

Technical Expert Panel (TEP) Nomination Form

Project Title:

End-Stage Renal Disease Vascular Access Technical Expert Panel

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 changes 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” or develop 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 rate of AV fistula use in dialysis patients requires a concerted effort to preserve superficial veins, availability of a team member with appropriate surgical skills, proper patient selection, and proper 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, marked regional differences in prevalence 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 consequences. Several editorial publications have suggested that the Fistula First Project's success has resulted in greater use of tunneled catheters, or at least a smaller decrease in the 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 infirm patients is associated with poorer overall outcomes. However, the model outlined by supporters 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 hampered 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 Expected Time Commitment:

- 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 Requirements:

We are seeking a TEP of approximately *nine* individuals with the following perspectives and areas of expertise:

- Subject matter expertise: Clinical providers (nephrologists and nurses) with expertise in chronic dialysis and vascular access; interventional radiologists and nephrologists; researchers in the area of vascular access; and surgeons with expertise in dialysis vascular access.
- Patient/consumer/family perspectives and experiences
- Health care disparities (experts in treatment of pediatric and geriatric population)
- Performance measurement
- Quality improvement
- Purchaser perspective
- Expertise in Medicare dialysis data

Potential TEP members must be aware that participation on the Technical Expert Panel is voluntary. As such, individuals wishing to participate on the TEP should understand that their input will be recorded in the meeting minutes. Proceedings of the TEP will be summarized in a report that is disclosed to the general public. If a participant has disclosed private, personal information by his or her own choice, then that material and those communications are not deemed to be covered by patient-provider confidentiality. Only patient participants can request to keep their names confidential. Any 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 to performing the tasks required of the TEP. All potential TEP members should be able to commit to the anticipated time frame needed to perform the functions of the TEP.

TEP members will be reimbursed for their travel expenses to the TEP in-person meeting.

Patient Nominees for TEP:

UM-KECC is seeking patients who can provide unique and essential input on these quality measures, based on their own experiences and outlooks as dialysis patients, particularly as they relate to vascular access type or related issues and complications of vascular access. Patient nominees should submit a completed and signed TEP Nomination Form and letter of interest as described below but are not required to submit a curriculum vitae.

Instructions:

Applicants/nominees must submit the following documents with this completed and signed form:

A letter of interest (not to exceed two pages) highlighting experience/knowledge relevant to the expertise described above and involvement in measure development.

Curriculum vitae or a summary of relevant experience (including publications) for a maximum of 10 pages. (Patient participants may elect to keep their names confidential in public documents.)

Disclosure of any current and past activities that may indicate a conflict of interest. As a contractor for the Centers for Medicare & Medicaid Services (CMS), UM-KECC must ensure independence, objectivity, scientific rigor, and balance in its measure development activities.*

Send the completed and signed TEP Nomination form, statement of interest, and CV to The University of Michigan Kidney Epidemiology and Cost Center (UM-KECC) with “Nomination” in the subject line at dialysisdata@umich.edu. **Due by close of business February 5, 2014, Eastern Time.**

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*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 contractor, other TEP members, and CMS about the source of TEP members’ perspectives and how that might affect discussions or recommendations.

Applicant/Nominee Information (Self-Nominations Are Acceptable):

Name, Credentials, Professional Role:

Organizational Affiliation, City, State:

Contact Information: (mailing address, telephone, email)

Person Recommending the Nominee:

Complete this section only if you are nominating a third party for the TEP. You must sign this form and attest that you have notified the nominee of this action and that they are agreeable to serving on the TEP. The measure contractor will request the required information from the nominee.

Name, Credentials, Professional Role:

Organizational Affiliation, City, State:

Contact Information: (mailing address, telephone, email)

I attest that I have notified the nominee of this action and that the nominee is agreeable to serve on the TEP.

Signature: _____

Date: _____

Applicant/Nominee's Disclosure:

Do you or any family members have a financial interest, arrangement, or affiliation with any corporate organizations that may create a potential conflict of interest? Yes/No.

If yes, please describe (grant/research support, consultant, speaker's bureau, and major stock shareholder, other financial or material support). Please include the name of the corporation/organization.

Do you or any family members have intellectual interest in a study or other research related to the quality measures under consideration? Yes/No.

If yes, please describe the type of intellectual interest and the name of the organization/group.

Applicant/Nominee's Agreement:

If at any time during my service as a member of this TEP my conflict of interest status changes, I will notify the measure contractor and the TEP chair.

It is anticipated that there will be one in-person meeting and 3-5 conference calls for this TEP. I am able to commit to attending the TEP meetings in person, by teleconference, or by mutually agreed-upon alternative means.

If selected to participate in the TEP and the measures are submitted to a measure endorsement organization (such as the National Quality Forum), I will be available to discuss the measures with the organization or its representatives and work with the measure contractor to make revisions to the measures, if necessary.

I understand that my participation on the Technical Expert Panel is voluntary. As such, I understand that my input will be recorded in the meeting minutes. Proceedings of the TEP will be summarized in a report that is disclosed to the general public. If I have disclosed private, personal data by my own choice, then that material and those communications are not deemed to be subject to any confidentiality laws.

If selected to participate in the TEP, I will keep all materials and discussions confidential until such time that CMS authorizes their release.

I have read the above and agree to abide by it.

Signature: _____

Date: _____

For patient participants only: I wish to keep my name confidential. Yes/No.