Technical Expert Panel Charter

Project Title: ***Practitioner Level Measurement of Effective Access to Kidney Transplantation***

TEP Expected Time Commitment and Dates:

4 - 6 virtual meetings, each being between 1 to 4 hours long. Meetings are tentatively scheduled in April, 2021 and subsequent meetings in May thru July, 2021.

Meetings will be held virtually, via the Zoom video conferencing platform.

Project Overview:

The Centers for Medicare & Medicaid Services (CMS) has contracted with the University of Michigan Kidney Epidemiology and Cost Center (UM-KECC) to develop practitioner-level measures in the area of access to kidney transplantation for dialysis patients. The contract name is Kidney Disease Quality Measure Development, Maintenance, and Support. The contract number is 75FCMC18D0041, task order number 75FCMC18F0001. As part of its measure development process, the University of Michigan Kidney Epidemiology and Cost Center convenes groups of stakeholders who contribute direction and thoughtful input to the measure developer during measure development and maintenance.

Project Objectives:

UM-KECC has been tasked by CMS to develop practitioner level quality measures that allow measurement of patient's access to kidney transplantation. Topic areas may include waitlist, referral, education, and other related issues.

The results of numerous studies have indicated that the recipients of renal transplants have better survival than comparable dialysis patients.[1] The ESRD Conditions for Coverage mandate a comprehensive reassessment of each patient annually (at minimum) with the revision of the Plan of Care. Both the patient assessment and Plan of Care should include reevaluation of treatment modality and transplant status. Specifically, Section 494.80(a)(10) of the revised Conditions for Coverage for ESRD Facilities, effective October 14, 2008, sets forth requirements for patient assessment with regard to transplantation referral: "Evaluation of suitability for a transplantation referral, based on criteria developed by the prospective transplantation center and its surgeon(s). If the patient is not suitable for transplantation referral, the basis for non-referral must be documented in the patient's medical record."[2] Additionally, objectives CKD-12 and CKD-13 of Healthy People 2020 have the goal to "increase the proportion of dialysis patients wait-listed and/or receiving a deceased donor kidney transplant within 1 year of ESRD start (among patients under 70 years of age)" and "increase the proportion of patients with treated chronic kidney failure who receive a transplant".[3] Substantial variations by facility

[1] Wolfe RA, Ashby VB, Milford EL, et al. Comparison of mortality in all patients on dialysis, patients on dialysis awaiting transplantation, and recipients of a first cadaveric transplant. N Engl J Med. 1999 Dec 2; 341(23):1725-30.

[2] Medicare and Medicaid Programs; Conditions for Coverage for End-Stage Renal Disease Facilities; Final Rule."*Federal Register* 73:73 (15 April 2008) p. 20479.

[3] http://www.healthypeople.gov/2020/topicsobjectives2020/objectiveslist.aspx?topicId=6

and geographic region, as well as disparities by race and socio-economic status in transplantation rates raise concerns about current processes for provision of access to transplantation.[4]

This work will build on the work of the 2015 TEP, which led to the development of two facility level metrics (the Standardized Waitlist Ratio, and the Percentage of Prevalent Patients Waitlisted).

Technical Expert Panel (TEP) Objectives:

The TEP will use existing data and their expert opinion to formulate recommendations to UM-KECC regarding the development of a draft measure that addresses potentially important quality gaps in access to transplantation. Recommended measures should be evidence based, scientifically acceptable (reliable and valid), feasible, and usable by CMS, providers, and the public.

Specifically, TEP discussions may include, but not be limited to, the following topics:

- Adaptation of the existing facility level transplant waitlist measures to the practitioner level;
- Review of prototype measure for patients active on the waitlist at the facility and practitioner level;
- Considerations for development of transplant education and transplant referral measures at the facility and practitioner level

TEP Requirements:

A TEP of approximately 9-15 individuals will evaluate measure concepts. The TEP will be composed of individuals with differing areas of expertise and perspectives, including:

- Transplant process expertise (from candidate evaluation through to transplantation) including transplant nephrologists, transplant surgeons, social workers, transplant coordinators/nursing;
- Dialysis facility perspective on referral to transplant evaluation including nephrologists, nurses, social workers
- Transplant policy expertise;
- Individuals with consumer/patient/family perspective and consumer and patient advocates; specifically, patients with experience with transplant work-up, time on the waitlist, transplantation and failed transplants
- Individuals with research expertise with Medicare data and issues pertaining to access to kidney transplantation;
- Individuals with perspectives on healthcare disparities in access to transplantation;
- Expertise in performance measurement and quality improvement

Scope of Responsibilities:

UM-KECC is seeking balanced representation of dialysis stakeholders and clinical experts representing patients and patient-advocates, dialysis providers, as well as clinical, statistical, and public health experts to evaluate several aspects of a draft quality measure intended to evaluate effective access to kidney transplantation for dialysis patients. The TEP will also have the opportunity to advance additional measure concepts via brainstorming sessions, as time allows. It is UM-KECC's intent to facilitate TEP

[4] Patzer RE et al. Dialysis facility and network factors associated with low kidney transplantation rates among United States dialysis facilities. American Journal of Transplantation 14(7):1562-1572.

discussion through presentation of background information and a description of the draft quality measure. The TEP will be led by one or two Chairpersons, whose responsibility is to lead the discussion and attempt to develop consensus opinions from TEP membership regarding the topics described in TEP Objectives section above. The TEP is intended to be advisory to UM-KECC, as UM-KECC continues to develop and refine the draft measure described in this document.

The role of each TEP member is to provide advisory input to UM-KECC.

Role of UM-KECC: As the CMS measure developer contractor, UM-KECC has a responsibility to support the development of quality measures for ESRD patients. The UM-KECC moderators will work with the TEP chair(s) to ensure the panel discussions focus on the review of draft measure specifications, as recommended by the contractor. During discussions, UM-KECC moderators may advise the TEP and chair(s) on the needs and requirements of the CMS contract and the timeline, and may provide specific guidance and criteria that must be met with respect to CMS and NQF review of revised candidate measures reflecting prevalent comorbidities.

Role of TEP chair(s): Prior to the TEP meetings, one or two TEP members are designated as the chair(s) by the measure contractor.. The TEP chair(s) are responsible, in partnership with the moderator, for directing the TEP to meet the expectations for TEP members, including provision of advice to the contractor regarding measure specifications.

Duties and Role of TEP members: According to the CMS Measure Management System Blueprint, TEPs are advisory to the measure contractor. In this advisory role, the primary duty of the TEP is to review any existing measures, provide input as to data sources and feasibility, and to suggest measure specifications. TEP members are expected to attend conference calls in 2021 and be available for additional follow-up teleconferences and correspondence as needed in order to support the submission and review of the candidate measure(s) by NQF. Some follow up activities may be needed after testing has occurred.

The TEP will review, edit (if necessary), and adopt a final charter at the first teleconference. A discussion of the overall tasks of the TEP and the goals/objectives of the ESRD Facility Level Measure Development project will be described. TEP members will be provided with a summary of peer reviewed literature and other related quality measures. TEP members will have the opportunity to submit additional studies to be included in the literature review. A review of the CMS and NQF measure development criteria will also be covered during the teleconference.

During the TEP Meetings: The TEP will review evidence to determine the basis of support for proposed measure(s). The key deliverables of the TEP include:

- Recommending draft measure specifications
- Assisting in completing the necessary documentation forms to support submission of the measures to CMS for review, and to the NQF for endorsement
- As needed TEP members may be asked to provide input to UM-KECC as they prepare responses to NQF and public comments

Following the TEP meetings the TEP chair(s) and TEP members will prepare a summary of recommendations. As necessary, the TEP chair(s) will have additional contact with UM-KECC moderators to work through any other issues. This will include votes for draft and final measures. TEP members will review a summary report of the TEP meeting discussions, recommendations, draft measure

specifications, and other necessary documentation forms required for submission to the NQF for endorsement.

Guiding Principles:

Participation as a TEP member is voluntary and the participant's input will be recorded in the meeting minutes, which will be summarized in a report that may be disclosed to the public. If a participant has chosen to disclose private, personal data, then related material and communications are not deemed to be covered by patient-provider confidentiality. Patient/caregiver participants may elect to keep their names confidential in public documents. If they chose to participate anonymously their name and information will not be included on any materials provided to the other TEP members or in the public reports. Additionally – they will be assigned a blinded alias which they will be able to use for all virtual conferencing. UM-KECC will answer any additional questions about confidentiality.

The TEP will use both verbal consensus and formal voting by secret ballot for decision-making, depending on the context of the decision. For administrative and other decisions about agenda, direction of discussion, and other minor operational decisions, informal verbal consensus directed by the TEP chairs will be utilized. In order to objectively record TEP recommendations about the validity of the quality measures presented and recommended changes, formal votes utilizing secret ballot will be employed. These techniques have been used for nearly all of clinical TEPs facilitated by the UM-KECC team over the last several years.

The measures evaluation standards included in the CMS Measures Blueprint and reflected in the National Quality Forum (NQF) criteria are presented during an early TEP teleconference, typically during the first call. This is done so that TEP Charter approval and initial direction of the TEP discussion occur after TEP members are informed of the national consensus criteria that will ultimately be used to evaluate the quality measure(s) being considered by the TEP.

All potential TEP members must disclose any significant financial interest or other relationships that may influence their perceptions or judgment. It is unethical to conceal (or fail to disclose) conflicts of interest. However, the disclosure requirement is not intended to prevent individuals with particular perspectives or strong points of view from serving on the TEP. The intent of full disclosure is to inform the measure developer, other TEP members, and CMS about the source of TEP members' perspectives and how that might affect discussions or recommendations.

Estimated Number and Frequency of Meetings:

4 - 6 virtual meetings, each being between 1 to 4 hours long. Meetings are tentatively scheduled in April 2021 and subsequent meetings in May thru July 2021.

Date Approved by TEP:

TBD

TEP Membership:

TBD