

Technical Expert Panel Charter

Project Title:

End-Stage Renal Disease Access to Kidney Transplantation Technical Expert Panel

Dates:

February – August 2015

Project Overview:

The Centers for Medicare & Medicaid Services (CMS) has contracted with The University of Michigan Kidney Epidemiology and Cost Center to develop a quality measure(s) for access to kidney transplantation. The contract name is the ESRD Quality Measure Development, Maintenance, and Support contract. The contract number is HHSM-500-2013-130171.

As part of its measure development process, CMS asks contractors to convene groups of stakeholders and experts who contribute direction and thoughtful input to the measure contractor during measure development and maintenance. For this project, TEP members will review available data on the three steps in the transplant process: referrals, waitlist, and receiving a transplant.

Background: 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 and geographic region, as well as disparities by race and socio-

¹ Wolfe RA, Ashby VB, Milford EL, Ojo AO, Ettenger RE, Agodoa LY, Held PJ, Port FK. Comment in N Engl J Med. 2000 Mar 23;342(12):893-4.

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>

economic status in transplantation rates raise concerns about current processes for provision of access to transplantation.⁴

In 2004 and 2005, ESRD Network 9/10 conducted a Technical Expert Panel (TEP) to develop transplant referral clinical performance measures.⁵ The TEP proposed three clinical performance measures, Incident Patient Discussion, Prevalent Patient Discussion, and Referral to Transplant Center, and two descriptors, Interest and Contraindication. In its report, the TEP and Contractor stated that attention and measurement of the dialysis facility side of process, without equal attention and measurement of the transplant center side of the process was shortsighted. Ensuring all appropriate dialysis patients are referred to a transplant center is important, but equally critical is what happens between the time of referral and time of wait listing for deceased donor transplantation or live donor transplantation. Therefore, two additional transplant center-specific measures were also recommended (wait listing and live donor transplantation).

Project Objectives:

The University of Michigan Kidney Epidemiology and Cost Center, through its contract with the Centers for Medicare and Medicaid Services will convene a technical expert panel to make recommendations on access to kidney transplantation measures that would be appropriate for public reporting.

TEP Objectives:

The TEP will use existing data and their expert opinion to formulate recommendations to UM-KECC regarding reevaluation and maintenance of existing measures and development of new measures that address important quality gaps. Recommended measures should be evidence based, scientifically acceptable (reliable and valid), feasible, and usable by CMS, providers, and the public.

Scope of Responsibilities:

The role of each TEP member is to provide advisory input to UM-KECC in the development of access to transplant measures for the US ESRD population.

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 development of draft measure specifications as recommended to the contractor. During discussions, UM-KECC moderators may advise the TEP and chair(s) on the needs and requirements of the CMS

⁴ Patzer RE et al, American Journal of Transplantation 14(7):1562-1572)

⁵ <http://www.therenalnetwork.org/qi/resources/TransTEPfinalrpt805.pdf>

contract and the timeline, and may provide specific guidance and criteria that must be met with respect to CMS and NQF review of candidate measures.

Role of TEP chair(s): Prior to the in-person TEP meeting, one or two TEP members are designated as the chair(s) by the measure contractor and CMS. 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 suggest candidate measures and related specifications, review any existing measures, and determine if there is sufficient evidence to support the proposed candidate measures. The level of supporting evidence is expected to vary by measure area.

TEP members are expected to participate in two to three pre-meeting teleconferences during March and April 2015, attend one in-person meeting in April of 2015 (dates are yet to be determined) in Baltimore, MD, and be available for additional follow-up teleconferences and correspondence as needed in order to support the submission and review of the candidate measures by NQF. Some follow up activities may occur after data collection and testing have 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 quality measurement project will be described. TEP members will be provided with a summary of current clinical practice guidelines, literature, and review of other related quality measures prior to the in-person meeting. TEP members will be asked 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 In-Person Meeting: The TEP will review evidence to determine the basis of support for proposed measure(s). The key deliverables of the TEP at the in-person meeting include:

- Recommending candidate measures if there is sufficient evidence to support the measures,
- 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 public comments

At the end of the two day meeting 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. After the In-Person Meeting (approximately April – August, 2015): 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:

Potential TEP members must be aware that:

- Participation on the Technical Expert Panel is voluntary.
- Input will be recorded in the meeting minutes.
- Proceedings of the in-person meeting will be summarized in a report that is disclosed to the general public.
- Potential patient participants may keep their names confidential, if they wish to do so.
- If a TEP member has chosen to disclose private, personal data, that material and those communications are not covered by patient-provider confidentiality.
- All questions about confidentiality will be answered by the TEP organizers.
- All potential TEP members must disclose any current and past activities that may pose a potential conflict of interest for performing the tasks required of the TEP.
- All potential TEP members must commit to the expected time frame outlined for the TEP.
- All issues included in the TEP summary report will be voted on by the TEP members
- Counts of the votes and written opinions of the TEP members will be included, if requested.

Estimated Number and Frequency of Meetings:

- TEP members should expect to come together for one to three teleconference calls prior to the in-person meeting held April 2015, in Baltimore, MD.
- The in-person meeting (dates to be determined).
- After the in-person meeting, additional conference calls may be needed.

Date Approved by TEP:

TBD

TEP Membership:

TBD