Summary of Technical Expert Panel (TEP) Meeting June 10, 2025: Increasing Organ Transplant Access (IOTA) Model, New Measure 1, Kidney Transplant Health-Related Quality of Life Patient-Reported Outcome-Based Performance Measure (KT HRQOL PRO-PM)

July 2025

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Table of Contents

Table of Contents 1
Background 2
Measure Development Team 2
The TEP 2
Specific Responsibilities of the TEP Members 3
TEP Meetings 6
Overview of First TEP Meeting (June 10, 2025) 6
Next Steps 17
Conclusion 18
Appendix A. CORE Measure Development Team 19
Appendix B. TEP Call Schedule 20
Appendix C. Detailed Summary of TEP Meeting #1 21

Background

The Centers for Medicare & Medicaid Services has contracted with Yale New Haven Health Services Corporation-Center for Outcomes Research and Evaluation (CORE) in collaboration with Health Services Advisory Group (HSAG) to develop two quality measures related to kidney transplant for the CMS Innovation Center's Increasing Organ Transplant Access (IOTA) Model. The measure concepts include a patient-reported outcome-based performance measure (PRO-PM) focused on health-related quality of life (HRQOL) among kidney transplant recipients (New Measure 1), and a process measure focused on access to the kidney transplant waitlist addressing pre-transplant process of care (New Measure 2). The contract name is Measure & Instrument Development and Support: Quality Measure Development and Analytic Support. The contract number is HHSM-75FCMC18D0042, Task Order HHSM-75FCMC24F0230.

As is standard with all measure development processes, CORE and HSAG have convened a Technical Expert Panel (TEP) of clinicians, patient advocates, and other stakeholders to obtain input on the proposed measures. Collectively, these TEP members provide expertise in performance measurement, quality improvement, PRO-PM development, and clinical, operational, and patient perspectives in the following areas: kidney transplant, nephrology, chronic kidney disease/end-stage renal disease (CKD/ESRD), dialysis experience, kidney transplant waitlist access/referrals, waitlisting barriers, and related processes of care (such as post-transplant care and oversight).

The CORE Measure Development Team is responsible for the development of the Kidney Transplant HRQOL PRO-PM; this team is composed of experts in the development and implementation of quality outcomes measures. This report summarizes the feedback and recommendations received from the TEP during the first meeting, facilitated by CORE, which focused on the PRO-PM development approach, HRQOL survey domains, and options for survey timing.

Measure Development Team

The Measure Development Team is composed of individuals with a range of expertise in outcome measure development, health services research, clinical medicine, and measurement methodology. Presenters for the meeting held on June 10, 2025 included CORE project co-leads Mr. Kyle Bagshaw and Ms. Genne Murphy, team clinical expert Dr. Ladan Golestaneh, and CORE stakeholder engagement expert Ms. Roisin Healy. See Appendix A for the full list of members for the CORE Measure Development Team.

The TEP

In alignment with the CMS Measures Management System (MMS), CORE and HSAG held a 30-day public call for nominations and convened a TEP for the development of quality measures to improve kidney transplant access and post-transplant outcomes. CORE and

HSAG solicited potential TEP members via emails to individuals and organizations recommended by the CORE and HSAG Measure Development Teams and stakeholder groups, emails sent to relevant CMS & CMS Innovation Center listservs, and through a posting on CMS's website. The TEP is composed of 21 members, listed in Table 1.

The role of this TEP is to provide feedback and recommendations to CORE and HSAG on their respective project work and analyses. This includes review of draft quality measure specifications, key measure constructs, and evaluation of the scientific acceptability of measure testing results. The appointment term for the TEP is from April 2025 to September 2027.

Specific Responsibilities of the TEP Members

- Complete and submit all nomination materials, including the TEP Nomination Form, statement of interest, and curriculum vitae
- Review background materials provided by CORE prior to each TEP meeting
- Attend and actively participate in TEP conference calls
- Provide input on key clinical, methodological, and other decisions
- Provide feedback on key policy or other non-technical issues
- Review the TEP summary report prior to public release
- Be available to discuss recommendations and perspectives following TEP meetings and public release of the TEP Summary Report to CMS

Table 1. TEP Member Name, Affiliation, and Location

Name & Area of Expertise	Professional Role	Organizational Affiliation & Location
Nicole M. Ali, MD (transplant nephrologist)	Medical Director, Kidney Transplant Program, Director of Transplant Outreach, Kidney and Pancreas Program, Director of Quality, Transplant Institute	NYU Langone Transplant Institute, New York, NY
Mary Baliker, BS (patient/advocate)	Patient and Family Advocate	Middleton, WI
Yolanda Becker, MD, FACS, FAST, CTBS (transplant surgeon)	Vice President and Chief Medical Officer	LifeGift Organ Donor Center, Fort Worth, TX

Name & Area of Expertise	Professional Role	Organizational Affiliation & Location
Megan Bell, RN, MSN, AGACNP-BC, CCTC (nurse practitioner, certified clinical transplant coordinator)	Associate Director, Abdominal Transplant	Cedars Sinai Comprehensive Transplant Center, Los Angeles, CA
Paul T. Conway (patient/advocate)	Vice President and Chair of Policy & Global Affairs	American Association of Kidney Patients (AAKP), Falls Church, VA
Mona D. Doshi, MD (transplant nephrologist)	Clinical Professor of Medicine (University of Michigan); Co-Medical Director, Kidney Pancreas Transplant Program, and Director, Live Kidney Donor Program	University of Michigan; University of Michigan Health System, Ann Arbor, MI
Jacqueline Garonzik Wang, MD, PhD, FACS (transplant surgeon)	Associate Professor, Division of Transplantation, Department of Surgery; Surgical Director, Kidney Transplant Program	University of Wisconsin School of Medicine and Public Health, Madison, WI
Ellen P. Green, PhD (behavioral economist)	Economist, Associate Professor, College of Health Solutions	Arizona State University, Phoenix, AZ
Jacfranz Guiteau, MD (transplant surgeon)	Director, Transplant Business Development	Ascension Saint Thomas West Kidney Transplant Center, Nashville, TN
Shekeila Harris, LPN, BA, MBA (patient/advocate)	Patient Advocate	Dialysis Patient Citizens, Vineland, NJ
Deanna Hayes, PT, DPT, MS (psychometric expert)	Deanna Hayes, PT, DPT, MS, Clinical Quality Director	Patient360 Dover, DE

Name & Area of Expertise	Professional Role	Organizational Affiliation & Location
Andrew D. Howard, MD, FACP (nephrologist)	Physician/Nephrologist (ret.)	National Forum of ESRD Networks, Walnut Creek, CA
Caroline (Carrie) Jadlowiec, MD (transplant surgeon)	Associate Professor, Surgical Director, Kidney Transplant	Mayo Clinic, Phoenix, AZ
Sireesha Koppula, MD, MPH, MBA, CPE, CMQ (nephrologist)	Associate Professor	University of New Mexico, Albuquerque, NM
Niesha Neal, BS, MCPC (patient/advocate)	Patient and Family Advocate	Exhale & Empower, LLC, Indianapolis, IN
Peter J. Nicastro, MBA, MS, BS (patient/advocate)	Patient and Family Advocate	Chesterfield, MO
Stephen Pastan, MD (transplant nephrologist)	Professor of Medicine (Emory University); Medical Director, (Emory Transplant Center)	Emory University School of Medicine & Emory Transplant Center, Atlanta, GA
Jesse Roach, MD (nephrologist)	Senior Vice President of Government Relations, Patient Advocacy Organization	National Kidney Foundation, District of Columbia
Jesse Schold, PhD, M. Stat., M.Ed. (PhD researcher & epidemiologist)	Professor of Surgery and Epidemiology; Director, Center for Outcomes Research and Policy; Director, Transplant Epidemiology	University of Colorado, Aurora, CO
Alvin Wee, MD, MBA (transplant surgeon)	Program Director, Ohio Kidney Transplantation Program	Cleveland Clinic, Cleveland, OH
Adam Wilk, PhD, PhD (PhD researcher)	Researcher, Associate Professor (Indiana University School of Medicine), Investigator (Center for Health Services Research, Regenstrief Institute)	Department of Surgery (Division of Transplantation), Indiana University School of Medicine; Regenstrief Institute, Indianapolis, IN

TEP Meetings

CORE held its first TEP meeting on June 10, 2025, at which the KT HRQOL PRO-PM concept and work to date were presented. CORE anticipates holding two additional TEP meetings between Winter 2025 and Spring 2026 focused on the PRO-PM development (see Appendix B for the TEP meeting schedule). This report contains a summary of the June 2025 TEP meeting.

TEP meetings follow a structured format consisting of the presentation of updates on measure development, updates on patient workgroup feedback (if relevant), key issues identified during measure development, CORE's proposed approaches to addressing the issues, followed by an open discussion of these issues by the TEP members.

Overview of First TEP Meeting (June 10, 2025)

Prior to the first TEP meeting, TEP members received detailed meeting materials outlining the project overview, measure background, and approach to the novel measure concept.

During the first TEP meeting, CORE presented relevant background information and solicitated input on the HRQOL PRO-PM survey approach, survey domains, options for survey timing, and related discussion questions.

Following the meeting, TEP members unable to join the TEP teleconference were provided with detailed meeting minutes, and all TEP members were invited to provide any additional feedback by email.

Summary of discussion

The following bullets represent a **high-level summary** of what was presented and discussed relevant to the Kidney Transplant HRQOL PRO-PM during the first meeting. For further details, please see the full meeting minutes in Appendix C. We have also taken this opportunity to digest and discuss the feedback we heard during the meeting, and we have prepared some post-meeting responses to answer some of the questions raised, clarify some points of discussion, and summarize how the TEP's feedback will inform ongoing measure development work.

Overview of project and measure background

- Mr. Kyle Bagshaw introduced the IOTA Model under the CMS Innovation Center's IOTA Model, noting its purpose to increase the number of kidney transplants and improve the quality of participating hospitals. He shared the planned implementation timeline for the IOTA Model New Measure 1, Kidney Transplant (KT) Health-related Quality of Life (HRQOL) Patient-Reported Outcome-based Performance Measure (PRO-PM) concept, with pay-for-reporting anticipated to begin July 1, 2027, and pay-for-performance anticipated to begin July 1, 2029.

- Mr. Bagshaw reviewed the PRO-PM project overview, including the concept origin, rationale for measuring HRQOL, definition of a PRO-PM, guiding principles for the project, a project timeline, and further detail on the TEP role.
- Mr. Bagshaw provided background on the initial PRO survey design, noting the goal is to survey patients both prior to and following kidney transplant to evaluate changes in HRQOL.

Presentation of HRQOL survey domains

- Ms. Genne Murphy overviewed HRQOL-focused survey domains and questions included in the first draft survey, as well as CORE's process for question selection. Questions were adapted from among a short list of existing validated PRO surveys with some established use among the intended measure population and available for use. Survey domains were categorized in three broad areas:
    - A core set of general HRQOL questions suitable for both pre- and post-transplant assessments, adapted from Patient-Reported Outcomes Measurement Information System- 16 item Profile (PROMIS-16) and 36- Item Short Form Survey (SF-36). Generic domains included General Health, Physical Function, Anxiety, Depression, Fatigue, Sleep Disturbance, Social Roles and Activities, Pain, and Cognitive Function.
    - For the pre-transplant assessment: condition-specific questions specific to chronic kidney disease (CKD), end-stage renal disease (ESRD), and dialysis experience, adapted from the Kidney Disease Quality of Life 36-item short form survey (KDQOL-36). These domains included Burden of Kidney Disease, Symptoms of Kidney Disease and Dialysis Treatment, Effects of Kidney Disease on Daily Life and Satisfaction with Care.
    - For the post-transplant assessment: questions specific to post-transplant life, adapted from the Renal Transplant Quality of Life survey (ReTransQOL), the Transplant Effects Questionnaire (TxEQ), and the End-Stage Renal Disease-Symptom Checklist (ESRD-SCL). These domains addressed patient experience/satisfaction with medical care and follow-up, worry about transplant/graft complications, medication symptoms and adherence, and transplant-associated psychological distress domains.
- Ms. Murphy noted final survey questions and survey length are not yet finalized and will be refined with TEP and expert feedback. She noted the draft survey will also undergo validation during alpha testing (i.e., validation of data elements to be used in the measure).

TEP feedback on HRQOL survey domains

- Prior to discussion, TEP members were polled if they agreed (Yes/No) with the HRQOL domains prioritized in the draft survey, with 14/20 Yes votes recorded (70% of attendees) and 6/20 No votes recorded (30%).
- Several TEP members emphasized questions should reflect areas under the hospital locus of control and prioritize actionable steps for transplant centers.
    - A few TEP members noted it is important to balance HRQOL domains that are meaningful to patients and clinicians with ensuring these can be accurately measured and tied to hospital quality.
    - A few TEP members raised concern that transplant centers may be evaluated on factors outside their control, specifically with the use of dialysis-focused questions for the pre-transplant assessment. However, other members felt inclusion of dialysis-specific questions was necessary to establish pre-transplant baseline HRQOL due to the large impact of dialysis experience on patient's self-assessment of HRQOL.
        - The CORE team clarified that dialysis-specific questions are not intended for direct pre/post comparison but for risk adjustment, as pre-transplant HRQOL is known to be a predictor of post-transplant HRQOL.
    - One TEP member suggested the transplant care team had some influence on a patient's choice of dialysis setting, although another member disagreed stating in this aspect the hospitals generally defer to the community nephrologist. Another TEP member added there is no universal consensus on who is primarily responsible for pre-transplant processes of care, and it may be difficult to establish baseline HRQOL that can be attributed to specific pre-transplant steps.
    - One TEP member felt if we are holding transplant centers responsible for HRQOL changes we should be careful about inclusion/exclusion criteria and how we control for risk factors.
    - Several TEP members supported the inclusion of pre/post questions that focus on activities under a hospital's influence, feeling these questions were valuable to assess HRQOL changes; a few others additionally noted pre-transplant questions may be useful for risk adjustment.
    - Several TEP members responded to note various factors impacting HRQOL outside of the hospital's influence, such as preemptive versus deceased-donor transplant or dialysis setting, vintage, and modality.
        - The CORE team responded to emphasize the complexity and variability of patients' pre-transplant experiences and noted several areas under consideration for risk adjustment including transplant

type, dialysis vintage and experience, time on waitlist, and comorbidity.
    - **CORE post-meeting response:** We appreciate this thoughtful feedback. We intend to use risk adjustment to account for factors such as patient case mix differences that are outside a hospital's control and ensure hospitals are compared on a fair basis. We will discuss risk adjustment in depth at a future meeting.
- A few members questioned how the measure intent aligned with the overall IOTA model goals, noting that while the main goal of the model is to increase the number of transplants and organ offer acceptance rates, measures such as this PRO-PM or graft survival may contrarily incentivize against more challenging transplants as securing positive outcomes is more difficult.
    - **CORE post-meeting response:** We appreciate this question. This PRO-PM, along with other measures in the IOTA model quality domain, is intended both to balance the model's main focus on increasing transplant rates by ensuring these additional transplants don't come at the expense of quality, and to encourage innovation in improving patient-centered outcomes compared to current standards of care. In addition, we note that risk adjustment of this measure will account for many these factors that lead to variation in outcome expectations. We will discuss risk adjustment in depth at a future meeting.
- Several TEP members expressed concern about comparing surveys with different pre/post questions and the ability to ensure measurement accuracy.
    - A few TEP members asked for clarity on the purpose of pre/post measurement.
        - The CORE team clarified that HRQOL changes from pre-to-post transplant depend heavily on a patient's starting point. The pre-transplant survey questions aim to account for baseline factors to ensure hospitals are not unfairly penalized for serving patients with lower HRQOL to begin with. The focus of the measure is assessing the quality of care provided by the transplant hospital and transplant team.
    - A few TEP members worried about survey completion rates or how to ensure patients complete surveys.
    - One TEP member noted if we intend to measure pre-to-post changes, we will have to account for HRQOL changes for those patients who remain on the waitlist for years before transplant.
    - One TEP member noted pre-to-post comparison may be challenging since many more patients will complete the pre-transplant survey while on the waitlist than will ultimately be transplanted.

    - One TEP member felt the condition-specific questions may lose comparability and measurement accuracy due to differences between pre- and post-transplant populations.
    - One TEP member felt a pre-to-post measurement approach may exclude other important HRQOL questions we could be tracking.
    - **CORE post-meeting response:** We appreciate this feedback. We intend to proceed with a mix of general HRQOL-focused questions and condition-specific pre/post-transplant questions for initial testing, through which we will be able to empirically evaluate some of the questions and concerns raised here. We will report back to the TEP on this testing and discuss the implications for the measure at a future meeting.
- While the majority of TEP members supported the generic HRQOL domains overall, several TEP members shared differing opinions on the condition-specific questions or suggested additional domain areas to better capture activities under the influence of transplant hospitals.
    - Several TEP members noted that each patient journey is different, with varied pathways to transplant, and acknowledged it may be difficult to reach consensus on relevant survey questions.
    - Several members suggested additional domain areas for pre-transplant assessment including pre-transplant psychological distress and questions focused on capturing patient experience with the transplant care team (i.e. medical testing, navigation of care system, adequate patient education, and if patients feel empowered with organ choice).
    - A few TEP members suggested survey tools should be as flexible, comprehensive, and able to capture as much relevant information as possible.
    - However, other TEP members expressed desire to see more specific questions (for example pre-transplant medical assessment or insurance delays that affect waitlist access which may impact HRQOL, or post-transplant questions more specifically tied to renal transplant).
    - A few members suggested waitlist experience could be applicable to both the pre and post assessment.
    - A few TEP members felt post-transplant questions should include the CKD/ESRD/dialysis-specific questions included for the pre-transplant assessment.
    - Two TEP members felt the survey should include questions focused on economic impacts or ability to work.
    - **CORE post-meeting response:** We appreciate this feedback. We will take it into account as we refine the draft survey instrument prior to initial testing and will report back to the TEP at a future meeting.

- A few TEP members felt questions reflected clinician and researcher interests over that of patients and expressed a desire for more patient-centered questions.
    - One TEP member felt current tools are too generic or clinically focused and fail to reflect what truly matters to patients, such as employment, economic security, social roles, and comparative difference to life on dialysis. This member then reiterated that dialysis-specific questions are critical part of a patient's overall treatment journey. However, others noted it may be challenging to attribute improvement of economic outcomes to hospital quality activities.
    - One TEP member felt questions may not fully capture patient experiences or motivations.
    - A few TEP members felt that while many HRQOL domains may be interesting and relevant to patients, for the purposes of this survey, the questions must target activities under a hospital's control.
    - Some TEP members noted the limitations of adopting questions from existing validated surveys versus creating a novel survey, and that novel questions may be more specific and/or comprehensive to this population; one member commented CMS should not be "limited by tools of the past." However, another TEP member noted that drafting and testing novel questions would be time and labor intensive and may not align with the timeline for measure completion / implementation.
    - **CORE post-meeting response**: We appreciate this feedback. We will consider opportunities for de novo questions as we refine the survey. However, we note that de novo survey development is an intensive process which may not be feasible for this project. In conversation with the IOTA model, we will further consider if adapting existing questions will be sufficient for this purpose, or if crafting de novo questions would add sufficient value.
- Many members expressed concern over survey length and corresponding burden for patients/providers.
    - Several TEP members suggested a shorter number of questions to reduce survey fatigue and encourage survey completion, noting differences in completion rates may impact the metrics this measure aims to capture. A few members suggested a final survey should aim for 10-15 questions.
    - One TEP member noted survey length is particularly important to consider if intending to survey all waitlisted patients at participating hospitals.
    - **CORE post-meeting response:** We appreciate this feedback. We will continue to refine the survey prior to testing, after which we will have additional empiric data to identify key items to include while ensuring reliability and validity are maintained. We fully expect the final survey to be

shorter than the current draft and will aim to ultimately bring it within 10-15 questions, provided scientific acceptability is satisfactory.

Presentation of pre-transplant survey timing options

- Mr. Bagshaw presented considerations for timing of pre-transplant survey administration.
    - Pre-transplant HRQOL is a predictor of post-transplant HRQOL, however pathways to transplant are varied and complex; the only pre-transplant events common to all transplant recipients are referral for transplant and completion of pre-transplant assessment.
- CORE proposed 2 options for standardized pre-transplant survey timing: 1) Survey patients first upon completion of pre-transplant assessment and regularly (e.g. annually) thereafter until transplant occurs; or 2) administer no survey before transplant, and instead ask transplant recipients retrospectively to evaluate their pre-transplant HRQOL.
    - CORE identified advantages of option 1 as being comprehensive (inclusive of all waitlisted & transplant-eligible patients), timely (with most recent responses consistently within 1 year before transplant), and consistent with importance of HRQOL as a global patient-centered outcome. Disadvantages include the administrative burden and cost of surveying all waitlisted patients annually, as well as greater burden on patients to complete surveys.
    - CORE identified advantages of option 2 as being substantially more efficient, requiring only one-time survey administration to patients who have actually had transplant. However the major disadvantage is the risk of poor recall or recall bias as patients' post-transplant HRQOL can heavily affect their characterization of their pre-transplant life.

TEP discussion on pre-transplant survey timing

- TEP feedback to these options was mixed. While TEP members conceptually supported the importance of HRQOL as a patient-centered quality indicator both before and after transplant, there was no consensus supporting either of the proposed options in practice for this measure and most members found neither option to be ideal. Broadly speaking, TEP members found option 1 to be more scientifically acceptable but not practical to implement on this scale but were concerned about the potential for recall bias in option 2.
- Multiple TEP members cited the high administrative burden and cost of administering a survey annually to all waitlisted patients.
    - Several noted that specifically in the context of the IOTA model, because many patients will be on the waitlist for years, option 1 would involve

surveying many patients who will not even receive a transplant during the IOTA performance period.
    - Several TEP members expressed concern about the opportunity cost to this option, noting the risk that hospital resources would be shifted to collecting survey responses from getting patients transplanted or ensuring quality in other domains of care contrary to the goals of the measure and the IOTA model overall.
    - TEP members noted the heterogeneity of pathways to transplant as a challenge to account for. For example, some patients may be transplanted very quickly after waitlisting and may not have the opportunity to take the survey in advance.
    - TEP members also noted the additional burden of taking an annual survey for patients (particularly those on dialysis, who are already asked to complete several surveys including SF-36 and CAHPS for dialysis facility metrics). Patient TEP members specifically noted that patients already have to complete much paperwork and take in much information during pre-transplant visits, and they may not see value in completing this additional survey because it would not affect their getting a transplant.
- TEP members noted some challenges inherent to any method of survey, for example dealing with low response rates or missing responses. A few TEP members acknowledged that any survey will involve some burden and there is never a perfect time to administer but agreed with the goal of minimizing burden as much as possible.
- A few TEP members suggested alternative approaches.
    - Some TEP members suggested that a survey could be administered in the hospital immediately prior to transplant. However, others noted the risk of biased responses as patients at that stage worry that negative responses once an organ is available will prevent them from getting the transplant.
    - Some TEP members suggested considering an option where only a subset of transplant-eligible patients would be surveyed (for example, those most likely to be transplanted in the next 3 months based on UNOS score). However, others noted this could be difficult for hospitals in practice and would result in missing data as it would be limited by the predictive nature of identifying this subset.
    - Some TEP members suggested obtaining pre-transplant HRQOL measurements from another source, such as the dialysis facility SF-36 questions. However, others noted that obtaining these data and matching to transplant recipients would be challenging; that the dialysis facility HRQOL instrument would not be directly comparable to the post-transplant

measure; and that this would inherently exclude preemptive transplant recipients.
    - Several TEP members recommended strongly against surveying at a single point in time pre-transplant as patients' status can change dramatically over years on the waitlist and noted there is value in measuring patient experience longitudinally.
    - A few TEP members suggested eliminating the pre-transplant survey altogether, instead measuring only the post-transplant HRQOL and using risk adjustment to account for differences in case mix.
    - Several TEP members cited other aspects of pre-transplant care or quality to measure rather than HRQOL, including education of transplant options, navigation to and on the waitlist, and support from the transplant team.
    - A TEP member stated that analyses showing how much HRQOL changes over time, and how that varies by patient or HRQOL domain area, would help inform their recommendation, as would input from patients and clinicians on that point.
- **CORE post-meeting response**: We appreciate this thoughtful feedback and we will relay this conversation to the IOTA model team for further discussion. We acknowledge the concerns related to burden and cost of option 1 (particularly for the transplant hospitals) as well as the risk of recall bias in option 2, and we appreciate the TEP's thoughtful exploration of potential alternative approaches. We intend to collect pre-transplant HRQOL assessments using option 2 in alpha testing due to its practicality and efficiency, but the decision for the final measure specifications remains open and will be informed by testing results and further TEP feedback.

Presentation of post-transplant survey timing options

- Mr. Bagshaw presented considerations for post-transplant survey timing.
    - Based on initial work, CORE suggested that the survey should be administered at least several months post-transplant (to allow for recovery from the surgery and stabilization of the graft), but not too long after the surgery (to ensure hospitals can still be accountable for outcomes and minimizing losses to follow-up).
    - Prior research shows that in general HRQOL is generally low immediately post-transplant but increases quickly within a few months, levelling out within the first year in most cases.
    - CORE's recommendation based on a balance of these considerations is to administer the post-transplant survey approximately 6 months post-transplant. This could be linked to patients' routine 6-month visits.

TEP discussion on post-transplant survey timing

- The TEP was generally amenable to this recommendation but shared some additional thoughts and considerations.
    - Most TEP members either supported the 6-month timepoint or stated that they would support if that was the consensus of the panel.
    - Several of TEP members expressed a preference for a one-year post-transplant measurement.
        - Several TEP members noted that the 1-year post-transplant timepoint is a standard endpoint in many other kidney transplant assessments (for example, the FDA often uses one-year survival in evaluation of transplant drugs). Transplant centers are broadly used to one-year outcomes in other metrics
        - Several TEP members noted that a large subset of patients may not be stabilized by 6 months (particularly for those with more complex clinical needs), and their one-year outcomes will look substantially different. Particularly for patients experiencing rejection or viral infection, at least one year post-transplant would allow most acute issues to be resolved.
        - A few TEP members suggested that 1 year may be a better option as that is when most patients will have not only stabilized & recovered from the surgery but have returned to regular activities such as work or travel.
    - However, other TEP members suggested that the outcome need not be measured at a point when all patients would be expected to have recovered, so long as the selected time point is comparable across hospitals.
- A few TEP members suggested an earlier time point (such as 3 months post-transplant) as direct engagement with many patients will have decreased substantially even before month 6. However, others noted that 3 months may not be sufficient to capture the full benefits of transplant, particularly for older patients.
    - A TEP member noted that many factors related to differences in 6-month outcomes could be accounted for by risk adjustment.
    - A TEP member suggested that in the context of the IOTA model specifically, patients could be surveyed at both 6- and 12-month post-surgery time points, to collect data for testing the optimal balance between timeliness and losses to follow-up for future implementations of the measure.
- **CORE post-meeting response:** We appreciate the thoughtful feedback. At this time, we will proceed with our original recommendation to use a 6-month post-transplant timepoint for outcome assessment (at least through initial testing), as we believe this best balances timeliness of the assessment and minimization

of losses to follow-up with sufficient opportunity for patients to recover from the procedure and largely realize a return to "normal" life. We acknowledge that some patients may not be fully recovered, but we believe that as long as the point of comparison is standardized across hospitals and the risk adjustment methodology robustly accounts for differences in case mix this will produce a valid and fair signal of provider quality. Ultimately, effects on post-transplant HRQOL that may result from intermediate processes and outcomes under hospital influence—such as communication quality and management of post-transplant complications—are important components of the quality signal this PRO-PM is intended to capture, reflecting areas where hospitals may reasonably be held accountable.

Additional feedback, questions, and considerations

- A number of TEP members raised questions or concerns that, while outside the immediate scope of topics for this meeting, will be relevant for future consideration by CORE and the IOTA model team as measure development continues.
    - A TEP member questioned the use of a PRO-PM in this context, as HRQOL is subjective and responses are affected by complex factors, and they felt a survey-based measure would not be satisfactory in the context of the IOTA model.
        - However other TEP members noted that survey-based instruments are essential for capturing patient perspectives, that extensive research has demonstrated strong reliability and validity for PRO measures in many other contexts, and that many of the factors mentioned would be accounted for by risk adjustment – the survey itself most importantly needs to get the patient's perspective but need not capture all other nuance (which could be gathered from other linked data sources).
    - A TEP member noted that as kidney care advances, hospitals are now accountable for more outcomes that they were not before; measures such as this PRO-PM can help clarify what hospitals truly are vs. are not responsible for.
    - Several TEP members acknowledged the substantial heterogeneity of the transplant recipient population and noted the need for robust risk adjustment to account for variations in patient population. TEP members cited a number of candidate risk factors (other than pre-transplant HRQOL) to consider, including type of transplant (living vs. deceased donor, preemptive vs. post-dialysis, recipient sensitization, quality of kidney), dialysis history (modality, vintage), time on waitlist, age, and comorbidities.

        - One TEP member also suggested stratification based on immediate vs. delayed graft function.
    - TEP members also noted the need for appropriate inclusion and exclusion criteria for the measure cohort.
    - A few members suggested the HRQOL PRO-PM remain on a pay-for-reporting basis rather than pay-for-performance to mitigate some of these methodologic concerns.
- **CORE post-meeting response:** We appreciate this additional input and look forward to future conversations with the TEP on these topics.

Post-meeting feedback

- Following the meeting, one TEP member contacted CORE by email to note some additional considerations and options for use of PROMIS, and particularly the options of creating custom short forms that can capture key domains of a longer instrument such as PROMIS-16 while retaining validated psychometric properties.
    - **CORE response:** We appreciate this suggestion and will bear it in mind as we refine the survey instrument.

Next Steps

Ongoing Measure Development

Key Takeaways and Considerations

CORE greatly appreciates the enthusiastic and thoughtful contributions of the TEP. Based on this feedback, over the next several months we will:

- Continue to refine the draft survey instrument
    - Primary focus will be on adaptation of existing questions vs. creation of de novo items; use and balance of more generic vs. more condition-specific items; and reducing overall survey length.
- Continue preparation for initial pilot testing of the measure
    - Testing will assess patients at 6-months post-transplant, with respondents asked to retrospectively characterize their pre-transplant HRQOL.

At a future TEP meeting, CORE will report on the progress of survey refinement and results of initial pilot testing. CORE also intends to further consider topics including survey scoring approach, inclusion/exclusion criteria, risk adjustment/stratification factors, and provider-level aggregate scoring to discuss with the TEP in future.

TEP & Stakeholder Engagement

Prior to the next TEP meeting anticipated for Winter 2025, CORE will continue to engage TEP feedback and/or respond to questions via email. Starting in Fall 2025, CORE intends to

additionally engage stakeholders as part of a planned Patient & Caregiver Working Group to solicit feedback on the HRQOL PRO-PM measure.

Conclusion

TEP feedback on CORE's approach to measure development will inform the refinement of the PRO survey instrument and plans for initial pilot testing. CORE will continue to engage and seek input from the TEP as the measure is developed.

Appendix A. CORE Measure Development Team

Table A: Center for Outcomes Research and Evaluation (CORE) Team Members

Name	Team Role
Kyle Bagshaw, MPH	Project Co-Lead
Genne Murphy, MFA	Project Co-Lead
Ladan Golestaneh, MD, MS, FASN	Clinical Subject Matter Expert
Jennifer Jacque, MPH	Project Co-Coordinator
Alexandra Stupakevich, MPH	Project Co-Coordinator
Floraine Evardo, MPH	Research Support
Rachel Johnson-DeRycke, MPH	Project Director
Michael Araas, MPH	Senior Health Services Researcher
Valery Danilack-Fekete, PhD, MPH	Senior Health Services Researcher
Megan LoDolce, MA	Contract Manager
Jennifer Falcone, BA	Project Manager
Chenxue (Tracy) Liang, MPH, MSc	Lead Analyst
Shu-Xia Li, PhD, MS	Senior Analyst
Zhenqiu Lin, PhD	Senior Director of Data Management and Analytics

Appendix B. TEP Call Schedule

The following meetings are anticipated for review of the Kidney Transplant HRQOL PRO-PM (IOTA Model New Measure 1). Additional meetings focused on the IOTA process measure (New Measure 2) will be scheduled separately by HSAG.

TEP Meeting #1: KT HRQOL PRO-PM

Tuesday, June 10, 2025 – 2:00-5:00PM EST (Zoom Teleconference)

TEP Meeting #2: KT HRQOL PRO-PM (Alpha testing results)

TBD – anticipated for Winter 2025

TEP Meeting #3: KT HRQOL PRO-PM (Beta testing results)

TBD – anticipated for Spring/Summer 2026

Appendix C. Detailed Summary of TEP Meeting #1

Tuesday, June 10, 2025 – 2:00-5:00PM EST

Participants

- **Technical Expert Panel (TEP) Participants**: Nicole Ali, Mary Baliker, Yolanda Becker, Megan Bell, Paul Conway, Mona Doshi, Jacqueline Garonzik Wang, Ellen Green, Jacfranz Guiteau, Shekeila Harris, Deanna Hayes, Andrew Howard, Carrie Jadlowiec, Niesha Neal, Peter Nicastro, Stephen Pastan, Jesse Roach, Alvin Wee, Adam Wilk
- **Yale New Haven Health Services Corporation — Center for Outcomes Research and Evaluation (YNHHSC/CORE):** Mike Araas, Kyle Bagshaw, Katie Balestracci, Valery Danilack-Fekete, Floraine Evardo, Jennifer Falcone, Ladan Golestaneh, Roisin Healy, Jennifer Jacque, Thushara John, Rachel Johnson-DeRycke, Erin Joyce, Shu-Xia Li, Zhenqiu Lin, Megan LoDolce, Genne Murphy, Jon Niederhauser, Allie Stupakevich, Tracy Liang
- **Centers for Medicare & Medicaid Services (CMS):** Taroon Amin, Stephanie Clark, Kate Detweiler, Matthew Hubbard, Christina McCormick, Whitney Saint-Fleur

Detailed Discussion Summary

Administrative Items

- Ms. Roisin Healy welcomed participants to the first meeting of the "Development of Quality Measures to Improve Kidney Transplant Access and Post-Transplant Outcomes" Technical Expert Panel (TEP), noting today's discussion would focus on the Increasing Organ Transplant Access (IOTA) Model New Measure 1. She introduced herself as a CORE Stakeholder Engagement Lead, reminded the group that the meeting was being recorded, provided instructions about the meeting controls for closed captioning, and encouraged TEP members to use the chat function.
- Ms. Healy reviewed the agenda, shared details about the specific CMS funding source supporting this work, reminded members about the confidentiality of meeting materials and discussion, provided participation guidelines and discussion decorum, provided an overview of CORE, and introduced the CORE project team.

Introductions

- Mr. Kyle Bagshaw and Ms. Genne Murphy introduced themselves as CORE project team co-leads for IOTA Model New Measure 1, and Dr. Ladan Golestaneh introduced herself as the team's clinical expert.

- Ms. Healy acknowledged that CMS staff may be joining the call and reviewed the TEP member composition.
- TEP members introduced themselves and shared their preferred name, location, relevant background, or interest in the IOTA model TEP, and disclosed any Conflicts of Interest (COI).
    - Nicole Ali (New York City, NY) is a transplant nephrologist at New York University (NYU) with an interest in the evolution of IOTA and improving patient centered outcomes; she is a medical director at a transplant program participating in the IOTA model but declared no other potential COI.
    - Mary Baliker (Middleton, Wisconsin) has a background in public health and clinical research. She worked at the School of Medicine Public Health at the University of Wisconsin working in clinical research, transplant, and procurement. She is also a four-time kidney transplant recipient with her last transplant 25 years ago and has been on in-center hemodialysis; no declared COI.
    - Yolanda Becker (Texas) was an abdominal transplant surgeon (kidney and pancreas) and is now the Chief Medical Officer of LifeGift Organ Procurement Organization (OPO), no declared COI.
    - Megan Bell (Los Angeles, California) previously worked as a kidney transplant coordinator and is currently the Associate Director of Abdominal Transplant at Cedar-Sinai; COI as a member of the Membership and Professional Standards Committee (MPSC) for the Organ Procurement and Transplant Network (OPTN).
    - Paul Conway (Falls Church, Virginia) is a 47-year kidney patient, and a 28-year kidney transplant recipient. His professional background is in implementing presidential policy initiatives and he serves as chair of Policy and Global Affairs for the American Association of Kidney Patients, no declared COI.
    - Mona Doshi (Michigan) is a transplant nephrologist at University of Michigan representing Renal Physician Association (RPA) Group and has been practicing for 20 years. She is interested in making sure kidneys last longer and improving living donor transplants; her transplant program participates in the IOTA model but declared no other potential conflicts of interest.
    - Jacqueline Garonzik Wang (Wisconsin) is a transplant surgeon at the University of Wisconsin and serve as the Surgical Director of the Kidney Transplant Program, no COI.

- Ellen Green (Arizona) is an associate professor at Arizona State University trained as a behavioral economist and interested in how policy influences clinical decision making, no declared COI.
- Jacques Guiteau (Nashville, Tennessee) is a kidney transplant surgeon and director of Transplant Business Development at Ascension, Saint Thomas West, no COI.
- Shekeila Harris (New Jersey) is a 16-year kidney transplant patient and nurse. She works in public health as the Equality Assurance Manager for her local health department, no declared COI.
- Deanna Hayes (Indianapolis, Indiana) has a background in research, development and clinical implementation of patient reported outcome measures, risk adjustment models, PRO-PM quality measures and physical therapy. She is passionate about patient focused assessment that is meaningful to patients and providers, no declared COI.
- Andy Howard (California) is a nephrologist of 40 years with background at Walter Reed Army Medical Center. He is a board member of the Delmarva Kidney Care Choices (KCC) Model.
- Carrie Jadlowiec (Pheonix, Arizona) is a transplant surgeon and Surgical Director for the Kidney Program at Mayo Clinic. She also serves as the Mayo Clinic Enterprise Kindey Chair, no declared COI.
- Niesha Neal (Indianapolis, Indiana) is a kidney and pancreas transplant recipient. She is also a member of the board of directors at Island Peer Review Organization (IPRO) End Stage Renal Disease (ESRD) Network, Network 9, no declared COI.
- Peter Nicastro (St. Louis, Missouri) is a cystic fibrosis patient, lung transplant recipient, and two-time kidney transplant recipient, receiving his latest kidney transplant last June. He is on the organ donor registry committee at his local state health department; he declared working at the finance department associated with Cigna's Federal TRICARE Contract.
- Stephen Pastan (Atlanta, Georgia) is a transplant nephrologist and medical director of the Kidney and Pancreas Transplant Program at the Emory Transplant Center. He is a health system researcher interested in access to transplants and improving transplant outcomes. He is the Medical Review Board (MRB) Chair for IPRO Network, Network 6, and previously worked as a dialysis doctor before becoming a transplant nephrologist, no declared COI.
- Jesse Roach (Washington, DC) is the head of Government Relations for the National Kidney Foundation and a pediatric/adult nephrologist. He previously worked at the University of Wisconsin for CMS and did Quality

Measurement and Measure Development for the ESRD program and the ESRD Quality Incentive Program (QIP), no declared COI.
    - Alvin Wee (Cleveland, Ohio) is the program director for the Kidney Transplant Program at Cleveland Clinic main campus; he declared that their program is a part of the randomized IOTA model, and he serves as interim Medical Director for Lifebanc OPO, but declared no other potential conflicts of interest
    - Adam Wilk (Indianapolis, Indiana) is a health economist by training and Associate Professor of Surgery at the Indiana University School of Medicine in Indianapolis. He is also an investigator at the Regent Institute; he noted that the Indiana University Transplant Center work is randomized to the IOTA model but declared no other potential conflicts of interest.

Review & Approval of TEP Charter

- Ms. Healy reminded the committee of the goals for TEP input.
- Ms. Healy reviewed TEP role and Charter, noting the purpose of the TEP is to gain stakeholder input on measure development and increase transparency. She reviewed the TEP member responsibilities and confirmed the TEP's approval of the TEP Charter.

Background: Orientation to Model and Measure

- Mr. Bagshaw introduced the IOTA Model under the CMS Innovation Center, noting its purpose to increase the number of kidney transplants and improve the quality of participating hospitals. He shared the following planned implementation timeline for the IOTA Model New Measure 1, Kidney Transplant (KT) Health-related Quality of Life (HRQOL) Patient-Reported Outcome-based Performance Measure (PRO-PM) concept:
    - Target to complete development by Summer 2026;
    - Pay-for-reporting anticipated to begin July 1, 2027, and;
    - Pay-for-performance anticipated to begin July 1, 2029.
- Mr. Bagshaw defined key terminology.
    - A Patient-Reported Outcome (PRO), or a patient's personal assessment of an experience at a healthcare encounter, is measured using tools also known as PRO surveys, PRO instruments, or PRO measures (PROMs). These instruments ask the question "What did this specific patient experience?"
    - A PRO-based Performance Measures (PRO-PM) aggregates PRO survey responses from across a healthcare provider's patients to assess their care supports good outcomes, asking the question "How did this

provider's patient-centered outcomes compare to those of other providers?"

- Mr. Bagshaw provided more background information on the IOTA PRO-PM concept.
    - The focus of the measure is to 1) assess post-transplant HRQOL improvement for kidney transplant recipients at IOTA transplant hospitals and 2) encourage and improve patient-centered care that leads to better HRQOL outcomes.
    - Mr. Bagshaw shared the rationale for measuring HRQOL. He noted that quality of life generally improves after kidney transplant, and it is a useful metric to assess post-transplant outcomes and quality of care. He added that HRQOL is also an important metric for patients and stakeholders because post-transplant outcomes and peri-transplant care quality can influence post-transplant HRQOL.
- Mr. Bagshaw established the parameters of the measure based on prior decisions and direction from CMS.
    - The measure will only include adult (18 years or above) patients at the time of transplant, and patients who receive a transplant and survive long enough to complete the survey. Patients will be attributed to the hospital that performed the transplant procedure, and the PRO survey will be administered at two points in time, once pre-transplant and once post-transplant.
- Mr. Bagshaw reviewed the timeline of the measure.
    - Development began in October 2025, with work in early months focused on information gathering including an environment scan, a literature review and the identification of existing PRO instruments. More recently, work has focused on survey development, survey timing considerations, planning for analyses, and collection of expert input.
    - Future work will include refining the survey, completing pilot surveys for testing, and finalizing performance measure specifications. He added that the focus today is to finalize the basics for development of the transplant quality of life survey instrument; CORE will discuss the other topics in greater depth at future meetings.
- Mr. Bagshaw reviewed the PRO survey instrument design background information.
    - The objective is to create a valid and reliable quality of life survey that is meaningful to both recent transplants recipients and to candidates for transplant, that is easy for patients to understand and respond to, and is as low burden as possible, while still ensuring sufficient data collection

to assess hospital performance. He added that through this meeting, the timing of the survey administration will be determined.

- Ms. Healy initiated a 10-minute break.

Health Related Quality of Life (HRQOL) Domains and Questions

- Ms. Murphy began presenting the draft HRQOL survey domains and questions.
    - The goal is to survey patients both prior to and following kidney transplant to evaluate changes in HRQOL. The pre-transplant assessment serves to establish a baseline, while the post-transplant evaluation measures improvements relative to that baseline. The survey instrument must be relevant and meaningful to individuals with chronic kidney disease (CKD), end-stage renal disease (ESRD), and kidney transplant recipients. Additionally, assessments should be conducted at specified points to ensure data is comparable.
- Ms. Murphy described the survey approach.
    - The aim was to develop a de novo survey instrument to assess HRQOL in kidney transplant patients, drawing on validated survey items where possible. The draft includes both general HRQOL questions which are broadly applicable to most patients and condition-specific items that are specific to CKD, ESRD, dialysis, and transplant populations. Condition-specific questions focus on the measure population and are valuable for tracking HRQOL changes from pre- to post-transplant. The survey will undergo validation during the alpha testing phase.
- Ms. Murphy provided a brief overview of the question selection process.
    - An environmental scan and literature review were conducted to identify existing validated PRO surveys relevant to HRQOL in the target population. From this, a shortlist of the most applicable instruments was developed, prioritizing those frequently cited in the literature, relevant to the measure population, and accessible to CMS with minimal licensing constraints. Survey questions and domains from the shortlisted tools were cross-walked, and input was gathered from clinical and technical experts to identify the most clinically relevant HRQOL items. All selected items were drawn from the previously identified PRO instruments. The initial draft of the de novo survey includes:
    - A core set of generic HRQOL questions suitable for both pre- and post-transplant assessments.
        - Additional questions specific to CKD, ESRD, and dialysis, intended for the pre-transplant assessment.
        - Questions specific to post-transplant life, included in the post-transplant assessment.

- Ms. Murphy discussed the various PRO instruments from which questions were adapted for the initial draft of the KT HRQOL survey.
    - Two validated general HRQOL instruments, Patient-Reported Outcomes Measurement Information System- 16 item Profile (PROMIS-16) and 36- Item Short Form Survey (SF-36), were used to adapt broadly applicable questions. SF-36 contributes a general health domain useful for both pre- and post-transplant assessments, while PROMIS-16 covers physical, mental, and social health domains relevant to both transplant candidates and recipients.
    - Kidney disease and dialysis-specific questions were drawn from the Kidney Disease Quality of Life 36-item short form survey (KDQOL-36), a validated tool suited for the pre-transplant assessment.
    - For the post-transplant assessment, transplant-specific questions were selected from three sources: the Renal Transplant Quality of Life survey (ReTransQOL), the Transplant Effects Questionnaire (TxEQ), and the End-Stage Renal Disease-Symptom Checklist (ESRD-SCL)
- Ms. Murphy reviewed the domains of the current draft survey which consists of thirty-two questions across generic and condition-specific domains.
    - Generic HRQOL Domains (17 questions): These domains, applicable to both pre- and post-transplant assessments, include areas such as fatigue, sleep disturbance, cognitive function, and physical functioning. While broadly relevant, many are also clinically significant for pre-transplant patients, particularly those undergoing dialysis or experiencing symptoms of ESRD.
    - Kidney Disease and Dialysis-Specific Domains (4 questions): These focus on the lived experience of kidney disease and the burden of dialysis and are intended for the pre-transplant assessment.
    - Transplant-Specific Domains (11 questions): These address aspects such as quality of transplant care, medication burden, and other post-transplant quality of life concerns, and are relevant for the post-transplant assessment.
- Ms. Murphy reviewed the domains and example questions for each domain. She noted that questions either utilize a five- or six-point scale response option, and some questions included a specific recall period while others do not.
    - Generic HRQOL Domains: One question related to General Health was drawn from SF-36. The remaining generic HRQOL domains were drawn from PROMIS-16 including Physical Function, Anxiety, Depression, Fatigue, Sleep Disturbance, Social Roles and Activities, Pain, and Cognitive Function.
- Condition Specific Domains: Questions targeting the experiences of pre-transplant patients with CKD and ESRD, or those undergoing dialysis were adapted from the KDQOL-36.

        - These domains include the Burden of Kidney Disease, Symptoms of Kidney Disease and Dialysis Treatment, Effects of Kidney Disease on Daily Life and Satisfaction with Care.
        - One question under the Satisfaction with Care domain - "How true or false is the following statement? Dialysis staff support me in coping with my kidney disease" - was included due to the significant influence of dialysis facilities on pre-transplant quality of care and health-related quality of life. This decision also reflects the complex considerations surrounding the timing of the pre-transplant survey.
    - Transplant Specific Domains: Questions related to satisfaction with transplant care and concerns about graft complications.
        - One question was adapted from the KDQOL-36 Satisfaction with Care domain to focus specifically on perceptions of transplant care team quality.
        - These questions address a patient's satisfaction with medical care and follow-up, worry about graft complications, worry about the transplant, medication symptoms and adherence, and transplant-associated psychological distress domains.
- Ms. Murphy noted the draft survey will undergo validation during alpha testing, as it incorporates items from multiple pre-existing validated instruments.
    - Current efforts are focused on identifying required data elements, defining survey administration parameters, and collaborating with CMS's implementation contractor to establish methods for identifying eligible patients and linking to registry data. Alpha data collection and analysis are scheduled to begin in September.
    - Final survey content and length are still under refinement, with input from clinical and patient experts, as well as feedback from today's TEP session.
    - Key considerations moving forward include balancing generic and condition-specific content, effectively capturing post-transplant lifestyle changes, and minimizing burden on patients and clinicians while maintaining a valid and reliable instrument.

Discussion #1: Draft Survey Domains

- TEP Members were asked to complete a poll question asking if they agreed (Yes/No) with the domains identified and prioritized for inclusion in the draft KT HRQOL survey.
    - A TEP member asked to clarify if the poll refers to the prioritization of questions amongst these domains, or simply if members agreed with the total list of domains.

        - Ms. Murphy clarified that the question is whether members agree with the domains listed as a whole.
    - **Results:** Yes received 14/20 votes (70%) and No received 6/20 (30%).
- Ms. Healy announced details on the facilitation of the discussion, and noted that the question for the first discussion will be "from your perspective, does the current draft survey capture the highest priority domains?"
- A TEP member noted that she believes it does capture the priority domains but raised concerns about the clarity and relevance of some post-transplant survey questions. She noted that patients are highly concerned about graft function and are typically diligent with medications and lab work because of this concern. She finds a disconnect between the intent of the questions and the response options provided to patients, suggesting that the questions may not fully capture patient experiences or motivations.
- A TEP member asked within the chat "Can we please clarify the goals of the survey- which should be different for pre vs post?"
    - Ms. Murphy clarified that the generic questions will be included in both pre- and post-transplant assessments. However, the pre-transplant questions (which are more specific to patients with ESRD and those on dialysis) will be used only in the pre-transplant assessment, while the post-transplant questions will be used only in the post-transplant assessment. The two sets of specific questions will remain distinct and tailored to their respective stages.
    - A TEP member expressed concern that pre-transplant questions are too focused on dialysis, which is not aligned with the IOTA model or the transplant process. She suggested the questions should instead emphasize transplant-specific knowledge, like waitlist status or testing. As a transplant nephrologist, she noted they have no control over dialysis-related issues, so the pre- and post-transplant questions should be distinct, with clear goals for each.
    - A TEP member explained that quality of life changes from pre- to post-transplant depend heavily on the patient's starting point, particularly their dialysis experience. Therefore, the difference in scores between the two assessments may need to be adjusted based on pre-transplant quality of life. Dialysis-specific questions asked before transplant will help in making that risk adjustment.
    - A TEP member responded to clarify her understanding that the focus of the assessment is on post-transplant outcomes, specifically how patients are doing mentally and psychosocially after transplant' it is not intended to evaluate their pre-transplant engagement, such as knowledge about organ offers or interactions with the transplant team. She continued that, if the

goal is truly to assess post-transplant well-being, then the current questions are appropriate.
    - Mr. Bagshaw acknowledged that transplant teams have a limited influence over pre-transplant quality of life, which can vary significantly between hospitals. To ensure fairness, the goal is to adjust for these differences when evaluating post-transplant outcomes. The pre-transplant survey is primarily used to account for baseline factors, so hospitals are not unfairly penalized for serving patients with lower initial quality of life. The main focus remains on assessing the quality of transplant hospital care.
    - A TEP member clarified her understanding that pre-transplant questions serve as a baseline for assessing quality of life before transplant. After transplant, at a set interval, like six months, patients complete a post-transplant survey with both generic and transplant-specific questions. Even though the questions differ, the goal is to compare similar domains (e.g., anxiety before vs. after transplant) to evaluate changes in patient well-being.
        - Mr. Bagshaw confirmed this understanding.
- Several TEP members asked within the chat about the purpose of utilizing different pre-and-post transplant questions, the subsequent scoring approach, and suggestions for combining domains.
- A TEP member noted that waitlist experience can be relevant both pre-and-post transplant, and another TEP member agreed.
    - A TEP member asked if the PROM would have a single summary score, and noted the difficulty of utilizing multiple domains, if so.
    - Mr. Bagshaw acknowledged that final question selection and the scoring methodology are still being determined. The current approach is to test both generic and specific questions to evaluate whether generic questions alone can effectively distinguish transplant hospital quality, or if more detailed, experience-specific questions are necessary for meaningful comparisons.
- Several TEP members discussed various other factors that could impact quality of life within the chat, such as preemptive transplant versus deceased-donor transplant, dialysis setting, vintage, and modality.
    - A TEP member felt transplant teams can have some influence on patient choice of dialysis setting, and can therefore impact pre-transplant factors, while another TEP member disagreed.
    - Mr. Bagshaw acknowledged factors that can affect outcomes, such as differences between living and deceased donor kidneys, and are under consideration for risk adjustment. He assured the group that risk adjustment decisions will be addressed in detail at a future meeting. For now, the focus remains on developing and refining the initial assessment instrument.

    - Dr. Golestaneh added that planned risk adjustment factors will include dialysis vintage and experience, time on waitlist, and comorbidity.
- A TEP member raised a concern about the timing for surveying patients' pre-transplant. She noted that since patients often wait for years and their experiences change over time (e.g., switching dialysis modalities or experiencing health fluctuations), to truly measure change, the baseline should be assessed just before transplant, when it most accurately reflects the patient's current state.
    - Dr. Golestaneh acknowledged that survey timing will be discussed later in the meeting.
- A TEP member also pointed out that while the focus is on health-related quality of life, there is a lack of attention to patient engagement on the pre-transplant side. She asked if this was because of the intent of the IOTA model to focus on transplants. She noted that while post-transplant surveys include questions about satisfaction with care and follow-up under the transplant hospital care team, there is no equivalent for pre-transplant experiences—such as whether patients felt empowered in decision-making, informed about organ offers, or supported in navigating the healthcare system.
- A TEP member shared that she felt like something important was missing from the overall picture, especially from the pre-transplant perspective. She highlighted that while post-transplant psychological stress is addressed, the psychological stress experienced during dialysis is not. From a patient's viewpoint, the current approach does not feel like a "one-size-fits-all" solution. It seems more tailored to individual experiences, which may not fully capture the diversity of patient journeys.
- A TEP member restated the goal of using pre-transplant assessments to establish a consistent baseline for comparing patient outcomes post-transplant, ideally after recovery. He stressed the importance of standardizing timing and context across patients to ensure meaningful comparisons. While acknowledging that question composition may differ pre- and post-transplant, he emphasized the need for comparable data. He also highlighted the role of risk adjustment, suggesting that pre-transplant responses could help characterize the patient population at each hospital. Despite recognizing the variability and limitations of PRO-PMs, he advocated for gathering as much relevant data as possible to support a meaningful measure.
    - Dr. Golestaneh emphasized the complexity and variability in patients' pre-transplant experiences. Some are preemptive, while others have been on dialysis for many years. Because of this, the focus should be on the change in scores from pre- to post-transplant, with careful risk adjustment to account for these differences. She supported the idea of developing clear parameters for adjustment, echoing similar suggestions made in the chat.

- A TEP member shared two points. First, each patient only serves as their own control since experiences and readiness differ widely by individual. Secondly, he cautioned against survey fatigue, noting that long instruments like the 53-question dialysis Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey are often seen as too burdensome. He emphasized the need to keep the questionnaire concise and manageable.
- A TEP member agreed with previous comments, emphasizing that pre-transplant experiences vary greatly (e.g., some patients are preemptive, others have long dialysis histories, and some have experienced both). She stressed the importance of capturing as much relevant information as possible, especially around psychological stress and infection risks, both pre- and post-transplant. She urged that the tool(s) developed should be flexible and comprehensive, enabling meaningful comparisons and ultimately driving improvement in care.
- A TEP member expressed appreciation for the thoughtful discussion but raised concerns about accountability; specifically, that transplant centers should only be evaluated on factors they can control. She stressed the importance of careful inclusion/exclusion criteria and risk adjustment when measuring change. She emphasized the importance of capturing a baseline patient perspective and liked the proposed set of generic questions. However, she felt the pre- and post-transplant questions may be too generic. She acknowledged that the surveys are well-studied but felt the pre- and post- transplant questions may not detect meaningful and actionable differences.
- A TEP member agreed with previous comments and supports using generic as well as pre- and post-transplant questions. However, she emphasized that transplant centers should only be evaluated on factors they can influence. She advocated for including pre-transplant questions such as staying active on the waitlist, education on the transplant process, and understanding transplant options (e.g., living donation). These are areas where transplant centers can directly impact patient outcomes. She also suggested that dialysis-related questions should be excluded from the pre-transplant survey, as they fall outside the transplant center's control.
- A TEP member emphasized that the IOTA model represents a transformative opportunity and urged CMS to think beyond traditional, limited survey instruments. He argued that current tools are too generic and clinically focused, failing to reflect what truly matters to patients (social roles, employment, economic security, and comparative difference to a life on dialysis) rather than "measuring the same stuff that we always measure." He advocated for new, more relevant questions that capture the full patient journey, including both dialysis and transplant experiences, rather than treating them as separate. He also stressed dialysis-related factors should be included as this would overlook critical parts of the patient experience as

"it is a treatment journey from dialysis through transplant" and patients do not make distinctions between dialysis and transplant centers.
    - Dr. Golestaneh questioned how much of the improvement in lifestyle and economic outcomes after transplant can be directly attributed to the care provided by transplant centers, as opposed to other external factors. She noted that this is an important consideration when evaluating transplant outcomes.
- A TEP member agreed with previous statements on the importance of considering economic outcomes but raised additional concerns on the current draft survey. She felt the survey is too long and burdensome and questioned whether comparing pre- and post-transplant responses was necessary or practical. She noted if all waitlisted patients are surveyed, many more will complete the pre-transplant survey than will actually receive a transplant, making pre-post comparisons difficult. She concluded by noting that she shares concerns already expressed by others.
- A TEP member noted that while transplant centers may not be responsible for dialysis care, excluding dialysis-related questions could lead to an incomplete assessment of pre-transplant quality of life. He also advocated for including questions about transparency, shared decision-making, and how well-informed patients feel, as these are areas transplant centers can influence. Finally, he asked how quickly the survey needs to be implemented and raised concern that the implementation timeline may affect whether new questions can be developed and validated in time.
    - Mr. Bagshaw responded that currently the team anticipates implementation of this PRO-PM beginning in Summer 2027. He noted there may be flexibility depending on the measure development process.
- A TEP member agreed with the previous points and raised two additional concerns. First, many IOTA model participating centers will be increasing transplant volume by using marginal kidneys (e.g., those at higher risk for delayed graft function or shorter longevity), which could lead to worse outcomes or increased anxiety for some patients. This variability should be considered when evaluating post-transplant quality of life and identifying the best practices for managing these cases. Second, with many centers rapidly implementing the new model, there is limited guidance and likely to be significant variation in workflows and practices. It may take time for centers to stabilize, which could affect the reliability and comparability of early survey data.
- A TEP member supported the idea that post-transplant patients should also answer pre-transplant questions to allow for better comparisons across time. He noted that both groups experience issues like symptom burden and adherence, making overlap in questions relevant. However, he expressed concern about the length of

the survey, especially when adding demographic questions. Lastly, he advocated for including questions about waitlist transparency, such as whether patients understand their waitlist status and expected wait time, to ensure they are actively engaged in their care.

- A TEP member agreed with previous comments and expressed several concerns she wanted to further emphasize. She felt the survey is too long, which may reduce completion rates and affect data quality. She expressed that comparing pre- and post-transplant surveys can be difficult if the questions differ and since patients spend varying amounts of time on the waitlist. She questioned whether a pre-transplant survey is necessary, suggesting a post-only approach might be more practical. She noted that survey questions should align with IOTA model's goals and focus on discrete, actionable metrics that transplant centers can influence. She also speculated that if TEP members were re-polled at this point in the discussion on their agreement with the survey concept, opinions may have shifted.
- A TEP member emphasized comments by previous TEP members and added that the process of preparing for kidney transplantation should begin early, specifically in the pre-dialysis stage once a patient is referred to a nephrologist. He highlighted the importance of close collaboration between nephrologists and transplant centers. He also noted a key but often overlooked provision in the IOTA model, which is scheduled to take effect in 2027. This provision encourages transplant centers to form partnerships with "key collaborators" (e.g., other providers such as nephrologists), recognizing that nephrologists play a crucial role in the success of the transplant process. He agreed that transplant centers excluding nephrologists from this process is a significant limitation.
- A TEP member emphasized the importance of quality pre-transplant care but highlighted a major challenge: there is no universal agreement on who is responsible for each step in the pre-transplant process. These steps include patient education, assessing eligibility criteria, managing comorbid conditions, and maintaining waitlist status etc. Because of this lack of clarity, it is difficult to measure pre-transplant care effectively or hold transplant centers accountable for their role if it the pre-transplant is simply considered "baseline." He supported collecting both pre- and post-transplant patient survey data to better understand how patients' experiences evolve and to capture their reflections at different stages. He argued that greater specificity in defining responsibilities and measures on the pre-transplant side would help establish meaningful baselines and clarify what actions are within the control of transplant centers versus other providers.
- A TEP member emphasized the need for actionable quality measures in the IOTA model so providers can identify ways to improve care. While quality of life is a broad and interesting area, he stressed that the focus should be on practical, care-related improvements that transplant centers can directly influence. He expressed

skepticism about focusing efforts on areas like psychological stress, questioning whether that is the best use of resources. Additionally, he highlighted the logistical challenge of surveying all active waitlist patients annually, suggesting that any data collection or quality measure must be feasible and directly tied to improving care.

- A TEP member built upon the previous point, raising practical concerns about surveying large patient populations (e.g., 1,000+ patients), especially when some may not respond. He questioned how to handle incomplete or missing data and how that might affect the reliability of outcomes. He also stressed that the IOTA model should stay aligned with its core goal: increasing transplants. He expressed concern that if the model emphasizes perfect outcomes and patient-reported measures, it could lead to increased selectivity by transplant centers. This could result in fewer transplants overall, as centers might avoid higher-risk cases to protect their scores. He concluded that the system should not force a choice between quality and access, both need to be balanced.
- A TEP member expressed concern about the measurement accuracy of the proposed quality of life metrics in the IOTA model. She emphasized the importance of designing questions that are both meaningful to patients and providers and are measurable. If questions are too specific, such as being tailored only to pre- or post-transplant stages, it could reduce comparability and consistency across transplant centers. She recommended focusing on the core purpose of the measure: to assess and compare how transplant hospitals improve patients' quality of life. While it would be helpful to include more detailed clinical questions, she cautioned against overloading the survey, especially if it compromises the clarity, comparability, or feasibility of the measure.
- A TEP member responded to a previous point by emphasizing that while increasing transplant numbers is important, quality of life and graft longevity must also be prioritized, especially as more marginal organs are being used. She argued that HRQOL questions are essential to determine whether these transplants are truly benefiting patients. She suggested moving away from rigid distinctions between pre- and post-transplant phases, as this may cause important questions to be overlooked. However, she also acknowledged the logistical challenges of surveying large waitlists, including uncertainty about who will respond and whether surveys will be completed, which could hinder meaningful comparisons.
- Mr. Bagshaw expressed appreciation for all the feedback received and acknowledged that, due to time constraints, the team cannot respond to every comment during the meeting. However, he wanted to assure participants that all input will be reviewed, consolidated, and used to inform updated recommendations. He also clarified that the IOTA model includes multiple incentives, not just the quality-of-life measure (e.g., increase the number of transplants, improve organ acceptance rates, and enhance graft survival rates). The

HRQOL measure is intended to complement and balance these goals, not serve as the sole assessment tool.

Discussion #2: Pre-Transplant Survey Timing

- Mr. Kyle Bagshaw initiated a discussion on survey timing, including the measure goal of surveying patients both before and after transplant to provide comparable information related to health-related quality of life (HRQOL) and to minimize bias and fairly represent and compare HRQOL across transplant patients.
- Mr. Bagshaw presented the timing considerations for administering the pre-transplant survey, noting that pre-transplant HRQOL is likely affected by the quality of dialysis facility and other providers, but that other determinants can play a role either directly or indirectly including transplant assessment & waitlist experience, comorbidities, demographics, and other determinants of health. An additional factor to consider is that patients have the ability to be waitlisted at multiple hospitals.
- Mr. Bagshaw explained that pre-transplant HRQOL is a predictor of post-transplant HRQOL, however the pathways to transplant are varied and complex with some patients being waitlisted for years and dialysis experience can vary depending on method, vintage, and facility. He further noted some transplant patients (preemptive) will never experience dialysis, while other donor transplants (deceased donor) are unscheduled and often occur with only a few hours advance notice as the kidney becomes available.
    - Mr. Bagshaw noted that the only events common to all transplant recipients are 1) referral for transplant and, 2) completion of pre-transplant assessment.
- Mr. Bagshaw presented two options for administering the pre-transplant survey. The first option would be to survey patients first upon completion of the pre-transplant medical assessment that makes a patient eligible for transplant, and once annually thereafter, until they receive a transplant. The second option would be not to administer a survey before transplant at all, but instead after the transplant, ask patients to retrospectively quantify their HRQOL pre-transplant.
    - Mr. Bagshaw noted that the pros and cons for each option had been identified.
    - For Option 1, surveying patients at completion of evaluation and once annually thereafter, the benefits would be to collect more comprehensive HRQOL measurements among waitlisted patients, noting the most recent response will always be within one year before transplant. It would emphasize the importance of HRQOL as a patient-centered outcome globally that can be monitored before transplant even occurs, and the survey could be linked to annual check-ins or visits with a transplant team.

    - Disadvantages of Option 1 are that it requires surveying all eligible patients annually, increasing higher burden and risk of survey fatigue, leading to missing data. Patients on dialysis are already asked to complete a separate annual HRQOL survey administered by the dialysis facility, further contributing to burden. Lastly, it would be an overall higher cost to administer the survey using this option.
    - Option two is the more efficient option, requiring transplant recipients to only complete two surveys, minimizing patient burden and survey fatigue. It would minimize the costs of administering the survey and provide greater freedom to calibrate the timing of the survey.
    - The major disadvantage of Option 2 is the possibility of recall bias in patients' assessment of their pre-transplant HRQOL; this could be heavily affected by their post-transplant experience, compromising the validity as a strict pre-transplant measure. It would also produce a less comprehensive representation of pre-transplant HRQOL among a hospital's patients, noting it would not include patients on a waitlist who did not receive a transplant.
    - Mr. Bagshaw noted that the team intends to use Option 2 for testing purposes as a practical consideration since Option 1 cannot be implemented in a short timeframe. He noted the options for the final measure specifications are open and there will be an opportunity to revisit this conversation following initial testing results.
    - A TEP member asked in the chat if the pre-transplant survey is part of the CMS scope of work or the idea of the contractor for conducting risk adjustment.
        - Ms. Murphy confirmed in the chat that CMS is interested in a survey that can be administered pre- and post-transplant.
    - A TEP member asked in the chat if the transplant center will be responsible for administering the survey or will CMS or the contractor administer it?
        - Ms. Murphy responded in the chat that the intention is the transplant hospital would be responsible for administering the survey.
- Participants were asked to complete a poll question asking if they preferred Option 1 or Option 2 for pre-transplant survey timing.
    - A TEP member commented in the chat that she thought we should offer a poll option of "neither" or a text box for participants to put in other options.
    - A TEP member commented in the chat that neither option is ideal, to which several TEP members concurred.
        - A TEP member commented in the chat that she thought we should offer a poll option of "neither" or a text box for participants to put in other options.
        - Ms. Healy responded that there would be some time for discussion to provide feedback once the poll was completed.

- A few TEP members clarified in the chat that they did not care for either option but found option one somewhat more acceptable.
- Several TEP members noted in the chat that option one would include surveying a much larger number of patients on the waitlist, which would be a much greater burden on transplant hospitals and staff to administer.
    - One member noted that this would also increase the likelihood of missing responses as pre-transplant response rates may be low.
    - A TEP member noted that dialysis facilities already administer an annual HRQOL survey, so waitlisted patients on dialysis would be asked to complete two similar surveys each year.
    - A TEP member asked if we could access the results of the dialysis unit surveys instead.
    - Dr. Golestaneh responded in the chat to another TEP member that she believed those surveys are owned by the dialysis facilities but there may be variability.
- A TEP member commented in the chat that recall bias (a risk of option 2) has been extensively demonstrated as something to avoid whenever possible. Several TEP members agreed.
    - A TEP member commented in the chat that it would be particularly problematic in this case if the goal is to incentivize transplant centers to improve patients' HRQOL. He anticipates patients with high HRQOL post-transplant would be likely to reflect more positively on their pre-transplant care regardless of what they would have said if asked pre-transplant. This would bias downward any observed impacts transplant centers apparently have, leading to poor investment in the survey and in patient HRQOL.
- A TEP member commented in the chat that the completion of the pre-transplant assessment can be so variable and should be taken into account.
    - A TEP member responded in the chat to this comment that he agreed with the previous member noting people enter the system at so many different places.
- **Results**: Option one received 9/17 votes (53%), and Option 2 received 8/17 votes (47%).

- Three discussion questions were posed to TEP participants: 1) do you see any other pros or cons to either of these options, 2) do you see any alternative approaches for collection of pre-transplant HRQOL responses, and 3) are there any analyses you would like to see in testing that might affect your recommendation?
- A TEP member was concerned about the level of burden on transplant centers in administering a pre-transplant survey annually. She noted the personal experience of her facility having a waitlist of 1,300 patients, a majority of whom remain on the

waitlist for an average of 8-10 years, would likely not receive their transplant during the IOTA measure performance period. She also raised concerns regarding recall bias in option two and recommended finding an alternative option.
    - She also raised the role of insurance companies in the process and how it can delay referral to evaluation and referral to waitlist. On the transplant center side, she noted patients often had difficulty obtaining the necessary testing required to be added to the waitlist, and that needs to be addressed when considering quality of life.
- A TEP member presented an alternate view, sharing that there are programs that transplant patients very quickly, that there is a certain patient cohort that may be waitlisted one day and be transplanted a week later and there will not be time to complete a survey. She believes the methodology is challenged in both options provided.
- A TEP member commented in the chat that if transplant centers have limited bandwidth, and acceptance criteria are more or less strict, it would be important to measure patients who drop off the list because of morbidity and mortality as the center should be considered at least partly accountable.
- A TEP member provided a patient perspective, stating she would not want to take the survey before transplant. During the pre-transplant visits, patients already take in a lot of information and complete burdensome paperwork. She noted patients may not see value or "reward" in answering these questions; this would be an extra step that, as a patient, she would avoid because not completing it would not stop her from receiving a transplant.
- A TEP member commented in the chat that waitlist mortality is a quality metric from United Network for Organ Sharing (UNOS).
- A TEP member noted low response rates to other patient surveys.
- A TEP member, noting the concerns previously expressed about survey fatigue and survey length, questioned whether survey results could be borrowed from dialysis centers. She noted that staff should not be focused on getting surveys administered, but rather on getting patients transplanted.
    - Dr. Golestaneh responded that she believed the results of the surveys mentioned by A TEP member are kept within the domain of the dialysis facilities and questioned the availability of those results, noting it could vary state-to-state.
- A TEP member commented in the chat that surveys will always include burden and that there is never a perfect time to administer one.
- A TEP member commented in the chat that another idea might be to have only a single point in time survey, such as after transplant. She noted that it would need rigorous risk adjustment, but then the measure would be assessed based on a single score rather than a change score. As an example, if you use one or more

PROMIS PROMs, “Performance Met” might be meets or exceeds 0.5 standard deviation (SD) based on the U.S. Census data from the PROMIS measures development.

- A TEP member noted a large majority of patients who receive kidney transplants are dialysis dependent, but all providers should be striving to increase preemptive numbers and this is a patient population we would be missing if we only rely on the quality-of-life (QOL) surveys from the dialysis units. He also addressed concerns that the questions from the QOL dialysis unit surveys may not be transferable to what is looking to be captured in this measure.
    - A TEP member commented in the chat that it is a national survey not done by the dialysis facility.
    - Dr. Golestaneh responded that the dialysis staff administered these.
- A TEP member commented in the chat that it would be difficult to match survey results at a dialysis facility (which is supposed to be anonymous) to one at a transplant center. A TEP member shared some background regarding the In-Center Hemodialysis (ICH) CAHPS survey, noting that the results are publicly posted but in aggregate with five areas measured including dialysis facility and dialysis provider, and posted on the Care Compare website. He also noted that one negative of using this survey is that it requires a minimum of 30 patient responses in order to be included in the posted results, and as a previous TEP member noted, it can be a challenge for facilities to obtain that many responses. He suggested expanded use of a care facilitator/care navigator to assist dialysis patients with completing surveys, identifying living donors, and assisting with the entire dialysis/transplant process. He further expressed his support for the IOTA model and the critical need for a patient-reported outcomes (PRO) measure and urged TEP members to help CORE and CMS develop the best PRO measure possible.
- A TEP member commented in the chat that many members of the TEP do not seem to think a pre-survey is a good idea and questioned the premise that a pre-survey is needed.
    - A TEP member replied in the chat that she would say we should survey, but instead ask about health quality, education of transplant options, knowledge about organ offers, living donation, support from the transplant team, and navigation through the system to get on the waitlist.
- A TEP member asked in the chat if the survey could be done digitally.
    - Mr. Bagshaw responded to Ms. Neal in the chat stating that we are planning a digital survey for pilot testing, ultimately TBD but ideally, we would have digital and some alternative for patients to choose.
- A TEP member proposed an alternative approach to pre-transplant survey timing, stating that if there was a way to determine the average number of patient visits prior to transplant (N) then surveying patients at visit # N-1 may be the ideal time.

Going once annually is tough on patients and centers and not realistic for larger centers. She believes there is valuable information to be collected regarding the pre-transplant QOL but is concerned regarding the bias of retrospectively quantifying QOL. She questioned whether someone could help the IOTA centers identify this subset of patients and survey them in a reasonable time.
    - A TEP member supported this alternative.
    - A TEP member noted another TEP member's suggestion was an interesting approach to focus on which waitlisted candidates to survey. She then noted this would be a very challenging methodology for a center such as hers, where they transplant top, middle, and bottom of the list depending on the type of organ in order to use every organ that is humanely transplantable. She continued by noting this methodology may not be applicable to many transplant hospitals especially as transplant workflows continues to change. She does feel it is important to get pre-transplant data, and she agrees with a previous member the things that are transplant focused may be difficult to obtain. She was concerned about the pre-transplant QOL questions focused on dialysis; she recommended reviewing a dialysis facility QOL survey to determine if adequate to provide the basis for pre-transplant survey, and then only administer a post-transplant using the comparator of the dialysis centers. The negative of this approach is that it eliminates the CKD Stage 5 patients (not on dialysis) and she is unsure how to address that but still believes it should be considered.
    - A TEP member, following up on what two previous TEP members stated, noted there is a tool, United Network for Organ Sharing (UNOS) Status Services on DonorNet that will identify the group of patients that are most likely to receive a transplant in the next three months, that could be used as a starting point to look at which groups of patients could be used to lessen the burden because you will never get 100% from any group of patients. This way you would not have to survey your entire waitlist, and you could look at a percentage of responses as a place to start.
- A TEP member believed pre-transplant HRQOL measurement is crucial, as in many ways QOL after the transplant could be related to how QOL was before the transplant. He believes that the risk of recall bias is real and should be avoided. In terms of surveying a patient only when they are first evaluated for transplant, this would not be useful particularly as some patients spend several years on the waitlist and many things can change over the years. He believes it would be valuable information to see how things can change over the years and the only way to obtain this information is through a survey, noting that we cannot read a patient's mind. He further acknowledged acceptance of a level of burden and work to minimize it as much as possible and make the survey as short as possible to get the information needed.

    - Several TEP members agreed with these comments.
- A TEP member commented in the chat that a lot of patients come in for transplant and have several hours before going into the operating room (OR) and speculated a higher percentage of patients would do the survey same-day in-person immediately prior to the transplant than would fill it out on the waitlist.
    - Several TEP members agreed with this comment.
    - A TEP member replied to a suggestion that it was a great alternative and that she would certainly fill out a survey on transplant day, either paper or digitally.
    - A TEP member questioned if it could be added to the questions the on-call coordinator asks when they call patients in for a transplant, noting that they ask patients if they've had a recent illness, any changes to their health, if their caregiver plan has changed and is conducted in EPIC with questions that the team reads off and completes. She noted it was something that could potentially be added to it.
- Mr. Bagshaw addressed some of the alternative suggestions, such as having the patient take the survey just prior to transplant, noting we originally ruled out that option due to the anticipated burden to patient and hospital. Based on the support noted for this approach, Mr. Bagshaw wanted to know if members thought this approach should be reconsidered.
    - A TEP member noted that when they contact a patient for transplant, their coordinator asks a multitude of questions, inquiring about their recent health, recent blood transfusions, has their caregiver plan changed, has your insurance plan changed, etc. Potentially adding these survey questions in, because they are the people who have the greatest contact with the patient directly prior to them being admitted for transplant. She is concerned about patient response when asking how they feel after being told an organ is available for them, they will of course respond positively.
    - A TEP member agreed with the previous comments, noting that if a patient were to respond that they had been feeling unwell, that they may not receive their transplant, and that would be a concern.
    - A TEP member agreed with these comments stating it would concern her as well.
- A TEP member commented in the chat that she was concerned about comparability and measurement accuracy if different questions are asked pre- and post-transplant. She was not familiar with how change would be assessed in that scenario.
- A TEP member expressed agreement that it would not be feasible to survey every patient on the waitlist and to do it annually. She believes it would be better to obtain the data from the dialysis facilities. She noted that the health of the patients

fluctuates throughout the course of waitlisting and depending on the time the survey is administered, may catch a patient when hospitalized or recovering from a hospitalization, or they have been placed on hold, they may report something very differently that changes over the course of a few months when they have recovered. A TEP member therefore proposes that we obtain HRQOL data from dialysis centers but hopes that there is a pre-transplant survey that will capture a patient's ability to navigate the system, the waitlist readiness, education about living donation, and education about donor options. She notes that they want to engage their patients and if it is not possible to obtain HRQOL, then she hopes someone at least asks patients about their experiences. It is an actionable item for the transplant center; it is under the control of the transplant center in how they deliver that care.
    - A TEP member commented in the chat that he agreed with A TEP member, noting that asking about the waitlist experience would be really valuable data to get, it is actionable, and it contributes to quality of care and patient experience which affects QOL.
- A TEP member addressed the final bullet point on the slide concerning the analyses that members would like to see in testing that might affect their recommendation. She would want to see how much the QOL changes across these domains and do people change in different ways? Is there some type of analysis that could do to try and understand an individual's trajectory over time? She noted she would love insights from patients and clinicians, to understand how it varies and if it is a feasible thing to do.
- A TEP member commented in the chat that he believes we must try to measure patient experience with waitlist management by the transplant center, but that cannot be one time at waitlisting, or one time immediately pre-transplant because of that bias just discussed.
- A TEP member asked in the chat what do the patients and providers in this group feel would be a reasonable number of questions that patients should be asked to answer in the new survey. She noted this may be a good starting point to help prioritize domains for inclusion and how important it is to have both a pre- and post-timed survey administration.
    - A TEP member recommended 10-15 questions max rather than the 21-28 currently included.
    - A TEP member clarified that the survey that CORE sent out will only be for the initial data collection phase. Once researchers have that data (i.e., patient responses to all the questions), they can run analyses to determine which questions will make the most optimal single survey and would expect fewer questions in the final survey.
- A TEP member commented in the chat that earlier in the meeting he talked about the risk that recall bias could likely lead to transplant centers' disinvestment in the

survey and in patient HRQOL if we have a post-transplant survey only, including items that reflect pre-transplant care. He wanted to be clear that he agrees also that an HRQOL survey requirement, imposed on transplant centers and asking them to complete the survey with the evaluated or waitlisted patients annually would be very burdensome. He believes the risk there, though, is different, that this burden would lead to disinvestment in other, non-patient HRQOL-related care processes when allocating staff time to field these surveys. CMS would not want to be responsible for that either. He advocates for a goal of minimizing the burden associated with administering any one patient survey.

- A TEP member questioned the purpose of capturing QOL information at all in the context of IOTA, noting there is already a big body of literature on QOL and that in general it improves after transplant. She noted there are patients that have poor outcomes with transplant because there is no guarantee with transplant, but that is not necessarily something specific to the transplant center. She felt that surveys are not a very good tool in general due to their subjectivity, as responses are affected by the complex factors previously mentioned, such as time of collection. She felt that a survey was a poor tool to capture metrics in a model meant to drive innovation in transplant.
    - Another TEP member responded by noting that the model will change the way organs are delivered, and it is very important to get the patient's perspective to see if this changes quality, such as if giving people lower quality organs causes HRQOL to go significantly down. He noted that patient survey is the only way to measure patient-reported outcomes.
    - The TEP member responded that there are so many complex variables within transplant, whether they are transplant related, patient related, or organ related. To have a survey that captures the essence of the difference between a patient that is preemptive getting a live donor transplant versus someone who has been on the waitlist for ten years getting a transplant or a highly sensitized patient undergoing their third transplant, would be impossible. She did not think it would be possible to account for all these variables within a survey given the various complexities and challenges for different patients (such as a third-time transplant with immunosuppression challenges or rejection challenges versus someone who had poor dialysis access or poor vascular access because they have been on dialysis for so long).
        - Dr. Golestaneh responded in the chat that such factors would be accounted for as part of risk adjustment.
        - A TEP member responded that he does not think the goal here is necessarily to capture all of the nuance within the survey itself. The goal is to measure the patient's experience. Analyses working with the survey data can account for many of the factors via adjusted

analyses with linked data; not all factors must be captured within the survey in order for them to be accounted for in practice.

- A TEP member responded to the previous comment via the chat stating that she agreed with previous statements; the challenge here is to focus on the specific thing to be measured in this specific measure. High quality PROMs have extensive research demonstrating strong reliability and validity for big picture outcomes.
- A TEP member commented in the chat that the measure could remain as a pay-for-results (PFR) and not become a pay-for-performance (PFP).
- A TEP member commented in the chat whether good or bad, transplant centers are now on the hook and accountable, as a matter of policy, for many issues they were not accountable for before. Measures may help clarify what they are not truly responsible for.

Discussion #3: Post-Transplant Survey Timing

- Mr. Bagshaw explained that post-transplant surveys have an advantage of knowing when the transplant happened, making it easier for all patients to receive one survey at a standardized point of time. He presented considerations to balance any factors that could affect post-survey timing. The working assumption is that the survey should be administered at least a few months after transplant to allow for time to recover from the surgery and stabilization of the graft. We would not want to administer the survey too long after the transplant because we want to ensure that the transplant team and the hospital can still affect the outcome, they are still regularly engaging with patients and minimizing losses to follow-up over time. Literature review identified a general trend where many transplant patients stabilize within the first three months after transplant but continue to have regular appointments with the transplant team through six months. Among patients, HRQOL is generally low immediately after transplant but greatly increases by month three and typically levels out within the first year.
- CORE recommends administering the survey approximately six months post-transplant to allow patients to stabilize and establish a "new normal." The transplant team is still meaningfully involved in patient care, but that involvement begins to taper off thereafter. The survey could also be linked to the patient's routine 6-month visit. The negative to this approach is that changes in HRQOL occurring after six months would be missed, so if there is significant variation in quality of life after this point that might need to be captured, we would have to consider administering the survey at a later time.
- Participants were asked to complete a poll asking if they would support CORE's recommendation to survey post-transplant HRQOL at six months post-transplant, yes or no.

    - **Results:** The “Yes” option received 15/19 votes (79%) and the “No” option received 4/19 votes (21%).
    - TEP members were asked if they saw any other pros or cons to this recommendation, as well as if they had any alternative suggestions or considerations they would like to share.
- A TEP member explained why he voted “no” in the poll, noting that he doesn’t have an objection to the six-month post-survey time, but stated that his facility would follow up with the transplant centers when there were no active surgical issues as early as one-month post-transplant. Transplant centers typically back a one-year follow-up, and his facility consults with them by phone for any issues, never modify immunosuppression without talking with them, and they send all their office notes to them. Most transplant centers definitely want a one-year follow-up, but his facility would be happy to administer the survey at the six-month mark if that was elected.
- A TEP member commented in the chat that FDA testimony of the one-year graft survival rate is over 97%. Additionally, he noted that one year survival is also a standard clinical outcome measure for transplant drug approvals.
- A TEP member commented that he would advocate for the survey being administered at the one-year time point versus six months based on the previous comments and comments made regarding the one-year graft survival rate by another TEP member in the chat. He shared his personal experience as a transplant recipient that it has been almost a year and he is still recovering. His answer now (to a survey) would be very different now than six months ago with that degree of improvement. If the availability is there and centers are going to see patients, he doesn’t see why the survey couldn’t be administered at the one-year point, but he was sensitive to the idea that if you stretch out the wait that long might lose patients to follow-up.
- A TEP member was concerned about the timing of the post-transplant survey, noting it would be worrisome because sometimes as far as six months post-transplant a patient will see their doctor once every 2-3 months, so it would be hard to coordinate. He would prefer to survey no later than three months post-transplant because patients are still following up regularly and you can see all the issues, but by six months or even a year, you can lose track of them because they have resumed their previous life.
- A TEP member stated that 70%-80% of the patients do well post-transplant and a six-month survey may be fine, but 30% of patients experience rejection or viral infections, that have complications post-transplant, so they will not even be stable by 3-6 months. He believes a year would be the minimum time to administer the post-transplant survey to most patients, noting that 10% of patients could still be struggling with acute issues, but believes the six-month mark is still too soon.

- A TEP member stated that he recommended something closer to the one-year mark, citing how the federal government views transplants beyond CMS, for example the FDA's arguments in November 2023 that there was no need a new generation of transplant drugs based on results of a trial in which the metric was one-year survival. At that point, most patients have not only stabilized but have begun returning to regular activities such as working or taking trips and journeys, and so it might get a better, substantive mark of where their HRQOL has ended up. He recommended looking at what other federal agencies are using in relation to kidney transplant and aligning if possible.
- A TEP member agreed a previous TEP member, noting that clinicians are already beholden to one-year outcomes in other metrics such as graft survival, patient survival, and UNOS. He would argue that the majority of transplant centers are trying to do a very good job of keeping track of where their patients are at the one-year mark. After the one-year mark, some patients return to their nephrologist if comfortable, but the transplant center still has an obligation to enter information on patients at the one-year mark.
    - A TEP member acknowledged in the chat that he would support one year as a better time point for administering the post-transplant survey but would also support it being conducted at six months if that was the consensus.
    - A TEP member noted in the chat that there should be a window of up to one year for transplant programs to complete the survey.
    - A TEP member noted in the chat that she voted yes in the poll but shared the patient perspective that at the six-month mark, some patients may still be experiencing complications or adjusting to their medications which could affect their responses.
    - A TEP member suggested in the chat that patients should be stratified in terms of immediate graft function, delayed graft function, living donor, or deceased donor.
    - A TEP member commented in the chat that if six months is the best timing to catch the most survey respondents, that timing does not need to be when patients are expected to be at full function, so long as the point in time be comparable across the hospitals.
    - A TEP member commented in the chat that for older patients, a three-month follow-up may not be adequate to capture the benefit of transplant.
    - A TEP member commented in the chat that he suspects many of the folks on the call today who voted "yes" for six months would be amenable to 1-year (or something in between) as an alternative.
        - A TEP member agreed, stating that we cannot account for all those things, but should be asking whether the patient feels they are better off and whether they were treated well. It is a very important metric

(he would argue one of the most important) and recommended getting that data and risk adjusting for all the things mentioned.
    - A TEP member commented in the chat that since IOTA is a finite (six year) model, perhaps data could be collected at both 6-months and 12-months when sustainable components are maintained. This would provide the data to determine with testing which timeframe is optimal in the long run for the balance of capturing improvement without too much loss to follow-up.
- Ms. Murphy acknowledged the great and very robust conversation today and reassured members that the team will be following up post-TEP via email to provide other opportunities to provide written feedback on any of the discussion topics presented today. She also noted that the team will take time to respond more specifically to questions and topics raised in the chat during the meeting, including factors of risk adjustment and scoring approach.
    - Mr. Bagshaw also expressed his appreciation for the incredible conversation and information to review. He thanked the TEP members for their time today.
    - A TEP member thanked the Yale Team in the chat for the inclusive agenda and opportunities for all involved to substantively share views.
    - A TEP member commented in the chat that he agreed with previous comment and complimented the Yale team for managing complex conversations and processes well.

Next Steps

- Ms. Healy addressed the next steps that will be taken by the CORE project team and explained how the feedback provided by participants today will be utilized.
    - The feedback collected today will be utilized to determine best survey timing and to refine survey questions for Pilot #1 (alpha testing data collection). CORE will be reaching out to TEP members to collect additional feedback and respond to some of the comments heard today.
    - The meeting minutes and TEP summary report will be distributed for TEP member review in the coming weeks.
    - CORE expects to hold another TEP meeting focusing on the KT HRQOL PRO-PM in Winter 2025 where they will review the initial pilot testing results and further refine the survey design.
    - Finally, the first meeting focused on the IOTA process measure (IOTA-2) is anticipated for August 2025.
- The stakeholder engagement team will be reaching out to TEP members for an opportunity to debrief on their experiences at the meeting today, noting that their feedback helps to make future meetings better.

Wrap-Up

- Ms. Healy ended the meeting by thanking TEP members for their time and valuable contributions to today's meeting, and encouraged them to reach out to CORE via email (cmskidneytransplantmeasures@yale.edu) with any additional feedback or questions.