

ESRD Vascular Access TEP Summary Report

April 22 & 23, 2015

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ESRD Vascular Access Technical Expert Panel Summary

The University of Michigan Kidney Epidemiology and Cost Center, through its contract with the Centers for Medicare and Medicaid Services, convened a technical expert panel to evaluate the existing NQF-endorsed vascular access measures. Specific objectives 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

Technical Expert Panel Objectives

The objectives of the ESRD Vascular Access TEP were described in the charter that was approved by the TEP members prior to the in-person meeting. The TEP was tasked with reviewing the current NQF-endorsed vascular access quality measures developed by CMS, which consider AV fistula use as a positive outcome and prolonged use of tunneled catheter as a negative outcome. These two measures, used together, incorporate 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 and maturation, 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. The TEP was asked to evaluate these measures for appropriateness, and provide 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.

Technical Expert Panel Meeting

The ESRD Vascular Access Technical Expert Panel (TEP) met in Baltimore, MD on April 22 and 23, 2015.

The following individuals participated in this TEP:

Name and Credentials	Organizational Affiliation, City, State	Conflicts of Interest
Joseph Vassalotti, MD, FASN, FNKF TEP Chair	<i>Chief Medical Officer, National Kidney Foundation Associate Professor of Medicine, Division of Nephrology Mount Sinai Medical Center, New York, NY</i>	None
Monet Carnahan, RN, BSN, CDN	<i>Renal Care Coordinator Program Manager Fresenius Medical Center (FMC), Franklin, TN American Nephrology Nurses Association</i>	None
Derek Forfang	<i>Patient Leadership Committee Chair ESRD Network 17 Board Member</i>	None

Name and Credentials	Organizational Affiliation, City, State	Conflicts of Interest
	<p>Intermountain End State Renal Disease Network Inc.</p> <p><i>Beneficiary Advisory Council (Vice Chair)</i> The National Forum of ESRD Networks</p> <p><i>Board Member</i> The National Forum of ERSD Networks</p> <p>San Pablo, CA</p>	
Lee Kirskey, MD	<p><i>Attending staff</i>, Department of Vascular Surgery Cleveland Clinic Foundation, Cleveland, OH</p>	None
Nance Lehman	<p><i>Board Member</i> Dialysis Patient Citizens (DPC) Billings, MT</p>	None
Charmaine Lok, MD, MSc, FRCPC (C)	<p><i>Medical Director of Hemodialysis and Renal Management Clinics</i> University Health Network</p> <p><i>Professor of Medicine</i> University of Toronto, Toronto, ON</p>	None
Lynn Poole, FNP-BC, CNN	<p><i>NCC Fistula First Catheter Last Project Clinical Lead</i> ESRD National Coordinating Center Lake Success, NY</p>	None
Rudy Valentini, MD	<p><i>Chief Medical Officer</i> Children’s Hospital of Michigan (CHM)</p> <p><i>Professor of Pediatrics, Division of Nephrology</i> Wayne State University School of Medicine</p>	Former consultant for Gambro (2013)
Daniel Weiner, MD, MS	<p><i>Nephrologist</i>, Tufts Medical Center <i>Associate Medical Director</i>, DCI Boston</p> <p><i>Associate Professor of Medicine</i> Tufts University School of Medicine, Boston, MA</p>	<p>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</p>

Name and Credentials	Organizational Affiliation, City, State	Conflicts of Interest
		per year honorarium for service on the ASN Public Policy Board. Member of the NKF KDOQI Hemodialysis Adequacy Guideline Workgroup.
Contractor Staff		
Jonathan Segal, MD, MS	Nephrologist/Clinical Associate Professor, Internal Medicine	None
Joe Messana, MD	Collegiate Professor of Nephrology and Professor of Internal Medicine	None
Sehee Kim, PhD	Research Assistant Professor, Biostatistics	None
Claudia Dahlerus, PhD, MA	Principal Scientist	None
Shu Chen	Research Analyst	None
Jie Tang	Research Analyst	None
Casey Parrotte	Research Analyst	None
Jennifer Sardone	Research Analyst	None

At the in person meeting, the following additional conflict of interest disclosures were provided:

- Joseph Vassalotti: Both volunteer and paid consultant for the Fistula First project since 2005; currently Lead Clinician Consultant for the ESRD National Coordinating Center that includes the Fistula First Catheter Last quality improvement project
- Lee Kirksey: Speaker and consultant for graft companies; PI on fistula studies
- Charmaine Lok: Past consultant for fistula and graft companies; PI on study regarding fistula creation

1. Introduction

This report summarizes the discussions and recommendations of the ESRD Vascular Access Technical Expert Panel (TEP) meeting convened on April 22 and 23, 2015 in Baltimore, MD. The TEP discussion was informed by a review of relevant clinical guidelines and literature as part of an environmental scan conducted by UM-KECC. Potential measure elements were evaluated using the criteria for clinical performance measures adopted by the National Quality Forum (NQF) and CMS. These criteria include each measure's importance, scientific acceptability, feasibility, and usability.

2. Overview of Measure Areas to be Discussed

The TEP has been charged with reviewing 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 be used 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, use of vascular mapping to detect appropriate vein caliber, 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. Vascular access experts and clinical practice guidelines recommend use of Duplex ultrasound to detect relatively deep vessels. For example, the basilic vein can be utilized to create an AV fistula on the basis of Duplex ultrasound.

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.

3. Preliminary Activities

3.1 Environmental Scan and Literature Review

Prior to the in-person TEP meeting, UM-KECC presented the TEP members with a summary of existing clinical guidelines and published literature relating to vascular access in dialysis patients. As a result of the TEP's review of the literature scan, an additional 4 articles were added to the literature review and referenced during the TEP deliberations. These supplementary citations are notated with an asterisk in the annotated bibliography.

Clinical Practice Guidelines that were provided in the literature review included guidelines from The National Kidney Foundation Kidney Disease Outcomes Quality Initiative (NKF KDOQI), The Kidney Health Australia - Caring for Australasians with Renal Impairment (KHA-CARI), The Renal Association, European Renal Best Practice, and the Canadian Society of Nephrology.

UM-KECC also provided the TEP with a summary of existing vascular access measures. This summary included the two NQF endorsed CMS measures (NQF #0256: Hemodialysis Vascular Access- Minimizing use of catheters as Chronic Dialysis Access and NQF #0257: Hemodialysis Vascular Access- Maximizing Placement of Arterial Venous Fistula) and two physician level measures that are currently under NQF review (#0251: Vascular Access—Functional Arteriovenous Fistula (AVF) or AV Graft or Evaluation for Placement” and #2594: Optimal End Stage Renal Disease (ESRD) Starts).

3.2 TEP Charter

The Vascular Access TEP Charter was distributed to the TEP members for review. The Charter was approved by the nine TEP members before the in-person meeting.

3.3 Pre-TEP Teleconference Calls

One teleconference call preceded the in-person TEP meeting. The April 3, 2015 pre-TEP conference call focused on the introduction of TEP members, the role of the TEP, and an overview of the measure development process.

4. In-Person TEP Meeting

4.1 Review of Literature

The TEP chair provided an overview of recent vascular access literature, including some of the articles that UM-KECC had selected for review (included in the annotated bibliography). The TEP discussed the existing literature, which fell largely into the following categories:

- Confirmatory studies (indicating that vascular access is actionable)
- Studies that examine the pros and cons of Fistula First initiatives and ESRD QIP vascular access measures
- Comparisons of AV Grafts to AV Fistulas. The literature in this area focused on a few important issues, including:
 - Whether a usable or mature AV fistula is generally superior to an AV graft
 - Whether the AV fistula time to maturation and high primary failure rate attenuates their advantage compared to an AV graft
 - Whether the differences between AV grafts and AV fistulas are less prominent than either when compared to catheters
- Studies that examine an individualized approach to access, especially by age and co-morbidities

4.2 Review of Preliminary Analyses

UM-KECC provided an overview of a preliminary analysis performed in preparation for the TEP. The goals of this analysis were to explore the impact of demographic and comorbidity adjustment on vascular access creation, and to evaluate surgical access success rates when including both AV Fistula and AV graft as a desired outcome. The analysis examined a common scenario in dialysis facilities by examining the vascular access type in use at the end of one year for incident hemodialysis patients who start hemodialysis treatment with a tunneled catheter.

This analysis described the baseline characteristics of the study population at ESRD onset. The results of this analysis were fairly consistent with literature. Those patients in the 75 and older age group were 18% less likely to have a fistula in use compared to the reference group (age 60-74). Women were 40% less likely to have a fistula, and Blacks were 13% less likely compared to whites. In addition, obese patients compared to those that were underweight, and those who received pre-ESRD care were more likely to have fistula, respectively. Nursing home patients were about half as likely to have a fistula by one year; however UM-KECC did note that for this analysis, nursing home status is defined as an ESRD patient who appeared in the Minimum Data Set (MDS) at any point during the year, therefore it does not reflect continuous nursing home care.

When the analysis is adjusted for comorbidities (from Medicare claims and the 2728), there is a slight increase in the fistula rate for patients over 75 and for nursing home patients. The rest of the groups remained fairly stable. Lastly, UM-KECC presented an analysis with fistulas OR grafts as the outcome (adjusted for comorbidities). In this analysis, the over 75 age group again improved slightly (to only 5% less likely, and was no longer significant). Fistula rate was slightly higher for women, Blacks, and nursing home patients.

UM-KECC reinforced that this was only a preliminary analysis, and further work is continuing on these analyses. One TEP member noted the competing risk of death, which is not randomly distributed across access types. UM-KECC acknowledged this, and explained that they are planning to examine this issue further.

4.3 Review of Existing Vascular Access Measures

The TEP reviewed four existing vascular access measures. The first two measures (#0256 and #0257) are the existing CMS measures, implemented in the ESRD Quality Incentive Program (QIP) and on Dialysis Facility Compare (DFC).

NQF #0256: Hemodialysis Vascular Access- Minimizing use of catheters as Chronic Dialysis Access

Measure Description	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.
Numerator	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.
Denominator	Patients on maintenance hemodialysis during the last HD treatment of study period.
Exclusions	Patients on acute hemodialysis, peritoneal dialysis, or patients <18 years of age.

UM-KECC noted that this measure is currently under NQF maintenance review and NQF has been notified that this TEP is taking place.

One TEP member noted that this measure is potentially subject to gaming in CROWNWeb. The way the data elements are currently specified, within a 90 day period one catheter could be removed and another reinserted before the 90- day mark. This would reset the 90 day time period and the patient would be excluded from the measure even if they had > 90 days of catheter exposure. UM-KECC noted that it is within the scope of the TEP to make recommendations on CROWNWeb data elements to address such issues, so this could be a point of discussion.

Another TEP member was concerned about the 90 day requirement. Limiting to greater than 90 days means that the measure does not account for overall catheter exposure, which is a concern. It was noted that there are reasons for the 90 day rule, including the Medicare ESRD benefit (begins after 90 days), and the fact that the dialysis facility staff does not interact with the patient until they start treatment in the clinic (and it can take months to place a permanent access and allow it to mature).

NQF #0257: Hemodialysis Vascular Access- Maximizing Placement of Arterial Venous Fistula (AVF)

Measure Title	Hemodialysis Vascular Access- Maximizing Placement of Arterial Venous Fistula (AVF)
Measure Description	Percentage of patients on maintenance hemodialysis during the last HD treatment of month using an autogenous AV fistula with two needles
Numerator	Patients who were on maintenance hemodialysis (HD) using an autogenous AV fistula with two needles at the last HD treatment of month
Denominator	Patients on maintenance hemodialysis during the last HD treatment of month including patients on home hemodialysis
Exclusions	Patients on acute hemodialysis, peritoneal dialysis, AVF and AVG reported, or patients <18 years of age

Like measure #0256, UM-KECC noted that this measure is also currently under NQF maintenance review, and NQF has been notified that this TEP is taking place.

NQF #0251: Vascular Access—Functional Arteriovenous Fistula (AVF) or AV Graft or Evaluation for Placement

Measure Description	Percentage of ESRD patients aged 18 years and older receiving hemodialysis during the 12-month reporting period and on dialysis >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
Numerator	As listed above
Denominator	All ESRD patients aged 18 years and older receiving hemodialysis during the 12-month reporting period and on dialysis for greater than 90 days.
Exclusions	None

This measure is a physician-level measure developed by the Kidney Care Quality Alliance (KCQA). The measure is currently endorsed, and is under NQF maintenance review.

One TEP member asked how data are obtained for the third requirement (“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”). Some TEP members expressed concern that the 12 month requirement in the KCQA measure does not create any sense of urgency for placement of a non-catheter vascular access. UM-KECC explained that this measure is currently implemented in the Physician Quality Reporting System (PQRS), but that data are currently not available to UM-KECC. It is not collected through CROWNWeb or Medicare claims.

NQF #2594: Optimal End Stage Renal Disease (ESRD) Starts

Measure Description	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.
Numerator	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).
Denominator	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.
Exclusions	None

This measure is a new measure proposed by The Permanente Federation, LLC. This is a physician-level measure, and is currently only used internally by the Permanente Federation to track the performance of 6 Kaiser Permanente Regions. It was included here for review because it considers both fistulas and grafts to be positive outcomes. One TEP member noted that the individual Large Dialysis Organizations (LDOs) are collecting this information locally. Another TEP member noted that individual physician or clinic attribution of this measure is challenging given care fragmentation in most U.S. health care settings.

4.4 Discussion of existing measures

NQF #0256: Hemodialysis Vascular Access- Minimizing use of Catheters as Chronic Dialysis Access

The TEP began their discussion of the existing CMS catheter measure by discussing possible exclusions for the measure, based on circumstances where catheter use may be appropriate or necessary. All TEP members agreed that catheters should be considered a negative outcome, but they also recognized that there is a role for catheters in some patients.

Proposed exclusions

The TEP developed the following list for consideration:

- For patients with limited life expectancy
- For a patient who knows they are going to get a transplant in a certain time frame
- For patients who have been on dialysis for a long time with a lot of failed AV accesses (they have exhausted their anatomic options)
- PD patients who develop complications (transient HD patients before returning to PD)
- Patients who experience delayed transplant graft function
- Patient preference

The group discussed the possibility of an exclusion for patient preference, but ultimately decided against it due to the fact that it would be hard to capture and be subject to manipulation by providers. After further discussion, the proposed exclusions for patients who are scheduled for a transplant and patients who experience delayed transplant graft function were removed from consideration, as they were not anticipated to be a significant percentage of the population. In addition, the group decided to limit the exclusion for peritoneal dialysis patients who are transiently receiving hemodialysis to less than 90 days.

The exclusion for patients with limited life expectancy will require additional information and analysis before it can be specifically defined. The TEP developed an initial list of conditions for UM-KECC to investigate. The proposed list includes (but is not limited to):

- Patients under hospice care
- Patients with metastatic cancer
- Patients with end stage liver disease that are not candidates for liver transplant
- Patients with end stage heart disease (advanced cardiomyopathy) who are not candidates for heart transplant
- Other (to be determined)

The recommendations outlined later in this report will include the general exclusions for limited life expectancy, and the TEP will continue to discuss the specific definition.

The TEP spent a significant amount of time discussing the proposed exclusion for patients who have exhausted anatomic options for permanent access. Everyone was in agreement that “exhausted anatomic options” is an important exclusion, but they also recognized that it would be hard to implement. Some TEP members felt that it would be very difficult to get a reliable/trustworthy indicator of this without the risk of abuse. Others felt that if the dialysis facility had to have the vascular access surgeon or other qualified access professional provide an attestation that the patient had exhausted all anatomic options, to satisfy the exclusion requirement.

The TEP voted on whether to include this exclusion as part of the measure. The question “should *exhausted anatomic options with documentation* be included as an exclusion criteria for catheter measure?” was posed to the group, and 6 TEP members were in favor of adding the exclusion to the measure. 3 TEP members were opposed. The recommendations later in this report will include this exclusion. More work will need to be done by the TEP and UM-KECC to develop the requirements for documentation of this exclusion. One TEP member suggested that this exclusion could potentially be monitored by CMS if enacted.

Thresholds

A number of TEP members expressed interest in setting a threshold for a catheter rate. Setting a threshold of achievement (such as a 10% or lower catheter rate) would allow facilities to treat a certain amount of patients with a catheter, which could account for those patients for which a catheter is the preferred access. This would address the concern about the difficult to define exclusion criteria.

CMS and UM-KECC acknowledged the desire for a threshold, but noted that there would need to be strong evidence to support that threshold. In addition, CMS indicated that use of a threshold related more to the implementation of the measure, than the actual development and design of the quality measure specifications. The TEP agreed to review preliminary analyses on a measure that excludes for the situations where a catheter may be appropriate before making any further decisions about whether a threshold would be appropriate.

Other considerations

The denominator of the existing catheter and fistula measures is limited to patients who have been on dialysis for 90 days or more. The TEP recommended that the 90 day requirement be removed from the denominator; the consensus was that the “clock” for getting a permanent access placed should start on day 1 of dialysis.

The TEP also discussed the appropriateness of the 90 day requirement in the numerator (“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”). There was interest from some TEP members in increasing the requirement to 120 days, to account for the time needed for a graft or fistula to mature. This may have the effect of encouraging fistula placement. However, there was a competing concern that increasing the time frame to 120 days would allow dialysis facilities to keep catheters in patients longer than is necessary. In the end, the TEP decided to recommend that the numerator include patients “with one or more dialysis catheters for > 90 days at the facility without the use of AVF or AVG in the interim”.

NQF #0257: Hemodialysis Vascular Access- Maximizing Placement of Arterial Venous Fistula (AVF)

The TEP began their discussion by outlining the strength and weaknesses of the existing CMS fistula measure. The TEP agreed that the measure does not account for patients where a fistula is not the best option. It also does not specify a time period to getting the access placed, however the group agreed that the focus should be on getting catheters out (which is accounted for by the 90 day requirement in the catheter measure). The patients on the TEP weighed in on how long it would take for them after starting dialysis to be comfortable making an informed decision about access type. They generally agreed that 30 days seemed like a reasonable time frame, assuming that the patient was appropriately educated by their dialysis facility about their access options. The TEP did acknowledge the role of vascular access surgeon in making access decisions, but agreed that referral for permanent access as well as the choice of surgeon is still the responsibility of the dialysis facility. One TEP member noted that the name of the measure should be changed to “maximizing use” of AVF, since the literature shows the functional AVF is superior to other access types. Also, creation of AVFs that never mature result in prolonged catheter exposure.

Proposed Risk Adjustors

The TEP agreed that while fistulas are preferred, many in the community feel that the measure has led to an unintended consequence that a fistula is the only option for all patients, regardless of health status. One TEP member noted that all fistulas are not created equal – some need repeated interventions, which can be a reflection of low quality. The group discussed the idea of an “AV access” measure to account for grafts. In such a measure, both fistulas and grafts would be considered positive outcomes. The group recognized that they could not make the statement that fistulas and grafts are truly equivalent in all patients, but wanted to ensure that the point was clear that that grafts were a strongly preferred outcome to catheters and should not be disincentivized.

As an alternative, the TEP discussed adjusting the measure for conditions or scenarios where a graft may be an acceptable or preferred alternative to a fistula. One TEP member noted that fistulas are heterogeneous; for example, a fistula placed in a young non-diabetic patient would be more likely to mature for use in hemodialysis than a fistula placed in a longstanding elderly diabetic patient. The TEP developed the following list of risk adjustment factors to be considered:

- Patients whose life expectancy is short (e.g. metastatic cancer, age, hospice status)
- Patients whose AV success rate is expected to be low, due to
 - Age
 - Diabetes mellitus
 - Vascular disease (PVD, Cardiovascular disease, Cerebrovascular disease)
 - Elevated BMI
- Sex
- Race

One TEP member noted that age and BMI are bimodal, and analyses need to be done before the committee could decide about making adjustments for these factors. For the adjustment for vascular disease, work will need to be done on the ICD9/10 codes used to identify vascular disease to ensure that the right patients are captured. Similarly, investigation is needed into the effect of sex and race on access type, to ensure that the differences are biologic and do not reflect disparities in care. These analyses and issues will be investigated by UM-KECC in the months following the in-person meeting.

Other considerations

The TEP was concerned about patients who are using a fistula with two needles to dialyze, but have a catheter still present in their body. In theory, a patient could have both accesses present, and the facility could only use the fistula on the treatment that is reported for the measure. To address this issue, the numerator will specify that the patient must be 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*. Data considerations around this requirement are discussed later in this report (see page 15).

As was done for the catheter measure, the TEP recommended that the 90 day requirement be removed from the denominator; the consensus was that the “clock” for getting a permanent access placed should start on day 1 of dialysis treatment in a non-hospital setting.

Addressing Grafts

The TEP discussed the merits of incorporating grafts specifically in a quality measure, rather than continuing with the current construct that treats grafts as neutral outcomes. There has been strong interest from the community for a measure that incorporates grafts as a positive outcome. There was general agreement among TEP members that grafts can be an appropriate means of access, however some TEP members felt that incorporating them explicitly (either through an overall AV access measure or through a separate graft-specific measure) could have the possible unintended consequence of lowering fistula rates.

TEP members agreed that there is generally not enough information disseminated to the community about how the existing measures implicitly address the role of grafts. To address the role of grafts in the catheter and fistula measures, the TEP recommended that following information will be included in the respective measure specifications:

- An explanation about how the catheter and fistula measures are intended to be used together. This explanation could be similar to the one that provided in this TEP summary report: *“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).”*
- An explicit note that the TEP has designed the risk adjustment strategy for the fistula measure to account for those cases where a graft may be the necessary or appropriate means of access.

4.5 Access Type Definitions

As part of their discussion, the TEP clearly identified which situations should be considered as being part of the numerator for the catheter and fistula measures. UM-KECC developed an exercise where the TEP reviewed all possible scenarios based on the current definition in Medicare claims and CROWNWeb data. Judgements were then made on how each situation should be counted.

Catheter with no other access indicated: should be counted as a **catheter**

AV fistula with no other access indicated: should be counted as a **fistula**

AV graft with no other access indicated: should be counted as a **graft**

Catheter with maturing graft or fistula: should be counted as a **catheter**

AV fistula or AV Graft in use, but a catheter is still present in the body: should be counted as a **catheter**

- The TEP felt that a patient who has a catheter with a functioning fistula or graft can still have adverse consequences related to the catheter.

AV fistula and AV graft: This category should only be used if there are two separate accesses present and one needle is being used in each. If there are two needles in one access, default to that access.

4.6 Data sources

The TEP discussed the two available data sources for access information: Medicare claims and CROWNWeb. In Medicare claims, there is a clear definition of when a catheter is present, due to the construction of the V-modifiers that facilities report. Medicare claims instructions require the reporting of two modifiers in cases where a catheter is present, even if not in use. The reporting requirements are as follows:

- 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

However, claims are limited to only Medicare fee-for-service patients, which the TEP felt was a major drawback. The Medicare benefit begins for ESRD patients after three months, which is a sensitive time for access. In comparison, CROWNWeb includes data for all patients (regardless of payor). However, CROWNWeb data elements are constructed in such a way that there is no ability to detect when a catheter is present but not in use.

Currently, the data elements are defined as follows:

- AVF only (2 needles)
- AVF with Catheter (1 needle and 1 lumen of a catheter)
- AVG only (2 needles)
- AVG with Catheter (1 needle and 1 lumen)
- Catheter only (option to indicate if maturing AVF/AVG is present)

If a catheter is present, but not being used, that patient is considered to have either a fistula or graft. Based on this information, the TEP made two recommendations related to the data sources for these measures:

1. Change CROWNWeb reporting requirements for vascular access type to match Medicare claims reporting requirements, in order to more accurately capture a patient's access status.
2. Measures should be calculated using CROWNWeb (to capture non-Medicare patients). Medicare claims would act as a backup until the CROWNWeb data elements have been revised.

As the current fistula and catheter measures implemented in Dialysis Facility Compare and in the ESRD QIP use Medicare claims as the data source, these changes will impact the vascular access measures used in both programs. The algorithm for calculating the numerator for the current catheter and fistula measures will change based on the recommendation to align definitions of vascular access type so that CROWNWeb definitions match those of Medicare claims. For example, the change to counting primary

access type as catheter, even if not in use when another access is present, could result in higher catheter rates and lower fistula rates. In addition to alignment of data element definitions to Medicare claims, the TEP recommended a move to CROWNWeb as the primary data source. Depending on if this change is made prior to or subsequent to definition changes in the CROWNWeb data elements, it is expected catheter and fistula rates will also be impacted by this change.

4.7 Proposed Measures and Other Recommendations

Revisions to #0256: Hemodialysis Vascular Access- Minimizing use of Catheters as Chronic Dialysis Access

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.

Numerator details: The 90 days is defined as being from the date of first dialysis in the facility for all patients. Use of a catheter “continuously” is defined as a patient with one or more dialysis catheters for > 90 days without the use of AVF or AVG in the interim.

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

Exclusions under consideration (note that these are not considered final):

- Pediatric patients (<18 years old)
- Limited life expectancy (e.g. < 6 months)
 - Patients under hospice care
 - Patients with metastatic cancer
 - Patients with end stage liver disease that are not candidates for liver transplant
 - End stage heart disease (advanced cardiomyopathy) that are not candidates for heart transplant
 - Other: tbd
- Exhausted anatomic options with documentation: based on second opinion from surgeon qualified vascular access provider
- Transient modality (< 90 days from PD)

Data source: CROWNWeb (with revisions)

Revisions to NQF #0257: Hemodialysis Vascular Access- Maximizing Placement of Arterial Venous Fistula (AVF)

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

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)

Risk Adjustments under consideration (note that these are not considered final):

The risk adjustment strategy for this measure has been designed to account for those occasions where a graft may be the necessary or appropriate means of access. These adjustments include:

- Life expectancy short (e.g. metastatic cancer, age, hospice status)
- AVF success rate low
 - Age
 - Diabetes Mellitus
 - Vascular disease: peripheral, cerebral vascular, cardiovascular
 - Body Mass Index low/high
- Sex
- Race

Data source: CROWNWeb (with revisions)

CROWNWeb data elements

The TEP recommended changes to CROWNWeb reporting requirements in order to more accurately capture a patient's access status. The following should be options for reporting access type in CROWNWeb:

- Catheter present
- AVG only with 2 needles
- AVF only with 2 needles
- AVG with catheter (either using 1 needle and 1 lumen or using 2 needles in AVG but catheter has not yet been removed)
- AVF with catheter (either using 1 needle and 1 lumen or using 2 needles in AVF but catheter has not yet been removed)

Pediatric Patients

As a result of the TEP deliberations, both the catheter and fistula measures remain limited to adult patients. The pediatric nephrologist on the TEP recommended (and other TEP members agreed) that the American Society of Pediatric Nephrology (ASPN) be consulted on whether the measures as recommended would be appropriate for pediatric patients. ASPN will convene a workgroup to discuss ESRD Vascular Access TEP recommendations to be considered in pediatric patients.

Grafts

The TEP did not specifically account for grafts in the measures discussed at the in-person meeting. They have recommended risk adjustments in the fistula measure to account for situations where a graft may be more appropriate. The TEP expressed interest in continuing the discussion of the possibility of a permanent access (AVF or AVG) measure, or a separate graft measure.

4.8 Feasibility and Usability

The recommendations made by the TEP are largely feasible, with two issues that need to be addressed long-term:

- Revisions to CROWNWeb data elements and timeline for implementation
- Implementation of the exclusion for “exhausted anatomic options” for the catheter measure, with documentation required.

Both of these issues will require longer term discussions with the CROWNWeb team. The TEP expressed interest in reporting these measures as soon as possible, and phasing in these revisions as they become available.

4.9 Measure Area Gaps for the ESRD Population

The TEP agreed that there was a lack of patient reported outcomes related to vascular access type. Collecting and measuring this information would help capture patient preferences and experience of care related to their access type.

4.10 In Person TEP Meeting Conclusion and Follow-up Plan

There are a number of issues discussed at the TEP meeting that require further examination from UM-KECC, including:

- Constructing a risk adjustment model for the fistula measure, based on the adjustments recommended by the TEP. Specific steps include:
 - Refining the model of AVF creation as an outcome in the first year of dialysis by including the competing risk of mortality in addition to the comorbidity adjustments
 - Determining ICD9/ICD10 codes to identify vascular disease for the AVF measure
 - Defining the adjustment for patients for whom the AV fistula success rate would be low
- Defining the exclusion for limited life expectancy for the catheter measure

The TEP also expressed interest in continuing discussion of the role of grafts. It is expected that further discussions will be held over the next few months.

5. Post-TEP Public Comment Period

A public comment period was held at the conclusion of the In-Person TEP Meeting on April 23, 2015. No comments were provided.

6. Follow-up TEP Teleconference Call

Following the in-person TEP meeting, it was determined that a follow-up call was necessary to refine the selected data elements, exclusion criteria, and risk adjustment analyses.

7. Summary

The objective of the TEP was to consider the current evidence on vascular access. From this starting point the TEP reviewed key areas of evidence in the current body of literature. Discussion covered concerns about the current paradigm that always treats AV fistula as the preferred access type and less recognition of AV graft (or catheter) as potentially a more appropriate access type for certain patients. The TEP also discussed at length the specific step of referral to vascular surgeon and how to best account for the role of the vascular surgeon in influencing fistula creation, and the role of the facility of ensuring timely referral, and issues related to fistula patency.

Recognizing the key issues observed in the literature related to potential barriers to successful fistula creation, such as age, and comorbidities, the TEP discussed preliminary analyses done by UM-KECC to examine the impact of comorbidity adjustments on rates of AVF creation in the first year of dialysis. The remainder of the TEP in-person meeting focused on review of the current AVF and catheter measures, potential changes and development of a risk adjusted fistula measure. The proposed recommendations reached at the conclusion of the meeting included:

Minimizing use of Catheters

- Proposed exclusions included (1) patients with limited life expectancy and (2) patients who have exhausted anatomic options for an AVF or AVG. A proposed list of conditions that are associated with limited life expectancy was developed and include: hospice care, metastatic cancer, and end stage liver or heart disease. Others to be determined.
- The TEP did not reach consensus on whether to include exhaustion of anatomic options as an exclusion criteria, and acknowledged the difficulties in implementation. An attestation from a qualified vascular access provider was proposed as a means to satisfy the exclusion criteria.
- The TEP recommended that the 90 day requirement be removed from the denominator.

Maximizing Placement of AVF

- The TEP agreed that AVF are the preferred access for most patients, and that AVG were still preferred relative to a vascular catheter. The group recommended that the AVF measure should be adjusted for conditions where an AVG may be an acceptable alternative such as: older age, diabetics, vascular disease, and BMI.
- The TEP recommended that the numerator statement be clarified so that patients are only counted if the AVF is being used with two needles and no dialysis catheter is present
- The TEP recommended that the 90 day requirement be removed from the denominator.
- TEP members agreed that how the existing measures implicitly address the role of grafts is not well understood in the community and should be clarified.

For both measures the TEP agreed that CROWNWeb was the preferred data source since it includes all dialysis patients as opposed to using CMS claims. In addition the TEP recommended aligning the data element definitions in CROWNWeb to those in the Medicare claims, in order to better capture cases where a catheter is present even if not in use. The TEP felt this was important in order to minimize potential adverse outcomes associated with prolonged catheter use whether present or in use with another access type. Finally, further work is needed to finalize the specific definitions and requirements for the proposed exclusion and risk adjustment criteria and incorporate these into the measures that CMS will submit to NQF.

8. Appendices

The following documents are appended to this report: annotated bibliography, summary of clinical practice guidelines, environmental scan, and TEP in-person meeting slides.

End Stage Renal Disease (ESRD) Quality Measure Development, Maintenance, and Support

Vascular Access Technical Expert Panel Annotated Bibliography

Literature Review Summary

UM-KECC's Literature Review supporting the Vascular Access Technical Expert Panel began in spring of 2014, when the existing vascular access measures were undergoing comprehensive re-evaluation (for eventual submission to NQF for maintenance endorsement). The two existing measures (Minimizing use of catheters as Chronic Dialysis Access and Maximizing Placement of Arterial Venous Fistula) were originally endorsed by NQF in 2007, were re-endorsed in 2010. The literature that was included with both of those measure reviews is included in the appendix.

For this review, a series of searches were undertaken iteratively to identify pertinent PubMed content describing fistula, graft, and catheter placement in the ESRD population. The first set of PubMed searches were executed in April 2014 based on the search criteria established by the group. Initial PubMed search results were screened for general topic applicability prior to a focused review by a clinician investigator associated with the team. These search terms were largely based on the search strategy used in the development of the KDOQI Vascular Access Guideline Update from 2006. Given that a literature review was conducted in 2009-2010, this search was restricted to materials published January 2010 – April 2014. The search resulted in a total of 705 articles, which were reviewed for relevancy. This review resulted in a final list of 26 articles for inclusion in the bibliography.

In January 2015, an additional search was conducted, limited to articles from January 2014 – January 2015. The term "Hemodialysis vascular access" was entered into PubMed, resulting in 337 articles. A total of 38 articles were flagged for review, and of those a total of 10 are included in the bibliography.

TEP members will be asked to provide additional citations of relevance when they review this bibliography.

Annotated Bibliography

Casey JR, Hanson CS, Winkelmayer WC, et al. **Patients' perspectives on hemodialysis vascular access: a systematic review of qualitative studies.** *Am J Kidney Dis.* 2014 Dec;64(6):937-53. doi: 10.1053/j.ajkd.2014.06.024. Epub 2014 Aug 10.

Abstract: BACKGROUND: Delayed creation of vascular access may be due in part to patient refusal and is associated with adverse outcomes. Concerns about vascular access are prevailing treatment-related stressors for patients on hemodialysis therapy. This study aims to describe patients' perspectives on vascular access initiation and maintenance in hemodialysis. STUDY DESIGN: Systematic review and thematic synthesis of qualitative studies. SETTING & POPULATION: Patients with chronic kidney disease who express opinions about vascular access for hemodialysis. SEARCH STRATEGY & SOURCES: MEDLINE, EMBASE, PsycINFO, CINAHL, reference lists, and PhD dissertations were searched to October 2013. ANALYTICAL APPROACH: Thematic synthesis was used to analyze the findings. RESULTS: From 46 studies involving 1,034 patients, we identified 6 themes: heightened vulnerability (bodily intrusion, fear of cannulation, threat of complications and failure, unpreparedness, dependence on a lifeline, and wary of unfamiliar providers), disfigurement (preserving normal appearance, visual reminder of disease, and avoiding stigma), mechanization of the body (bonded to a machine, internal abnormality, and constant maintenance), impinging on way of life (physical incapacitation, instigating family tension, wasting time, and added expense), self-preservation and ownership (task-focused control, advocating for protection, and acceptance), and confronting decisions and consequences (imminence of dialysis therapy and existential thoughts). LIMITATIONS: Non-English articles were excluded. CONCLUSIONS: Vascular access is more than a surgical intervention. Initiation of vascular access signifies kidney failure and imminent dialysis, which is emotionally confronting. Patients strive to preserve their vascular access for survival, but at the same time describe it as an agonizing reminder of their body's failings and "abnormality" of being amalgamated with a machine disrupting their identity and lifestyle. Timely education and counseling about vascular access and building patients' trust in health care providers may improve the quality of dialysis and lead to better outcomes for patients with chronic kidney disease requiring hemodialysis.

Al-Jaishi AA, Oliver MJ, Thomas SM, et al. **Patency rates of the arteriovenous fistula for hemodialysis: a systematic review and meta-analysis.** *Am J Kidney Dis.* 2014 Mar;63(3):464-78. doi: 10.1053/j.ajkd.2013.08.023. Epub 2013 Oct 30. Review.

Notes: Meta-analysis of AVF patency rates: AVF patency rates lower in more modern cohorts. Patient factors: sex/upper arm/diabetes influenced patency rates

Abstract: Background: Advantages of the arteriovenous fistula (AVF), including long patency and few complications, were ascertained more than 2 decades ago and may not apply to the contemporary dialysis population. Study Design: Systematic review and meta-analysis. Estimates were pooled using a random-effects model and sources of heterogeneity were explored using metaregression. Setting

& Population: Patients treated with long-term hemodialysis using an AVF. Selection Criteria for Studies: English-language studies indexed in MEDLINE between 2000 and 2012 using prospectively collected data on 100 or more AVFs. Predictor: Age, AVF location, and study location. Outcomes: Outcomes of interest were primary AVF failure and primary and secondary patency at 1 and 2 years. Results: 7,011 citations were screened and 46 articles met eligibility criteria (62 unique cohorts; n 5 12,383). The rate of primary failure was 23% (95% CI, 18%-28%; 37 cohorts; 7,393 AVFs). When primary failures were included, the primary patency rate was 60% (95% CI, 56%-64%; 13 studies; 21 cohorts; 4,111 AVFs) at 1 year and 51% (95% CI, 44%-58%; 7 studies; 12 cohorts; 2,694 AVFs) at 2 years. The secondary patency rate was 71% (95% CI, 64%-78%; 10 studies; 11 cohorts; 3,558 AVFs) at 1 year and 64% (95% CI, 56%-73%; 6 studies; 11 cohorts; 1,939 AVFs) at 2 years. In metaregression, there was a significant decrease in primary patency rate in studies that started recruitment in more recent years. Limitations: Low quality of studies, variable clinical settings, and variable definitions of primary AVF failure. Conclusions: 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. -Am J Kidney Dis. 63(3):464-478. © 2014 by the National Kidney Foundation, Inc.

Solid CA, Collins AJ, Ebben JP, et al. **Agreement of reported vascular access on the medical evidence report and on medicare claims at hemodialysis initiation.** *BMC Nephrol.* 2014 Feb 8;15:30. doi: 10.1186/1471-2369-15-30.

Notes: Comparison of incident vascular access between 2728 and medicare claims for patients > 67 yo. Agreement 94% of time and not dependant on age/sex/race.

Abstract: BACKGROUND: The choice of vascular access type is an important aspect of care for incident hemodialysis patients. However, data from the Centers for Medicare & Medicaid Services (CMS) Medical Evidence Report (form CMS-2728) identifying the first access for incident patients have not previously been validated. Medicare began requiring that vascular access type be reported on claims in July 2010. We aimed to determine the agreement between the reported vascular access at initiation from form CMS-2728 and from Medicare claims. METHODS: This retrospective study used a cohort of 9777 patients who initiated dialysis in the latter half of 2010 and were eligible for Medicare at the start of renal replacement therapy to compare the vascular access type reported on form CMS-2728 with the type reported on Medicare outpatient dialysis claims for the same patients. For each patient, the reported access from each data source was compiled; the percent agreement represented the percent of patients for whom the access was the same. Multivariate logistic analysis was performed to identify characteristics associated with the agreement of reported access. RESULTS: The two data sources agreed for 94% of patients, with a Kappa statistic of 0.83, indicating an excellent level of agreement. Further, we found no evidence to suggest that agreement was associated with the patient characteristics of age, sex, race, or primary cause of renal failure. CONCLUSION: These results suggest that vascular access data as reported on form CMS-2728 are valid and reliable for use in research studies.

Oliver MJ, Quinn RR. **Recalibrating vascular access for elderly patients.** *Clin J Am Soc Nephrol.* 2014 Apr;9(4):645-7. doi: 10.2215/CJN.01560214. Epub 2014 Mar 20.

Abstract: Hemodialysis patients should be well informed about their vascular access options. Fistulas are strongly encouraged by guidelines and quality improvement initiatives. Governments in numerous jurisdictions have set targets for fistula utilization and some have tied reimbursement to attaining these targets. This creates an environment in which it is tempting to overemphasize the benefits of fistulas and the risks of catheters when discussing vascular access options with our patients. However, informed consent requires us to not only present the options, but to also provide an accurate, unbiased description of the risks and benefits.

Goldfarb-Rumyantzev AS, Syed W, Patibandla BK, et al. **Geographic disparities in arteriovenous fistula placement in patients approaching hemodialysis in the United States.** *Hemodial Int.* 2014 Jul;18(3):686-94. doi: 10.1111/hdi.12141. Epub 2014 Feb 16.

Abstract: Arteriovenous fistula (AVF) is the preferred vascular access for hemodialysis (HD). Several factors associated with AVF placement have been identified (e.g., age, sex, race, comorbidities). We hypothesized that geographic location of patient residence might be associated with the probability of AVF placement as the initial access. We used the data from the United States Renal Data System (USRDS) database (2005-2008) linked to Medicare claims (2003-2008). Logistic regression was used to estimate specific characteristics of population associated with the AVF as first access placed or attempted for HD initiation. Our primary variable of interest was the geographic location, and the multivariate model was adjusted for age, sex, race, body mass index, primary cause of end-stage renal disease (ESRD), duration of pre-ESRD nephrology care, comorbidities, employment status, substance abuse, and income. Geographic location was determined using the data collected by the RUCA project and divided population into metropolitan, micropolitan, and rural categories. Patients (n = 111,953) identified from the USRDS database with linked Medicare claims were examined. Rates of fistula placement in the metropolitan, micropolitan, and rural population were 18.5%, 22.4%, and 21.6%, respectively. In comparison, patients who received catheter as the first access were 81.5%, 77.6% and 78.4%, respectively. The odds ratio of AVF placement as a first HD access in the rural and metropolitan population compared with the micropolitan population were 0.96 (0.90-1.03; P = 0.26) and 0.80 (0.76-0.84; P < 0.001), respectively. Our results indicate the presence of geographic disparities in AVF placement with decreased rates of AVF as the first access created in the metropolitan (but not rural) populations compared with the micropolitan communities. © 2014 International Society for Hemodialysis.

Erickson KF, Mell M, Winkelmayr WC, et al. **Provider Visits and Early Vascular Access Placement in Maintenance Hemodialysis.** *J Am Soc Nephrol.* 2014 Dec 1. doi:pj: ASN.2014050464. [Epub ahead of print]

Notes: More frequent provider visits in first 90 days increase proportion with AVF by 90 days. Also studied incident Medicare patients with CVC. Instrumental analysis with similar results although not as pronounced.

Abstract: Medicare reimbursement policy encourages frequent provider visits for patients with ESRD undergoing hemodialysis. We hypothesize that patients seen more frequently by their nephrologist or advanced practitioner within the first 90 days of hemodialysis are more likely to undergo surgery to create an arteriovenous (AV) fistula or place an AV graft. We selected 35,959 patients aged ≥ 67 years starting hemodialysis in the United States from a national registry. We used multivariable regression to evaluate the associations between mean visit frequency and AV fistula creation or graft placement in the first 90 days of hemodialysis. We conducted an instrumental variable analysis to test the sensitivity of our findings to potential bias from unobserved characteristics. One additional visit per month in the first 90 days of hemodialysis was associated with a 21% increase in the odds of AV fistula creation or graft placement during that period (95% confidence interval, 19% to 24%), corresponding to an average 4.5% increase in absolute probability. An instrumental variable analysis demonstrated similar findings. Excluding visits in months when patients were hospitalized, one additional visit per month was associated with a 10% increase in odds of vascular access surgery (95% confidence interval, 8% to 13%). In conclusion, patients seen more frequently by care providers in the first 90 days of hemodialysis undergo earlier AV fistula creation or graft placement. Payment policies that encourage more frequent visits to patients at key clinical time points may yield more favorable health outcomes than policies that operate irrespective of patients' health status.

Drew DA, Lok CE, Cohen JT, et al. **Vascular access choice in incident hemodialysis patients: a decision analysis.** *J Am Soc Nephrol.* 2015 Jan;26(1):183-91. doi: 10.1681/ASN.2013111236. Epub 2014 Jul 25.

Notes: Decision analysis of incident pts starting with CVC: Older age, women, DM had less survival benefit with AVF vs. AVG and only modest increase in cost. Patient population studied: incident patients with CVC.

Abstract: Hemodialysis vascular access recommendations promote arteriovenous (AV) fistulas first; however, it may not be the best approach for all hemodialysis patients, because likelihood of successful fistula placement, procedure-related and subsequent costs, and patient survival modify the optimal access choice. We performed a decision analysis evaluating AV fistula, AV graft, and central venous catheter (CVC) strategies for patients initiating hemodialysis with a CVC, a scenario occurring in over 70% of United States dialysis patients. A decision tree model was constructed to reflect progression from hemodialysis initiation. Patients were classified into one of three vascular access choices: maintain CVC, attempt fistula, or attempt graft. We explicitly modeled probabilities

of primary and secondary patency for each access type, with success modified by age, sex, and diabetes. Access-specific mortality was incorporated using preexisting cohort data, including terms for age, sex, and diabetes. Costs were ascertained from the 2010 USRDS report and Medicare for procedure costs. An AV fistula attempt strategy was found to be superior to AV grafts and CVCs in regard to mortality and cost for the majority of patient characteristic combinations, especially younger men without diabetes. Women with diabetes and elderly men with diabetes had similar outcomes, regardless of access type. 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.

Wish JB. **Catheter last, fistula not-so-first.** *J Am Soc Nephrol.* 2015 Jan;26(1):5-7. doi: 10.1681/ASN.2014060594. Epub 2014 Jul 25.

Notes: Incremental cost-effectiveness of AVF over AVG is dependent on patient specific factors, many of which are identifiable from 2728

Abstract: The issue of vascular access choice is not as black and white as the Centers for Medicare & Medicaid Services (CMS) would like it to appear, with arteriovenous fistula (AVF) always being good or “first” and central venous catheters (CVCs) always being bad or “last.” Nonetheless, CMS has instituted a quality incentive program (QIP) for dialysis providers that rewards high AVF prevalence and penalizes high CVC prevalence without regard to patient mix. For payment year 2014, vascular access constitutes 30% of the total QIP score.¹ This may have already led to access to care issues, as some dialysis providers are refusing to accept patients with CVCs. CMS has recently given ground on this issue by renaming the “Fistula First” initiative “Fistula First Catheter Last” (FFLC) to emphasize that CVC avoidance is as important or more important than AVF use.²

Grubbs V, Wasse H, Vittinghoff E, et al. **Health status as a potential mediator of the association between hemodialysis vascular access and mortality.** *Nephrol Dial Transplant.* 2014 Apr;29(4):892-8. doi: 10.1093/ndt/gft438. Epub 2013 Nov 13.

Abstract: BACKGROUND: It is unknown whether the selection of healthier patients for arteriovenous fistula (AVF) placement explains higher observed catheter-associated mortality among elderly hemodialysis patients. METHODS: From the United States Renal Data System 2005-2007, we used proportional hazard models to examine 117 277 incident hemodialysis patients aged 67-90 years for the association of initial vascular access type and 5-year mortality after accounting for health status. Health status was defined as functional status at dialysis initiation and number of hospital days within 2 years prior to dialysis initiation. RESULTS: Patients with catheter alone had more limited functional status (25.5 versus 10.8% of those with AVF) and 3-fold more prior hospital days than those with AVF (mean 18.0 versus 5.4). In the unadjusted model, the likelihood of death was higher

for arteriovenous grafts (AVG) {Hazard ratio (HR) 1.20 [95% CI (1.16-1.25)], catheter plus AVF [HR 1.34 (1.31-1.38)], catheter plus AVG [HR 1.46 (1.40-1.52)] and catheter only [HR 1.95 (1.90-1.99)]}, compared with AVF ($P < 0.001$). The association attenuated -23.7% (95% CI -22.0, -25.5) overall (AVF versus all other access types) after adjusting for the usual covariates (including sociodemographics, comorbidities and pre-dialysis nephrology care) {AVG [HR 1.21 (1.17-1.26)], catheter plus AVF [HR 1.27 (1.24-1.30)], catheter plus AVG [HR 1.38 (1.32-1.43)] and catheter only [HR 1.69 (1.66-1.73)], $P < 0.001$ }. Additional adjustment for health status further attenuated the association by another -19.7% (-18.2, -21.3) overall but remained statistically significant <AVG [HR 1.18 (1.13-1.22)], catheter plus AVF [HR 1.20 (1.17-1.23)], catheter plus AVG {HR 1.38 [1.26 (1.21-1.31)]} and catheter only [HR 1.54 (1.50-1.58)], $P < 0.001$ >. CONCLUSIONS: The observed attenuation in mortality differences previously attributed to access type alone suggests the existence of selection bias. Nevertheless, the persistence of an apparent survival advantage after adjustment for health status suggests that AVF should still be the access of choice for elderly individuals beginning hemodialysis until more definitive data eliminating selection bias become available.

Murea M, James KM, Russell GB, et al. **Risk of catheter-related bloodstream infection in elderly patients on hemodialysis.** *Clin J Am Soc Nephrol.* 2014 Apr;9(4):764-70. doi: 10.2215/CJN.07710713. Epub 2014 Mar 20.

Abstract: BACKGROUND AND OBJECTIVES: Elderly patients require tunneled central vein dialysis catheters more often than younger patients. Little is known about the risk of catheter-related bloodstream infection in this population. DESIGN, SETTING, PARTICIPANTS, & MEASUREMENTS: This study identified 464 patients on hemodialysis with tunneled central vein dialysis catheters between 2005 and 2007 and excluded patients who accrued <21 catheter-days during this period. Outpatient and inpatient catheter-related bloodstream infection data were collected. A Cox proportional hazards regression analysis adjusting for sex, ancestry, comorbidities, dialysis vintage, dialysis unit, immunosuppression, initial catheter site, and first antimicrobial catheter lock solution was performed for risk of catheter-related bloodstream infection between nonelderly (18-74 years) and elderly (≥ 75 years) patients. RESULTS: In total, 374 nonelderly and 90 elderly patients with mean (SD) ages of 54.8 (12.3) and 81.3 (4.9) years and dialysis vintages of 1.8 (3.3) and 1.5 (2.9) years ($P=0.47$), respectively, were identified. Mean at-risk catheter-days were 272 (243) in nonelderly and 318 (240) in elderly patients. Between age groups, there were no significant differences in initial catheter site, type of catheter lock solution, or microbiology results. A total of 208 catheter-related bloodstream infection events occurred (190 events in nonelderly and 18 events in elderly patients), with a catheter-related bloodstream infection incidence per 1000 catheter-days of 1.97 (4.6) in nonelderly and 0.55 (1.6) in elderly patients ($P<0.001$). Relative to nonelderly patients, the hazard ratio for catheter-related bloodstream infection in the elderly was 0.33 (95% confidence interval, 0.20 to 0.55; $P<0.001$) after multivariate analysis. CONCLUSION: Elderly patients on hemodialysis using tunneled central vein dialysis catheters are at lower risk of catheter-related bloodstream infection than their younger counterparts. For some elderly patients, tunneled central vein dialysis

catheters may represent a suitable dialysis access option in the setting of nonmaturing arteriovenous fistulae or poorly functioning synthetic grafts.

Rosenblum, Alex & Wang, Weiling & Ball, et al. **Hemodialysis catheter care strategies: a cluster-randomized quality improvement initiative.** *Am J Kidney Dis.* 2014 Feb;63(2):259-67. doi: 10.1053/j.ajkd.2013.08.019. Epub 2013 Dec 2.

Abstract: BACKGROUND: The prevalence of central venous catheters (CVCs) for hemodialysis remains high and, despite infection-control protocols, predisposes to bloodstream infections (BSIs). STUDY DESIGN: Stratified, cluster-randomized, quality improvement initiative. SETTING & PARTICIPANTS: All in-center patients with a CVC within 211 facility pairs matched by region, facility size, and rate of positive blood cultures (January to March 2011) at Fresenius Medical Care, North America. QUALITY IMPROVEMENT PLAN: Incorporate the use of 2% chlorhexidine with 70% alcohol swab sticks for exit-site care and 70% alcohol pads to perform "scrub the hubs" in dialysis-related CVC care procedures compared to usual care. OUTCOME: The primary outcome was positive blood cultures for estimating BSI rates. MEASUREMENTS: Comparison of 3-month baseline period from April 1 to June 30 and follow-up period from August 1 to October 30, 2011. RESULTS: Baseline BSI rates were similar (0.85 vs 0.86/1,000 CVC-days), but follow-up rates differed at 0.81/1,000 CVC-days in intervention facilities versus 1.04/1,000 CVC-days in controls (P = 0.02). Intravenous antibiotic starts during the follow-up period also were lower, at 2.53/1,000 CVC-days versus 3.15/1,000 CVC-days in controls (P < 0.001). Cluster-adjusted Poisson regression confirmed 21%-22% reductions in both (P < 0.001). Extended follow-up for 3 successive quarters demonstrated a sustained reduction of bacteremia rates for patients in intervention facilities, at 0.50/1,000 CVC-days (41% reduction; P < 0.001). Hospitalizations due to sepsis during 1-year extended follow-up were 0.19/1,000 CVC-days (0.069/CVC-year) versus 0.26/1,000 CVC-days (0.095/CVC-year) in controls (approximately 27% difference; P < 0.05). LIMITATIONS: Inability to capture results from blood cultures sent to external laboratories, underestimation of sepsis-specific hospitalizations, and potential crossover adoption of the intervention protocol in control facilities. CONCLUSIONS: Adoption of the new catheter care procedure (consistent with Centers for Disease Control and Prevention recommendations) resulted in a 20% lower rate of BSIs and intravenous antibiotic starts, which were sustained over time and associated with a lower rate of hospitalizations due to sepsis.

Al-Jaishi, Ahmed A & Oliver, Matthew J & Thomas, Sonia M et al. **Patency rates of the arteriovenous fistula for hemodialysis: a systematic review and meta-analysis.** *Am J Kidney Dis.* 2014 Mar;63(3):464-78. doi: 10.1053/j.ajkd.2013.08.023. Epub 2013 Oct 30.

Abstract: BACKGROUND: Advantages of the arteriovenous fistula (AVF), including long patency and few complications, were ascertained more than 2 decades ago and may not apply to the contemporary dialysis population. STUDY DESIGN: Systematic review and meta-analysis. Estimates were pooled using a random-effects model and sources of heterogeneity were explored using

metaregression. SETTING & POPULATION: Patients treated with long-term hemodialysis using an AVF. SELECTION CRITERIA FOR STUDIES: English-language studies indexed in MEDLINE between 2000 and 2012 using prospectively collected data on 100 or more AVFs. PREDICTOR: Age, AVF location, and study location. OUTCOMES: Outcomes of interest were primary AVF failure and primary and secondary patency at 1 and 2 years. RESULTS: 7,011 citations were screened and 46 articles met eligibility criteria (62 unique cohorts; n = 12,383). The rate of primary failure was 23% (95% CI, 18%-28%; 37 cohorts; 7,393 AVFs). When primary failures were included, the primary patency rate was 60% (95% CI, 56%-64%; 13 studies; 21 cohorts; 4,111 AVFs) at 1 year and 51% (95% CI, 44%-58%; 7 studies; 12 cohorts; 2,694 AVFs) at 2 years. The secondary patency rate was 71% (95% CI, 64%-78%; 10 studies; 11 cohorts; 3,558 AVFs) at 1 year and 64% (95% CI, 56%-73%; 6 studies; 11 cohorts; 1,939 AVFs) at 2 years. In metaregression, there was a significant decrease in primary patency rate in studies that started recruitment in more recent years. LIMITATIONS: Low quality of studies, variable clinical settings, and variable definitions of primary AVF failure. CONCLUSIONS: 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.

Dember, Laura M & Imrey, Peter B & Beck, Gerald J et al. **Objectives and design of the hemodialysis fistula maturation study.** *Am J Kidney Dis.* 2014 Jan;63(1):104-12. doi: 10.1053/j.ajkd.2013.06.024. Epub 2013 Aug 28.

Abstract: BACKGROUND: A large proportion of newly created arteriovenous fistulas cannot be used for dialysis because they fail to mature adequately to support the hemodialysis blood circuit. The Hemodialysis Fistula Maturation (HFM) Study was designed to elucidate clinical and biological factors associated with fistula maturation outcomes. STUDY DESIGN: Multicenter prospective cohort study. SETTING & PARTICIPANTS: Approximately 600 patients undergoing creation of a new hemodialysis fistula will be enrolled at 7 centers in the United States and followed up for as long as 4 years. PREDICTORS: Clinical, anatomical, biological, and process-of-care attributes identified pre-, intra-, or postoperatively. OUTCOMES: The primary outcome is unassisted clinical maturation, defined as successful use of the fistula for dialysis for 4 weeks without maturation-enhancing procedures. Secondary outcomes include assisted clinical maturation, ultrasound-based anatomical maturation, fistula procedures, fistula abandonment, and central venous catheter use. MEASUREMENTS: Preoperative ultrasound arterial and venous mapping, flow-mediated and nitroglycerin-mediated brachial artery dilation, arterial pulse wave velocity, and venous distensibility; intraoperative vein tissue collection for histopathologic and molecular analyses; postoperative ultrasounds at 1 day, 2 weeks, 6 weeks, and prior to fistula intervention and initial cannulation. RESULTS: Assuming complete data, no covariate adjustment, and unassisted clinical maturation of 50%, there will be 80% power to detect ORs of 1.83 and 1.61 for dichotomous predictor variables with exposure prevalences of 20% and 50%, respectively. LIMITATIONS: Exclusion of 2-stage transposition fistulas limits generalizability. The requirement for study visits may result in a cohort that is healthier than the overall population of patients undergoing fistula creation. CONCLUSIONS: The HFM Study will be of sufficient size and scope to: (1) evaluate a broad range of

mechanistic hypotheses, (2) identify clinical practices associated with maturation outcomes, (3) assess the predictive utility of early indicators of fistula outcome, and (4) establish targets for novel therapeutic interventions to improve fistula maturation.

de Leur, Kevin & Ozturk, Cigdem & Van Zeeland, Michiel L P et al. **Vascular access outcome in the elderly dialysis patient in combination with the quality of life.** *Vasc Endovascular Surg.* 2013 Aug;47(6):444-8. doi: 10.1177/1538574413495464. Epub 2013 Jul 12.

Abstract: PURPOSE: We performed a retrospective study on hemodialysis fistulae in patients aged 75 years and older. METHODS: Dialysis records of 2 hospitals were searched for patients of 75 years and older who had primary autologous radiocephalic arteriovenous fistulae (RCAVFs) and brachiocephalic arteriovenous fistulae (BCAVFs). Outcome measures were primary, primary-assisted, and secondary patency rates. Also, quality of life (QOL) was measured. RESULTS: A total of 107 fistulae were placed in 90 patients; 65 (61%) RCAVFs and 42 (39%) BCAVFs were created. The primary patency rate ($P = .026$) and the primary-assisted patency rate ($P = .016$) of BCAVFs were significantly higher than that of RCAVFs. Secondary patency rates at 1 year ($P = .01$) and 2 years ($P = .035$) were higher in BCAVFs than in RCAVFs. CONCLUSIONS: The BCAVFs give significantly higher primary and primary-assisted patency rates and also significantly higher secondary patency rates at 1 and 2 years. Therefore, we suggest the placement of elbow fistulae in the elderly patients. The QOL was surprisingly high in this population despite a high mortality rate.

Lok, Charmaine E & Foley, Robert. **Vascular access morbidity and mortality: trends of the last decade.** *Clin J Am Soc Nephrol.* 2013 Jul;8(7):1213-9. doi: 10.2215/CJN.01690213.

Abstract: During the past decade, clear trends in the types of incident and prevalent hemodialysis vascular access can be observed. There has been a steady increase and recent stabilization of patients initiating hemodialysis with a central venous catheter, representing approximately 80% of all incident accesses. There has also been a steady increase in prevalent fistula use, currently greater than 50% within 4 months of hemodialysis initiation. Patient and vascular access related morbidity and mortality are reflected in the type of vascular access used at initiation and for long-term maintenance dialysis. There is a three- to fourfold increase in risk of infectious complications in patients initiating dialysis with a catheter compared with either a fistula or graft and a sevenfold higher risk when the catheter is used as a prevalent access. Procedure rates have increased two- to threefold for all types of access. There is a significant increased risk of mortality associated with catheter use, especially within the first year of dialysis initiation.

Mustafa, Reem A & Zimmerman, Deborah & Rioux, Jean-Philippe et al. **Vascular access for intensive maintenance hemodialysis: a systematic review for a Canadian Society of Nephrology clinical practice guideline.** *Am J Kidney Dis.* 2013 Jul;62(1):112-31. doi: 10.1053/j.ajkd.2013.03.028.

Abstract: BACKGROUND: Practices in vascular access management with intensive hemodialysis may differ from those used in conventional hemodialysis. STUDY DESIGN: We conducted a systematic review to inform clinical practice guidelines for the provision of intensive hemodialysis. SETTING & POPULATION: Adult patients receiving maintenance (>3 months) intensive hemodialysis (frequent [≥ 5 hemodialysis treatments per week] and/or long [> 5.5 hours per hemodialysis treatment]). SELECTION CRITERIA FOR STUDIES: We searched EMBASE and MEDLINE (1990-2011) for randomized and observational studies. We also searched conference proceedings (2007-2011). INTERVENTIONS: (1) Central venous catheter (CVC) versus arteriovenous (AV) access, (2) buttonhole versus rope-ladder cannulation, (3) topical antimicrobial cream versus none in buttonhole cannulation, and (4) closed connector devices among CVC users. OUTCOMES: Access-related infection, survival, hospitalization, patency, access survival, intervention rates, and quality of life. RESULTS: We included 23, 7, and 5 reports describing effectiveness by access type, buttonhole cannulation, and closed connector device, respectively. No study directly compared CVC with AV access. On average, bacteremia and local infection rates were higher with CVC compared with AV access. Access intervention rates were higher with more frequent hemodialysis, but access survival did not differ. Buttonhole cannulation was associated with bacteremia rates similar to those seen with CVCs in some series. Topical mupirocin seemed to attenuate this effect. No direct comparisons of closed connector devices versus standard luer-locking devices were found. Low rates of actual or averted (near misses) air embolism and bleeding were reported with closed connector devices. LIMITATIONS: Overall, evidence quality was very low. Limited direct comparisons addressing main review questions, small sample sizes, selective outcome reporting, publication bias, and residual confounding were major factors. CONCLUSIONS: This review highlights several differences in the management of vascular access in conventional and intensive hemodialysis populations. We identify a need for standardization of vascular access outcome reporting and a number of priorities for future research.

Urbanes, Aris Q. **Interventional nephrology: When should you consider a graft?** *Clin J Am Soc Nephrol.* 2013 Jul;8(7):1228-33. doi: 10.2215/CJN.01270213. Epub 2013 Apr 18.

Abstract: The patient's vascular access is critical in ensuring that hemodialysis is successful, effective, relatively uncomplicated, and consistently reproducible from one treatment to another. The choice of vascular access is dictated by a multitude of factors, some of which are generalizable to a larger system, and others of which are flavored by local experience and expertise; an important fraction is specific to the patient presenting to the clinician at a particular point in time. Some of these factors, such as patient age and sex, are not modifiable; others, like comorbidity, vessel size and urgency of presentation to the renal provider, are manageable and sometimes modifiable. The role of the autologous arteriovenous fistula as the ideal conduit for hemodialysis treatments is well

established. The role of the prosthetic graft warrants discussion and investigation to most optimally apply to patients this important alternative within the armamentarium of vascular access.

Ocak, Gurbey & Rotmans, Joris I & Vossen, Carla Y. **Type of arteriovenous vascular access and association with patency and mortality.** *BMC Nephrol.* 2013 Apr 4;14:79. doi: 10.1186/1471-2369-14-79.

Abstract: BACKGROUND: There are only a few risk factors known for primary patency loss in patients with an arteriovenous graft or fistula. Furthermore, a limited number of studies have investigated the association between arteriovenous access modality and primary patency loss and mortality. The aim of this study was to investigate risk factors for patency loss and to investigate the association between graft versus fistula use and outcomes (patency loss and mortality). METHODS: We prospectively followed 919 incident hemodialysis patients and calculated hazard ratios (HRs) for putative risk factors of primary patency loss using Cox regression. Furthermore, HRs were calculated to study the association between graft versus fistula use and two-year primary patency loss and two-year mortality. RESULTS: Cardiovascular disease, prior catheter use, lowest tertile of albumin, highest tertile of hsCRP, and lowest tertile of fetuin-A were associated with primary patency loss in both patients with grafts and fistulas. Increased age, female sex, and diabetes mellitus were only associated with primary patency loss in patients with a fistula. We did not observe an association between primary patency loss and BMI, residual GFR, levels of calcium, phosphorus, and total cholesterol. Furthermore, graft use as compared with fistula use was associated with an 1.4-fold (95% CI 1.0-1.9) increased risk of primary patency loss and with an 1.5-fold (95% CI 1.0-2.2) increased mortality risk. CONCLUSION: Cardiovascular disease, prior catheter use, albumin, hsCRP, and fetuin-A are risk factors for patency loss. Graft use as compared with fistula use was associated with an increased risk of patency loss and mortality.

Ravani, Pietro & Palmer, Suetonia C & Oliver, Matthew J et al. **Associations between hemodialysis access type and clinical outcomes: a systematic review.** *J Am Soc Nephrol.* 2013 Feb;24(3):465-73. doi: 10.1681/ASN.2012070643. Epub 2013 Feb 21.

Abstract: Clinical practice guidelines recommend an arteriovenous fistula as the preferred vascular access for hemodialysis, but quantitative associations between vascular access type and various clinical outcomes remain controversial. We performed a systematic review of cohort studies to evaluate the associations between type of vascular access (arteriovenous fistula, arteriovenous graft, and central venous catheter) and risk for death, infection, and major cardiovascular events. We searched MEDLINE, EMBASE, and article reference lists and extracted data describing study design, participants, vascular access type, clinical outcomes, and risk for bias. We identified 3965 citations, of which 67 (62 cohort studies comprising 586,337 participants) met our inclusion criteria. In a random effects meta-analysis, compared with persons with fistulas, those individuals using catheters had higher risks for all-cause mortality (risk ratio=1.53, 95% CI=1.41-1.67), fatal infections

(2.12, 1.79-2.52), and cardiovascular events (1.38, 1.24-1.54). Similarly, compared with persons with grafts, those individuals using catheters had higher risks for mortality (1.38, 1.25-1.52), fatal infections (1.49, 1.15-1.93), and cardiovascular events (1.26, 1.11-1.43). Compared with persons with fistulas, those individuals with grafts had increased all-cause mortality (1.18, 1.09-1.27) and fatal infection (1.36, 1.17-1.58), but we did not detect a difference in the risk for cardiovascular events (1.07, 0.95-1.21). The risk for bias, especially selection bias, was high. 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.

Salmela, Birgitta & Hartman, Jari & Peltonen, Seija et al. **Thrombophilia and arteriovenous fistula survival in ESRD.** *Clin J Am Soc Nephrol.* 2013 Jun;8(6):962-8. doi: 10.2215/CJN.03860412. Epub 2013 Feb 14.

Abstract: BACKGROUND AND OBJECTIVES: The role of thrombophilia in failing arteriovenous fistula (AVF) among patients with ESRD undergoing hemodialysis is not established. This study aimed to assess whether AVF primary patency is associated with thrombophilia and coagulation abnormalities. DESIGN, SETTING, PARTICIPANTS, & MEASUREMENTS: This observational study screened 219 patients between 2002 and 2004 for thrombophilia before AVF surgery. Thrombophilia included factor V Leiden and prothrombin G20210A mutations, protein C and antithrombin activities, and protein S. Coagulation abnormalities included high factor VIII:C, homocysteine, fibrinogen, and d-dimer levels; presence of antiphospholipid antibodies; and short thrombin time. We reviewed patient charts for comorbid conditions, AVF maturation and interventions, kidney transplantation, and patient survival (mean follow-up duration, 3.6 [range, 2.3-5.8] years). Primary patency from the AVF placement and functional primary patency from the first AVF cannulation were analyzed with Kaplan-Meier and Cox proportional hazards models. RESULTS: Thrombophilia was present in 9% of the patients, and coagulation abnormalities occurred in 77%. One-year primary patency was 68%; 46% of the AVF failures occurred before the initiation of hemodialysis. Female sex (hazard ratio [HR], 2.6; 95% confidence interval [CI], 1.7-4.1) and thrombophilia (HR, 2.2; 95% CI, 1.2-4.2) were independent risk factors for loss of primary patency. Thrombophilia mutations or low antithrombin level (HR, 3.8), female sex (HR, 2.5), and diabetes (HR, 1.9) were associated with shortened functional primary patency of AVF. CONCLUSIONS: Against the background of frequent coagulation abnormalities, thrombophilia and female sex predispose patients with ESRD to access failure, mostly due to thrombosis or stenosis.

Lok, Charmaine E & Sontrop, Jessica M & Tomlinson, George et al. **Cumulative patency of contemporary fistulas versus grafts (2000-2010).** *Clin J Am Soc Nephrol.* 2013 May;8(5):810-8. doi: 10.2215/CJN.00730112. Epub 2013 Jan 31.

Abstract: BACKGROUND AND OBJECTIVES: Comparisons of fistulas and grafts often overlook the high primary failure rate of fistulas. This study compared cumulative patency (time from access creation to permanent failure) of fistulas and grafts. DESIGN, SETTING, PARTICIPANTS, & MEASUREMENTS: Vascular accesses of 1140 hemodialysis patients from two centers (Toronto and London, Ontario, Canada, 2000-2010) were analyzed. Cumulative patency was compared between groups using Kaplan-Meier survival curves and log-rank tests. Hazard ratios (HRs) for fistula failure relative to grafts and 95% confidence intervals (95% CIs) are reported. RESULTS: There were 1012 (88.8%) fistulas and 128 (11.2%) grafts. The primary failure rate was two times greater for fistulas than for grafts: 40% versus 19% ($P<0.001$). Cumulative patency did not differ between fistulas and grafts for the patients' first access (median, 7.4 versus 15.0 months, respectively [HR, 0.99; 95% CI, 0.79-1.23; $P=0.85$]) or for 600 with a subsequent access (7.0 versus 9.0 months [HR, 0.93; 95% CI, 0.77-1.13; $P=0.39$]). However, when primary failures were excluded, cumulative patency became significantly longer for fistulas than for grafts for both first and subsequent accesses (61.9 versus 23.8 months [HR, 0.56; 95% CI, 0.43-0.74; $P<0.001$] and 42.8 versus 15.9 months [HR, 0.56; 95% CI, 0.44-0.72; $P<0.001$]). Results were similar for forearm and upper-arm accesses. Compared with functioning fistulas, grafts necessitated twice as many angioplasties (1.4 versus 3.2/1000 days, respectively; $P<0.001$) and significantly more thrombolysis interventions (0.06 versus 0.98/1000 days; $P<0.001$) to maintain patency once matured and successfully used for dialysis. CONCLUSIONS: Cumulative patency did not differ between fistulas and grafts; however, grafts necessitated more interventions to maintain functional patency.

Moist, Louise M & Lok, Charmaine E & Vachharajani, Tushar J et al. **Optimal hemodialysis vascular access in the elderly patient.** *Semin Dial.* 2012 Nov-Dec;25(6):640-8. doi: 10.1111/sdi.12037.

Abstract: The optimal vascular access for elderly patients remains a challenge due to the difficulty balancing the benefits and risks in a population with increased comorbidity and decreased survival. Age is commonly associated with failure to mature in fistula and decreased rates of primary and secondary patency in both fistula and grafts. In the elderly, at 1 and 2 years, primary patency rates range from 43% to 74% and from 29% to 67%, respectively. Secondary patency rates at 1 and 2 years range from 56% to 82% and 44% to 67%, respectively. Cumulative fistula survival is no better than grafts survival when primary failures are included. Several observational studies consistently demonstrate a lower adjusted mortality among those using a fistula compared with a catheter; however, catheter use in the elderly is increasing in most countries with the exception of Japan. Both guidelines and quality initiatives do not acknowledge the trade-offs involved in managing the elderly patients with multiple chronic conditions and limited life expectancy or the value that patients place on achieving these outcomes. The framework for choice of vascular access presented in this article considers: (1) likelihood of disease progression before death, (2) patient life expectancy, (3) risks and benefits by vascular access type, and (4) patient preference. Future studies evaluating the timing and type of vascular access with careful assessments of complications, functionality, cost benefit, and patients' preference will provide relevant information to individualize and optimize care to improve morbidity, mortality, and quality of life in the elderly patient.

Schmidt, Rebecca J & Goldman, Richard S & Germain, Michael. **Pursuing permanent hemodialysis vascular access in patients with a poor prognosis: juxtaposing potential benefit and harm.** *Am J Kidney Dis.* 2012 Dec;60(6):1023-31. doi: 10.1053/j.ajkd.2012.07.020. Epub 2012 Sep 19.

Abstract: For patients with end-stage renal disease requiring hemodialysis, the native arteriovenous fistula remains the gold standard of vascular access, with tunneled cuffed central venous catheters reserved for temporary use or as a last resort in patients for whom a permanent vascular access is not possible. It is expected that most patients receiving hemodialysis will be suitable for arteriovenous fistula placement, with suitable patients defined as those: (1) for whom long-term dialysis is expected to confer benefit, (2) with vascular anatomy amenable to arteriovenous fistula placement, and (3) with progressive irreversible kidney failure who are more likely to require dialysis than to die before reaching dialysis dependence. The present article reviews considerations for vascular access decision making, focusing on older patients and those with a poor prognosis, weighing the risks and benefits of arteriovenous fistulas, arteriovenous grafts, and central venous catheters and emphasizing that in the process of vascular access decision making for such patients, medical and ethical obligations to avoid central venous catheters must be balanced by the obligation to do no harm.

Wilson, Steven M & Robertson, John A & Chen, Grace et al. **The IMPACT (Incident Management of Patients, Actions Centered on Treatment) program: a quality improvement approach for caring for patients initiating long-term hemodialysis.** *Am J Kidney Dis.* 2012 Sep;60(3):435-43. doi: 10.1053/j.ajkd.2012.04.009. Epub 2012 May 17.

Abstract: BACKGROUND: Patients beginning dialysis therapy are at risk of death and illness. The IMPACT (Incident Management of Patients, Actions Centered on Treatment) quality improvement program was developed to improve incident hemodialysis patient outcomes through standardized care. STUDY DESIGN: Quality improvement report. SETTING & PARTICIPANTS: Patients who started hemodialysis therapy between September 2007 and December 2008 at DaVita facilities using the IMPACT program (n = 1,212) constituted the intervention group. Propensity score-matched patients who initiated hemodialysis therapy in the same interval at DaVita facilities not using the IMPACT program (n = 2,424) made up the control group. QUALITY IMPROVEMENT PLAN: IMPACT intervention included a structured intake process and monitoring reports; patient enrollment in a 90-day patient education program and 90-day patient management pathway. OUTCOMES: Mean dialysis adequacy (Kt/V), hemoglobin and albumin levels, percentage of patients using preferred vascular access (arteriovenous fistula or graft), and mortality at each quarter. RESULTS: Compared with the non-IMPACT group, the IMPACT group was associated with a higher proportion of patients dialyzing with a preferred access at 90 days (0.50 [95% CI, 0.47-0.53] vs 0.47 [95% CI, 0.45-0.49]; P = 0.1) and 360 days (0.63 [95% CI, 0.61-0.66] vs 0.48 [95% CI, 0.46-0.50]; P < 0.001) and a lower mortality rate at 90 days (24.8 [95% CI, 19.0-30.7] vs 31.9 [95% CI, 27.1-36.6] deaths/100 patient-

years; P = 0.08) and 360 days (17.8 [95% CI, 15.2-20.4] vs 25.1 [95% CI, 20.7-25.2] deaths/100 patient-years; P = 0.01). LIMITATIONS: The study does not determine the care processes responsible for the improved outcomes. CONCLUSIONS: Intense management of incident dialysis patients with the IMPACT quality improvement program was associated with significantly decreased first-year mortality. Focused attention to the care of incident patients is an important part of a dialysis program.

Vassalotti, Joseph A & Jennings, William C & Beathard, Gerald A et al. **Fistula first breakthrough initiative: targeting catheter last in fistula first.** *Semin Dial.* 2012 May;25(3):303-10. doi: 10.1111/j.1525-139X.2012.01069.x. Epub 2012 Apr 4.

Abstract: An arteriovenous fistula (AVF) is the optimal vascular access for hemodialysis (HD), because it is associated with prolonged survival, fewer infections, lower hospitalization rates, and reduced costs. The AVF First breakthrough initiative (FFBI) has made dramatic progress, effectively promoting the increase in the national AVF prevalence since the program's inception from 32% in May 2003 to nearly 60% in 2011. Central venous catheter (CVC) use has stabilized and recently decreased slightly for prevalent patients (treated more than 90 days), while CVC usage in the first 90 days remains unacceptably high at nearly 80%. This high prevalence of CVC utilization suggests important specific improvement goals for FFBI. In addition to the current 66% AVF goal, the initiative should include specific CVC usage target(s), based on the KDOQI goal of less than 10% in patients undergoing HD for more than 90 days, and a substantially improved initial target from the current CVC proportion. These specific CVC targets would be disseminated through the ESRD networks to individual dialysis facilities, further emphasizing CVC avoidance in the transition from advanced CKD to chronic kidney failure, while continuing to decrease CVC by prompt conversion of CVC-based hemodialysis patients to permanent vascular access, utilizing an AVF whenever feasible.

Basile, Carlo & Lomonte, Carlo. **Pro: the arteriovenous fistula is a blessing of God.** *Nephrol Dial Transplant.* 2012 Oct;27(10):3752-6. doi: 10.1093/ndt/gfs085. Epub 2012 Apr 3.

Abstract: Life-sustaining haemodialysis (HD) requires durable vascular access (VA) to the circulatory system. The ideal permanent VA must provide longevity of use with minimal complication rate and supply high enough blood flow to deliver the prescribed dialysis dosage [1]. While evidence from randomized controlled trials is lacking, there is a broad consensus that the VA type not only contributes to patient morbidity but also may contribute independently to patient mortality [2–6]. The native arteriovenous fistula (AVF) is considered the best access to initiate patients on HD because of its longer survival and lower complication rates as compared with other forms of VA, such as the synthetic arteriovenous grafts and the central venous catheters (CVCs) [2–6]. Large studies show a graded mortality risk from both cardiovascular (CV) and infectious diseases

depending on access type, with the highest risk associated with catheters, followed by grafts and then AVFs [2–6].

Amerling, Richard. **Con: on cardiovascular outcomes and the arteriovenous fistula: lesser of evils.** *Nephrol Dial Transplant.* 2012 Oct;27(10):3756-7. doi: 10.1093/ndt/gfs415.

Abstract: The arteriovenous fistula (AVF) was adopted in the clinical practice of dialysis in the 1960s without prospective randomized trials, simply on the basis of utility. It was widely hailed as a major improvement from the Scribner shunt, and is rightfully credited with allowing chronic hemodialysis (HD) to flourish as a modality [1]. But this history does not negate the fact that the AVF is a harmful, non-physiological anomaly, with considerable downsides. These are either not mentioned or downplayed in programs to increase fistula use [2]. Anointing any particular remedy in medicine is hazardous, in that it deters research into better alternatives.

I am not advocating that the AVF be banned, nor am I a catheter proponent. I wish to encourage a thoughtful, common sense, individualized approach to HD access; an approach that matches the access to the needs of each patient, and that takes into account the negative effects of the AVF. I am suggesting that emotion be removed from this process and replaced by cool, clinical judgment.

Hayes, Wesley N & Watson, Alan R & Callaghan, Nichola et al. **Vascular access: choice and complications in European paediatric haemodialysis units.** *Pediatr Nephrol.* 2012 Jun;27(6):999-1004. doi: 10.1007/s00467-011-2079-3. Epub 2011 Dec 30.

Abstract: BACKGROUND: European and U.S. guidelines emphasise that permanent vascular access in the form of arteriovenous fistulae (AVF) or grafts (AVG) are preferable to central venous catheters (CVC) in paediatric patients on long-term haemodialysis. We report vascular access choice and complication rates in 13 European paediatric nephrology units. METHODS: A survey of units participating in the European Pediatric Dialysis Working Group requesting data on type of vascular access, routine care and complications in patients on chronic haemodialysis between March 2010 and February 2011. RESULTS: Information was compiled on 111 patients in 13 participating centres with a median age of 14 (range 0.25-20.2) years. Central venous catheters were used in 67 of 111 (60%) patients, with 42 patients (38%) having an AVF and two patients (2%) having an AVG. Choice of vascular access was significantly related to patient age, with patients with AVF/AVG having a median age of 16 years compared to 12 years for patients with CVCs ($p < 0.001$). Routine CVC exit site care and catheter lock solution use differed between centres. CVC infections requiring intravenous antibiotics were reported at a rate of 1.9 and exit site infections at a rate of 1.8 episodes/1000 catheter days. Overall infective complications necessitating CVC change occurred at a rate of 0.9 episodes/1000 catheter days. No infective complications were reported in patients with AVF/AVG access. The rate of CVC infections requiring intravenous antibiotics was significantly lower in patients in whom CVC exit sites were cleaned weekly as opposed to every dialysis session (relative

risk with every session cleaning vs. weekly cleaning 2.58, 95% confidence interval 1.17-5.69). Catheter malfunction (inadequate blood flow) was a more prevalent complication necessitating 22.4 thrombolytic interventions/1000 catheter days and 2.1 CVC changes/1000 catheter days.

CONCLUSIONS: Central venous catheters remain the predominant choice of vascular access in Europe despite problems of malfunction and infection. AVF/AVG were predominantly used in adolescents without reported complications. More regular exit site cleaning may predispose to CVC infection, but this observation requires prospective evaluation.

Tamura, Manjula Kurella & Tan, Jane C & O'Hare, Ann M. **Optimizing renal replacement therapy in older adults: a framework for making individualized decisions.** *Kidney Int.* 2012 Aug;82(3):261-9. doi: 10.1038/ki.2011.384. Epub 2011 Nov 16.

Abstract: It is often difficult to synthesize information about the risks and benefits of recommended management strategies in older patients with end-stage renal disease since they may have more comorbidity and lower life expectancy than patients described in clinical trials or practice guidelines. In this review, we outline a framework for individualizing end-stage renal disease management decisions in older patients. The framework considers three factors: life expectancy, the risks and benefits of competing treatment strategies, and patient preferences. We illustrate the use of this framework by applying it to three key end-stage renal disease decisions in older patients with varying life expectancy: choice of dialysis modality, choice of vascular access for hemodialysis, and referral for kidney transplantation. In several instances, this approach might provide support for treatment decisions that directly contradict available practice guidelines, illustrating circumstances when strict application of guidelines may be inappropriate for certain patients. 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.

Castledine, Clare & van Schalkwyk, Dirk & Feest, Terry. **UK Renal Registry 13th Annual Report (December 2010): Chapter 7: the relationship between the type of vascular access used and survival in UK RRT patients in 2006.** *Nephron Clin Pract.* 2011;119 Suppl 2:c135-40. doi: 10.1159/000331757. Epub 2011 Aug 26.

Abstract: INTRODUCTION: The type of vascular access used by haemodialysis patients is thought to be one of the predictors of patient survival. However, many previous studies have been unable to separate the effect of access type from the effects of other differences between patients groups or have included incident patients. Some centres report excellent outcomes using dialysis catheters in stable prevalent patients and challenge the current guidelines about the use of long term catheters. This is an observational UK centre level study reporting on the relationship between the percentage of established prevalent patients using definitive access and the subsequent 1 year survival.

METHOD: Vascular access audit data from 2005 and UKRR survival data at 1 year for patients who had been on HD for over 3 months was obtained from the UKRR database. Regression analysis was used to assess the amount of variation in 1 year survival that could be explained by the percentage of patients using an AVF or AVG in a centre. RESULTS: From the renal centres reporting to the UKRR in 2005, 16,984 patients had vascular access data. The mean centre level 1 year survival was 86.4% (95% CI: 82.2-90.9) and was 86.9% (95% CI: 82.8-91.2) after censoring for transplantation. The mean percentage of haemodialysis patients using definitive access (AVF or AVG) in a centre was 69.8% (SD 10.4). A small positive association was found between the percentage of HD patients using an AVF

or AVG in a centre and 1 year uncensored survival ($\beta = 0.06$, $p = 0.04$). The type of access in use was able to explain 6% of the variation in centre level survival. **CONCLUSIONS:** To some extent, this study has repeated work done by DOPPS and in the US but for the first time has studied only prevalent dialysis patients and looked at the UK dialysis population. Whilst increased venous catheter use was associated with an increase in one year mortality of prevalent established haemodialysis patients, this effect was very small and only accounted for some 6% of the variation in one year mortality between renal centres. Further work using data from the current large vascular access audit needs to be done to further elucidate best practice within the UK.

Chang, Tara I & Paik, Jane & Greene, Tom et al. **Intradialytic hypotension and vascular access thrombosis.** *J Am Soc Nephrol.* 2011 Aug;22(8):1526-33. doi: 10.1681/ASN.2010101119.

Abstract: Identifying potential modifiable risk factors to reduce the incidence of vascular access thrombosis in hemodialysis could reduce considerable morbidity and health care costs. We analyzed data from a subset of 1426 HEMO study subjects to determine whether more frequent intradialytic hypotension and/or lower predialysis systolic BP were associated with higher rates of vascular access thrombosis. Our primary outcome measure was episodes of vascular access thrombosis occurring within a given 6-month period during HEMO study follow-up. There were 2005 total episodes of vascular access thrombosis during a median 3.1 years of follow-up. The relative rate of thrombosis of native arteriovenous fistulas for the highest quartile of intradialytic hypotension was approximately twice that of the lowest quartile, independent of predialysis systolic BP and other covariates. There was no significant association of intradialytic hypotension with prosthetic arteriovenous graft thrombosis after multivariable adjustment. Higher predialysis systolic BP was associated with a lower rate of fistula and graft thrombosis, independent of intradialytic hypotension and other covariates. In conclusion, more frequent episodes of intradialytic hypotension and lower predialysis systolic BP associate with increased rates of vascular access thrombosis. These results underscore the importance of including vascular access patency in future studies of BP management in hemodialysis.

Ng, Leslie J & Chen, Fangfei & Pisoni, Ronald L et al. **Hospitalization risks related to vascular access type among incident US hemodialysis patients.** *Nephrol Dial Transplant.* 2011 Nov;26(11):3659-66. doi: 10.1093/ndt/gfr063. Epub 2011 Mar 3.

Abstract: **BACKGROUND:** The excess morbidity and mortality related to catheter utilization at and immediately following dialysis initiation may simply be a proxy for poor prognosis. We examined hospitalization burden related to vascular access (VA) type among incident patients who received some predialysis care. **METHODS:** We identified a random sample of incident US Dialysis Outcomes and Practice Patterns Study hemodialysis patients (1996-2004) who reported predialysis nephrologist care. VA utilization was assessed at baseline and throughout the first 6 months on dialysis. Poisson regression was used to estimate the risk of all-cause and cause-specific

hospitalizations during the first 6 months. RESULTS: Among 2635 incident patients, 60% were dialyzing with a catheter, 22% with a graft and 18% with a fistula at baseline. Compared to fistulae, baseline catheter use was associated with an increased risk of all-cause hospitalization [adjusted relative risk (RR) = 1.30, 95% confidence interval (CI): 1.09-1.54] and graft use was not (RR = 1.07, 95% CI: 0.89-1.28). Allowing for VA changes over time, the risk of catheter versus fistula use was more pronounced (RR = 1.72, 95% CI: 1.42-2.08) and increased slightly for graft use (RR = 1.15, 95% CI: 0.94-1.41). Baseline catheter use was most strongly related to infection-related (RR = 1.47, 95% CI: 0.92-2.36) and VA-related hospitalizations (RR = 1.49, 95% CI: 1.06-2.11). These effects were further strengthened when VA use was allowed to vary over time (RR = 2.31, 95% CI: 1.48-3.61 and RR = 3.10, 95% CI: 1.95-4.91, respectively). A similar pattern was noted for VA-related hospitalizations with graft use. Discussion. Among potentially healthier incident patients, hospitalization risk, particularly infection and VA-related, was highest for patients dialyzing with a catheter at initiation and throughout follow-up, providing further support to clinical practice recommendations to minimize catheter placement.

Ocak, Gurbey & Halbesma, Nynke & le Cessie, Saskia et al. **Haemodialysis catheters increase mortality as compared to arteriovenous accesses especially in elderly patients.** *Nephrol Dial Transplant.* 2011 Aug;26(8):2611-7. doi: 10.1093/ndt/gfq775. Epub 2011 Jan 31.

Abstract: BACKGROUND: Catheter use has been associated with an increased mortality risk in haemodialysis patients. However, differences in the all-cause and cause-specific mortality risk between catheter use and arteriovenous access use in young and elderly haemodialysis patients have not yet been investigated. METHODS: In this prospective cohort study of 1109 incident haemodialysis patients from 38 centres in the Netherlands, hazard ratios (HRs) with 95% confidence intervals (95% CIs) were calculated for 2-year all-cause, infection-related and cardiovascular mortality in patients with a catheter as compared to patients with an arteriovenous access stratified for age (< 65 years and \geq 65 years). RESULTS: Of the 1109 patients, 919 had an arteriovenous access and 190 had a catheter. The mortality rate was 76 per 1000 person-years in young patients with an arteriovenous access, 129 per 1000 person-years in young patients with a catheter, 222 per 1000 person-years in elderly patients with an arteriovenous access and 427 per 1000 person-years in elderly patients with a catheter. The adjusted HR was 3.15 (95% CI: 2.09-4.75) for elderly patients with a catheter as compared to young patients with an arteriovenous access. The adjusted HRs in elderly patients with a catheter as compared to elderly patients with an arteriovenous access were 1.54 (95% CI: 1.13-2.12) for all-cause mortality, 1.60 (95% CI: 0.62-4.19) for infection-related mortality and 1.67 (95% CI: 1.04-2.68) for cardiovascular mortality. CONCLUSIONS: Especially, elderly haemodialysis patients with a catheter have an increased all-cause, infection-related and cardiovascular mortality risk as compared to patients with an arteriovenous access.

Allon, Michael & Lok, Charmaine E. **Dialysis fistula or graft: the role for randomized clinical trials.** *Clin J Am Soc Nephrol.* 2010 Dec;5(12):2348-54. doi: 10.2215/CJN.06050710. Epub 2010 Oct 28.

Abstract: The Fistula First Initiative has strongly encouraged nephrologists, vascular access surgeons, and dialysis units in the United States to make valiant efforts to increase fistula use in the hemodialysis population. Unfortunately, the rigid "fistula first" recommendations are not based on solid, current, evidence-based data and may be harmful to some hemodialysis patients by subjecting them to prolonged catheter dependence with its attendant risks of bacteremia and central vein stenosis. Once they are successfully cannulated for dialysis, fistulas last longer than grafts and require fewer interventions to maintain long-term patency for dialysis. However, fistulas have a much higher primary failure rate than grafts, require more interventions to achieve maturation, and entail longer catheter dependence, thereby leading to more catheter-related complications. Given the tradeoffs between fistulas and grafts, there is equipoise about their relative merits in patients with moderate to high risk of fistula nonmaturation. The time is right for definitive, large, multicenter randomized clinical trials to compare fistulas and grafts in various subsets of chronic kidney disease patients. Until the results of such clinical trials are known, the optimal vascular access for a given patients should be determined by the nephrologist and access surgeon by taking into account (1) whether dialysis has been initiated, (2) the patient's life expectancy, (3) whether the patient has had a previous failed vascular access, and (4) the likelihood of fistula nonmaturation. Careful clinical judgment should optimize vascular access outcomes and minimize prolonged catheter dependence among hemodialysis patients.

Goodkin, David A & Pisoni, Ronald L & Locatelli, Francesco et al. **Hemodialysis vascular access training and practices are key to improved access outcomes.** *Am J Kidney Dis.* 2010 Dec;56(6):1032-42. doi: 10.1053/j.ajkd.2010.08.010. Epub 2010 Oct 20.

Abstract: Recognizing that autologous arteriovenous fistula use was associated with improved outcomes in hemodialysis patients, the 1997 Dialysis Outcomes Quality Initiative (DOQI) vascular access practice guidelines from the National Kidney Foundation stressed fistulas as the optimal means of dialysis vascular access. In the United States, this emphasis has continued with the Fistula First Breakthrough Initiative. Much of the data supporting fistulas for dialysis access are derived from longitudinal cohorts, including the Dialysis Outcomes and Practice Patterns Study (DOPPS), dialysis provider databases, and other sources. This article reviews major findings from these data sources, focusing on specific practices and characteristics associated with greater arteriovenous fistula use in dialysis facilities worldwide. Important and often overlooked characteristics that are discussed in detail include specific preferences of dialysis staff regarding access type and the emphasis placed on fistula primacy and the number of fistulas created during surgical training. For example, in the DOPPS, the risk of initial fistula failure was 34% lower when fistulas were placed by surgeons who had created at least 25 fistulas during training (P = 0.002). It is imperative that dialysis clinicians advocate actively for specific dialysis access types on behalf of individual patients. Vascular

surgery teaching programs must supervise adequate numbers of fistula procedures for every trainee.

Ravani, Pietro & Parfrey, Patrick & MacRae, Jennifer et al. **Modeling survival of arteriovenous accesses for hemodialysis: semiparametric versus parametric methods.** *Clin J Am Soc Nephrol.* 2010 Jul;5(7):1243-8. doi: 10.2215/CJN.06190809. Epub 2010 Apr 22.

Abstract: BACKGROUND AND OBJECTIVES: Comparing outcomes of arteriovenous grafts and fistulas is challenging because the pathophysiology of access dysfunction and failure rate profiles differ by access type. Studying how risks vary over time may be important. DESIGN, SETTING, PARTICIPANTS, & MEASUREMENTS: Longitudinal data from 535 incident hemodialysis patients were used to study the relationship between access type and access survival, without (semiparametric Cox modeling) and with specification of the underlying hazard function (parametric Weibull modeling). RESULTS: The hazard for failure of fistulas and grafts declined over time, becoming proportional only after 3 months from surgery, with a graft versus fistula hazard ratio of 3.2 (95% confidence interval 1.9 to 5.3; Cox and Weibull estimation) and time ratio of 0.11 (i.e., the estimated access survival time was approximately one tenth shorter in grafts; 95% confidence interval 0.04 to 0.28; Weibull estimation only). Considering the entire observation period, grafts had slower hazard decline ($P < 0.001$) with shorter median survival times than fistulas (8.4 versus 38.3 months; Weibull regression only). CONCLUSIONS: Parametric models of arteriovenous access survival may provide relevant information about temporal risk profiles and predicted survival times.

Appendix

Results from 2006-2007 and 2009-2010 literature searches.

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End Stage Renal Disease (ESRD) Quality Measure Development, Maintenance, and Support

Vascular Access Technical Expert Panel Clinical Guideline Summary

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KDOQI: 2006 Updates Clinical Practice Guidelines and Recommendations – Vascular Access

Group: The National Kidney Foundation Kidney Disease Outcomes Quality Initiative (NKF KDOQI)

Target population: ESRD patients on Hemodialysis

Link to complete guidelines: https://www.kidney.org/sites/default/files/docs/12-50-0210_jag_dcp_guidelines-va_oct06_sectionc_ofc.pdf

Date: 2006

GUIDELINE 2. SELECTION AND PLACEMENT OF HEMODIALYSIS ACCESS

A structured approach to the type and location of long-term HD accesses should help optimize access survival and minimize complications. The access should be placed distally and in the upper extremities whenever possible. Options for fistula placement should be considered first, followed by prosthetic grafts if fistula placement is not possible. Catheters should be avoided for HD and used only when other options listed are not available.

2.1 The order of preference for placement of fistulae in patients with kidney failure who choose HD as their initial mode of KRT should be (in descending order of preference):

2.1.1 Preferred: Fistulae. (B)

2.1.1.1 A wrist (radiocephalic) primary fistula. (A)

2.1.1.2 An elbow (brachiocephalic) primary fistula. (A)

2.1.1.3 A transposed brachial basilic vein fistula: (B)

2.1.2 Acceptable: AVG of synthetic or biological material, such as: (B)

2.1.2.1 A forearm loop graft, preferable to a straight configuration.

2.1.2.2 Upper-arm graft.

2.1.2.3 Chest wall or “necklace” prosthetic graft or lower extremity fistula or graft; all upper-arm sites should be exhausted.

2.1.3 Avoid if possible: Long-term catheters. (B)

2.1.3.1 Short-term catheters should be used for acute dialysis and for a limited duration in hospitalized patients. Non-cuffed femoral catheters should be used in bed-bound patients only. (B)

2.1.3.2 Long-term catheters or dialysis port catheter systems should be used in conjunction with a plan for permanent access. Catheters capable of rapid flow rates are preferred. Catheter choice should be based on local experience, goals for use, and cost. (B)

2.1.3.3 Long-term catheters should not be placed on the same side as a maturing AV access, if possible. (B)

Special attention should be paid to consideration of avoiding femoral catheter access in HD patients who are current or future kidney transplant candidates. MRA imaging of both arteries and veins is the diagnostic procedure of choice for evaluating central vessels for possible chest wall construction.

KHA-CARI: Vascular Access – Selection of Type of Access

Group: The Kidney Health Australia - Caring for Australasians with Renal Impairment (KHA-CARI). Pamela Lopez Vargas, Kevan Polkinghorne

Target population: ESRD patients on Hemodialysis

Link: http://www.cari.org.au/Dialysis/dialysis%20vascular%20access/Selection_of_access_type.pdf
http://www.cari.org.au/Dialysis/dialysis%20vascular%20access/Summaries/Polkinghorne_2013_701.pdf

Date: 2012

1. Selection of appropriate vascular access
Guideline recommendations (No recommendations possible based on Level I or II evidence.*)

SUGGESTIONS FOR CLINICAL CARE

(Suggestions are based on Level III and IV evidence)

Whenever possible it is suggested that a native arteriovenous fistula is created and used for haemodialysis, as it is superior to an arteriovenous graft and to a central venous catheter. (Level III evidence)

When a native arteriovenous fistula is not possible, an artificial arteriovenous graft should be used in preference to a central venous catheter. Arteriovenous grafts have similar patency to arteriovenous fistula after accounting for arteriovenous fistula primary failure at the expense of greater interventions to maintain patency. (Level III evidence)

**Of note: The NHMRC levels of evidence were adhered to in this guideline update. This was a joint decision made by the KHA-CARI Steering Committee and the Vascular Access working group at the time of guideline update commencement.*

The Renal Association: Vascular Access for Haemodialysis

Group: The Renal Association (UK)

Target population: ESRD patients on Hemodialysis

Link: <http://www.renal.org/guidelines/modules/vascular-access-for-haemodialysis#sthash.FVbWf0Gp.dpbs>

Date: 2011

1. Preferred type of vascular access (Guidelines 1.1 – 1.3)

Guideline 1.1 – Incident patient vascular access

We recommend that any individual who commences haemodialysis should do so with an arteriovenous fistula as first choice, an arteriovenous graft as second choice, a tunnelled venous catheter as third choice and a non tunnelled catheter as an option of necessity. (1B)

Guideline 1.2 – Prevalent patient vascular access

We suggest that any patients on long term haemodialysis should have vascular access monitored and maintained to minimise failure to allow timely planning for subsequent replacement of optimal vascular (or PD) access and avoid the need for emergency access. (2B)

Guideline 1.3 – Complications related to vascular access

We recommend that any patients on long term haemodialysis should have the risk of complications, especially infection, related to vascular access minimised by appropriate interventions. (1B)

Diagnosis, prevention and treatment of haemodialysis catheter-related bloodstream infections (CRBSI): a position statement of European Renal Best Practice (ERBP)

Group: European Renal Best Practice (ERBP)

Target population: ESRD patients on Hemodialysis

Link: <http://ckj.oxfordjournals.org/content/3/3/234.full>

Date: 2010

ERBP recommendations:

- A.1.1: The use of non-tunnelled catheters, except in acute kidney injury (AKI), is undesirable. In chronic maintenance haemodialysis patients, it is recommended to remove temporary catheters as soon as possible, even without or with only minor complications, and to have them replaced preferentially by an arterio-venous fistula (AVF) or, if that is impossible, an arterio-venous graft (AVG) or, if that is impossible, a tunnelled central vein catheter (CVC).
- A.2.2: If haemodialysis catheters are required either due to need or because patients refuse an AVF, the occurrence of a catheter-related complication should be a trigger to re-evaluate options for alternative access, such as an AVF.

Report of the Canadian Society of Nephrology Vascular Access Working Group

Group: Canadian Society of Nephrology

Target population: ESRD patients on Hemodialysis

Link: <http://onlinelibrary.wiley.com/doi/10.1111/j.1525-139X.2011.01009.x/pdf>

Date: 2011

(a) National Recommendations

(1) We recommend that CSN establish as a policy that “Functional AVF, which are associated with better outcomes, including patient survival, and which are generally more cost effective, should be encouraged by renal providers for suitable patients.”

This statement mirrors an existing CSN policy that is widely supported by Canadian nephrologists (Home and Self Care, which generally are more cost effective, should be encouraged by renal care providers, but not be mandatory (5).

(2) We interpret the evidence available to suggest that CVCs are, in general, the least preferred type of VA for most patients, and that AVGs are preferred over CVCs in most instances when an AVF is not possible.

(3) We suggest that the optimal access distribution will include a minority of patients with AVG or CVC. Indications for an AVG/CVC include patients with (a) limited life expectancy, (b) in whom AVF maturity is not likely to occur, and / or (c) expected transition to peritoneal dialysis (PD) or transplantation in the near future.

End Stage Renal Disease (ESRD) Quality Measure Development, Maintenance, and Support

Vascular Access Technical Expert Panel Environmental Scan

Environmental Scan Summary

UM-KECC performed a preliminary scan of the leading quality measure databases, inventories, and measure development programs to identify existing quality measures related to assessing vascular access use for chronic dialysis patients. Some of the resources utilized in our efforts during January 2015 include a search of the National Quality Forum (NQF) measures database, the National Quality Measures Clearinghouse (NQMC), and the U.S. Department of Health and Human Services Inventory— both via the Agency for Healthcare Research and Quality (AHRQ). The two existing CMS measures are also included in the scan.

Measure list

Measure Title	Hemodialysis Vascular Access- Minimizing use of catheters as Chronic Dialysis Access
Measure Developer	Centers for Medicare & Medicaid Services
Measure Description	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.
Numerator	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.
Denominator	Patients on maintenance hemodialysis during the last HD treatment of study period.
Exclusions	Patients on acute hemodialysis, peritoneal dialysis, or patients <18 years of age.

NQF Endorsed	Yes, 0256
Clinical Condition	End Stage Renal Disease (ESRD)
Risk Adjusted	No
Link	http://www.qualityforum.org/QPS/0256

Measure Title	Hemodialysis Vascular Access- Maximizing Placement of Arterial Venous Fistula (AVF)
Measure Developer	Centers for Medicare & Medicaid Services
Measure Description	Percentage of patients on maintenance hemodialysis during the last HD treatment of month using an autogenous AV fistula with two needles
Numerator	Patients who were on maintenance hemodialysis (HD) using an autogenous AV fistula with two needles at the last HD treatment of month
Denominator	Patients on maintenance hemodialysis during the last HD treatment of month including patients on home hemodialysis
Exclusions	Patients on acute hemodialysis, peritoneal dialysis, or patients <18 years of age
NQF Endorsed	Yes, 0257
Clinical Condition	End Stage Renal Disease (ESRD)
Risk Adjusted	No
Link	http://www.qualityforum.org/QPS/0257

Measure Title	Vascular Access—Functional Arteriovenous Fistula (AVF) or AV Graft or Evaluation for Placement
Measure Developer	KCQA
Measure Description	<p>Percentage of end stage renal disease (ESRD) patients aged 18 years and older receiving hemodialysis during the 12-month reporting period and on dialysis >90 days who:</p> <p>(1) have a functional autogenous AVF (defined as two needles used or a single-needle device [NOT one needle used in a two-needle device]) (computed and reported separately);</p> <p>(2) have a functional AV graft (computed and reported separately); or</p> <p>(3) have a catheter but have been seen/evaluated by a vascular surgeon, other surgeon qualified in the area of vascular access, or interventional nephrologist trained in the primary placement of vascular access for a functional autogenous AVF or AV graft at least once during the 12-month reporting period (computed and reported separately).</p> <p>Reporting should be stratified by incident versus prevalent patients, as defined by USRDS.</p>
Numerator	<p>Number of patients from the denominator who:</p> <p>(1) have a functional autogenous AVF (defined as two needles used or a single-needle device) (computed and reported separately); or</p> <p>(2) have a functional AV graft (computed and reported separately); or</p> <p>(3) have a catheter but have been seen/evaluated by a vascular surgeon, other surgeon qualified in the area of vascular access, or interventional nephrologist trained in the primary placement of vascular access for a functional autogenous AVF (defined as two needles used or a single needle device) or AV graft at least once during the 12-month reporting period (computed and reported separately).</p> <p>Reporting should be stratified by incident versus prevalent patients, as defined by USRDS.</p>
Denominator	<p>All ESRD patients aged 18 years and older receiving hemodialysis during the 12-month reporting period and on dialysis for greater than 90 days.</p> <p>This measure includes both in-center and home hemodialysis patients.</p>
Exclusions	None
NQF Endorsed	Yes, 0251
Clinical Condition	End Stage Renal Disease (ESRD)
Risk Adjusted	No
Link	http://www.qualityforum.org/QPS/0251

Measure Title	Proportion of new hemodialysis patients who use arteriovenous fistulas as the primary mode of vascular access. (Healthy People 2020 Chronic Kidney Disease - 11.1 [CKD - 11.1]) HHS:005621
Measure Developer	U.S. Department of Health & Human Services: Office of the Assistant Secretary for Health (OASH)
Measure Description	
Numerator	Number of persons aged 18 years and older in the CMS CPM data collection who are reported to use arteriovenous (AV) fistula as the primary mode of vascular access
Denominator	Number of persons in the CPM data collection aged 18 years and older on hemodialysis
Exclusions	
NQF Endorsed	No
Clinical Condition	Public Health, Renal & Genitourinary - Chronic Kidney Disease
Risk Adjusted	No
Link	https://www.healthypeople.gov/2020/topics-objectives/topic/chronic-kidney-disease/objectives

Measure Title	Hemodialysis Vascular Access Decision-making by surgeon to Maximize Placement of Autogenous Arterial Venous Fistula
Measure Developer	Society for Vascular Surgery
Measure Description	Percentage of patients with advanced chronic disease (CKD4 or 5) or end-stage renal disease (ESRD) undergoing open surgical implantation of permanent hemodialysis access who receive an autogenous arterial venous fistula (AVF).
Numerator	Patients undergoing a hemodialysis vascular access procedure who receive an autogenous arteriovenous fistula
Denominator	All patients with CKD4, CKD5 or ESRD who undergo open surgical placement of permanent hemodialysis access.
Exclusions	Clinician documented the patient was not an eligible candidate for autogenous AV fistula. A typical medical exclusion would include patient not eligible for autogenous AV fistula based on results of vein mapping
NQF Endorsed	No, endorsement removed. 0259
Clinical Condition	Renal, Surgery: General Surgery, Surgery: Vascular Surgery
Risk Adjusted	No
Link	http://www.qualityforum.org/QPS/0259

Measure Title	Vascular Access—Catheter Vascular Access and Evaluation by Vascular Surgeon for Permanent Access.
Measure Developer	KCQA
Measure Description	Percentage of patients aged 18 years and older with a diagnosis of end stage renal disease (ESRD) with a catheter after 90 days on hemodialysis who are seen/evaluated by a vascular surgeon or other surgeon qualified in the area of vascular access for permanent vascular access at least once during the 12-month reporting period.
Numerator	Number of patients from the denominator who are seen/evaluated by a vascular surgeon or other surgeon qualified in the area of vascular access for permanent vascular access at least once during the 12-month reporting period.
Denominator	All patients aged 18 years and older with a diagnosis of ESRD with a catheter after 90 days on hemodialysis.
Exclusions	Patients enrolled in hospice.
NQF Endorsed	No, endorsement removed. 0262
Clinical Condition	End Stage Renal Disease (ESRD)
Risk Adjusted	No
Link	http://www.qualityforum.org/QPS/0262

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 |
| <i>12:00 – 1:00</i> | <i>LUNCH</i> |
| 1:00 – 3:00 | Evaluation and Revision of current Vascular Access measures |
| | Consideration of risk adjustment strategies |
| <i>3:00 - 3:15</i> | <i>BREAK</i> |
| 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

Name and Credentials	Organizational Affiliation	Conflicts of Interest
Monet Carnahan, RN, BSN, CDN	Renal Care Coordinator Program Manager Fresenius Medical Center (FMC), Franklin, TN American Nephrology Nurses Association	None
Lynn Poole, FNP-BC, CNN	NCC Fistula First Catheter Last Project Clinical Lead ESRD National Coordinating Center Lake Success, NY	None
Joseph Vassalotti, MD, FASN, FNKF	Chief Medical Officer, National Kidney Foundation Associate Professor of Medicine, Division of Nephrology Mount Sinai Medical Center, New York, NY	None

Disclosures of potential conflicts of interest – TEP members (Continued)

Name and Credentials	Organizational Affiliation	Conflicts of Interest
<p>Charmaine Lok, MD, MSc, FRCPC (C)</p>	<p>Medical Director of Hemodialysis and Renal Management Clinics University Health Network</p> <p>Professor of Medicine University of Toronto, Toronto, ON</p>	<p>None</p>
<p>Daniel Weiner, MD, MS</p>	<p>Nephrologist, Tufts Medical Center Associate Medical Director, DCI Boston</p> <p>Associate Professor of Medicine Tufts University School of Medicine, Boston, MA</p>	<p>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.</p>
<p>Rudy Valentini, MD</p>	<p>Chief Medical Officer Children’s Hospital of Michigan (CHM) Professor of Pediatrics, Division of Nephrology Wayne State University School of Medicine</p>	<p>Former consultant for Gambro (2013)</p>

Disclosures of potential conflicts of interest – TEP members (Continued)

Name and Credentials	Organizational Affiliation	Conflicts of Interest
Lee Kirskey, MD	Attending staff, Department of Vascular Surgery Cleveland Clinic Foundation, Cleveland, OH	None
Derek Forfang	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	None
Nance Lehman	Board Member Dialysis Patient Citizens (DPC) Billings, MT	None

Disclosures of potential conflicts of interest – UM-KECC

Name	Title & Organization	Conflicts of Interest
Jonathan Segal, MD, MS	Nephrologist/Clinical Associate Professor, Internal Medicine	None
Joe Messana, MD	Collegiate Professor of Nephrology and Professor of Internal Medicine	None
Sehee Kim, PhD	Research Assistant Professor, Biostatistics	None
Claudia Dahlerus, PhD, MA	Principal Scientist	None
Shu Chen	Research Analyst	None
Jie Tang	Research Analyst	None
Casey Parrotte	Research Analyst	None
Jennifer Sardone	Research Analyst	None



Review of Literature

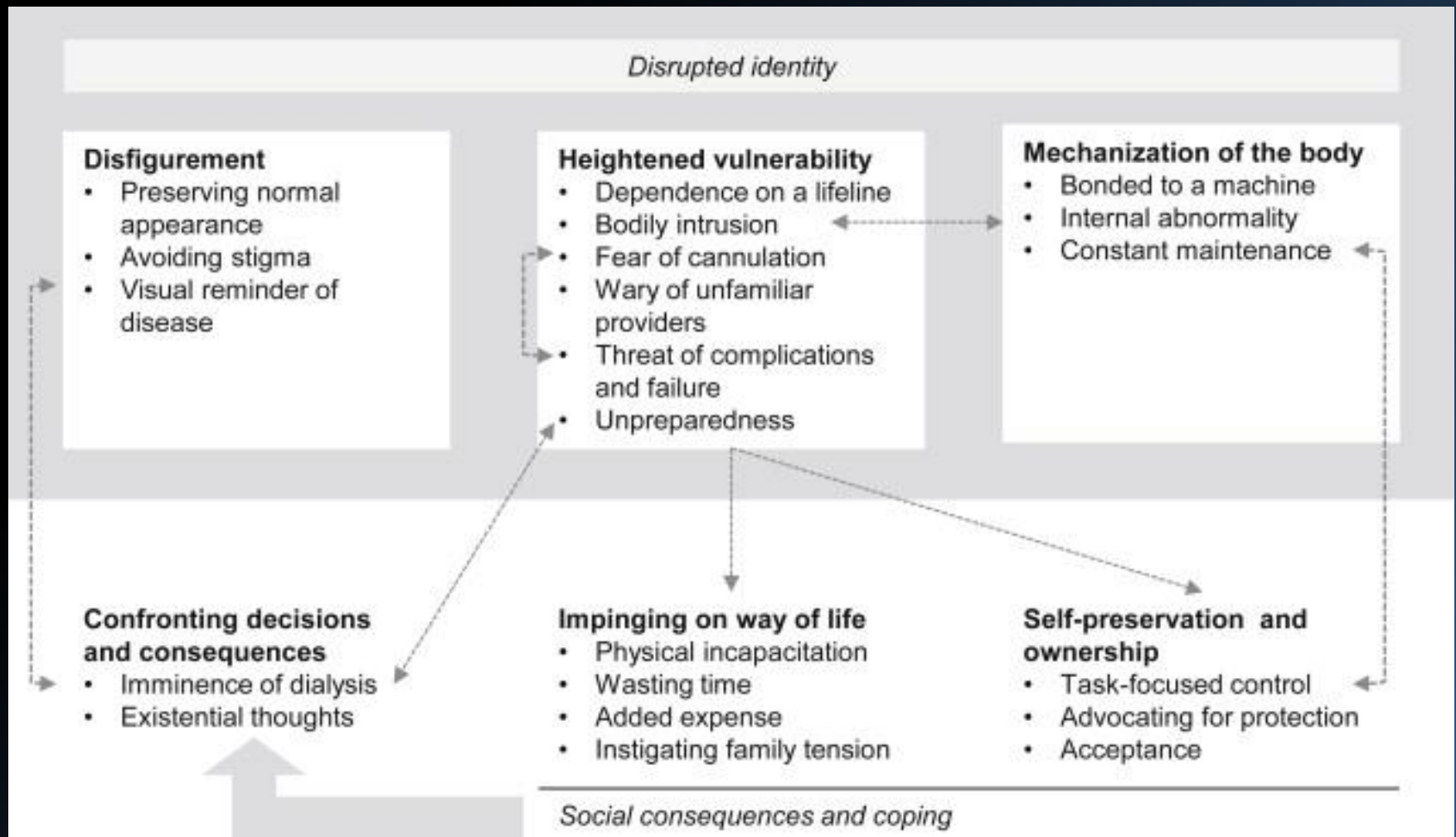
UM-KECC Literature Review

- 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



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.

Table 1. Advantages and disadvantages of different vascular access types

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

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

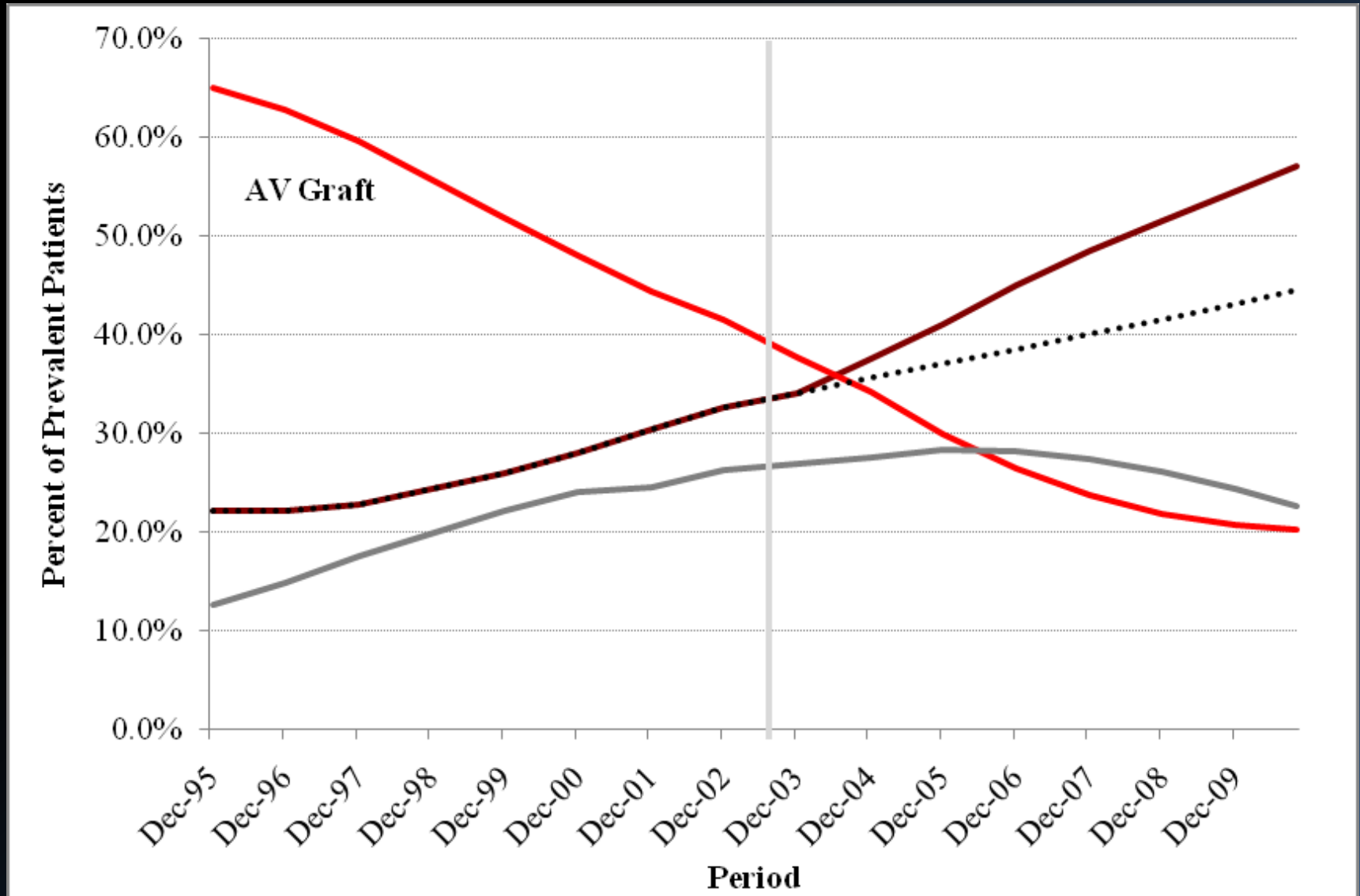
- Perceived as rigid approach to fistula for all, although it was never intended.
- Above is reinforced by the ESRD QIP.
- Role of AVG not clearly defined.
- High primary AVF rate and prolonged time to maturation results in prolonged catheter exposure.

Semin Dial. 25(3):303-310, 2012

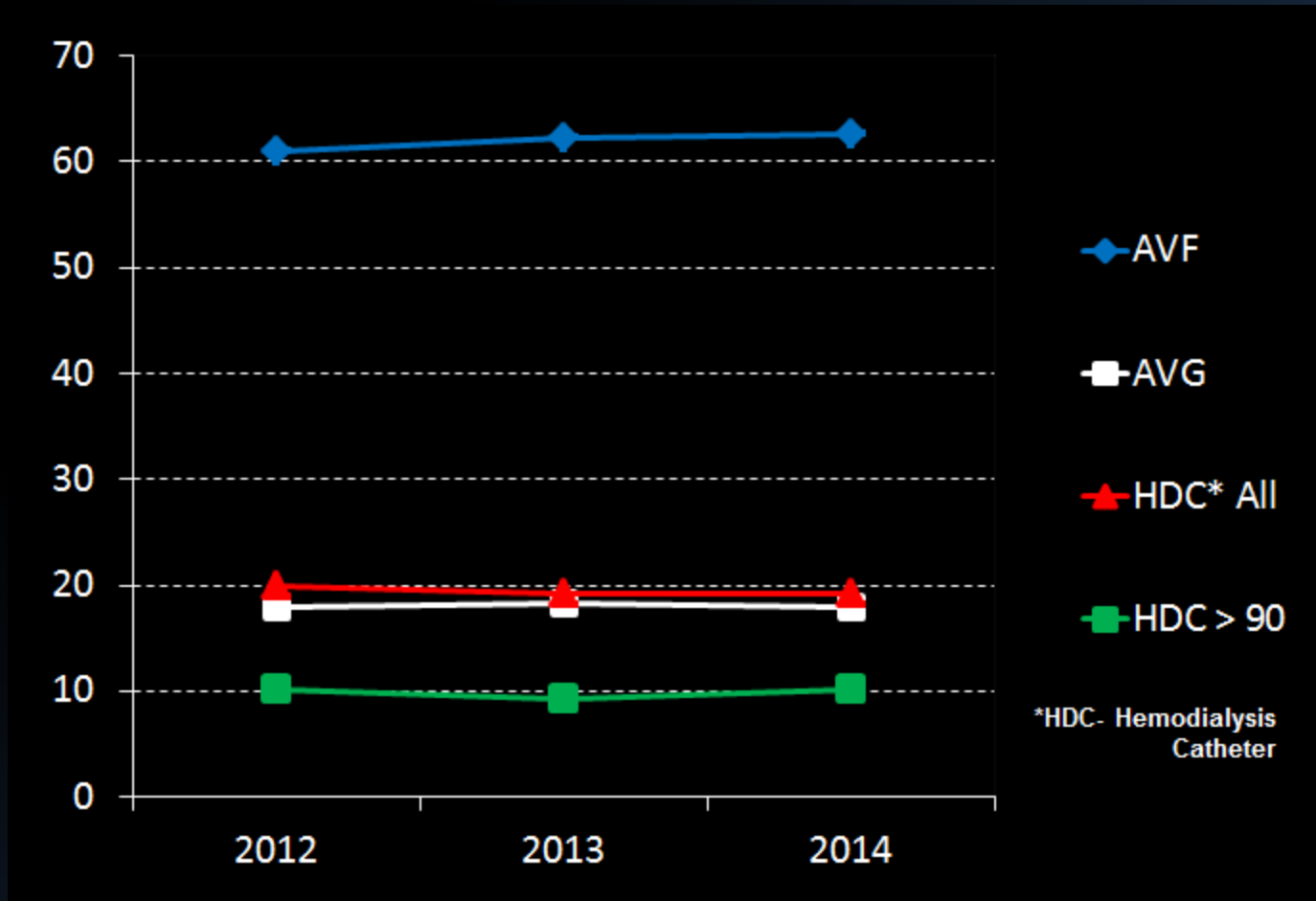
Nephrol Dial Transplant 27: 3752–3756, 2012

J Am Soc Nephrol 26: 5–7, 2015.

U.S. Vascular Access Prevalence

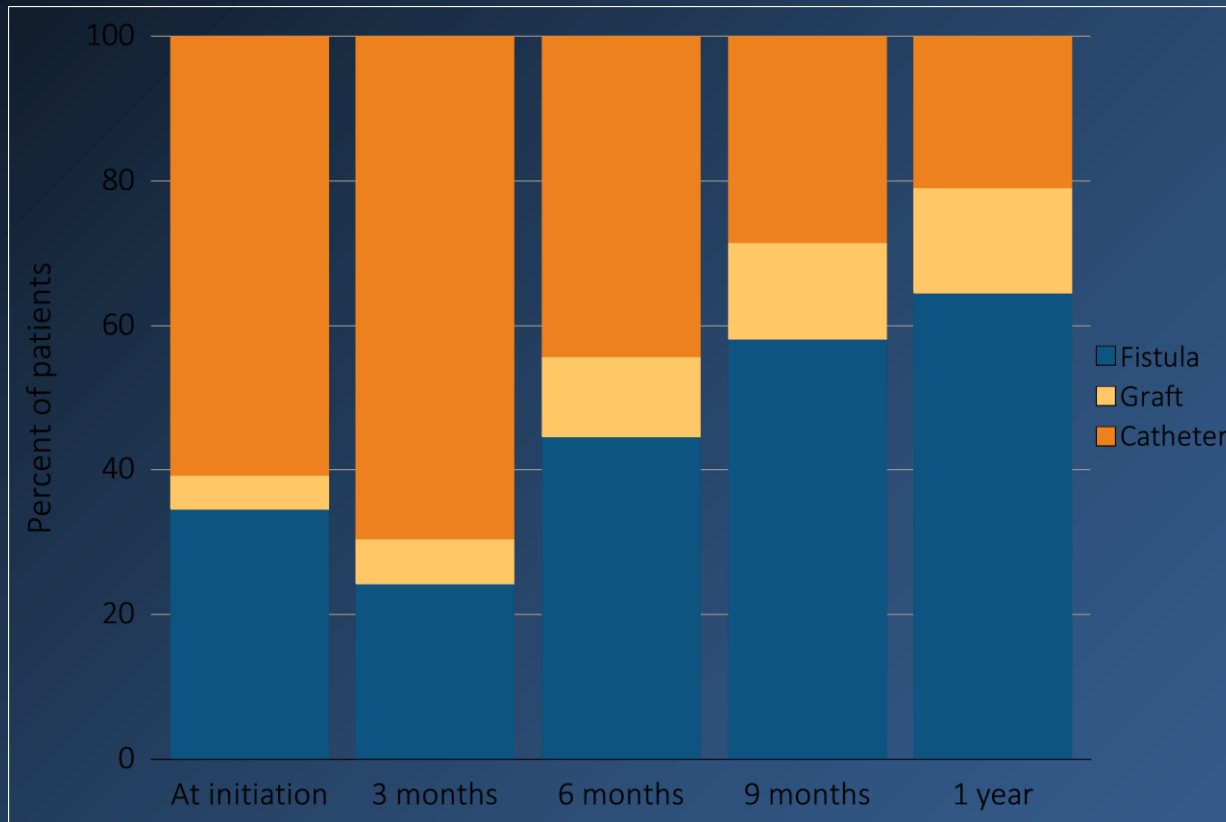


Fistula First Catheter Last Data



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

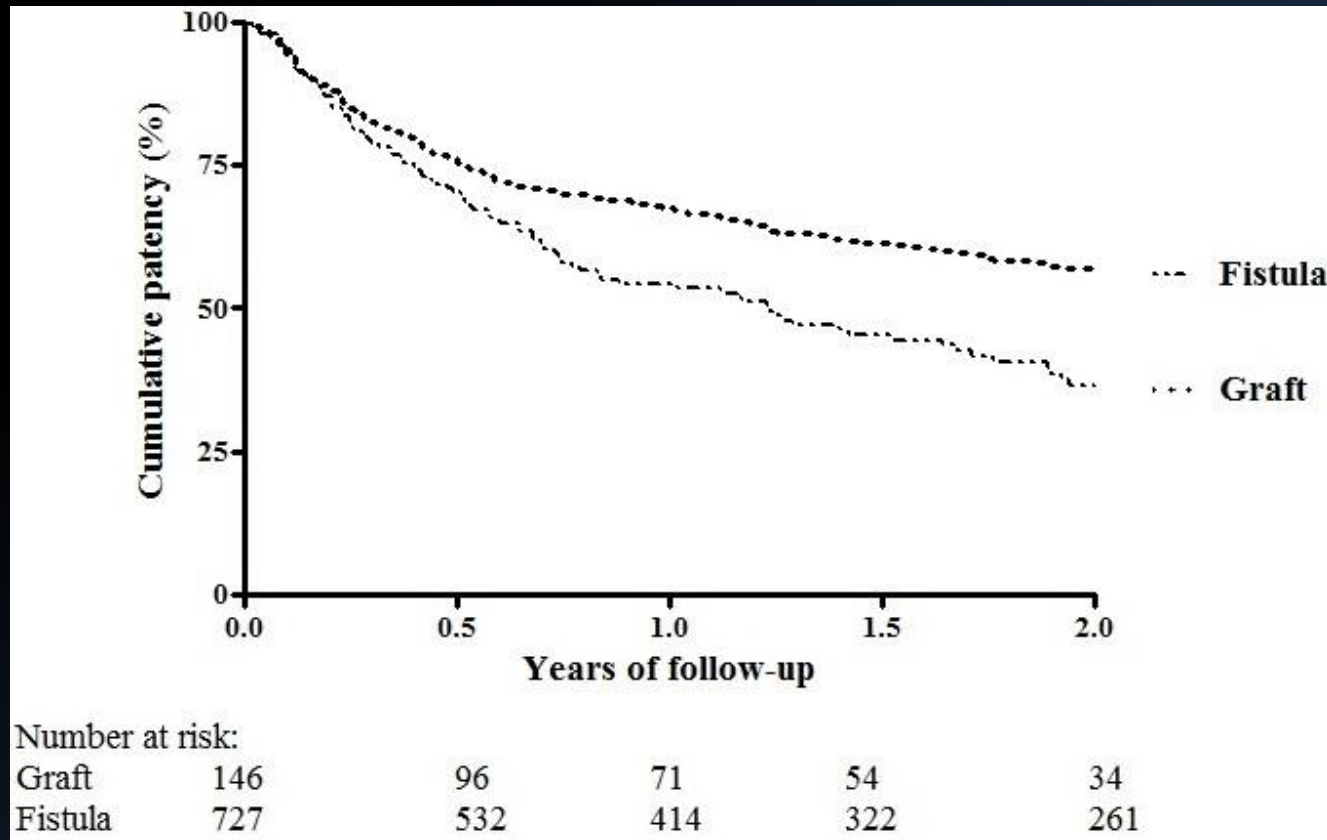


78% of hemodialysis patients start with a dialysis catheter

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

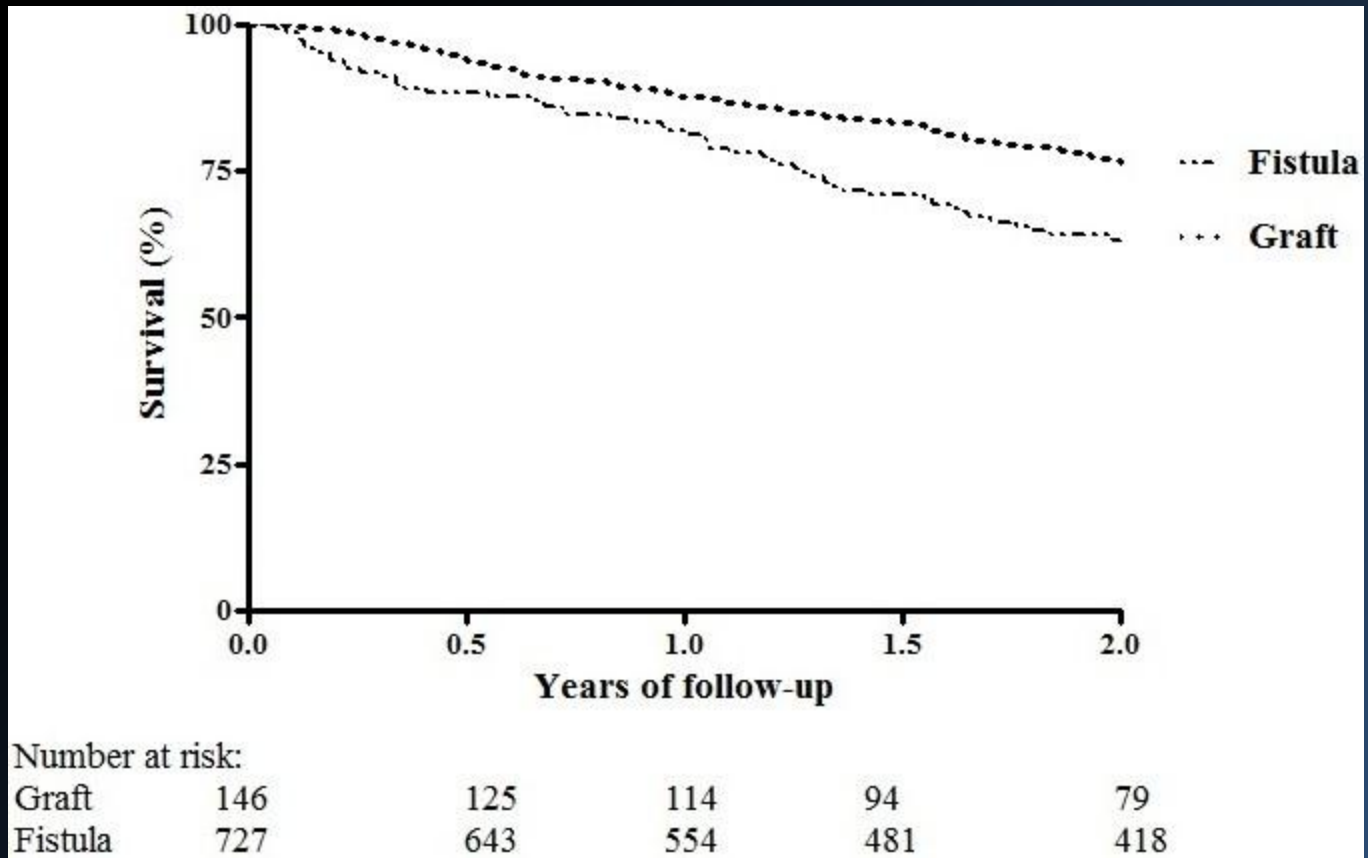
Type of arteriovenous vascular access and association with patency and mortality



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



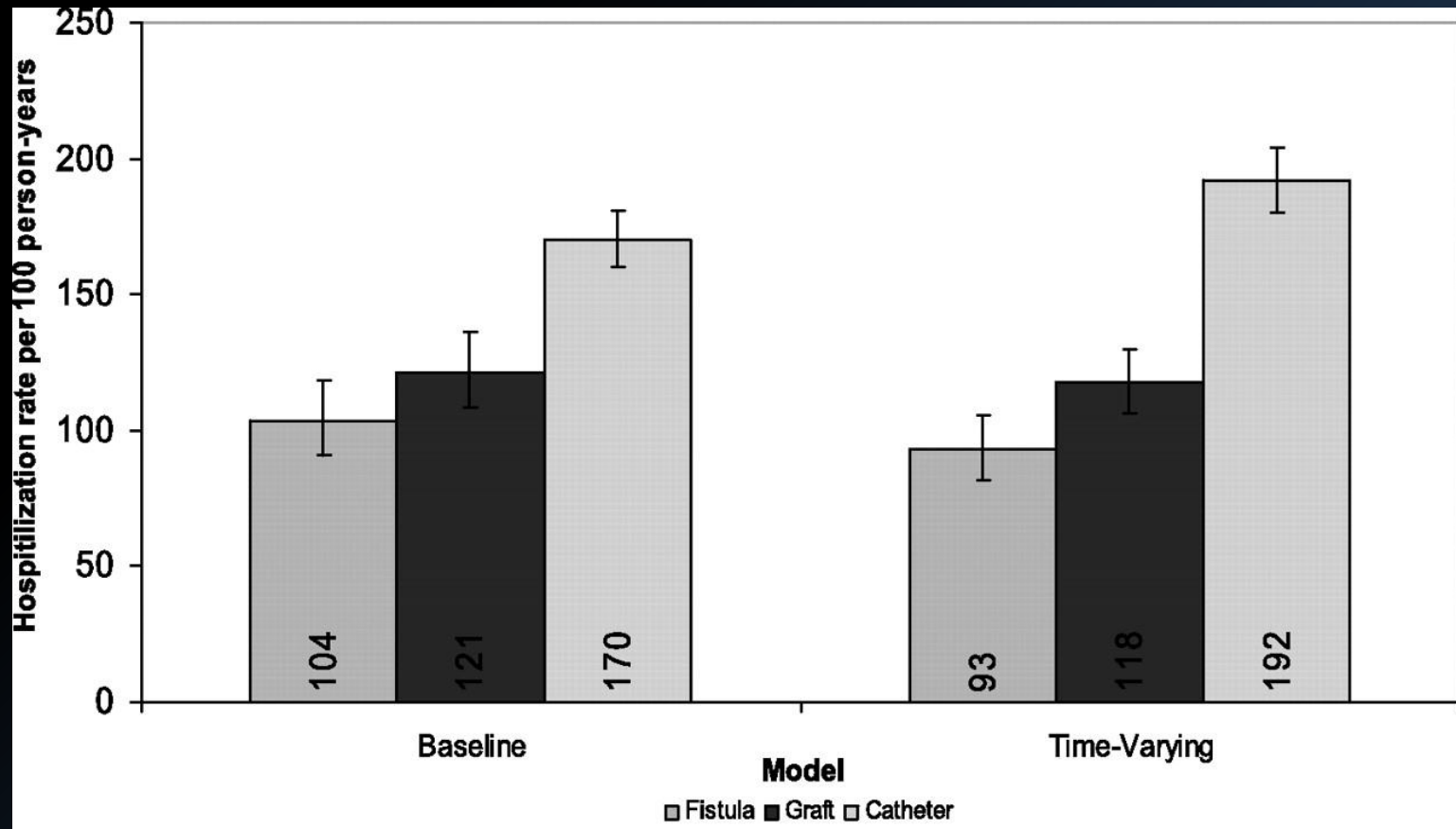
Kaplan-Meier survival curve for two-year primary patency loss after first successful cannulation.

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).

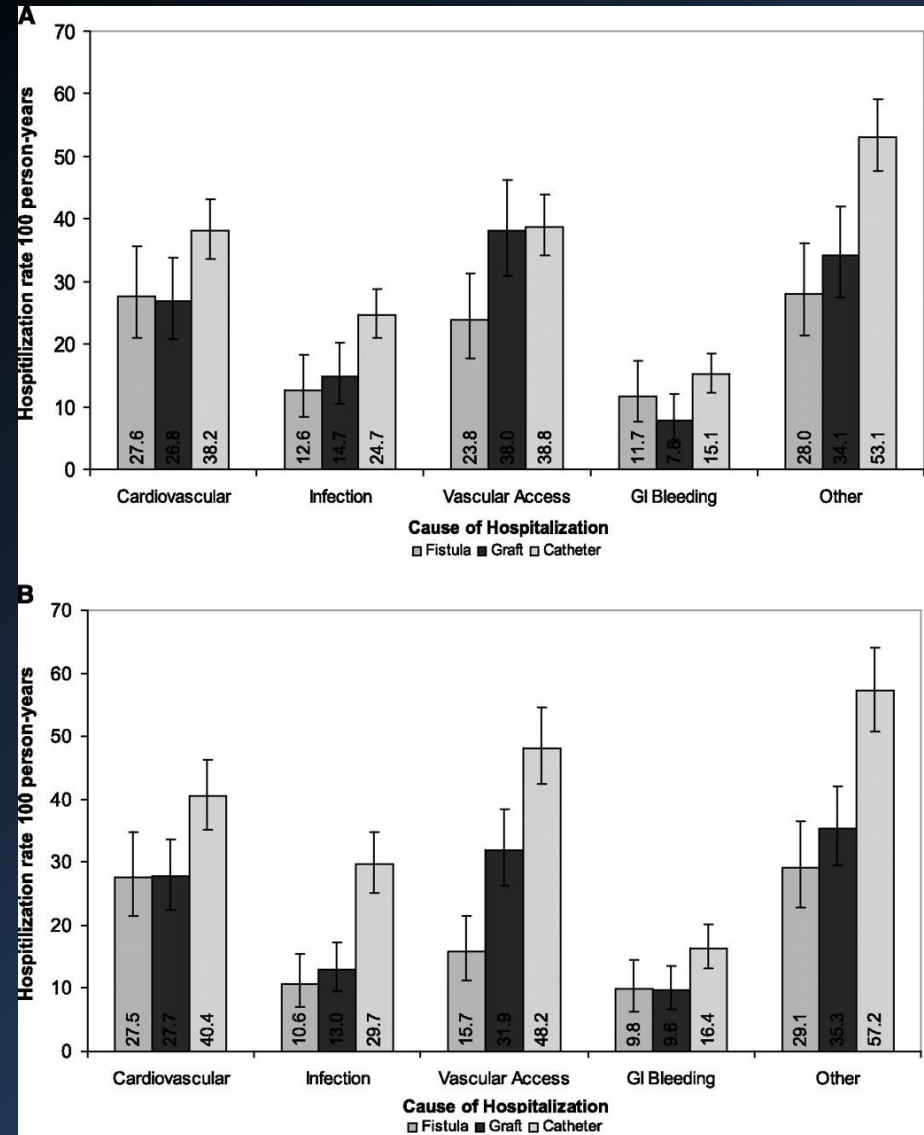
This is an example of a study that compares usable AVF and AVG.

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.

Leslie J. Ng et al. Nephrol. Dial. Transplant. 2011;26:3659-3666



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.

Study ID	Cohort Characteristics	No. of Patients	Risk Ratio	RR	95% CI	Weight
Ekbal 2008	Prevalent & Incident Patients	146		2.66	[0.79; 8.96]	0.5%
Garcia-Cortes 2005	Incident Patients	32		1.59	[0.64; 3.96]	0.8%
Thomson 2007	Patients with Perm. Catheters	237		2.75	[1.25; 6.05]	1.1%
Krzanowski 2011	Prevalent & Incident Patients	209		1.97	[0.91; 4.26]	1.1%
Ocak 2011	Incident Patients (<65)	496		1.54	[0.87; 2.73]	1.9%
Astor 2005	Incident Patients	495		1.47	[1.01; 2.14]	3.5%
Lorenzo 2004	Incident Patients	538		1.75	[1.25; 2.45]	4.0%
Dhingra 2001	Incident Patients (65+)	1517		1.70	[1.24; 2.33]	4.3%
Ocak 2011	Incident Patients (.65)	613		1.54	[1.13; 2.10]	4.4%
Dhingra 2001	Prevalent Diabetics	638		1.54	[1.17; 2.03]	5.1%
Foley 2009	Incident Patients	220157		1.78	[1.38; 2.30]	5.5%
Pastan 2002	Prevalent Patients	2470		1.40	[1.10; 1.78]	5.7%
Polkinghorne 2004	Prevalent & Incident Patients	3381		2.59	[2.04; 3.29]	5.8%
Wasse 2008	Incident Patients	4196		1.05	[0.88; 1.25]	7.3%
Moist 2008	Incident Patients	14809		1.60	[1.45; 1.77]	9.2%
Pisoni 2009	Prevalent & Incident Patients	12854		1.32	[1.22; 1.43]	9.6%
Xue 2003	Incident Patients	44244		1.70	[1.59; 1.81]	9.9%
Lacson 2009 A	Prevalent & Incident Patients	46268		1.39	[1.31; 1.47]	10.0%
Lacson 2009 B	Prevalent & Incident Patients	57768		1.30	[1.25; 1.35]	10.2%

Pooled RR

Heterogeneity: I-squared=83.1%, Q=106.6, df=18, p<0.0001



Krzanowski 2011	Prevalent & Incident Patients	32		1.60	[0.26; 9.85]	0.3%
Inrig 2006	Prevalent & Incident Patients	106		1.53	[0.31; 7.53]	0.4%
Astor 2005	Incident Patients	531		1.21	[0.70; 2.09]	2.6%
Polkinghorne 2004	Prevalent & Incident Patients	1491		1.67	[1.15; 2.43]	4.5%
Dhingra 2001	Prevalent Non-diabetics	2613		1.58	[1.10; 2.27]	4.6%
Dhingra 2001	Prevalent Diabetics	1281		1.09	[0.77; 1.54]	4.9%
Allon 2006	Prevalent Non-diabetics	1012		2.08	[1.52; 2.85]	5.5%
Allon 2006	Prevalent Diabetics	814		3.11	[2.31; 4.19]	5.8%
Foley 2009	Incident Patients	220157		1.28	[0.98; 1.67]	6.5%
Pastan 2002	Prevalent Patients	5888		1.30	[1.10; 1.54]	9.1%
Wasse 2008	Incident Patients	4228		1.08	[0.94; 1.23]	10.1%
Pisoni 2009	Prevalent & Incident Patients	6304		1.15	[1.03; 1.28]	10.6%
Lacson 2009 B	Prevalent & Incident Patients	45210		1.23	[1.14; 1.33]	11.4%
Lacson 2009 A	Prevalent & Incident Patients	48621		1.24	[1.17; 1.31]	11.7%
Xue 2003	Incident Patients	56634		1.46	[1.41; 1.51]	12.1%

Pooled RR

Heterogeneity: I-squared=85.2%, Q=94.5, df=14, p<0.0001



Wada 1996	Prevalent & Incident Patients	162		3.72	[0.20; 69.19]	0.1%
Krzanowski 2011	Prevalent & Incident Patients	185		1.27	[0.19; 8.49]	0.2%
Woo 2009	Prevalent & Incident Patients	358		1.16	[0.33; 4.00]	0.3%
Basel 2011	Prevalent & Incident Patients	147		2.80	[0.90; 8.71]	0.4%
Astor 2005	Incident Patients	206		1.21	[0.82; 1.79]	2.8%
Polkinghorne 2004	Prevalent & Incident Patients	2631		1.55	[1.15; 2.09]	4.1%
Wasse 2008	Incident Patients	1284		0.97	[0.76; 1.24]	5.2%
Dhingra 2001	Prevalent Diabetics	1337		1.41	[1.12; 1.78]	5.5%
Pastan 2002	Prevalent Patients	6436		1.10	[0.90; 1.34]	6.3%
Oliver 2004	Incident Patients	5924		1.34	[1.10; 1.63]	6.4%
Allon 2006	Prevalent & Incident Patients	1733		0.97	[0.80; 1.18]	6.6%
Dhingra 2001	Prevalent Non-diabetics	3010		1.08	[0.92; 1.27]	7.6%
Pisoni 2009	Prevalent & Incident Patients	14510		1.15	[1.06; 1.25]	10.3%
Xue 2003	Incident Patients	25226		1.16	[1.08; 1.24]	10.7%
Foley 2009	Incident Patients	220157		1.39	[1.32; 1.46]	11.1%
Lacson 2009 A	Prevalent & Incident Patients	58815		1.13	[1.08; 1.19]	11.1%
Lacson 2009 B	Prevalent & Incident Patients	56112		1.05	[1.00; 1.10]	11.3%

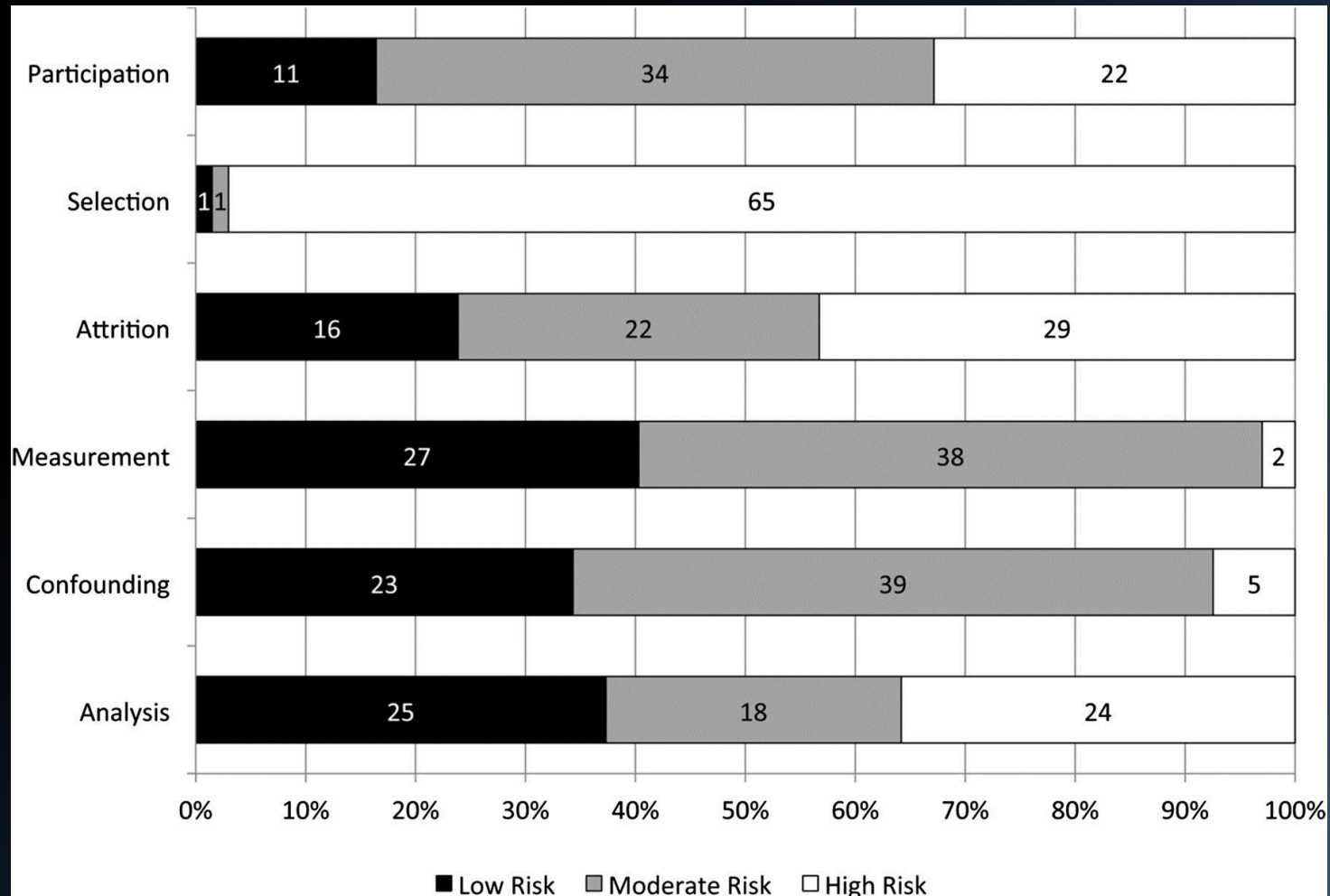
Pooled RR

Heterogeneity: I-squared=80.9%, Q=83.9, df=16, p<0.0001



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

Selection Bias – Suggests Risk Adjustment

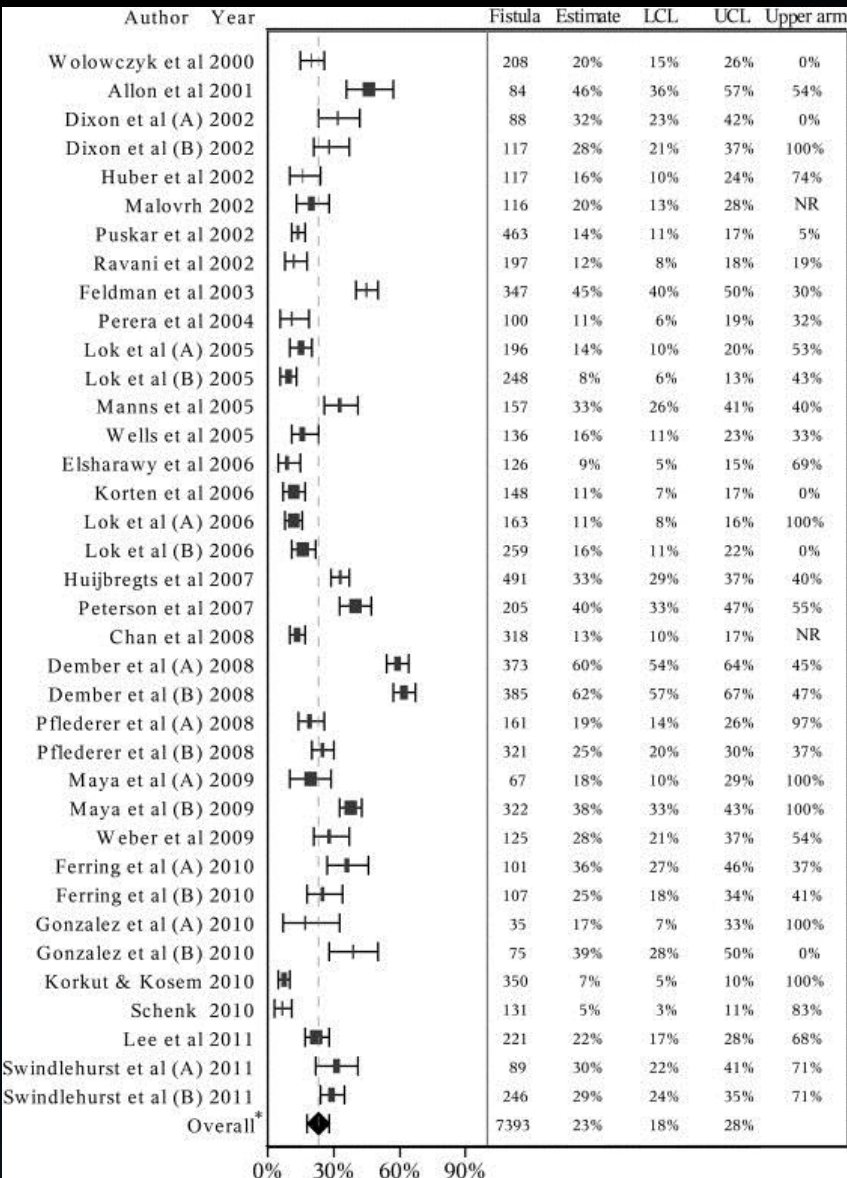


Risk of bias in the included articles. Numbers indicate the number of articles (n=67)

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

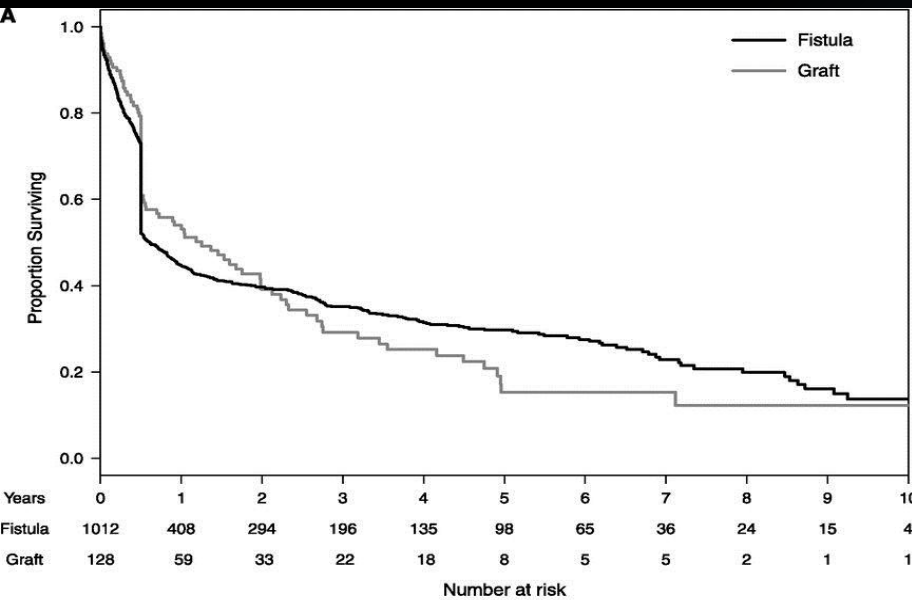


MEDLINE between 2000 and 2012 using prospectively collected data on 100 or more AVFs.

Conclusion

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.

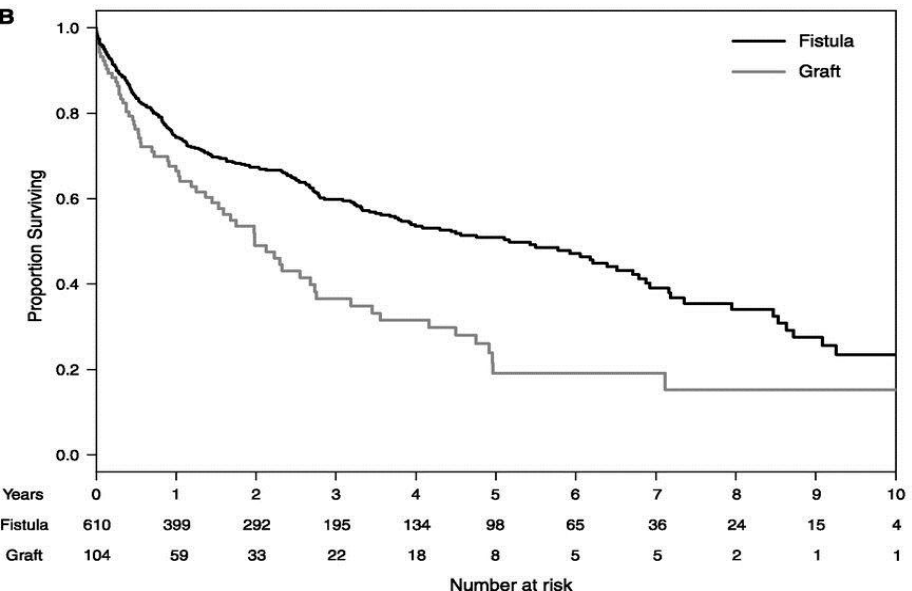
Cumulative Patency of Contemporary Fistulas versus Grafts (2000–2010)



Decision Analysis

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).

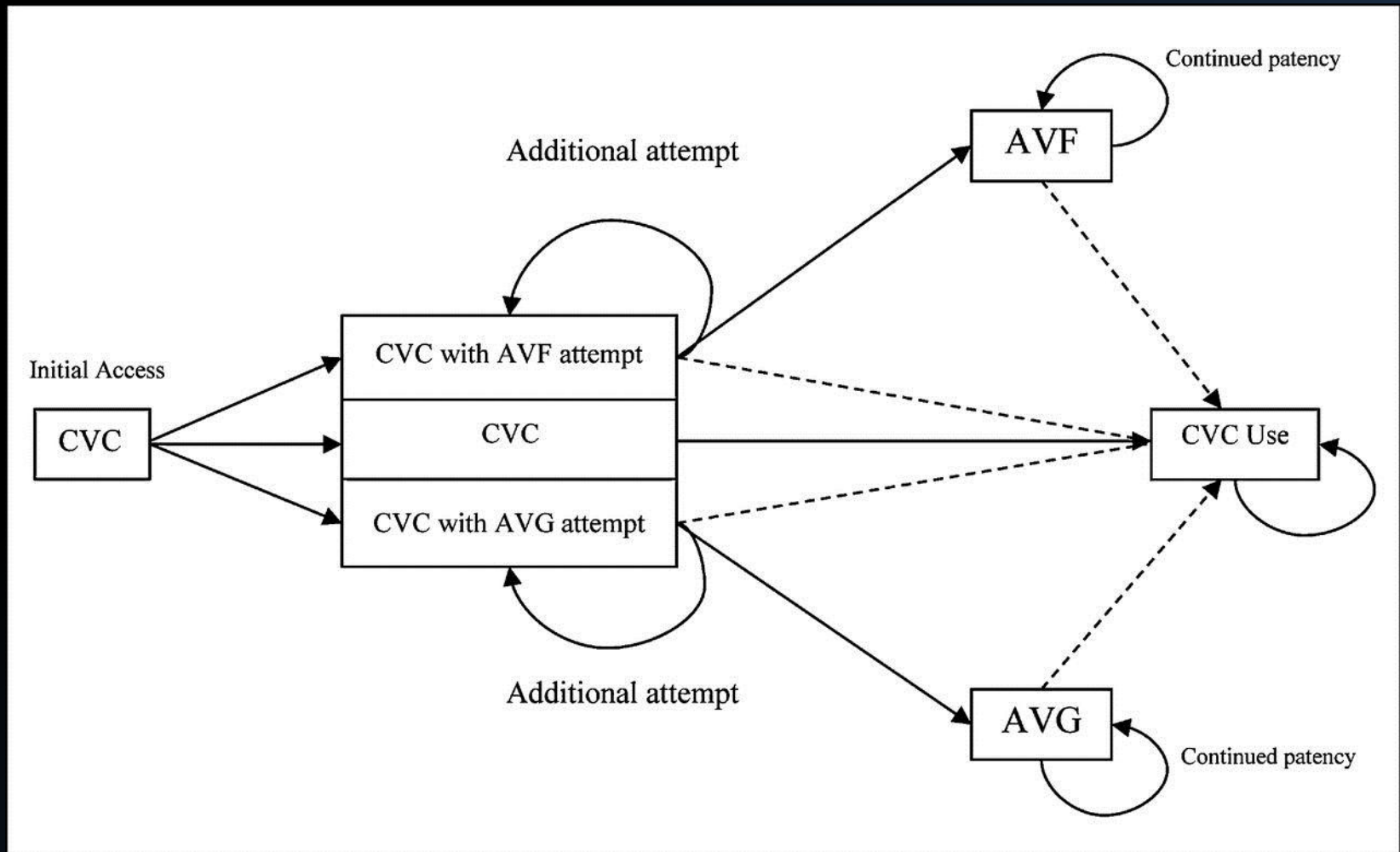


(B) 714 patients after excluding 426 primary failures: arteriovenous fistulas versus arteriovenous grafts (HR, 0.56; 95% CI, 0.43–0.74).

Cumulative Patency of Contemporary Fistulas versus Grafts (2000–2010) Patients: A Decision Analysis

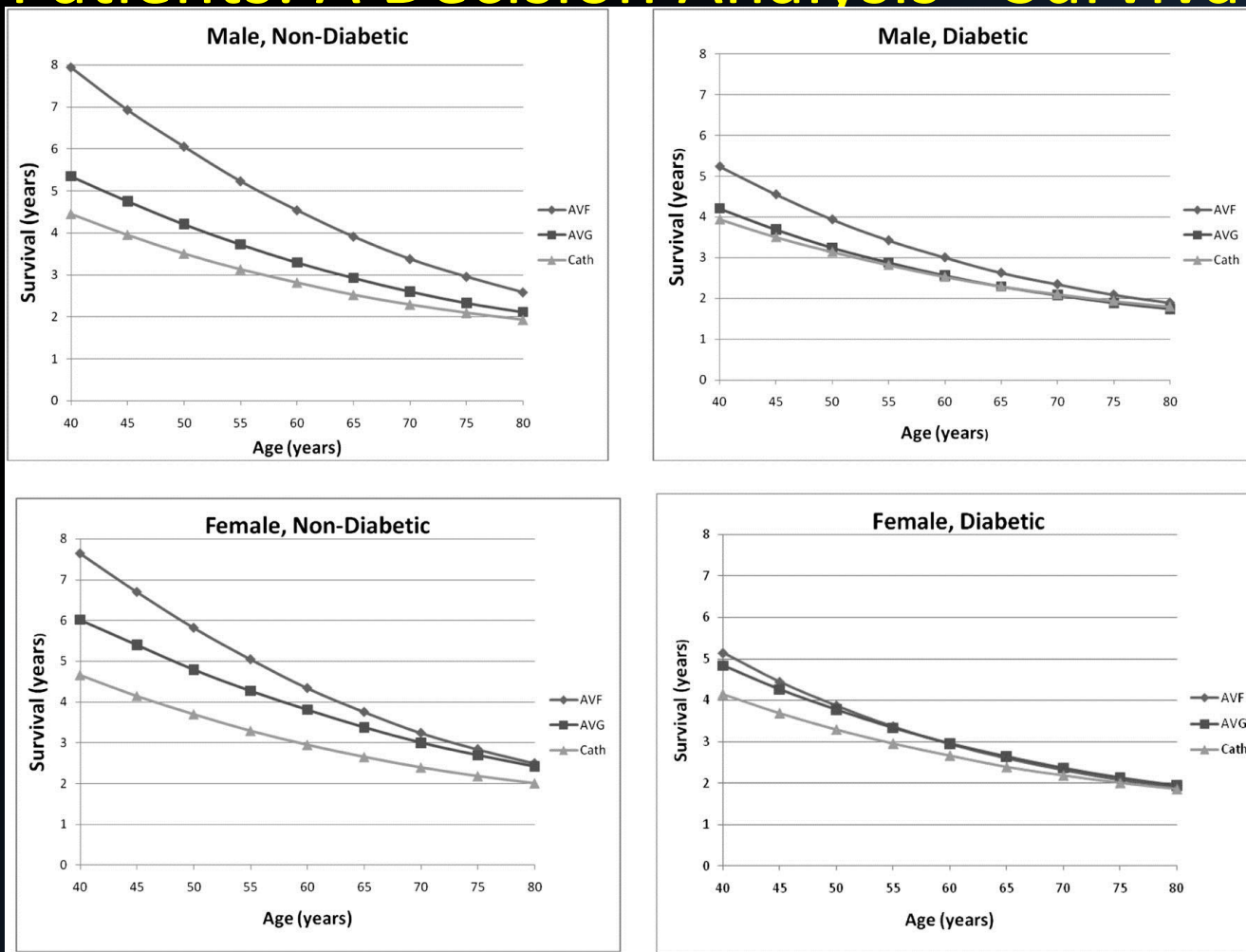
- The primary failure rate was two times greater for fistulas than for grafts: 40% versus 19% ($P < 0.001$).
- For the patients' first access (median, 7.4 versus 15.0 months, respectively [HR, 0.99; 95%CI, 0.7921.23; $P = 0.85$]) or for 600 with a subsequent access (7.0 versus 9.0 months [HR, 0.93; 95% 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.

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

Patients: A Decision Analysis

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

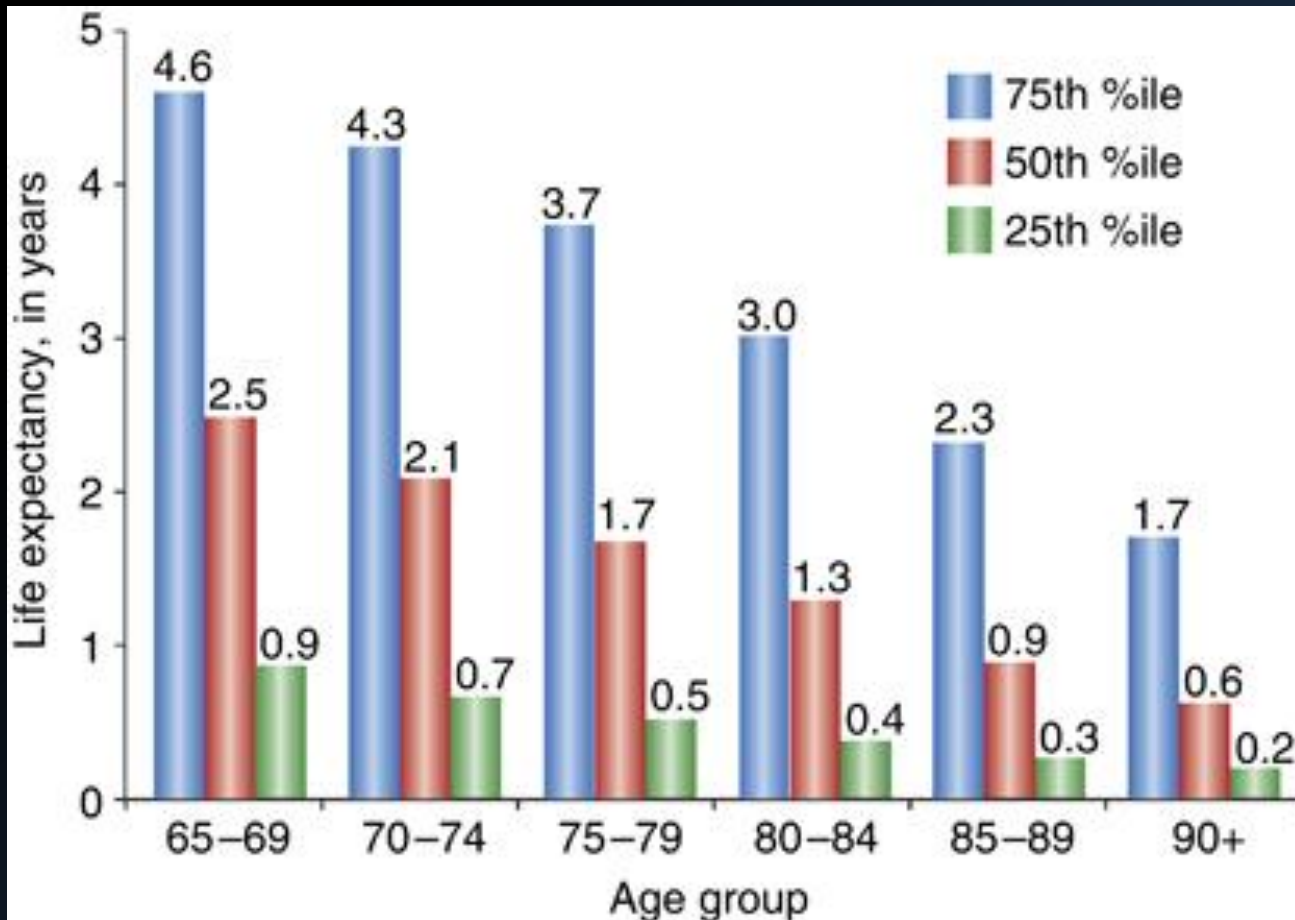
- 6 articles
- Heterogeneous definition of elderly
- Individualized approaches emphasized
 - Life Expectancy
 - Different Risks and Benefits
 - Distinction between pre-dialysis and established on dialysis
 - Personal Preferences

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

Optimizing Renal Replacement Therapy in Older Adults: A Framework for Individualized Decision Making



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.

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

Optimizing Vascular Access in the Elderly Patient

...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.

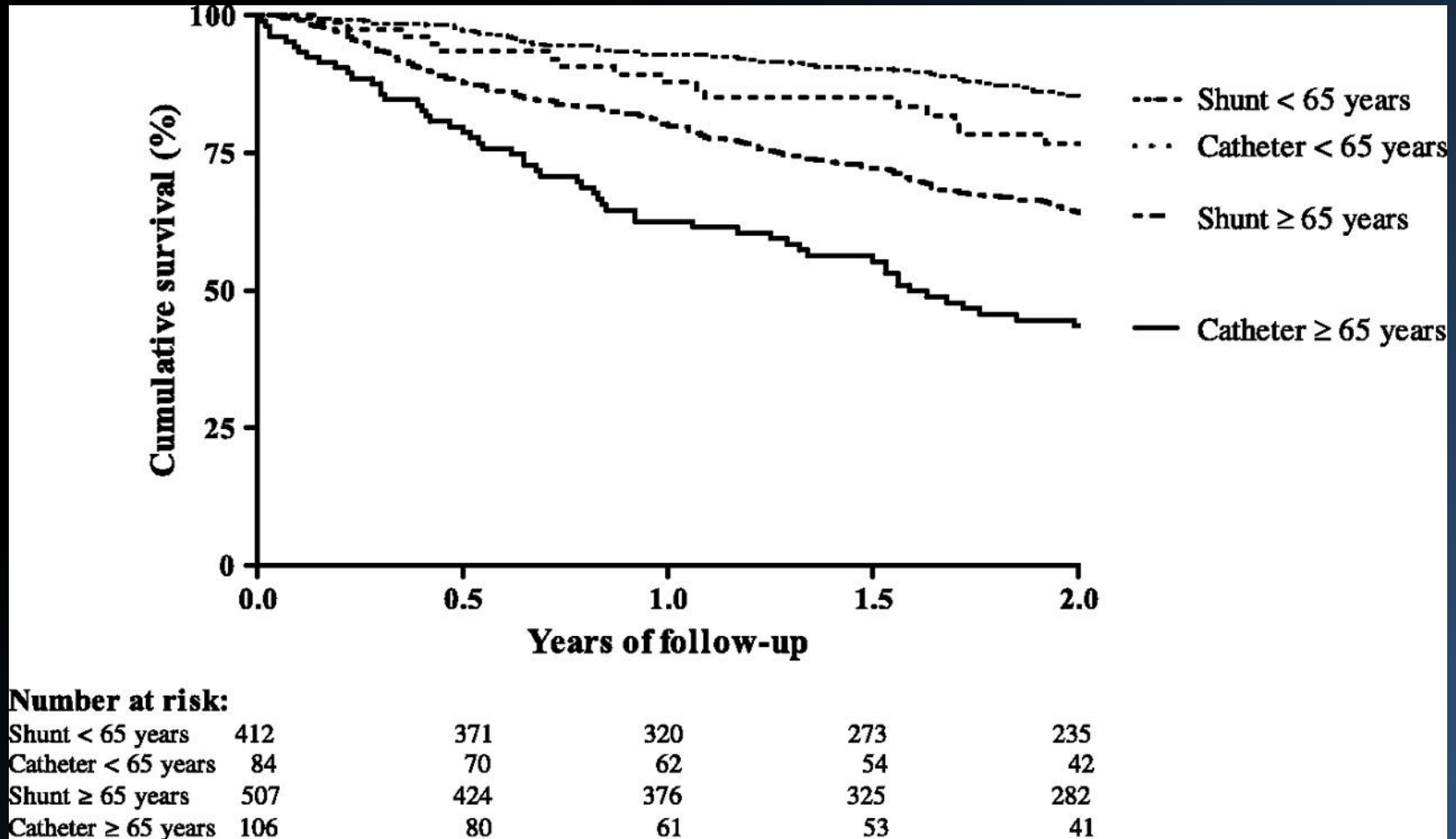
Vascular Access Outcome in the Elderly Dialysis Patient in Combination With the Quality of Life

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.

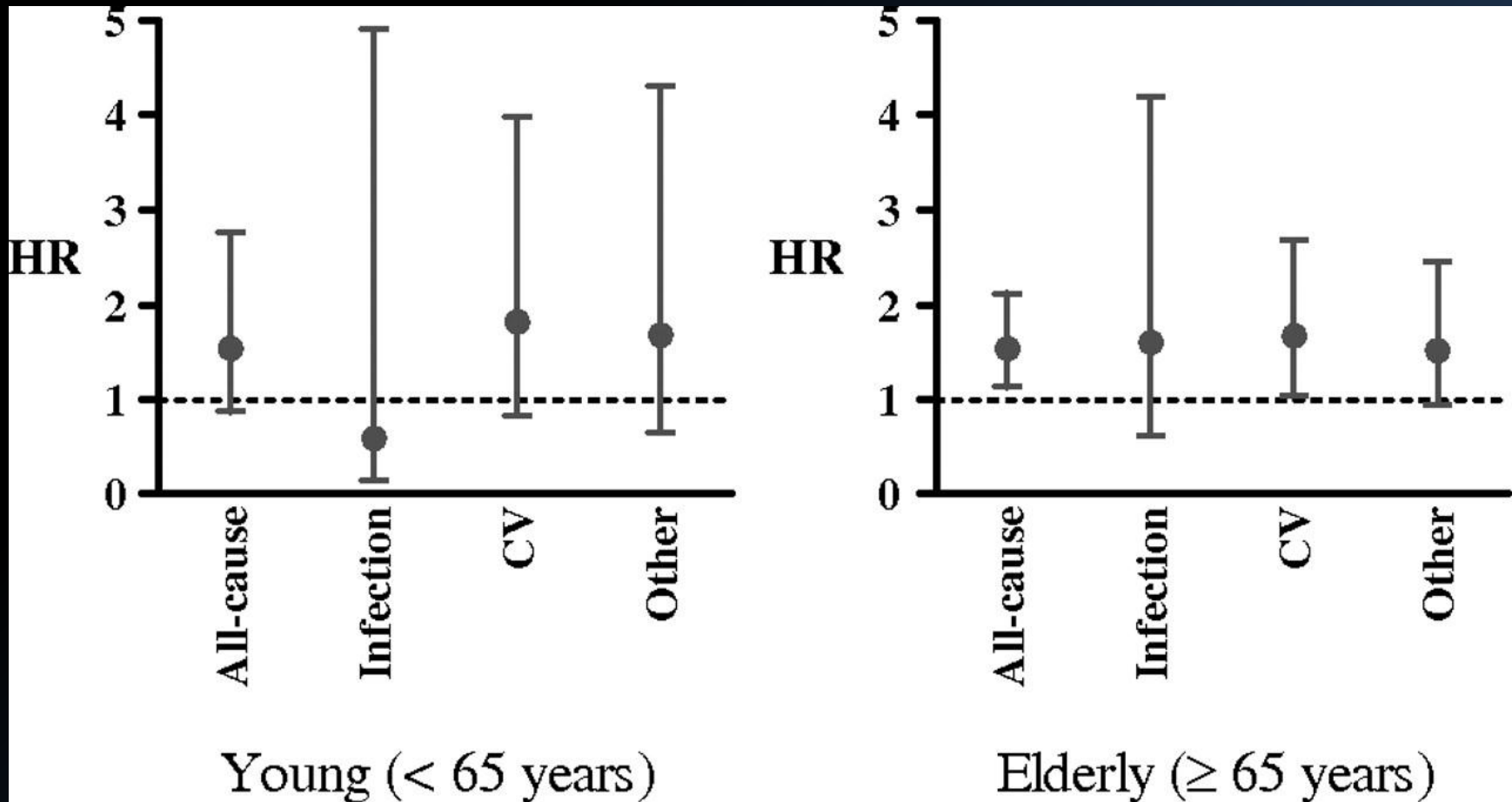
Haemodialysis catheters increase mortality as compared to arteriovenous accesses especially in elderly patients



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

Nephrol Dial Transplant (2011) 26: 2611–2617

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

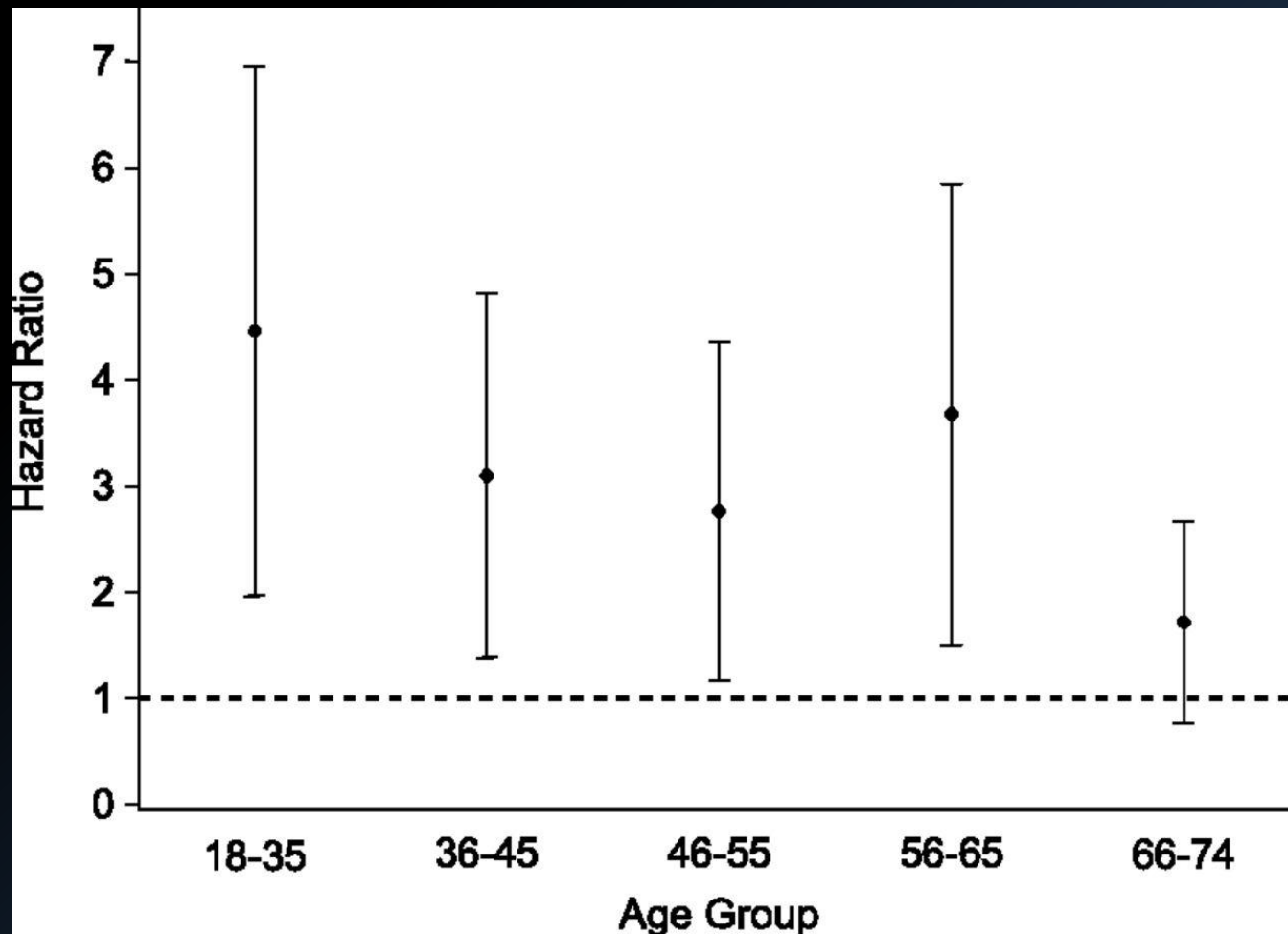


Kaplan–Meier survival curve for arteriovenous access versus catheter in young and elderly haemodialysis patients.

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



Hazard ratios for catheter-related bloodstream infections across the range of ages.

Reference Age 75 and older. Single Center Study of 464 patients with dialysis catheters .

Murea et al. Clin J Am Soc Nephrol 9: 764–770, 2014.

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

- 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



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?

Process Flow

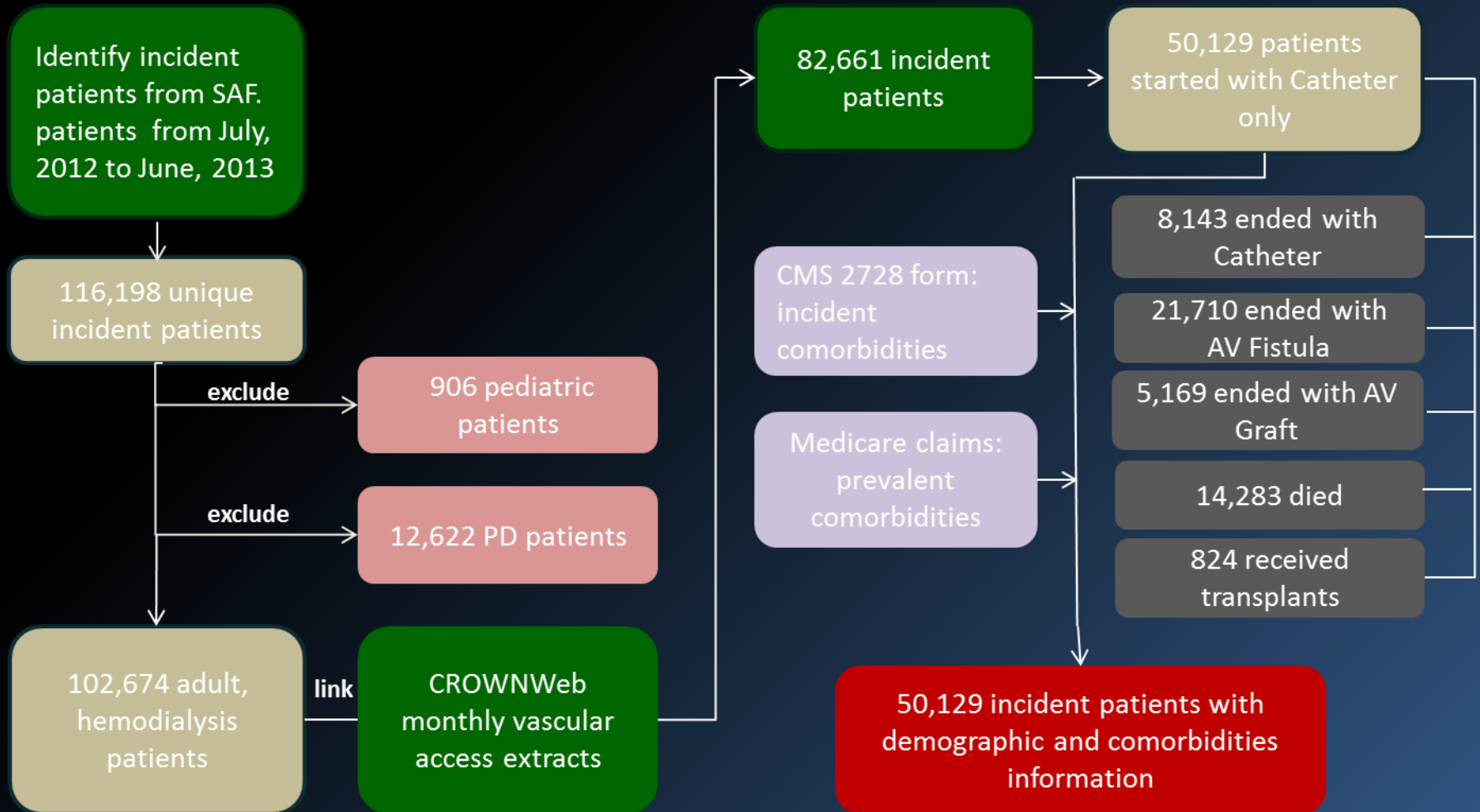


Table 1: Baseline characteristics of study population at ESRD onset and analysis results for AVF, compared to Catheter access (N=29,853)

Predictor	Total N (%)	Success in AVF N=21,710 N (%)	Multivariate Analysis Model 1 (Unadjusted by Comorbidities)	
			OR	P
Age				
18-<25	349(1.17)	243(69.63)	0.95(0.75, 1.2)	0.647
25-<45	3546(11.88)	2650(74.73)	1.12(1.03, 1.23)	0.010
45-<60	8640(28.94)	6474(74.93)	1.09(1.03, 1.17)	0.007
60-<75	11109(37.21)	8105(72.96)	Ref	
75+	6209(20.8)	4238(68.26)	0.82(0.77, 0.88)	<.001
Sex				
Female	12518(41.93)	8349(66.70)	0.60(0.57, 0.63)	<.001
Male	17335(58.07)	13361(77.08)	Ref	
Race				
White	19188(64.27)	14037(73.16)	Ref	
Black	8643(28.95)	6053(70.03)	0.87(0.82, 0.92)	<.001
Other	2022(6.77)	1620(80.12)	1.52(1.36, 1.71)	<.001
BMI				
underweight(< 18.5)	841(2.82)	546(64.92)	0.83(0.72, 0.97)	0.019
normal(18.5 - 24.9)	8024(26.88)	5676(70.74)	Ref	
overweight(24.9 – 29.9)	8351(27.97)	6162(73.79)	1.14(1.06, 1.22)	<.001
obesity(> 29.9)	12637(42.33)	9326(73.80)	1.18(1.10, 1.26)	<.001
Nursing home status				
Yes	462(1.55)	254(54.98)	0.52(0.43, 0.63)	<.001
No	29391(98.45)	21456(73.00)	Ref	
Primary Cause of ESRD				
Diabetes	15112(50.62)	11181(73.99)	1.06(1.00, 1.12)	0.041
Other	14741(49.38)	10529(71.43)	Ref	
Nephrologist's Care prior to ESRD				
Yes	16237(54.39)	12231(75.33)	1.35(1.28, 1.43)	<.001
No/Unknown	13616(45.61)	9479(69.62)	Ref	

Table 1: Baseline characteristics of study population at ESRD onset and analysis results for AVF, compared to Catheter access (N=29,853)

Predictor	Total N (%)	Success in AVF N=21,710 N (%)	Multivariate Analysis Model 1 (Unadjusted by Comorbidities)		Multivariate Analysis Model 2 (Adjusted by Comorbidities)	
			OR	P	OR	P
Age						
18-<25	349(1.17)	243(69.63)	0.95(0.75, 1.2)	0.647	0.78(0.61, 0.99)	0.045
25-<45	3546(11.88)	2650(74.73)	1.12(1.03, 1.23)	0.010	0.94(0.85, 1.04)	0.212
45-<60	8640(28.94)	6474(74.93)	1.09(1.03, 1.17)	0.007	1.00(0.93, 1.07)	0.920
60-<75	11109(37.21)	8105(72.96)	Ref		Ref	
75+	6209(20.8)	4238(68.26)	0.82(0.77, 0.88)	<.001	0.90(0.84, 0.97)	0.005
Sex						
Female	12518(41.93)	8349(66.70)	0.60(0.57, 0.63)	<.001	0.60(0.57, 0.64)	<.001
Male	17335(58.07)	13361(77.08)	Ref		Ref	
Race						
White	19188(64.27)	14037(73.16)	Ref		Ref	
Black	8643(28.95)	6053(70.03)	0.87(0.82, 0.92)	<.001	0.84(0.80, 0.90)	<.001
Other	2022(6.77)	1620(80.12)	1.52(1.36, 1.71)	<.001	1.43(1.28, 1.61)	<.001
BMI						
underweight(< 18.5)	841(2.82)	546(64.92)	0.83(0.72, 0.97)	0.019	0.85(0.73, 0.99)	0.034
normal(18.5 - 24.9)	8024(26.88)	5676(70.74)	Ref		Ref	
overweight(24.9 – 29.9)	8351(27.97)	6162(73.79)	1.14(1.06, 1.22)	<.001	1.13(1.06, 1.22)	<.001
obesity(> 29.9)	12637(42.33)	9326(73.80)	1.18(1.10, 1.26)	<.001	1.22(1.14, 1.30)	<.001
Nursing home status						
Yes	462(1.55)	254(54.98)	0.52(0.43, 0.63)	<.001	0.70(0.57, 0.85)	<.001
No	29391(98.45)	21456(73.00)	Ref		Ref	
Primary Cause of ESRD						
Diabetes	15112(50.62)	11181(73.99)	1.06(1.00, 1.12)	0.041	1.11(1.04, 1.19)	0.003
Other	14741(49.38)	10529(71.43)	Ref		Ref	
Nephrologist's Care prior to ESRD						
Yes	16237(54.39)	12231(75.33)	1.35(1.28, 1.43)	<.001	1.34(1.27, 1.41)	<.001
No/Unknown	13616(45.61)	9479(69.62)	Ref		Ref	

Table 2: Multivariate analysis establishing 1) AVF and 2) AVF/AVG after 1 year (compared to Catheter)

Predictor	Multivariate Analysis 1) AVF vs Catheter (Adjusted by Comorbidities)		Multivariate Analysis 2) AVF/AVG vs Catheter (Adjusted by Comorbidities)	
	OR	P	OR	P
Age				
18-<25	0.78(0.61, 0.99)	0.045	0.70(0.55, 0.89)	0.003
25-<45	0.94(0.85, 1.04)	0.212	0.88(0.81, 0.97)	0.010
45-<60	1.00(0.93, 1.07)	0.920	0.96(0.90, 1.03)	0.238
60-<75	Ref		Ref	
75+	0.90(0.84, 0.97)	0.005	0.95(0.88, 1.01)	0.116
Sex				
Female	0.60(0.57, 0.64)	<.001	0.70(0.66, 0.73)	<.001
Male	Ref		Ref	
Race				
White	Ref		Ref	
Black	0.84(0.80, 0.90)	<.001	0.98(0.93, 1.04)	0.485
Other	1.43(1.28, 1.61)	<.001	1.41(1.25, 1.58)	<.001
BMI				
underweight(< 18.5)	0.85(0.73, 0.99)	0.034	0.89(0.77, 1.03)	0.124
normal(18.5 - 24.9)	Ref		Ref	
overweight(24.9 – 29.9)	1.13(1.06, 1.22)	<.001	1.12(1.04, 1.20)	0.002
obesity(> 29.9)	1.22(1.14, 1.30)	<.001	1.17(1.10, 1.25)	<.001
Nursing home status				
Yes	0.70(0.57, 0.85)	<.001	0.75(0.63, 0.90)	0.002
No	Ref		Ref	
Primary Cause of ESRD				
Diabetes	1.11(1.04, 1.19)	0.003	1.11(1.04, 1.19)	0.001
Other	Ref		Ref	
Nephrologist's Care prior to ESRD				
Yes	1.34(1.27, 1.41)	<.001	1.32(1.25, 1.39)	<.001
No/Unknown	Ref		Ref	

Review existing Vascular Access measures

NQF #0256

Measure Title	Hemodialysis Vascular Access- Minimizing use of catheters as Chronic Dialysis Access
Measure Description	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.
Numerator	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.
Denominator	Patients on maintenance hemodialysis during the last HD treatment of study period.
Exclusions	Patients on acute hemodialysis, peritoneal dialysis, or patients <18 years of age.

NQF #0257

Measure Title	Hemodialysis Vascular Access- Maximizing Placement of Arterial Venous Fistula (AVF)
Measure Description	Percentage of patients on maintenance hemodialysis during the last HD treatment of month using an autogenous AV fistula with two needles
Numerator	Patients who were on maintenance hemodialysis (HD) using an autogenous AV fistula with two needles at the last HD treatment of month
Denominator	Patients on maintenance hemodialysis during the last HD treatment of month including patients on home hemodialysis
Exclusions	Patients on acute hemodialysis, peritoneal dialysis, AVF and AVG reported, or patients <18 years of age

NQF #0251

Measure Title	Vascular Access—Functional Arteriovenous Fistula (AVF) or AV Graft or Evaluation for Placement
Measure Description	Percentage of ESRD patients aged 18 years and older receiving hemodialysis during the 12-month reporting period and on dialysis >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
Numerator	As listed above
Denominator	All ESRD patients aged 18 years and older receiving hemodialysis during the 12-month reporting period and on dialysis for greater than 90 days.
Exclusions	None

NQF #2594

Measure Title	Optimal End Stage Renal Disease (ESRD) Starts
Measure Description	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.
Numerator	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).
Denominator	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
Exclusions	None

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)

Public Comment

Agenda: April 23, 2015

- | | |
|---------------|---|
| 9:00 – 10:45 | Draft measure specifications |
| 10:45 – 11:00 | <i>BREAK</i> |
| 11:00 – 12:00 | Draft measure specifications (continued) |
| 12:00 – 1:00 | <i>LUNCH</i> |
| 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

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

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