Measure Justification Form

Project Title:

End-Stage Renal Disease Vascular Access Measure Development

Project Overview:

The Centers for Medicare & Medicaid Services (CMS) has contracted with the University of Michigan Kidney Epidemiology and Cost Center (UM-KECC) to review the NQF endorsed Vascular Access measures (Minimizing Use of Catheters as Chronic Dialysis Access, and Maximizing Placement of Arterial Venous Fistula) and consider possible revisions to the existing measures, including potential risk adjustment. The contract name is ESRD Quality Measure Development, Maintenance, and Support. The contract number is HHSM-500-2013-13017I.

Date:

Information included is current on December 21, 2015.

Measure Name

Hemodialysis Vascular Access: Standardized Fistula Rate

Type of Measure

Intermediate Outcome

Importance

1a—Opportunity for Improvement

1a.1. This is a Measure of Intermediate Clinical Outcome (standardized fistula rate)

1a.2.—Linkage

1a.2.1 Rationale

N/A

1a.3.—Linkage

Several observational studies have demonstrated an association between type of vascular access used for hemodialysis and patient mortality. Arteriovenous fistulae (AVF) are associated with the lowest mortality risk while long term catheters have the highest mortality. Arteriovenous grafts (AVG) have been found to have a risk of death that is higher than AVF but lower than catheters.

The measure focus is the process of calculating AV Fistula use at chronic dialysis facilities.

This process leads to improvement in mortality as follows:

Measure AV Fistula Rate--> Assess value -->Identify patients who do not have an AV Fistula-->Evaluation for an AV fistula by a qualified dialysis vascular access provider →Increase Fistula Rate →Lower patient mortality.

1a.3.1. Source of Systematic Review

Clinical Practice Guideline

1a.4.—Clinical Practice Guideline Recommendation

1a.4.1. Guideline Citation

National Kidney Foundation KDOQI Clinical Practice Guidelines and Clinical Practice Recommendations for 2006 Updates: Hemodialysis Adequacy, Peritoneal Dialysis Adequacy and Vascular Access. Am J Kidney Dis 48:S1-S322, 2006 (suppl 1).

http://www.kidney.org/professionals/KDOQI/guidelines_commentaries

1a.4.2. Specific Guideline

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. 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)

2.1.2 Acceptable: AVG of synthetic or biological material. (B)

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

2.1.4 Patients should be considered for construction of a primary fistula

after failure of every dialysis AV access. (B)

1a.4.3. Grade

KDOQI Guideline 2.1 was graded B, indicating moderate evidence supports the guideline.

The "B" rating indicates: It is recommended that clinicians routinely follow the guideline for eligible patients. There is moderately strong evidence that the practice improves health outcomes.

1a.4.4. Grades and Associated Definitions

The rating system defined in the KDOQI Guidelines was used to grade the strength of the Guideline recommendation. KDOQI defined grades as follows:

Grade A: It is strongly recommended that clinicians routinely follow the guideline for eligible patients. There is strong evidence that the practice improves health outcomes.

Grade B: It is recommended that clinicians routinely follow the guideline for eligible patients. There is moderately strong evidence that the practice improves health outcomes.

Grade CPR: It is recommended that clinicians consider following the guideline for eligible patients. This recommendation is based on either weak evidence or on the opinions of the Work Group and reviewers that the practice might improve health outcomes.

1a.4.5. Methodology Citation

National Kidney Foundation. KDOQI Clinical Practice Guidelines and Clinical Practice Recommendations for 2006 Updates: Hemodialysis Adequacy, Peritoneal Dialysis Adequacy and Vascular Access. Am J Kidney Dis 48:S1-S322, 2006 (suppl 1).

http://www.kidney.org/professionals/KDOQI/guidelines_commentaries

1a.4.6. Quantity, Quality, and Consistency

Yes, see 1a.7

1a.5.—United States Preventative Services Task Force Recommendation

1a.5.1. Recommendation Citation

1a.5.2. Specific Recommendation

1a.5.3. Grade

1a.5.4. Grades and Associated Definitions

1a.5.5. Methodology Citation

1a.6.—Other Systematic Review of the Body of Evidence

1a.6.1. Review Citation

1a.6.2. Methodology Citation

1a.7.—Findings from Systematic Review of Body of the Evidence Supporting the Measure

1a.7.1. Specifics Addressed in Evidence Review

The evidence review focuses on the advantages of AV fistula compared to other types of vascular access and highlights the superior patency, reduced need for interventions, and lower infection rates associated with AV fistula.

1a.7.2. Grade

The quality of evidence was not explicitly graded in the KDOQI guidelines. However, it was implicitly assessed according to the criteria outlined in the table in 1a.7.3 below. The workgroup considered the overall methodological quality, the target population (e.g. patients on dialysis), and whether the health outcome was studied directly or not.

Overall, the evidence that supports the guideline was assessed as: Moderately Strong.

The workgroup defined "Moderately Strong" as: Evidence is sufficient to determine effects on health outcomes in the target population, but the strength of the evidence is limited by the number, quality, or consistency of the individual studies; OR evidence is from studies with some problems in design and/or analysis; OR evidence is from well-designed, well-conducted studies on surrogate endpoints for efficacy and/or safety in the target population.

1a.7.3. Grades and Associated Definitions

Outcome	**Population**	**Well designed and analyzed (little if any potential bias)**	**Some problems in design and/or analysis (some potential bias)**	**Poorly designed and/or analyzed (large potential bias)**
Health Outcomes	Target Population	Strong	Moderately Strong	Weak
Health Outcomes	Other than target population	Moderately Strong	Moderately Strong	Weak
Surrogate	Target	Moderately Strong	Weak	Weak

Outcome	Population	Well designed and analyzed (little if any potential bias)	Some problems in design and/or analysis (some potential bias)	Poorly designed and/or analyzed (large potential bias)
Measure	Population			
Surrogate Measure	Other than target population	Weak	Weak	Weak

<u>Strong</u>- Evidence includes results from well-designed, well-conducted study/studies in the target population that directly assess effects on health outcomes.

<u>Moderately strong</u>- Evidence is sufficient to determine effects on health outcomes in the target population, but the strength of the evidence is limited by the number, quality, or consistency of the individual studies; OR evidence is from a population other than the target population, but from well-designed, well conducted studies; OR evidence is from studies with some problems in design and/or analysis; OR evidence is from well-designed, well-conducted studies on surrogate endpoints for efficacy and/or safety in the target population.

<u>Weak</u>- Evidence is insufficient to assess the effects on net health outcomes because it is from studies with some problems in design and/or analysis on surrogate endpoints for efficacy and/or safety in the target population; OR the evidence is only for surrogate measures in a population other than the target population; OR the evidence is from studies that are poorly designed and/or analyzed.

1a.7.4. Time Period

January 1997 – June 2005

1a.7.5. Number and Type of Study Designs

The 2006 Clinical Practice Guidelines for Vascular Access is an update to the original vascular access guidelines published in 1997 by the National Kidney Foundation. In the eight years that the literature review included for the update, there have been no randomized controlled trials for type of vascular access. Specifically, for the guideline used to support this measure, a total of 84 peer-reviewed publications are included in the body of evidence presented. While these are all observational studies, some are based on either national data such as the United States Renal Data System (USRDS) that includes all patients with end stage kidney disease in the US, or international data, such as the Dialysis Outcomes Practice Pattern Study (DOPPS) that provides a global perspective for US vascular access outcomes.

1a.7.6. Overall Quality of Evidence

The overall quality of evidence is moderately strong. All studies are in the target population of hemodialysis patients. Some studies have evaluated health outcomes such as patient mortality, but have limitations due to the observational nature of the design. Other studies have more rigorous design, but use surrogate outcomes such as access thrombosis.

1a.7.7. Estimates of Benefit

The 12 studies listed below highlight the core benefits such as reduced mortality and morbidity associated with using an AV fistula relative to either an AV graft or a tunneled catheter. Specifically, AV fistulae have:

- Lowest risk of thrombosis: in a systematic review of 34 studies evaluating access patency, AVF were found to have superior primary patency at 18 months compared to AV grafts (51% vs. 33%).[1]
- Lowest rate of angioplasty/intervention: Procedure rates have been reported as 0.53 procedures/patient/year for AV fistula compared to 0.92 procedures/patient/year for AV grafts.[2]
- Longest survival: Case-mix adjusted survival analysis indicated substantially better survival of AV fistula compared with AV grafts in the US [risk ratios (RR) of failure 0.56, P < 0.0009][3]
- Lowest Cost[4-6]: Based on 1990 costs to Medicare, graft recipients cost HCFA $3,700 more than fistula patients when pro-rating graft reimbursements to the median fistula survival time.[5]
- Lowest rates of infection: AV fistula have the lowest rates of infection followed by AV grafts and then tunneled dialysis catheters[7]. Vascular access infections are common, and represent the second most common cause of death for patients receiving hemodialysis.[8]
- Lowest mortality and hospitalization: Patients using catheters (RR 2.3) and grafts (RR 1.47) have a greater mortality risk than patients dialyzed with fistulae[9]. Other studies have also found that use of fistulae reduces mortality and morbidity[14-17] compared to AV grafts or catheters.

References:

1. Huber TS, Carter JW, Carter RL, Seeger JM: Patency of autogenous and polytetrafluoroethylene upper extremity arteriovenous hemodialysis accesses: A systematic review. J Vasc Surg 38(5):1005-11, 2003
2. Perera GB, Mueller MP, Kubaska SM, Wilson SE, Lawrence PF, Fujitani RM: Superiority of autogenous arteriovenous hemodialysis access: Maintenance of function with fewer secondary interventions. Ann Vasc Surg 18:66-73, 2004
3. Pisoni RL, Young EW, Dykstra DM, et al: Vascular access use in Europe and the United States: Results from the DOPPS. Kidney Int 61:305-316, 2002
4. Mehta S: Statistical summary of clinical results of vascular access procedures for haemodialysis, in Sommer BG, Henry ML (eds): Vascular Access for Hemodialysis-II (ed 2). Chicago, IL, Gore, 1991, pp 145-157
5. The Cost Effectiveness of Alternative Types of Vascular access and the Economic Cost of ESRD. Bethesda, MD, National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, 1995, pp 139-157
6. Eggers P, Milam R: Trends in vascular access procedures and expenditures in Medicare's ESRD program, in Henry ML (ed): Vascular Access for Hemodialysis-VII. Chicago, IL, Gore, 2001, pp 133-143

7. Nassar GM, Ayus JC: Infectious complications of the hemodialysis access. Kidney Int 60:1-13, 2001
8. Gulati S, Sahu KM, Avula S, Sharma RK, Ayyagiri A, Pandey CM: Role of vascular access as a risk factor for infections in hemodialysis. Ren Fail 25:967-973, 2003
9. Dhingra RK, Young EW, Hulbert-Shearon TE, Leavey SF, Port FK: Type of vascular access and mortality in U.S. hemodialysis patients. Kidney Int 60:1443-1451, 2001
10. Woods JD, Port FK: The impact of vascular access for haemodialysis on patient morbidity and mortality. Nephrol Dial Transplant 12:657-659, 1997
11. Xue JL, Dahl D, Ebben JP, Collins AJ: The association of initial hemodialysis access type with mortality outcomes in elderly Medicare ESRD patients. Am J Kidney Dis 42:1013-1019, 2003
12. Polkinghorne KR, McDonald SP, Atkins RC, Kerr PG: Vascular access and all-cause mortality: A propensity score analysis. J Am Soc Nephrol 15:477-486, 2004

1a.7.8. Benefits Over Harms

The potential harms of placing an AV fistula include: (1) failure of the AV fistula to mature such that additional surgery is needed for vascular access, (2) steal syndrome where the distal arm becomes ischemic, and (3) prolonged maturation times that increase reliance on a tunneled dialysis catheter and its attendant risk of infection. Overall these risks associated with an AV fistula are considered to be small and overshadowed by the long-term benefits outlined above.

1a.7.9. Provide for Each New Study

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*.

This systematic review and thematic synthesis of qualitative studies describes patients' perspectives on vascular access initiation and maintenance in hemodialysis. 46 studies were reviewed and found that 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.*

This systematic review and meta-analysis reported that 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.

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.*

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 patients.

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.*

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. 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.*

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. 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.

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. 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 a fully adjusted model including health status, mortality differences between access type were attenuated, 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.

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 stabilizaton 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.

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.

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.

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.

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.

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.

1a.8.—Other Source of Evidence

1a.8.1. Process Used

1a.8.2. Citation

1b.—Evidence to Support Measure Focus

1b.1. Rationale

The NKF K/DOQI guidelines state the following: 1) AV fistulas have the lowest rate of thrombosis and require the fewest interventions, 2) cost of AV fistula use and maintenance is the lowest, 3) fistulas have the lowest rates of infection, and 4) Fistulas are associated with the highest survival and lowest hospitalization rates. Indeed, a number of epidemiologic studies consistently demonstrate the reduced morbidity and mortality associated with greater use of AV fistulas for vascular access in maintenance hemodialysis.

As the updated literature review above indicates, there are a growing number of studies reporting that creating AVF in some patients is less likely to be successful in the presence of certain comorbidities. In addition, certain patient groups may have less incremental benefit from an AV fistula relative to an AV graft. By adjusting the fistula rate for patient characteristics and comorbidities associated with low AV fistula success rates, this measure accounts for patients where a graft or even a catheter may be a more appropriate option.

1b.2. Performance Scores

Analysis of CROWNWeb data from January 2014- December 2014 indicated the facility level mean percentage of patient-months with a fistula was 63.15% (SD=10.00%). Distribution: Min=6.73%, Max=96.13%, 1st quartile=56.58%, median=63.28%, 3rd quartile=70.04%.

Information about the data used in these analyses can be found under “Scientific Acceptability”.

1b.3. Summary of Data Indicating Opportunity

N/A

1b.4. and 1b.5. Disparities

Using data from January 2014, age, sex, race and ethnicity were evaluated in a logistic regression model for AV Fistula use. The table below shows the odds ratios for these patient characteristics. The other covariates included in the model are not shown here as the odds ratios were very similar to those reported in Table 5 (risk adjusted model results). Age, sex, race, and ethnicity are all statistically significant predictors of AVF use. The analysis results indicate potential disparity in fistula use among these groups. Specifically, females are about half as likely to have fistulas as males, and blacks are about 33% less likely to have fistulas than whites; while patients 75 years of age or older were 16% less likely to have an AV fistula when compared to the younger reference group. In the absence of biological effects explaining these differences, risk adjustment for these demographic factors could potentially mask disparities in care.

Table 1: Odds ratio of AV Fistula use

Covariate	**Odds Ratio (95% CI)**	**P-value**
Age		
18-<25	0.983 (0.904, 1.069)	0.6877
25-<59	1.063 (1.045, 1.082)	<.0001
60-<75	reference	
75+	0.839 (0.823, 0.856)	<.0001
Race		
White	reference	
Black	0.674 (0.66, 0.688)	<.0001
Other race	1.068 (1.028, 1.108)	0.0006
Sex		
Female	0.521 (0.514, 0.529)	<.0001
Male	reference	
Ethnicity		
Hispanic	1.157 (1.127, 1.188)	<.0001
non-Hispanic	reference	

1c.—High Priority

1c.1. Demonstrated High-Priority Aspect of Health Care

- Affects large numbers
- A leading cause of morbidity/mortality

1c.3. Epidemiologic or Resource Use Data

Numerous studies demonstrate that the use of AV fistulas have the best 5-year patency rates and require the fewest interventions compared with other access types. The advantages of AV fistula over other accesses are clearly delineated in the NKF K/DOQI guidelines, summarized as follows: 1) AV fistulas have the lowest rate of thrombosis and require the fewest interventions, 2) cost of AV fistula use and maintenance is the lowest, 3) fistulas have the lowest rates of infection, and 4) Fistulas are associated with the highest survival and lowest hospitalization rates. Indeed, a number of epidemiologic studies consistently demonstrate the reduced morbidity and mortality associated with greater use of AV fistulas for vascular access in maintenance hemodialysis.

1c.4. Citations

1. National Kidney Foundation: DOQI Clinical Practice Guidelines for Vascular Access. http://www.kidney.org/Professionals/kdoqi/guideline_upHD_PD_VA/index.htm

1c.5. Patient-Reported Outcome Performance Measure (PRO-PM)

N/A

Scientific Acceptability

1.—Data Sample Description

1.1. What Type of Data was Used for Testing?

Measure Specified to Use Data From: administrative claims, clinical database/registry

Measure Tested with Data From: administrative claims, clinical database/registry

1.2. Identify the Specific Dataset

National CROWNWeb data from January 2014-December 2014 and Medicare claims data from January 2013 – December 2014

1.3. What are the Dates of the Data Used in Testing?

January 2013-December 2014

1.4. What Levels of Analysis Were Tested?

Measure Specified to Measure Performance of: hospital/facility/agency

Measure Tested at Level of: hospital/facility/agency

1.5. How Many and Which Measured Entities Were Included in the Testing and Analysis?

Patients on both home and in-center hemodialysis during the last HD treatment of month from January 2014- December 2014 were included in the analyses. The number of facilities per month ranged from 5,783-5,917 and the total number of patients per month ranged from 369,727-388,133.

Public reporting of this measure on DFC or in the ESRD QIP would be restricted to facilities with at least 11 eligible patients throughout the year for the measure. We have applied this restriction to all the reliability and validity testing reported here.

1.6. How Many and Which Patients Were Included in the Testing and Analysis?

There were a total of 4,555,159 eligible patient-months. Among those patient-months over the whole year, the average age was 63 years, 43.78% of patient-months were female, 56.76% were white, 36.67% were black, 6.57% had race listed as other, 18.21% were Hispanic and 46.49% had type II diabetes as the primary cause of ESRD.

1.7. Sample Differences, if Applicable

N/A

2a.2—Reliability Testing

2a2.1. Level of Reliability Testing

Performance measure score (e.g., signal-to-noise analysis)

2a2.2. Method of Reliability Testing

We used January 2014 – December 2014 CROWNWeb data to calculate facility-level annual performance scores. The NQF-recommended approach for determining measure reliability is a one-way analysis of variance (ANOVA), in which the between and within facility variation in the measure is determined. The inter-unit reliability (IUR) measures the proportion of the measure variability that is attributable to the between-facility variance. We assessed reliability by calculating inter-unit reliability (IUR) for the annual performance scores. If the measure were a simple average across individuals in the facility, the usual ANOVA approach would be used. The yearly based measure, however, is not a simple average and we instead estimate the IUR using a bootstrap approach, which uses a resampling scheme to estimate the within facility variation that cannot be directly estimated by ANOVA. For specific details regarding this calculation, please see Appendix C. A small IUR (near 0) reveals that most of the variation of the measures between facilities is driven by random noise, indicating the measure would not be a good characterization of the differences among facilities, whereas a large IUR (near 1) indicates that most of the variation between facilities is due to the real difference between facilities.

The reliability of SFR calculation only included facilities with at least 11 patients during the entire year.

2a2.3. Statistical Results from Reliability Testing

The IUR is 0.741 which indicates that 74% of the variation in the annual SFR can be attributed to between-facility differences in performance (signal) and about 26% to the within-facility variation (noise).

2a2.4. Interpretation

The result of IUR suggests a high degree of reliability.

2b2—Validity Testing

2b2.1. Level of Validity Testing

Performance measure score

- Empirical validity testing
- Systematic assessment of face validity: TEP consensus for this measure provides face validity

2b2.2. Method of Validity Testing

Validity was assessed using Poisson regression models to measure the association between facility level quintiles of performance scores and the 2014 Standardized Mortality Ratio (SMR, NQF 0369) and 2014 Standardized Hospitalization Ratio (SHR, NQF 1463). Facility-level performance scores were divided into quintiles and the relative risk (RR) of mortality (and hospitalization, separately) was calculated for each quintile. The fifth quintile was used as the reference group. Thus, a RR>1.0 for the lower performance score quintiles would indicate a higher relative risk of mortality or hospitalization.

2b2.3. Statistical Results from Validity Testing

Quintiles of the performance scores were defined as follows:

Q1: 0.0%-<54.7%

Q2: 54.7%-<60.8%

Q3: 60.8-<66.0%

Q4: 66.0%-<71.9%

Q5: 71.9%-<100.0% (Reference)

Results from the Poisson model indicated that the percent of patient-months with a fistula was significantly associated with both SMR (p<0.0001) and SHR (p<0.0001). For 2014 SMR, relative risk of mortality was the highest in quintile 1 that has the lowest rate of AVF (RR=1.128; 95% CI: 1.101, 1.156). For quintile 2, RR=1.083 (95% CI: 1.058, 1.110), quintile 3, RR=1.054 (95% CI: 1.029, 1.080) and was 1.042 for quintile 4 (95% CI: 1.017, 1.067).

Similarly for 2014 SHR, the relative risk of hospitalization increased as the performance measure quintile decreased (with the highest risk in quintile 1). For quintile 1, RR=1.140 (95% CI1.135, 1.142), quintile 2, RR=1.117 (95% CI: 1.114, 1.121), quintile 3, RR=1.078 (95% CI: 1.074, 1.082) and was 1.058 for quintile 4 (95% CI: 1.054, 1.061).

2b2.4. Interpretation

These results of the Poisson regression suggest the predictive relationship of lower fistula use with higher mortality and hospitalization, as measured by the respective standardized mortality and hospitalization rates, compared to facilities with higher fistula use.

2b3—Exclusions Analysis

2b3.1. Method of Testing Exclusions

The following exclusions are applied to the denominator:

Patients with Limited life expectancy (e.g. < 6 months):

- Patients under hospice care in the current reporting month
- Patients with metastatic cancer in the past 12 months
- Patients with end stage liver disease in the past 12 months
- Patients with coma or anoxic brain injury in the past 12 months

The facility-level standardized fistula rate with and without the patient-month exclusions are calculated and compared.

2b3.2. Statistical Results From Testing Exclusions

The following tables show percent of patient months at risk and number of unique patients excluded as a result of the above mentioned exclusion strategy.

Table 2: Percent of patient-months at risk excluded

Year	Before Exclusion	After Exclusion	Percent
2014	4,738,075	4,555,159	3.90%

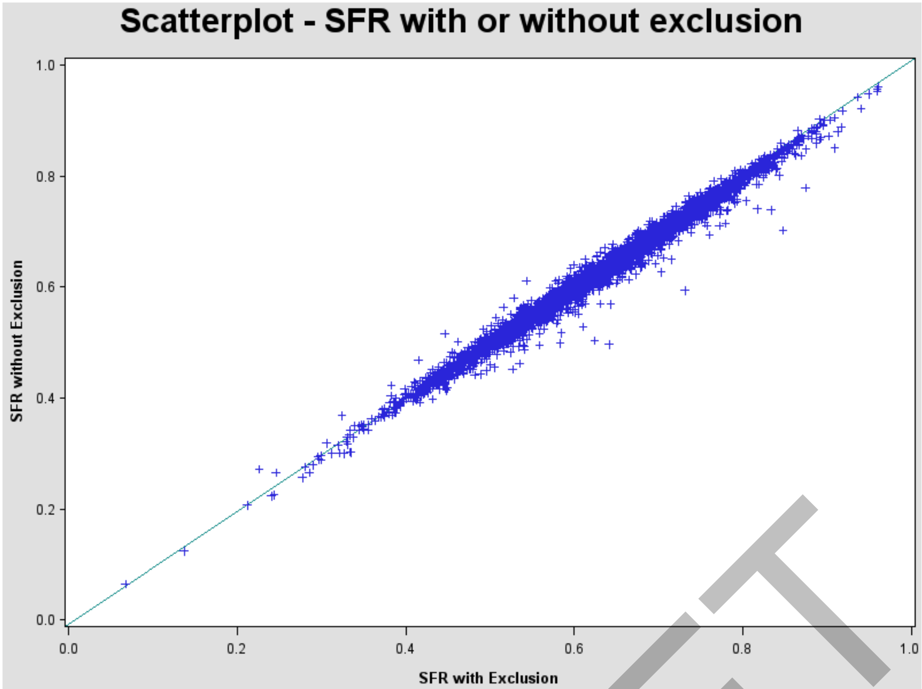
Table 3: Number and percent of unique patients excluded

Year	Before Exclusion	After Exclusion	Percent
2014	606,310	588,186	3.00%

Table 4: Distribution of performance scores before and after the exclusion

Standardized Fistula Rate	N	Mean	Standard Deviation	Minimum	Maximum
Before exclusion	5986	0.628	0.100	0.065	0.961
After exclusion	5986	0.632	0.100	0.067	0.961

Figure 1: Scatterplot –SFR with and without measure exclusions



2b3.3. Interpretation

The exclusion criteria are necessary since the percentage of patients excluded at each facility is not evenly distributed across facilities (Distribution: Min=0%, Max=39.5%,% (17 out of 26 patients at that facility), 1st quartile=1.4%, median=2.7%, 3rd quartile=4.2%). Due to the unequal distribution across facilities, the exclusion criteria take into account that some facilities treat a higher portion of patients with limited life expectancy. Additionally, our results shown in both the scatter-plot (Figure 1) as well as the Pearson Correlation Coefficient of 0.994 (p-value <0.0001) between SFRs with and without the exclusion suggests that the overall impact of the exclusion on the measure's validity is not substantial since the two are highly correlated.

2b4—Risk Adjustment or Stratification

Risk adjustment is based on a logistic regression model for AVF use. The analysis uses national data on adult hemodialysis patients, including all incident and prevalent patients who meet the inclusion criteria.

2b4.1. Method of controlling for differences

Statistical risk model with 19 patient-month level risk factors

2b4.2. Rationale why Risk Adjustment is not Needed

N/A

2b4.3. Conceptual, Clinical, and Statistical Methods

Although there have been significant gains in the proportion of dialysis patients that have an AV fistula, it is generally recognized that some patients on hemodialysis will need to have an AV graft or even a catheter. As evidence, the CMS AV fistula target at the facility level is 68%, rather than 100%, which recognizes that one third of patients will require a different type of access. Given that there is variation in the burden of comorbidities between different facilities, adjusting for these factors when calculating an AV fistula rate implicitly recognizes that some patients are more likely to have AV grafts. Several of the studies listed in 1a.7.9 above detail particular patient characteristics that are associated with a decreased likelihood of having a successful AV fistula created. Ultimately, evaluation and selection of the clinical and patient risk factors was informed by the final TEP recommendations. The TEP recognized that while fistulas are preferred, an unintended consequence of a fistula measure that doesn't account for the patient's overall health status could harm patients by subjecting them to fistula surgery that is less likely to succeed or limit access to care for patients with more comorbidities. The TEP recognized that they could not make the statement that fistulas and grafts are truly equivalent in all patients, but wanted to ensure that grafts were a strongly preferred outcome to catheters and should not be disincentivized. To accomplish this goal the TEP discussed adjusting the measure for conditions or scenarios where a graft may be an acceptable or preferred alternative to a fistula. The covariates in the final model represent a combination of those recommended by the TEP for inclusion as well as factors that empiric analyses indicated were predictive of AV fistula use. Final decisions of the risk factors were based on both the clinical and statistical association with the lower likelihood of fistula use in patients with these risk factors, and that these factors were not likely to be associated with facility care.

Risk adjustment is based on a multivariate logistic regression model. The adjustment is made for age, BMI at incident, nursing home status, nephrologist's care prior to ESRD, duration of ESRD, diabetes as primary cause of ESRD and comorbidities. Although covariates are assumed to have the same effects across facilities, the adjustment model is fitted with different facility effects (through facility-specific intercept terms), which provides valid estimates even if the distribution of adjustment variables differs across facilities. The common risk effects are assumed in order to improve computational stability in estimating facility-specific effects. All analyses are done using SAS. The adjustments included in the model are all statistically significant.

In general, adjustment factors for the SFR were selected based on several considerations. We began with a large set of patient characteristics, including demographics, comorbidities at ESRD incidence or past 12 months, and other characteristics. Factors considered appropriate were then investigated with statistical models to determine if they were related to AVF use. Factors related to the SFR were also evaluated for face validity before being included.

We performed separate analyses to assess disparities (see disparities sections 1b.4 and 1b.5), and we do not adjust for sex, race and ethnicity in the final model.

We used two data sources to collect comorbidity information: CMS-2728 and Medicare claims filed in prior 12 months. The covariates for comorbidities included in the final model take a value of 1 if there was any evidence of the condition in either CMS-2728 or Medicare claims, otherwise 0. Some patient characteristics or comorbidities are only available in CMS-2728, some are only available in Medicare claims, and some are available from both sources. We considered the condition to be present if it was noted in either the CMS-2728 form, or Medicare claims, or both. Table 5 shows that all of the comorbidities defined as above had a statistically significant association with AVF use. As a comparison, using data from January 2014 we compared analysis results of two additional risk adjustment models that included: 1) no comorbidity adjustment at all (denoted as Model 0), and 2) comorbidities defined by CMS-2728 only (denoted as Model 1). Table A1 of Appendix C shows that the c-statistic of our final model was the highest, compared with Model 0 and Model 1 (c-statistic=0.693 for Model 0; 0.697 for Model 1; and 0.705 for our final model). In Table A2 of Appendix C, some of regression coefficients (especially for age, nursing home status and peripheral vascular disease) increased or decreased from those in Models 0 and 1.

2b4.4. Statistical Results

In the table below, we list results from the adjusted model described above. For a given covariate, the regression coefficient represents the logit of the rate. We also report the odds ratio for each covariate. With the exception of the youngest age group, all main effects are statistically significant at the 0.05 level.

Table 5. Model Coefficients and Odds Ratios, Data Year 2014

Covariate	Coefficient	Odds Ratio	P-value
Age			
18-<25	0.022	1.022	0.837
25-<59	0.075	1.078	0.001
60-<75	reference		
75+	-0.181	0.834	<.0001
BMI			
underweight(< 18.5)	-0.203	0.816	0.001
normal(18.5 - 24.9)	reference		
overweight(>24.9)	0.075	1.078	0.001
Nursing home status*	-0.316	0.729	<.0001
Nephrologist's Care prior to ESRD*	0.263	1.301	<.0001
Duration of ESRD			
<1 year	-1.323	0.266	<.0001
1-<5 years	reference		
5-<9 years	-0.206	0.814	<.0001
9+	-0.57	0.566	<.0001
Primary Cause of ESRD			
Diabetes	-0.059	0.943	0.015
Other	reference		
Comorbidities*			
Diabetes (NOT as primary cause of ESRD)	-0.139	0.870	<.0001
Heart Failure	-0.075	0.928	0.002
Other Heart Diseases	-0.052	0.949	0.018
Peripheral Vascular Disease	-0.326	0.722	<.0001
Cerebrovascular Disease	-0.113	0.893	<.0001
Chronic Obstructive Pulmonary Disease	-0.094	0.910	<.0001
Alcohol/Drug Dependence	-0.111	0.895	0.006
Inability to ambulate/transfer	-0.494	0.610	<.0001
Anemia (unrelated to ESRD/CKD)	-0.071	0.931	0.054
Non-Vascular Access-Related Infections: Pneumonia/Hepatitis/HIV/Tuberculosis	-0.255	0.775	<.0001
No Medicare Claims filed in past 12 months	-0.36	0.698	<.0001

* 'No' was used as reference.

2b4.5. Method Used to Develop the Statistical Model or Stratification Approach

Risk factors were selected for the final model based on both the magnitude and statistical significance of the estimates, and c-statistics.

2b4.6. Statistical Risk Model Discrimination Statistics (e.g., c-statistic, R^2)

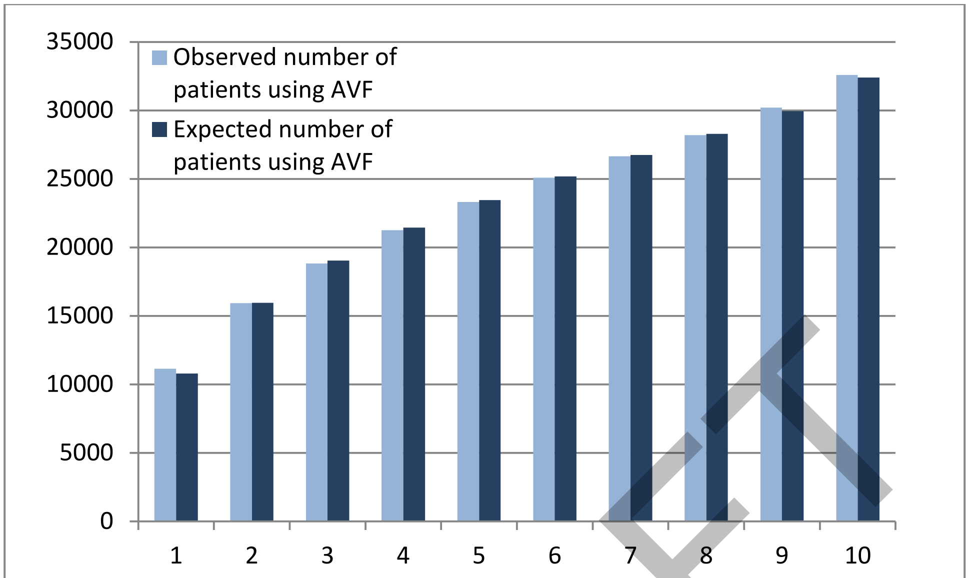
The C-statistic (also known as the Index of Concordance) was 0.71. This indicates that the model correctly ordered 71% of the pairs of patient-months that were discordant with respect to the response variate.

2b4.7. Statistical Risk Model Calibration Statistics (e.g., Hosmer-Lemeshow statistic)

The Hosmer-Lemeshow test statistic based on deciles of risk is 50.9 with p-value <0.0001. In very large samples such as this even relatively small departures from the model will lead to significant results. The c-statistic and risk decile plot show that the model provides an overall good fit to the data.

2b4.8. Statistical Risk Model Calibration—Risk decile plots or calibration curves

Figure 2: Decile plots for the number of patients using AVF



2b4.9. Results of Risk stratification Analysis

N/A

2b4.10. Interpretation

The decile plot (Figure 2) shows that the risk factors in the model are discriminating well between patients. There is good separation among all 10 groups by risk scores, and the ordering is as predicted by the model (i.e., patients predicted to have a lower probability of AVF use actually do have a lower percentage of AVF use). The absolute differences between the risk groups are also large, with patients predicted to have the highest likelihood of AVF use (Group 10) having 3 times higher AVF rate than those predicted to have the lowest likelihood (Group 1). This means that the model fit is good and therefore adequately adjusts for patient characteristics (case mix).

2b4.11. Optional Additional Testing for Risk Adjustment

N/A

2b5—Identification of statistically significant and clinically meaningful differences

2b5.1. Method for determining

Differences in measure performance were evaluated separately for each facility, where the annual standardized fistula rate (SFR) of each facility was compared to the overall national distribution. The statistical approach to this evaluation is described in Appendix C.

2b5.2. Statistical Results

Proportion of facilities with statistically significant differences (p-values < 0.025) is shown as follows:

Category	Number of facilities	Percent of facilities
As expected	5,197	86.8%
Worse than expected	789	13.2%

2b5.3. Interpretation

For the annual SFR, 5,197 (87%) facilities have achieved expected performance, and 789 (13%) facilities have performed worse than expected (lower fistula prevalence).

In general, a higher rate of fistula use represents better quality of care. This analysis demonstrates both practical and statistically significant differences in performance across facilities based on their adjusted proportion of patient months with a fistula in use.

2b6—Comparability of performance scores

2b6.1. Method of testing conducted to demonstrate comparability

2b6.2. Statistical Results

2b6.3. Interpretation

Feasibility

3a.1. How are the data elements needed to compute measure scores generated

Generated or collected by and used by healthcare personnel during the provision of care (e.g., blood pressure, lab value, diagnosis, depression score).

3b.1. Are the data elements needed for the measure as specified available electronically

All data elements are in defined fields in a combination of electronic sources including CROWNWeb and Medicare claims.

3b.3. If this is an eMeasure, provide a summary of the feasibility assessment

N/A

3c.1. Describe what you have learned or modified as a result of testing

N/A

3c.2. Describe any fees, licensing, or other requirements

N/A

Usability and Use

4.1—Current and Planned Use

4a.1. Program, sponsor, purpose, geographic area, accountable entities, patients

Use	**Planned**	**Current**	**For current use, provide Program Name and URL**
a. Public Reporting	X		
b. Public Health/Disease Surveillance			
c. Payment Program	X		
d. Regulatory and Accreditation Programs			
e. Professional Certification or Recognition Program			
f. Quality Improvement with Benchmarking (external benchmarking to multiple organizations)			
g. Quality Improvement (Internal to the specific organization)			
h. Not in use			

4a.2. If not publicly reported or used for accountability, reasons

Measure is currently under development.

4a.3. If not, provide a credible plan for implementation

CMS will determine if and when the measure will be implemented in a CMS program.

4b.1. Progress on improvement

N/A

4b.2. If no improvement was demonstrated, what are the reasons

The measure is not yet implemented in a public reporting program, so improvement could not be evaluated. CMS currently anticipates implementation of the standardized fistula rate. Once implemented facility performance on the measure can be evaluated to determine if the measure has supported and detected quality improvement in promoting fistula use for the incident and prevalent populations, while also taking into account those patient risk factors that hinder successful fistula use in certain subpopulations.

Related and Competing Measures

5—Relation to Other NQF-Endorsed Measures

5.1a. The measure titles and NQF numbers are listed here

0251: Vascular Access—Functional AVF or Evaluation by Vascular Surgeon for Placement (KCQA)

2594: Optimal End Stage Renal Disease Starts (Kaiser)

5.1b. If the measures are not NQF-endorsed, indicate the measure title

5a—Harmonization

5a.1. Are the measure specifications completely harmonized

No

5a.2. If not completely harmonized, identify the differences rationale, and impact

Measure 0251 contains several components in addition to assessing fistula use. It is a referral process measure. The most basic requirement to get into the numerator is referral to a vascular surgeon (or other qualified physician). This has the potential for facilities to score well on the measure separate from whether patients are receiving treatment with a fistula, graft, or catheter, as long as the patient was referred to or evaluated by a vascular surgeon. We acknowledge this is an important step to fistula placement however it departs from the intent of the fistula measure to function as a more direct incentive to encourage fistula use. Moreover, consistent with the concerns and recommendations made by the vascular access TEP, the SFR is risk adjusted and includes risk factors to account for patients where fistula may not be the appropriate access type.

Measure 2594 is not directed toward dialysis facilities. The setting focus addresses a different provider type which falls outside the purview of measures evaluating dialysis facility performance on fistula use. This suggests a fundamental difference in the measure target populations, setting and intent that cannot be harmonized. Additionally, the measure is limited to incident patients, while the SFR (and paired measure catheter ≥ 90 days) includes both incident and prevalent patients as the measured population.

5b—Competing measures

5b.1 Describe why this measure is superior to competing measures

There are no competing measures.

Additional Information

Co.1.—Measure Steward Point of Contact

Co.1.1. Organization

Centers for Medicare & Medicaid Services

Co.1.2. First Name

Corette

Co.1.3. Last Name

Byrd

Co.1.4. Email Address

corette.byrd@cms.hhs.gov

Co.1.5. Phone Number

Co.2.—Developer Point of Contact (indicate if same as Measure Steward Point of Contact

Co.2.1. Organization

University of Michigan Kidney Epidemiology and Cost Center

Co.2.2. First Name

Jennifer

Co.2.3. Last Name

Sardone

Co.2.4. Email Address

jmsto@med.umich.edu

Co.2.5. Phone Number

Ad.1. Workgroup/Expert Panel Involved in Measure Development

According to the CMS Measure Management System Blueprint, TEPs are advisory to the measure contractor. In this advisory role, the primary duty of the TEP is to suggest candidate measures and related specifications, review any existing measures, and determine if there is sufficient evidence to support the proposed candidate measures.

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Nephrologist, Tufts Medical Center
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Tufts University School of Medicine
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Ad.2. Year the Measure Was First Released
2015
Ad.3. Month and Year of Most Recent Revision
December 2015
Ad.4. What is your frequency for review/update of this measure?
Annually
Ad.5. When is your next scheduled review/update for this measure?
TBD
Ad.6. Copyright Statement
N/A
Ad.7. Disclaimers
N/A
Ad.8. Additional Information/Comments
N/A

Appendix C

2a2.2. Method of Reliability Testing

Here we describe our approach to calculating IUR. Let $T_1,\ldots,T_N$ be the Standardized Fistula Rate (SFR) for N facilities. Since the variation in $T_1,\ldots,T_N$ is mainly driven by the estimates of facility-specific intercepts ($\alpha_1,\ldots,\alpha_N$), we use their asymptotic distributions to estimate a bootstrapped SFRs. That is, randomly draw a bootstrap sample of ($\alpha_1^*,\ldots,\alpha_N^*$) from a normal distribution with mean and standard deviation of ($\alpha_1,\ldots,\alpha_N$) estimates, calculate SFR_i^* using ($\alpha_1^*,\ldots,\alpha_N^*$), and repeat the process B times (we set B=100). For the ith facility, we have bootstrapped SFRs ($T_{i,1}^*,\ldots,T_{i,B}^*$) and their sample variance (S_i^*). From this it can be seen that

$$s_{t,w}^2 = \frac{\sum_{i=1}^N [(n_i - 1)S_i^{*2}]}{\sum_{i=1}^N (n_i - 1)}$$

is a bootstrap estimate of the within-facility variance in the SFR, namely, $\sigma_{t,w}^2$, where n_i is the number of subjects in the ith facility. Calling on formulas from the one-way ANOVA, the total variation in SFR (i.e., $\sigma_b^2 + \sigma_{t,w}^2$) can be estimated by

$$s_t^2 = \frac{1}{n'(N-1)} \sum_{i=1}^N n_i (T_i - \bar{T})^2$$

where

$$\bar{T} = \sum n_i T_i / \sum n_i$$

is the overall weighted mean of SFRs, σ_b^2 is the between-facility variance, the true signal reflecting the differences across facilities, and

$$n' = \frac{1}{N-1} \left(\sum n_i - \sum n_i^2 \Big/ \sum n_i\right)$$

is approximately the average facility size (number of patients per facility). Thus, the IUR

$$IUR = \frac{\sigma_b^2}{\sigma_b^2 + \sigma_{t,w}^2}$$

can be estimated by $(s_t^2 - s_{t,w}^2)/s_t^2$.

2b4.3. Conceptual, Clinical, and Statistical Methods

Using data from January 2014 we compared analysis results of two additional risk adjustment models that included: 1) no comorbidity adjustment at all (denoted as Model 0), and 2) comorbidities defined by CMS-2728 only (denoted as Model 1) to our final model.

Table A1: Comparison of C-statistics adjusted (with different definitions) and not adjusted for comorbidities

	Adjusted Predictors	**C-statistic**
Model 0	Age, BMI, nursing home status, nephrologist's care prior to ESRD, duration of ESRD, primary cause of ESRD	0.693
Model 1	All predictors in Model 0 + comorbidities in CMS-2728 only	0.697
Final Model	All predictors in Model 0 + comorbidities in either CMS-2728 or Medicare claims filed in past 12 months	0.705

Table A2: Multivariate analyses results from the models with and without comorbidity adjustment. Definition of comorbidity covariates was different in Model 1 and Final Model.

Covariate	**Model 0**		**Model 1**		**Final Model**	
	Coefficient	P	Coefficient	P	Coefficient	**P**
Age						
18-<25	0.102	0.0143	0.018	0.6656	-0.018	0.6735
25-<59	0.127	<.0001	0.094	<.0001	0.076	<.0001
60-<75	reference		reference		reference	
75+	-0.191	<.0001	-0.186	<.0001	-0.181	<.0001
BMI						
underweight(< 18.5)	-0.216	<.0001	-0.207	<.0001	-0.208	<.0001
normal(18.5 - 24.9)	reference		reference		reference	
overweight(>24.9)	0.055	<.0001	0.067	<.0001	0.066	<.0001
Nursing home status*	-0.588	<.0001	-0.518	<.0001	-0.376	<.0001
Nephrologist's Care prior to ESRD*	0.284	<.0001	0.275	<.0001	0.277	<.0001
Duration of ESRD						
<1 year	-1.275	<.0001	-1.268	<.0001	-1.264	<.0001
1-<5 years	reference		reference		reference	
5-< 9 years	-0.195	<.0001	-0.219	<.0001	-0.208	<.0001
9+	-0.531	<.0001	-0.593	<.0001	-0.574	<.0001
Primary cause of ESRD						
Diabetes	-0.058	<.0001	-0.071	<.0001	-0.072	<.0001
Other	reference		reference		reference	

Covariate	Model 0		Model 1		Final Model	
Comorbidities*						
Diabetes (NOT as primary cause of ESRD)			-0.137	<.0001	-0.147	<.0001
Heart Failure			-0.099	<.0001	-0.073	<.0001
Other Heart Diseases			-0.009	0.3105	-0.046	<.0001
Peripheral Vascular Disease			-0.068	<.0001	-0.320	<.0001
Cerebrovascular Disease			-0.135	<.0001	-0.104	<.0001
Chronic Obstructive Pulmonary Disease			-0.118	<.0001	-0.088	<.0001
Alcohol/Drug Dependence			-0.147	<.0001	-0.113	<.0001
Inability to ambulate/transfer			-0.515	<.0001	-0.486	<.0001
Anemia (unrelated to ESRD/CKD)			N/A		-0.054	0.0005
Non-Vascular Access-Related Infections: Pneumonias/Hepatitis /HIV/AIDS/Tuberculosis			N/A		-0.244	<.0001
No Medicare Claims filed in past 12 months			N/A		-0.374	<.0001

* **'No' was used as reference.**

2b5.1. Method for determining

Differences in measure performance were evaluated separately for each facility, where the annual standardized fistula rate (SFR) of each facility was compared to the overall national distribution.

Here we describe our approach. Let $T_1,\ldots,T_N$ be the SFR for N facilities. Since the variation in $T_1,\ldots,T_N$ is mainly driven by the estimates of facility-specific intercepts ($\alpha_1,\ldots, \alpha_N$), we use their asymptotic distributions to estimate a bootstrapped SFRs. That is, randomly draw a bootstrap sample of ($\alpha_1^*,\ldots, \alpha_N^*$) from a normal distribution with mean and standard deviation of ($\alpha_1,\ldots, \alpha_N$) estimates, calculate SFR_i^* using ($\alpha_1^*,\ldots, \alpha_N^*$), and repeat the process B times (we set B=100). For the ith facility, we have bootstrapped SFRs ($T_{i,1}^*,\ldots, T_{i,B}^*$) and S_i^*, the standard error of SFR of the ith facility, is estimated by the sample variance of ($T_{i,1}^*,\ldots, T_{i,B}^*$). The test-statistic is then calculated by (T_i - national average of SFR)/ S_i^*, which asymptotically follows the standard normal distribution under the null hypothesis. To test for 'worse than expected national rate', a one-sided test with significance level 0.025 is used (corresponding to a cutoff=0.05 in a two-sided test).