

## Technical Expert Panel (TEP) Charter

### **Project Title: End-Stage Renal Disease Vascular Access 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 (UM-KECC) to review the NQF endorsed Vascular Access measures (Minimizing Use of Catheters as Chronic Dialysis Access, and Maximizing Placement of Arterial Venous Fistula) and consider possible revisions to the existing measures, including potential risk adjustment.

Of the three vascular access options, the AV fistula has been widely considered the best option for long-term vascular access. AV fistulae have a longer median survival, require less costly and invasive intervention to maintain patency and are less likely to become infected than AV grafts. However, successful creation of a functional AV fistula requires the presence of adequate superficial veins and arterial supply (usually radial or brachial artery), surgical skill, and generally three months or more time after the initial surgery to allow the fistula to “mature” before use. In addition, fistulae have a higher primary non-function rate, defined as failure to mature enough to ever use successfully for dialysis compared to AV grafts. Thus, achievement of high AV fistula prevalence in a population of dialysis patients requires a concerted effort to preserve superficial veins, availability of a team member with appropriate surgical skills, proper patient selection, and future planning for access placement. Placement of a usable AV graft is associated with a much lower primary non-function rate, and does not rely as heavily on intact superficial veins compared to AV fistula creation.

Observational studies published over a decade ago highlighted the marked differences in vascular access distribution across countries represented in the early DOPPS cohort. Of note, the US dialysis population had very low AV fistula prevalence rates and some of the highest rates of tunneled venous catheter use, particularly in incident patients. In addition, major regional differences in the occurrence of AV fistula use and overall vascular access distribution were present within the US Medicare dialysis population. These data were seen as an opportunity for improvement (both for patient outcomes as well as cost reduction for the Medicare ESRD Program). The Fistula First Project was initiated over a decade ago, with the goal of increasing AV fistula use in US chronic dialysis patients. Prior to Fistula First, approximately 30% of all US dialysis patients used AV fistulae for regular dialysis access. Under the current CMS Fistula first, Catheter Last initiative, the most recent

data demonstrate that 63 % of prevalent US dialysis patients use AV fistula as regular access for dialysis.

This success has not been without some unintended outcomes. Several editorial publications have suggested that the Fistula First Project's success has resulted in greater use of tunneled catheters, or at the least, less reduction in use of tunneled catheters than could have been achieved over the last decade. These authors express concern that the price of raising the overall AV fistula rate in the population has come at the cost of prolonged catheter use, particularly in those patients who are marginal candidates for AV fistula, including the elderly and chronically ill patients. Given the increased difficulty of creating AV fistulae in patients with poor superficial veins and/or inadequate arterial supply, attempting to create an AV fistula in some subsets of the US dialysis population may result in high failure rates, resulting in longer exposure to the risks associated with use of a tunneled catheter (bacteremia, vein thrombosis, possibly inadequate dialysis). These authors advocate for increased use of AV grafts and less emphasis on AV fistulae, with the assertion that reduction in use of tunneled venous catheters should be the goal of vascular access care in chronic dialysis patients.

Of note, there is a scarcity of literature describing controlled interventional trials testing the hypothesis that attempting to create AV fistulae in old and or frail patients is associated with poorer overall outcomes. However, the model outlined by advocates for relaxed efforts at AV fistula creation in elderly and frail patients has some clinical face validity. In addition, observational studies on this topic may be particularly affected by confounding, given the importance of comorbidities and unobserved clinical factors (e.g. presence of intact superficial veins) in the outcomes of interest.

## **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 evaluate the existing NQF-endorsed vascular access measures, considering the issues raised above. Specific objectives will include:

- Review of the current NQF endorsed Vascular Access measures (Minimizing Use of Catheters as Chronic Dialysis Access, and Maximizing Placement of Arterial Venous Fistula)
- Consider revisions to the vascular access measure set
- Consider including potential risk adjustment

## **TEP Objectives:**

The current NQF-endorsed vascular access quality measures supported by CMS consider AV fistula use as a positive outcome and prolonged use of tunneled catheter as a negative

outcome, incorporating the clinical equipoise regarding these access types, effectively creating three categories of outcomes (AV fistula=positive; AV graft= neutral; prolonged use of tunneled catheter= negative). Positive incentives are provided for AV fistula creation, but dialysis providers must remain aware of the clinical impact of long term use of tunneled catheters because of the negative incentive provided for that outcome. Does this paired incentive structure reflect agreement in best practice? Considering the above discussion, we would like the TEP to evaluate this model for appropriateness, and provider recommendations on revisions to the existing vascular access measure set, including consideration of risk adjustment to account for factors that may make fistula use in certain patient subpopulations more difficult to achieve. The TEP will be asked to consider the following questions:

- Should exclusion of subcategories of patients based on age or other criteria be considered?
- Is incorporation of other risk adjustment approaches via statistical modeling appropriate?

## Scope of Responsibilities:

The role of each TEP member is to provide advisory input to UM-KECC in the development and revision of Vascular Access 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 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.

February and March 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.

**TEP Membership:** TBD

**Date Approved by TEP:**