Vascular Access

Technical Expert Panel
April 22 and 23, 2015
Agenda: April 22, 2015

9:00 – 9:30  Introductions and Conflict of Interest
9:30 – 10:30 Review of literature
10:30 – 10:45 Break
10:45 – 11:45 Preliminary KECC Analyses
11:45 – 12:00 Review existing Vascular Access measures
12:00 – 1:00 LUNCH
1:00 – 3:00 Evaluation and Revision of current Vascular Access measures
Consideration of risk adjustment strategies
3:00 – 3:15 BREAK
3:15 – 5:00 Revision of current measures and draft measure specifications
Agenda: April 23, 2015

9:00 – 10:45  Draft measure specifications (continued)

10:45 – 11:00  BREAK

11:00 – 12:00  Draft measure specifications (continued)

12:00 – 1:00  LUNCH

1:00 – 2:20  Recommendations from TEP for future direction

2:20 – 2:30  Wrap-up

2:30 – 3:00  Public Comment Period
## Disclosures of potential conflicts of interest – TEP members

<table>
<thead>
<tr>
<th>Name and Credentials</th>
<th>Organizational Affiliation</th>
<th>Conflicts of Interest</th>
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</thead>
<tbody>
<tr>
<td>Monet Carnahan, RN, BSN, CDN</td>
<td>Renal Care Coordinator Program Manager Fresenius Medical Center (FMC), Franklin, TN</td>
<td>None</td>
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<tr>
<td></td>
<td>American Nephrology Nurses Association</td>
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<tr>
<td>Lynn Poole, FNP-BC, CNN</td>
<td>NCC Fistula First Catheter Last Project Clinical Lead</td>
<td>None</td>
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<tr>
<td>Joseph Vassalotti, MD, FASN, FNKF</td>
<td>Chief Medical Officer, National Kidney Foundation</td>
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<tr>
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<td>Associate Professor of Medicine, Division of Nephrology</td>
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<tr>
<td></td>
<td>Mount Sinai Medical Center, New York, NY</td>
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### Disclosures of potential conflicts of interest – TEP members (Continued)

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<th>Name and Credentials</th>
<th>Organizational Affiliation</th>
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</table>
| **Charmaine Lok, MD, MSc, FRCPC (C)** | Medical Director of Hemodialysis and Renal Management Clinics University Health Network  
Professor of Medicine  
University of Toronto, Toronto, ON | None |
| **Daniel Weiner, MD, MS** | Nephrologist, Tufts Medical Center  
Associate Medical Director, DCI Boston  
Associate Professor of Medicine  
Tufts University School of Medicine, Boston, MA | Receives salary support from DCI as a medical director. Receives some salary support for DCI for research work within DCI (10% salary support). Member of the American Society of Nephrology Public Policy Board, and as such participates in some KCP calls. There is a $2,000 per year honorarium for service on the ASN Public Policy Board. Member of the NKF KDOQI Hemodialysis Adequacy Guideline Workgroup. |
| **Rudy Valentini, MD** | Chief Medical Officer  
Children’s Hospital of Michigan (CHM)  
Professor of Pediatrics, Division of Nephrology  
Wayne State University School of Medicine | Former consultant for Gambro (2013) |
## Disclosures of potential conflicts of interest – TEP members (Continued)

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<tr>
<td>Lee Kirskey, MD</td>
<td>Attending staff, Department of Vascular Surgery Cleveland Clinic Foundation, Cleveland, OH</td>
<td>None</td>
</tr>
<tr>
<td>Derek Forfang</td>
<td>Patient Leadership Committee Chair ESRD Network 17 Board Member Intermountain End State Renal Disease Network Inc. Beneficiary Advisory Council (Vice Chair) The National Forum of ESRD Networks Board Member The National Forum of ERSD Networks San Pablo, CA</td>
<td>None</td>
</tr>
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<td>Nance Lehman</td>
<td>Board Member Dialysis Patient Citizens (DPC) Billings, MT</td>
<td>None</td>
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## Disclosures of potential conflicts of interest – UM-KECC

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<tr>
<th>Name</th>
<th>Title &amp; Organization</th>
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<tbody>
<tr>
<td>Jonathan Segal, MD, MS</td>
<td>Nephrologist/Clinical Associate Professor, Internal Medicine</td>
<td>None</td>
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<tr>
<td>Joe Messana, MD</td>
<td>Collegiate Professor of Nephrology and Professor of Internal Medicine</td>
<td>None</td>
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<td>Sehee Kim, PhD</td>
<td>Research Assistant Professor, Biostatistics</td>
<td>None</td>
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<td>Principal Scientist</td>
<td>None</td>
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<td>Research Analyst</td>
<td>None</td>
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<tr>
<td>Jie Tang</td>
<td>Research Analyst</td>
<td>None</td>
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<td>Casey Parrotte</td>
<td>Research Analyst</td>
<td>None</td>
</tr>
<tr>
<td>Jennifer Sardone</td>
<td>Research Analyst</td>
<td>None</td>
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Review of Literature
UM-KECC Literature Review

• PubMed Search: January 2010 to April 2014
  – 705 abstracted
  – 26 selected for relevance

• PubMed Search: January 2014 to January 2015
  – 337 abstracted
  – 10 selected for relevance
Literature Review Summary

• Confirmatory Studies – Vascular Access is Actionable

• Pros and Cons of Fistula First Initiatives and ESRD QIP Measures

• AVG and AVF Comparisons
  – Usable or Mature AVF is generally superior to AVG
  – AVF time to Maturation and high Primary Failure rate attenuate advantage
  – Overall AVG vs. AVF differences are less prominent than either vs. catheters

• Individualize Approach especially by age and co-morbidities – risk adjustment?

• Miscellaneous

• Future Directions
  – Hemodialysis Fistula Maturation (HFM) Study Observational Study
  – Randomized Trials AVG versus AVF - proposed to guide decision making
Patient’s Perspective on Hemodialysis Vascular Access: A Systematic Review of Quantitative Analysis

Disrupted identity

Disfigurement
- Preserving normal appearance
- Avoiding stigma
- Visual reminder of disease

Heightened vulnerability
- Dependence on a lifeline
- Bodily intrusion
- Fear of cannulation
- Wary of unfamiliar providers
- Threat of complications and failure
- Unpreparedness

Mechanization of the body
- Bonded to a machine
- Internal abnormality
- Constant maintenance

Confronting decisions and consequences
- Imminence of dialysis
- Existential thoughts

Impinging on way of life
- Physical incapacitation
- Wasting time
- Added expense
- Instigating family tension

Self-preservation and ownership
- Task-focused control
- Advocating for protection
- Acceptance

Social consequences and coping
Patient’s Perspective on Hemodialysis Vascular Access: Selected Quotations from the 6 Themes

“The only thing that reminded me of my sickness was my arm.”

Disfigurement

“My biggest fear is the clogging.”

Heightened vulnerability

“In this way the machine and body become an interwoven unit.”

Mechanization of the body
Patient’s Perspective on Hemodialysis Vascular Access: Selected Quotations from the 6 Themes

“I did not have the operation at that time because I told myself that I could resist [dialysis].”

Confronting Decisions and Consequences

“Sometimes I get a little angry. It’s hard to get my needle in place and my dialysis takes 4.5 hours.”

Impinging on Way of Life

“I scrub my arm and take care of my graft”

Self-Preservation & Ownership
Patient’s Perspective on Hemodialysis Vascular Access: Conclusion

Timely education and counseling about vascular access and building patients’ trust in health care professionals may improve the quality of dialysis and lead to better outcomes for patients with chronic kidney disease requiring hemodialysis.

This unique article describes the patient’s perspective and experience, emphasizing the importance of vascular access.

American Journal of Kidney Diseases, Volume 64, Issue 6, 2014, 937 - 953
<table>
<thead>
<tr>
<th>Access Type</th>
<th>Advantages</th>
<th>Disadvantages</th>
</tr>
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<tbody>
<tr>
<td>Tunneled hemodialysis catheter</td>
<td>Universally applicable</td>
<td>Catheter occlusion</td>
</tr>
<tr>
<td></td>
<td>Multiple potential sites available</td>
<td>Highest risk of catheter and systemic infection</td>
</tr>
<tr>
<td></td>
<td>Immediately useable</td>
<td>Vascular thrombosis/stenosis with loss of future potential arteriovenous sites</td>
</tr>
<tr>
<td></td>
<td>Venipuncture not required</td>
<td>Aesthetic concern</td>
</tr>
<tr>
<td></td>
<td>Minimal patient preparation required</td>
<td>Shortest access survival</td>
</tr>
<tr>
<td></td>
<td>Relatively low cost of placement and replacement</td>
<td>Lower blood flow rates</td>
</tr>
<tr>
<td></td>
<td>Provides access over several months</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Lower burden on cardiac function</td>
<td></td>
</tr>
<tr>
<td>Prosthetic arteriovenous graft</td>
<td>Minimal to moderate maturation time required</td>
<td>Prone to higher cost of placement and creation</td>
</tr>
<tr>
<td></td>
<td>May provide years of access</td>
<td>Higher cost of revision or repair</td>
</tr>
<tr>
<td></td>
<td>Relative ease of cannulation</td>
<td>May develop pseudoaneurysms and/or aneurysms</td>
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<tr>
<td></td>
<td>May provide opportunity for development and creation of secondary fistula</td>
<td>Moderate risk for infection</td>
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<tr>
<td></td>
<td>Low burden on cardiac function</td>
<td></td>
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<tr>
<td></td>
<td>Less prone to dialysis access-related distal ischemia (steal)</td>
<td></td>
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<tr>
<td>Autologous arteriovenous fistula</td>
<td>Provides longest access survival</td>
<td>Considerable risk for maturation failure</td>
</tr>
<tr>
<td></td>
<td>Lowest risk of access thrombosis</td>
<td>Longest time to mature</td>
</tr>
<tr>
<td></td>
<td>Lowest risk of access infection</td>
<td>May require more preoperative evaluation and testing</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Higher risk for dialysis access-related distal ischemia (steal)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>May develop aneurysms and megafistula</td>
</tr>
<tr>
<td></td>
<td></td>
<td>May have higher burden on cardiac function with high-flow arteriovenous fistula</td>
</tr>
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Pros and Cons of Fistula First

**Pro**
- Nephrology ownership
- Elevate the priority of vascular access in medical community
- Surgical Training
- Cannulation Training
- Access Coordinator
- ESRD Network and dialysis clinic staff engagement in QI

**Con**
- Perceived as rigid approach to fistula for all, although it was never intended.
- Above is reinforced by the ESRD QIP.
- Role of AVG not clearly defined.
- High primary AVF rate and prolonged time to maturation results in prolonged catheter exposure.

Semin Dial. 25(3):303-310, 2012
U.S. Vascular Access Prevalence

Seminars in Dialysis 25(3):303-310, 2012
Fistula First Catheter Last Data

CROWNWeb Data
A ‘patient first, not fistula first, but avoid a catheter if at all possible approach might be the best.
vol 2 Figure i.5 VA use during the first year of HD by time since initiation of ESRD treatment, among patients new to HD in 2012, from the ESRD Medical Evidence 2728 Form and CROWNWeb data

78% of hemodialysis patients start with a dialysis catheter
Literature Review:
AVG and AVF Comparisons

• Usable or Mature AVF is generally superior to AVG

• AVF Time to Maturation and High Primary Failure rate attenuate advantage

• Overall, AVG and AVF differences are less than either compared to catheters
Type of arteriovenous vascular access and association with patency and mortality

Kaplan-Meier survival curve for two-year mortality.
This is an example of a study that compares usable AVF and AVG.
Incident Patients
Ocak et al. BMC Nephrology 2013, 14:79
Type of arteriovenous vascular access and association with patency and mortality

Kaplan-Meier survival curve for two-year primary patency loss after first successful cannulation. This is an example of a study that compares usable AVF and AVG. Incident Patients

Ocak et al. BMC Nephrology 2013, 14:79
Hospitalization risks related to vascular access type among incident US hemodialysis patients

All-cause hospitalization rates and 95% CI according to VA type at baseline and accounting for conversions occurring within the first 6 months of follow-up (time-varying). This is an example of a study that compares usable AVF and AVG.

Hospitalization risks related to vascular access type among incident US hemodialysis patients

Cause-specific hospitalization rates and 95% CI according to VA type among patients:
(A) at baseline and
(B) accounting for conversions occurring within the first 6 months (time-varying).

This is another example of a study that compares usable AVF and AVG.

Associations between Hemodialysis Access Type and Clinical Outcomes: A Systematic Review

• Identified 3965 citations, of which 67 (62 cohort studies comprising 586,337 participants) met inclusion criteria.

• In conclusion, persons using catheters for hemodialysis seem to have the highest risks for death, infections, and cardiovascular events compared with other vascular access types, and patients with usable fistulas have the lowest risk.
Associations between Hemodialysis Access Type and Clinical Outcomes: A Systematic Review

Selection Bias – Suggests Risk Adjustment

Risk of bias in the included articles. Numbers indicate the number of articles (n=67)

Pietro Ravani et al. JASN 2013;24:465-473
Literature Review: AVG and AVF Comparisons

• Usable or Mature AVF is generally superior to AVG

• AVF Time to Maturation and High Primary Failure rate attenuate advantage

• Overall, AVG and AVF differences are less than either compared to catheters
Patency Rates of the Arteriovenous Fistula for Hemodialysis: A Systematic Review and Meta-analysis

In recent years, AVFs had a high rate of primary failure and low to moderate primary and secondary patency rates. Consideration of these outcomes is required when choosing a patient’s preferred access type.

Survival curves of cumulative patency in hemodialysis patients.

(A) 1140 patients: arteriovenous fistulas versus arteriovenous grafts (hazard ratio [HR], 0.99; 95% confidence interval [CI], 0.79–1.23).

(B) 714 patients after excluding 426 primary failures: arteriovenous fistulas versus arteriovenous grafts (HR, 0.56; 95% CI, 0.43–0.74).


- The primary failure rate was two times greater for fistulas than for grafts: 40% versus 19% (P<0.001).

- For the patients’ first access (median, 7.4 versus 15.0 months, respectively [HR, 0.99; 95%CI, 0.7921.23; P=0.85]) or for 600 with a subsequent access (7.0 versus 9.0 months [HR, 0.93; 95% CI, 0.7721.13; P=0.39]).

- Cumulative patency did not differ between fistulas and grafts, however grafts necessitated more interventions to maintain functional patency.
Vascular Access Choice in Incident Hemodialysis Patients: A Decision Analysis - Model

Concept model of simulated progression across vascular access options beginning at hemodialysis initiation. Death can be reached from all states; in all failure states, dialysis persists with a CVC. Dashed lines represent failure to achieve or loss of access patency. AVF, AV fistula; AVG, AV graft.

Vascular Access Choice in Incident Hemodialysis Patients: A Decision Analysis - Survival

Patient survival by access attempt strategy. Plots are stratified by sex and diabetes status. The x axis represents the age in years of modeled patients. The y axis represents the survival in years for modeled patients. Patient survival in years by age stratified by sex and diabetes status. AVF, AV fistula; AVG, AV graft; cath, CVC.

Overall, the advantages of an AV fistula attempt strategy lessened considerably among older patients, particularly women with diabetes, reflecting the effect of lower AV fistula success rates and lower life expectancy. These results suggest that vascular access-related outcomes may be optimized by considering individual patient characteristics.
Literature Review: The Elderly

• 6 articles

• Heterogeneous definition of elderly

• Individualized approaches emphasized
  – Life Expectancy
  – Different Risks and Benefits
  – Distinction between pre-dialysis and established on dialysis
  – Personal Preferences
Optimizing Renal Replacement Therapy in Older Adults: A Framework for Individualized Decision Making

- Life Expectancy
- Risks and Benefits of Competing Strategies
- Patient Preferences

*Kidney International* (2012) 82, 261–269
Quartiles of life expectancy after dialysis initiation by age group.

*Kidney International* (2012) 82, 261–269
Optimizing Renal Replacement Therapy in Older Adults: A Framework for Individualized Decision Making

Vascular Access

• Number Needed to Treat to Prevent one Vascular Access BSI (Table 2 data not shown)
  – AVF vs. AVG - 2 models – modest reduction in BSI
  – AVG vs. Catheter – 2 models – order of magnitude reduction BSI
  – Both of the above differences attenuated with advancing age.

• By combining quantitative estimates of benefits and harms with qualitative assessments of patient preferences, clinicians may be better able to tailor treatment recommendations to individual older patients, thereby improving the overall quality of end-stage renal disease care.

Kidney International (2012) 82, 261–269
Optimizing Vascular Access in the Elderly Patient

Framework

- Likelihood of Disease Progression Before Death
- Life Expectancy
- Risks and Benefits of Vascular Access Type
- Patient Preferences

Optimizing Vascular Access in the Elderly Patient

Pragmatic Approach Considerations

• AVF
  – Minimal co-morbidities
  – Pre-dialysis
  – Life expectancy at least 2 years (implied)

• AVG
  – Moderate co-morbidities
  – Less than 1-2 years life expectancy

• Catheter
  – Severe Co-morbidities
  – Minimal life expectancy

...all of these decisions are dependent on the access to care, time to surgical creation, expertise of the surgeon and surgical outcomes, facility practice patterns, availability of procedures to assist with maturation, and the rates of complications including catheter related bacteremia.
107 AVF in 90 patients aged 75 and older at 2 hospitals in the Netherlands.

Upper arm (Brachiocephalic) had higher primary patency at 1 & 2 years than Forearm (Radiocephalic) AVF. Secondary patency at 2 years was 57 and 50 %, respectively.

Relevant to surgical decision making since all patients had AVF.
Haemodialysis catheters increase mortality as compared to arteriovenous accesses especially in elderly patients.

Kaplan–Meier survival curve for arteriovenous access versus catheter in young and elderly haemodialysis patients.

Haemodialysis catheters increase mortality as compared to arteriovenous accesses especially in elderly patients.

Kaplan–Meier survival curve for arteriovenous access versus catheter in young and elderly haemodialysis patients.

*Nephrol Dial Transplant (2011) 26: 2611–2617*
Risk of Catheter Related Bloodstream Infection in Elderly Patients on Hemodialysis

• 274 (age 18-74) and 90 (age 75 & older) prevalent hemodialysis catheter treated patients at a single center. Similar mean catheter days.

• BSI 1.97 in younger versus 0.55 in elderly per 1000 catheter days, P<0.001.

• Conclusion: Elderly patients using catheters are at lower BSI risk than younger counterparts.

Risk of Catheter Related Bloodstream Infection in Elderly Patients on Hemodialysis

Recalibrating Vascular Access for Elderly Patients

Editorial on Murea et al.

• BSI 0.55 in elderly reflects one event every 5.4 years.

Limitations

• Small single-center study & incident patients not included.

Conclusion

• Individualized approach to vascular access in the elderly. Catheters are appropriate for some patients.

Literature Review Summary

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• Individualize Approach especially by age and co-morbidities – risk adjustment?

• Miscellaneous

• Future Directions
  – Hemodialysis Fistula Maturation (HFM) Study Observational Study
  – Randomized Trials AVG versus AVF - proposed to guide decision making
Vascular Access Measures
Preliminary Analyses
Goals

• Explore the impact of demographic and comorbidity adjustment on vascular access creation
• Evaluate surgical access success rates when including both AV Fistula and AV graft as a desired outcome
Scenario

• Incident hemodialysis patients who start treatment with a tunneled catheter
• At the end of one year, what type of vascular access is in use?
Identify incident patients from SAF. patients from July, 2012 to June, 2013

116,198 unique incident patients

exclude

906 pediatric patients

exclude

12,622 PD patients

link

CROWNWeb monthly vascular access extracts

102,674 adult, hemodialysis patients

82,661 incident patients

82,661 incident patients

exclude

CMS 2728 form: incident comorbidities

50,129 incident patients started with Catheter only

8,143 ended with Catheter

21,710 ended with AV Fistula

5,169 ended with AV Graft

14,283 died

824 received transplants

50,129 incident patients with demographic and comorbidities information
Table 1: Baseline characteristics of study population at ESRD onset and analysis results for **AVF**, compared to Catheter access (N=29,853)

<table>
<thead>
<tr>
<th>Predictor</th>
<th>Total N (%)</th>
<th>Success in AVF N=21,710 N (%)</th>
<th>Multivariate Analysis Model 1 (Unadjusted by Comorbidities)</th>
<th>OR</th>
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<td><strong>Age</strong></td>
<td></td>
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<td>18-&lt;25</td>
<td>349(1.17)</td>
<td>243(69.63)</td>
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<td>0.95(0.75, 1.2)</td>
<td>0.647</td>
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<td>25-&lt;45</td>
<td>3546(11.88)</td>
<td>2650(74.73)</td>
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<td>1.12(1.03, 1.23)</td>
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<td>45-&lt;60</td>
<td>8640(28.94)</td>
<td>6474(74.93)</td>
<td></td>
<td>1.09(1.03, 1.17)</td>
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<td>60-&lt;75</td>
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<td>8105(72.96)</td>
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<td>75+</td>
<td>6209(20.8)</td>
<td>4238(68.26)</td>
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<td>0.82(0.77, 0.88)</td>
<td>&lt;.001</td>
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<td><strong>Sex</strong></td>
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<tr>
<td>Female</td>
<td>12518(41.93)</td>
<td>8349(66.70)</td>
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<td>0.60(0.57, 0.63)</td>
<td>&lt;.001</td>
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<tr>
<td>Male</td>
<td>17335(58.07)</td>
<td>13361(77.08)</td>
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<td><strong>Race</strong></td>
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<td>White</td>
<td>19188(64.27)</td>
<td>14037(73.16)</td>
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<td>8643(28.95)</td>
<td>6053(70.03)</td>
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<td>0.87(0.82, 0.92)</td>
<td>&lt;.001</td>
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<td>Other</td>
<td>2022(6.77)</td>
<td>1620(80.12)</td>
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<td>1.52(1.36, 1.71)</td>
<td>&lt;.001</td>
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<td><strong>BMI</strong></td>
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<td>underweight(&lt; 18.5)</td>
<td>841(2.82)</td>
<td>546(64.92)</td>
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<td>0.83(0.72, 0.97)</td>
<td>0.019</td>
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<td>normal(18.5 - 24.9)</td>
<td>8024(26.88)</td>
<td>5676(70.74)</td>
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<td>overweight(24.9 – 29.9)</td>
<td>8351(27.97)</td>
<td>6162(73.79)</td>
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<td>1.14(1.06, 1.22)</td>
<td>&lt;.001</td>
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<td>obesity(&gt; 29.9)</td>
<td>12637(42.33)</td>
<td>9326(73.80)</td>
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<td>1.18(1.10, 1.26)</td>
<td>&lt;.001</td>
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<td><strong>Nursing home status</strong></td>
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<td>Yes</td>
<td>462(1.55)</td>
<td>254(54.98)</td>
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<td>0.52(0.43, 0.63)</td>
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<tr>
<td>No</td>
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<td>21456(73.00)</td>
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<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Diabetes</td>
<td>15112(50.62)</td>
<td>11181(73.99)</td>
<td></td>
<td>1.06(1.00, 1.12)</td>
<td>0.041</td>
</tr>
<tr>
<td>Other</td>
<td>14741(49.38)</td>
<td>10529(71.43)</td>
<td></td>
<td>Ref</td>
<td></td>
</tr>
<tr>
<td><strong>Nephrologist’s Care prior to ESRD</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>16237(54.39)</td>
<td>12231(75.33)</td>
<td></td>
<td>1.35(1.28, 1.43)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>No/Unknown</td>
<td>13616(45.61)</td>
<td>9479(69.62)</td>
<td></td>
<td>Ref</td>
<td></td>
</tr>
</tbody>
</table>
Table 1: Baseline characteristics of study population at ESRD onset and analysis results for **AVF**, compared to Catheter access (N=29,853)

<table>
<thead>
<tr>
<th>Predictor</th>
<th>Total N (%)</th>
<th>Success in AVF N=21,710 (%)</th>
<th>Multivariate Analysis Model 1 (Unadjusted by Comorbidities)</th>
<th>Multivariate Analysis Model 2 (Adjusted by Comorbidities)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>OR</td>
<td>P</td>
<td>OR</td>
<td>P</td>
</tr>
<tr>
<td><strong>Age</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>18-&lt;25</td>
<td>349(1.17)</td>
<td>243(69.63)</td>
<td>0.95(0.75, 1.2)</td>
<td>0.647</td>
</tr>
<tr>
<td>25-&lt;45</td>
<td>3546(11.88)</td>
<td>2650(74.73)</td>
<td>1.12(1.03, 1.23)</td>
<td>0.010</td>
</tr>
<tr>
<td>45-&lt;60</td>
<td>8640(28.94)</td>
<td>6474(74.93)</td>
<td>1.09(1.03, 1.17)</td>
<td>0.007</td>
</tr>
<tr>
<td>60-&lt;75</td>
<td>11109(37.21)</td>
<td>8105(72.96)</td>
<td>Ref</td>
<td>Ref</td>
</tr>
<tr>
<td>75+</td>
<td>6209(20.8)</td>
<td>4238(68.26)</td>
<td>0.82(0.77, 0.88)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td><strong>Sex</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>12518(41.93)</td>
<td>8349(66.70)</td>
<td>0.60(0.57, 0.63)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Male</td>
<td>17335(58.07)</td>
<td>13361(77.08)</td>
<td>Ref</td>
<td>Ref</td>
</tr>
<tr>
<td><strong>Race</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>19188(64.27)</td>
<td>14037(73.16)</td>
<td>Ref</td>
<td>Ref</td>
</tr>
<tr>
<td>Black</td>
<td>8643(28.95)</td>
<td>6053(70.03)</td>
<td>0.87(0.82, 0.92)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Other</td>
<td>2022(6.77)</td>
<td>1620(80.12)</td>
<td>1.52(1.36, 1.71)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td><strong>BMI</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>underweight(&lt; 18.5)</td>
<td>841(2.82)</td>
<td>546(64.92)</td>
<td>0.83(0.72, 0.97)</td>
<td>0.019</td>
</tr>
<tr>
<td>normal(18.5 - 24.9)</td>
<td>8024(26.88)</td>
<td>5676(70.74)</td>
<td>Ref</td>
<td>Ref</td>
</tr>
<tr>
<td>overweight(24.9 – 29.9)</td>
<td>8351(27.97)</td>
<td>6162(73.79)</td>
<td>1.14(1.06, 1.22)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>obesity(&gt; 29.9)</td>
<td>12637(42.33)</td>
<td>9326(73.80)</td>
<td>1.18(1.10, 1.26)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td><strong>Nursing home status</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>462(1.55)</td>
<td>254(54.98)</td>
<td>0.52(0.43, 0.63)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>No</td>
<td>29391(98.45)</td>
<td>21456(73.00)</td>
<td>Ref</td>
<td>Ref</td>
</tr>
<tr>
<td><strong>Primary Cause of ESRD</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diabetes</td>
<td>15112(50.62)</td>
<td>11181(73.99)</td>
<td>1.06(1.00, 1.12)</td>
<td>0.041</td>
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<td>Other</td>
<td>14741(49.38)</td>
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<td>Yes</td>
<td>16237(54.39)</td>
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<td>1.35(1.28, 1.43)</td>
<td>&lt;.001</td>
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<tr>
<td>No/Unknown</td>
<td>13616(45.61)</td>
<td>9479(69.62)</td>
<td>Ref</td>
<td>Ref</td>
</tr>
</tbody>
</table>
Table 2: Multivariate analysis establishing 1) AVF and 2) AVF/AVG after 1 year (compared to Catheter)

<table>
<thead>
<tr>
<th>Predictor</th>
<th>Multivariate Analysis 1) AVF vs Catheter (Adjusted by Comorbidities)</th>
<th>Multivariate Analysis 2) AVF/AVG vs Catheter (Adjusted by Comorbidities)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>OR</td>
<td>P</td>
</tr>
<tr>
<td><strong>Age</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>18-&lt;25</td>
<td>0.78(0.61, 0.99)</td>
<td>0.045</td>
</tr>
<tr>
<td>25-&lt;45</td>
<td>0.94(0.85, 1.04)</td>
<td>0.212</td>
</tr>
<tr>
<td>45-&lt;60</td>
<td>1.00(0.93, 1.07)</td>
<td>0.920</td>
</tr>
<tr>
<td>60-75</td>
<td>Ref</td>
<td></td>
</tr>
<tr>
<td>75+</td>
<td>0.90(0.84, 0.97)</td>
<td>0.005</td>
</tr>
<tr>
<td><strong>Sex</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>0.60(0.57, 0.64)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Male</td>
<td>Ref</td>
<td></td>
</tr>
<tr>
<td><strong>Race</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>Ref</td>
<td></td>
</tr>
<tr>
<td>Black</td>
<td>0.84(0.80, 0.90)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Other</td>
<td>1.43(1.28, 1.61)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td><strong>BMI</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>underweight(&lt;18.5)</td>
<td>0.85(0.73, 0.99)</td>
<td>0.034</td>
</tr>
<tr>
<td>normal(18.5 - 24.9)</td>
<td>Ref</td>
<td></td>
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<tr>
<td>overweight(24.9 - 29.9)</td>
<td>1.13(1.06, 1.22)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>obesity(&gt;29.9)</td>
<td>1.22(1.14, 1.30)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td><strong>Nursing home status</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>0.70(0.57, 0.85)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>No</td>
<td>Ref</td>
<td></td>
</tr>
<tr>
<td><strong>Primary Cause of ESRD</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diabetes</td>
<td>1.11(1.04, 1.19)</td>
<td>0.003</td>
</tr>
<tr>
<td>Other</td>
<td>Ref</td>
<td></td>
</tr>
<tr>
<td><strong>Nephrologist’s Care prior to ESRD</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>1.34(1.27, 1.41)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>No/Unknown</td>
<td>Ref</td>
<td>&lt;.001</td>
</tr>
</tbody>
</table>
Review existing Vascular Access measures
### NQF #0256

<table>
<thead>
<tr>
<th>Measure Title</th>
<th>Hemodialysis Vascular Access- Minimizing use of catheters as Chronic Dialysis Access</th>
</tr>
</thead>
<tbody>
<tr>
<td>Measure Description</td>
<td>Percentage of patients on maintenance hemodialysis during the last HD treatment of study period with a chronic catheter continuously for 90 days or longer prior to the last hemodialysis session.</td>
</tr>
<tr>
<td>Numerator</td>
<td>Patients who were continuously using a chronic catheter as hemodialysis access for 90 days or longer prior to the last hemodialysis session during the study period.</td>
</tr>
<tr>
<td>Denominator</td>
<td>Patients on maintenance hemodialysis during the last HD treatment of study period.</td>
</tr>
<tr>
<td>Exclusions</td>
<td>Patients on acute hemodialysis, peritoneal dialysis, or patients &lt;18 years of age.</td>
</tr>
<tr>
<td>Measure Title</td>
<td>Hemodialysis Vascular Access- Maximizing Placement of Arterial Venous Fistula (AVF)</td>
</tr>
<tr>
<td>---------------</td>
<td>----------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Measure Description</td>
<td>Percentage of patients on maintenance hemodialysis during the last HD treatment of month using an autogenous AV fistula with two needles</td>
</tr>
<tr>
<td>Numerator</td>
<td>Patients who were on maintenance hemodialysis (HD) using an autogenous AV fistula with two needles at the last HD treatment of month</td>
</tr>
<tr>
<td>Denominator</td>
<td>Patients on maintenance hemodialysis during the last HD treatment of month including patients on home hemodialysis</td>
</tr>
<tr>
<td>Exclusions</td>
<td>Patients on acute hemodialysis, peritoneal dialysis, AVF and AVG reported, or patients &lt;18 years of age</td>
</tr>
<tr>
<td>Measure Title</td>
<td>Vascular Access—Functional Arteriovenous Fistula (AVF) or AV Graft or Evaluation for Placement</td>
</tr>
<tr>
<td>---------------</td>
<td>-------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Measure Description</td>
<td>Percentage of ESRD patients aged 18 years and older receiving hemodialysis during the 12-month reporting period and on dialysis &gt;90 days who: (1) have a functional autogenous AVF; (2) have a functional AV graft; or (3) have a catheter but have been seen/evaluated by a surgeon for a functional AVF or AV graft at least once during the 12-month reporting period</td>
</tr>
<tr>
<td>Numerator</td>
<td>As listed above</td>
</tr>
<tr>
<td>Denominator</td>
<td>All ESRD patients aged 18 years and older receiving hemodialysis during the 12-month reporting period and on dialysis for greater than 90 days.</td>
</tr>
<tr>
<td>Exclusions</td>
<td>None</td>
</tr>
<tr>
<td>Measure Title</td>
<td>Optimal End Stage Renal Disease (ESRD) Starts</td>
</tr>
<tr>
<td>---------------------</td>
<td>---------------------------------------------</td>
</tr>
<tr>
<td>Measure Description</td>
<td>Percentage of new ESRD patients who experience a planned start of renal replacement therapy by receiving a preemptive kidney transplant, by initiating home dialysis, or by initiating outpatient in-center hemodialysis via AVF or AVG.</td>
</tr>
<tr>
<td>Numerator</td>
<td>The number of new ESRD patients who initiate renal replacement therapy in the twelve month measurement period with an optimal ESRD therapy (specific optimal ESRD therapies are defined in section S.6).</td>
</tr>
<tr>
<td>Denominator</td>
<td>The number of patients who receive a preemptive kidney transplant or initiate long-term dialysis therapy (do not recover kidney function by 90 days) for the first time in the twelve month measurement period</td>
</tr>
<tr>
<td>Exclusions</td>
<td>None</td>
</tr>
</tbody>
</table>
Evaluation of current Vascular Access measures
Draft measure specifications
Measure Evaluation Criteria

- Evidence, Performance Gap, and Priority (Impact) - Importance to Measure and Report
- Reliability and Validity - Scientific Acceptability
- Feasibility
- Usability
- Comparison to Related or Competing Measures (Harmonization)
Measure Specification

- Numerator
- Denominator
- Exclusions
- Risk Adjustments
Data Sources

• CrownWeb

• Claims

• Medical Evidence Form (CMS 2728)
Recommendations from TEP for future direction
Wrap Up
Public Comment
Agenda: April 23, 2015

9:00 – 10:45 Draft measure specifications

10:45 – 11:00 BREAK

11:00 – 12:00 Draft measure specifications (continued)

12:00 – 1:00 LUNCH

1:00 – 2:20 Recommendations from TEP for future direction

2:20 – 2:30 Wrap-up

2:30 – 3:00 Public Comment Period
Tasks

• Both Measures
  – Determine how to categorize patients with more than one access
  – Recommendation Data Source: CROWNWeb vs. Claims
  – Numerator / Denominator Statements

• Catheter Measure
  – Review exclusion criteria
  – Decide if there is rationale for changing the time frame (e.g. >90 days)

• AVF Measure
  – Review Risk adjustment
## Access Type

<table>
<thead>
<tr>
<th>Category</th>
<th>Access in Use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cath</td>
<td>Catheter Only</td>
</tr>
<tr>
<td>Cath</td>
<td>Catheter with maturing AV Fistula or AV Graft</td>
</tr>
<tr>
<td>Cath</td>
<td>AV Fistula with Catheter (using both or AVF only, but catheter still present)</td>
</tr>
<tr>
<td>Cath</td>
<td>AV Graft with Catheter (using both or AVG only, but catheter still present)</td>
</tr>
<tr>
<td>AVF</td>
<td>AVF (no catheter present)</td>
</tr>
<tr>
<td>AVG</td>
<td>AVG (no catheter present)</td>
</tr>
<tr>
<td>AVG</td>
<td>AVF + AVG: two separate accesses with one needle in each; if two needles in one access it should be considered as above</td>
</tr>
<tr>
<td>Other</td>
<td></td>
</tr>
</tbody>
</table>
Data Sources

• Medicare Claims:
  – Pro: clear definition of when a catheter is present
  – Con: only Medicare beneficiaries

• CROWNWeb:
  – Pro: All dialysis patients
  – Con: Unable to detect when a catheter is present but not being used
Medicare Claims

- Modifier V5 - Any Vascular Catheter (alone or with any other vascular access),
- Modifier V6 - Arteriovenous Graft Only (2 needles)
- Modifier V7 - Arteriovenous Fistula Only (2 needles)

**Instructions:** Modifier V5 must be entered if a vascular catheter is present even if it is not being used for the delivery of the hemodialysis. In this instance 2 modifiers should be entered, V5 for the vascular catheter and either V6 or V7 for the access that is being used for the delivery of hemodialysis.
Medicare Claims Reporting

- V5: Catheter (alone or with other vascular access)
- V6: AVG only with 2 needles
- V7: AVF only with 2 needles
- V5 + V6: AVG with catheter
- V5 + V7: AVF with catheter
CROWNWeb

- AVF only (2 needles; no catheter in place)
- AVF with Catheter (1 needle and 1 lumen, or two needles with catheter still present)
- AVG only (2 needles)
- AVG with Catheter (1 needle and 1 lumen)
- Catheter only (option to indicate if maturing AVF/AVG is present)

- Note: If catheter is present, but not being used, it is considered AVF or AVG
Data Source Recommendation

• Current: Measure is designed for CROWNWeb, but can be calculated with Claims. Claims data are used to calculate measures for public reporting: (e.g. QIP)
• Recommendation: CROWNWeb.
  — Change instructions
Catheter Denominator

• All patients at least 18 years old who are determined to be maintenance hemodialysis patients (in-center and home HD)

• Exclusions:
  – [Pediatric patients (<18 years old)]
  – Acute hemodialysis (<91 days)
  – As previously defined (limited life expectancy etc)
Catheter Exclusion Criteria (appropriate for catheter)

- limited life expectancy (e.g. < 6 months)
  - Hospice care
  - Metastatic Cancer
  - End stage liver
    - Non-transplant candidates
  - End stage heart disease (advanced cardiomyopathy)
  - Other: tbd

- Exhausted anatomic options
  - Attestation: validation issues
  - External documentation? Documentation by IDT and one other qualified professional (surgeon / interventional)

- Scheduled Kidney transplant?
- Transient modality from PD complications
- transient modality < 90 from PD
- Delayed transplant graft function
Options

1. Evaluation by qualified external professional (vascular access surgeon/interventional radiologist/neph)
   With documentation
   With reporting option

   Are you in favor of removing anatomic exclusion:
   YES / NO

2. Remove from exclusion
   With consensus statement from group
Re-Vote

• Should “exhausted anatomic options with documentation” be included as an exclusion criteria for catheter measure?
  – **Include**: includes this category as an exclusion criteria for the catheter measure
  – **Don’t Include**: this category will **not** be considered as an exclusion criteria
Catheter Numerator

• Patient-months in the denominator who were on maintenance hemodialysis with a chronic catheter continuously for 90 days or longer prior to the last hemodialysis session of the month.
  – From date of first dialysis for all patients
  – With one or more dialysis catheters for > 90 days without the use of AVF or AVG in the interim
Catheter: Other recommendations

• Date access type for dialysis changed: include explicit instructions not to change date when tunneled catheter exchanged for infection/malfunction?

• Change instructions to CROWNWeb: AVF only means 2 needles and no catheter; use AVF and catheter category for either one needle and one lumen or AVF with 2 needles but catheter is still present.
AVF Access

• Risk Adjustment for conditions when AVG acceptable:
  – Life expectancy short (age)
  – AVF success rate low
    • Age
    • DM
    • Vascular disease: peripheral, cerebral vascular, cardiovascular
    • BMI low/high

  – Sex/Race: disparity vs. biologic
AVF Numerator

• The numerator will be determined by counting the patient months in the denominator who were on maintenance hemodialysis using an AV fistula with two needles and without dialysis catheter as the means of access at the last treatment of the month.
AVF Denominator

- All patients at least 18 years old who are determined to be maintenance hemodialysis patients (in-center and home HD)
- Exclusions:
  - [Pediatric patients (<18 years old)]
  - Acute hemodialysis (<91 days)
Recommendations from TEP for future direction
Wrap Up
Public Comment