Dr. Bernheim answered that in the case of these variables, we had data for almost every patient in the cohort, and therefore did not have to define a formal cutoff.
- A TEP member stated that they were not surprised that when combining rural and suburban settings in the urbanicity variable, there was no effect on outcome. They noted that rural and suburban risk factors are much different in patients and wondered why they were combined.
 - Dr. Bernheim stated that in the future when we learn the extent to which model participants are in more rural areas, we can explore this more, to make sure that we are not missing an important signal that differs for rural providers. Currently we do not think at this point that we would need to adjust for the location of providers.
- A TEP member stated that they believed that social and economic factors do play a role in the progression of kidney disease, and whether there are other SRFs we can use.
 - Dr. Bernheim stated that dual-eligibility is a useful indicator of lower wealth for older adults. The ARHQ indicator evaluates seven different factors within a zip code, and is a continuous variable that considers occupancy, education, poverty

- level. Patients with socioeconomic factors that may influence their progression commonly, though not always, also have substantial additional comorbidities, so the SRFs are accounted for after comprehensive risk adjustment.
- A TEP member asked if it is possible to use Medicare Part D low income subsidy status in the risk model. We now have medications that can reduce CKD progression and we think that they are great tools.
 - Dr. Bernheim stated that it is a great variable that we are considering, though not every patient is on Part D, so we would deal with a missing data issue.

Measure Score Performance

- Ms. Voll reminded TEP members that the measure score performance is a predicted rate over an expected rate and describes the amount of time that each patient spends in the cohort; it can also be expressed as a ratio.
 - The measure score performance results were very similar to results at the prior TEP meeting. The range (min-max) was wide, showing adequate variation between high- and low-performing providers. The results are not greatly affected by applying minimum case count. Smaller providers tend toward the median.
- Ms. Voll showed the measure score performance distribution, and explained that for the
 risk standardized ratio, lower scores are indicative of better outcomes. Ultimately, the
 measure performance is reasonably evenly distributed across providers.

Reliability Testing

- CORE calculated a reliability statistic (signal-to-noise) using a Weibull survival model
 with lognormal frailty. At least half of providers have a reliability of over 0.614, and
 among those providers with at least 25 cases, at least half have reliability of over 0.787.
 Per the National Quality Forum (NQF) and the literature, these results indicate
 "Acceptable" reliability. The measure score is reliable with or without a minimum case
 count.
- Overall, CORE's opinion of the measure is that it performs well as a standalone measure of quality. There is a good range of performance scores, and the measure performs well on discrimination and calibration. The c-statistic of the risk model is high, at 0.792.

Data Element Validity Testing

 CORE re-ran the Stage 4 CKD data element validity analysis for ICD-10 code N18.4 in a larger dataset that contained electronic health record (EHR) data. Dataset contained all encounters of patients who were diagnosed with Stage 4 CKD during an outpatient visit during July 2018 through December 2021. There were nearly 15,000 CKD patients in this cohort.

- For each encounter with a Stage 4 CKD diagnosis, CORE defined a "match" if the
 patient had an estimated glomerular filtration rate (eGFR) of 15-29 within a
 period of 180 days prior, or 30 days after the diagnosis. This was based on
 clinical guidelines regarding how often a patient with Stage 4 CKD should be seen
 by a provider.
- Among all encounters in which the patient had a Stage 4 CKD claim and any eGFR documented, the positive predictive value (match rate) was 83%. Among all patients (including missing eGFR), the match rate is 64%. Last year, we showed a match rate among all patients of 82%, so this is a very comparable figure.
 - o CORE did not expect a confirmatory eGFR for every patient.
 - The data element validity results confirmed previous findings that the cohort of patients with Stage 4 CKD are justified by eGFR values. This supports the use of claims to identify Stage 4 CKD patients for the measure cohort.
- Ms. Voll noted that implementing a measure using claims data does not add provider burden. Requiring eGFR would add burden to providers, depending on the resources of each provider. If CMS providers were to submit data, it would likely be a laboratory value such as creatinine that would require providers to capture the value regularly for all CKD patients, store the values in a standardized manner in a designated data field (not in clinical notes or a PDF), be able to query the EHR system, and be able to verify data accuracy to ensure validity before submitting to CMS. Adding more data would increase the c-statistic of the risk model but may not affect the measure scores of providers, especially the relative ranking of participants.
- CORE team asked for feedback on the measure specifications, and the use of eGFR in the measure.

Summary of TEP Feedback

- *Praise from the TEP*. Several TEP members acknowledged CORE by thanking them for their work, and the materials being comprehensive.
- Confidence in the claims-based measure and quality signal. Most members felt that the claims-based measure performs well and captures a signal of provider quality.
 - This question was raised in the meeting but there was not time for thorough answers during the meeting. However, five TEP members responded after the meeting to agree with the above. This question is more fully answered in the TEP face validity survey sent after the meeting, wherein most TEP members agreed the measure performs well and captures a signal of quality (see <u>Survey Results</u>).
 - Several TEP members noted that the c-statistic is excellent but had other concerns.
 - Several TEP members shared a concern regarding gaming the measure with respect to a practice inappropriately delaying the onset of dialysis from one measurement year to another.

- Use of claims data to identify patients with Stage 4 CKD. Based on presented results and testing, almost all TEP members agreed that claims data adequately captures Stage 4 CKD patients for the purposes of the measure.
 - Twelve TEP members explicitly agreed with the statement (six present at the meeting and six through follow-up email).
 - Most members stated that the claims measure could be used as specified, particularly given the agreement between the claims data and the laboratory results shown by CORE's extensive electronic health record (EHR) testing.
 - Some members stated that the claims data do not adequately capture CKD.
 Reasons included:
 - Fluctuations in staging over time.
 - Too much variability in claims coding (no "gold standard").
 - Some Stage 4 CKD patients may have much lower eGFR than others, which is considered (along with other laboratory values) as highly predictive of progression.
- Preference for a measure that includes eGFR, given the additional provider burden to submit laboratory data from EHRs. Most members preferred the eventual addition of eGFR.
 - Seven members preferred adding eGFR in a future measure revision, with another TEP member feeling it was required. Two members felt it was not required.
 - One TEP member noted the most accurate risk prediction is using albuminuria/proteinuria, as eGFR does not capture the entire clinical picture.
 - Rationale for adding eGFR in a future measure version included:
 - Addition of eGFR would improve the risk model.
 - Reduction in the potential for gaming.
 - Alignment with physician preference.
 - Future possibility of connecting to eligibility for kidney transplant waiting list.
 - Several TEP members acknowledged the additional provider burden, particularly on smaller practices.
 - One TEP member suggested using a standardized creatinine to eGFR calculation but noted there is still eGFR variability no matter which equation is used, due to fluctuations in levels of creatinine.
- Some TEP members suggested including kidney transplant information.
 - Several members mentioned the regional variation in transplant waiting times and how that would factor into the measure outcome. There was a suggestion that the eGFR data element may be important to show a patient's eligibility for

the transplant waiting list, which they suggested may be able to be incorporated into the measure specifications.

- A TEP member asked about the reason for the non-inclusion of the Medicare race variable.
- Several TEP members noted the need for a measure that addresses Stage 3 CKD patients.
- Summary: The second round of data element validity was reassuring to TEP members and many felt that the inclusion of creatinine data will strengthen the measure, but most members felt that this is not required (only preferred).

Meeting Wrap-Up

 Mr. Miller thanked the TEP members for their engagement and encouraged them to communicate any questions or additional thoughts via email to CMMIKidneyMeasure@yale.edu.

Third TEP Conclusion

CORE thanks all TEP members for their continued participation and feedback. The majority of TEP members believed that this measure can distinguish provider quality for nephrologists caring for Stage 4 CKD patients. Additionally, the majority of TEP members agreed on the implementation of the claims-based measure in a voluntary payment model as is, particularly as an initial option while a measure that uses EHR data is developed.

Several TEP members shared a concern regarding gaming the measure with respect to a practice inappropriately delaying the onset of dialysis from one measurement year to another. CORE responded that the attribution approach somewhat alleviates this concern, and the measure does not create a strong incentive for mishandling dialysis. A provider could still perform well given that it is a time-to-event measure if they have patients who progress in December of the measurement year. This measure is being used in the context of the Kidney Care Choices Model which will be considering a large aggregate of patients and there is a suite of several other measures in the model. However, this issue will be investigated during measure reevaluation.

Several members mentioned the regional variation in transplant waiting times and how that would factor into the measure outcome. This is a topic that can be explored in reevaluation. We anticipate little impact on the measure outcome rates given the relative rarity of transplants within the cohort.

A TEP member asked about the amount of time that patients who receive a transplant can be enrolled in Medicare ESRD before receiving a transplant while not being counted in the outcome. For transplants, there is a one-month time period built into measure, for which the patient will not be counted in the outcome. CORE will consider regional variation in transplant wait lists during reevaluation.

A TEP member asked about the reason for the non-inclusion of the Medicare race variable. Historically, there has been an issue with how the data were collected; since there were very limited choices, the information is largely incorrect, except for Black patients.

Several TEP members noted the need for a measure that addresses Stage 3 CKD patients. CORE agrees that this should be a priority for inclusion in a future measure.

Overall, the feedback from the TEP members will inform topics for reevaluation, and whether to move toward a version of the measure which includes EHR data.

Survey Results

- Following the meeting, CORE distributed a survey to assess face validity of the measure and answer some key questions. TEP members were asked on a 5-point Likert scale whether they "strongly agreed" to "strongly disagreed". All 15 TEP members responded to the survey.
- The majority of members, 73%, felt that the claims-based measure performs well and captures a signal of provider quality.
 - o Eleven TEP members responded they strongly or somewhat agreed.
 - Four TEP members responded they strongly or somewhat disagreed.
- The majority of members indicated support for use of the claims-based measure as specified in a voluntary payment model.
 - o Twelve members responded they strongly or somewhat support.
 - Three members responded they strongly or somewhat do not support.
- The majority of members supported the use of the claims-based measure as specified while a hybrid measure that incorporates EHR data is under development.
 - o Ten members responded they strongly or somewhat support.
 - o Five members responded they strongly or somewhat do not support.

Appendix A. CORE Development Team

Table 1. Center for Outcomes Research and Evaluation (CORE) Team Members

Name	Role
Nicole Voll, MPH, PMP	Project Lead
Susannah Bernheim, MD, MHS	Contract Director; Family Physician and Associate Professor at Yale School of Medicine
Karen Dorsey Sheares, MD, PhD	Project Director
Shu-Xia Li, PhD	Lead Analyst
Yongfei Wang, MS	Analyst
Kyaw Sint, PhD	Analyst
Xin Xin, MS, MA	Former Analyst
Afrin Howlader, MPH	Contract Manager
Jacob Miller, MS	Team Coordinator
Elena Hughes, MSc	Team Coordinator
Danielle Raso, MPH	Former Team Coordinator
Faseeha Altaf, MPH	Innovation Model Expert and Measure Development Advisor
Kristina Burkholder, MS, CAS	Implementation Expert
Deidra Crews, MD, ScM	Nephrology Clinical Consultant
Perry Wilson, MD	Nephrology Clinical Consultant