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 (#0256), and Maximizing Placement of Arterial Venous Fistula (#0257)) 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 April 15, 2016.

Measure Name

Hemodialysis Vascular Access: Long-term Catheter Rate

Descriptive Information

Measure Name (Measure Title De.2.)

Hemodialysis Vascular Access: Long-term Catheter Rate

Measure Type De.1.

Intermediate Clinical Outcome

Brief Description of Measure De.3.

Percentage of adult hemodialysis patient-months using a catheter continuously for three months or longer for vascular access.

If Paired or Grouped De.4. N/A

Subject/Topic Areas De.5. Renal, Renal : End Stage Renal Disease (ESRD)

Crosscutting Areas De 6. N/A

Measure Specifications

Measure-specific Web Page S.1. N/A

If This Is an eMeasure S.2a. This is not an eMeasure

Data Dictionary, Code Table, or Value Sets S.2b. See Data Dictionary/Code Table

For Endorsement Maintenance S.3.

N/A

Numerator Statement S.4.

The numerator is the number of adult patient-months in the denominator who were on maintenance hemodialysis using a catheter continuously for three months or longer as of the last hemodialysis session of the reporting month.

Time Period for Data S.5.

12 months

Numerator Details S.6.

The number of patient-months with a long-term catheter in use. Long-term catheter use is defined as using a catheter, at the same facility, for at least three consecutive complete months as of the last day of the reporting month.

For a given month, if any of the following CROWNWeb "Access Type IDs" (16,18,19,20,21,"·") has been recorded, a catheter is considered in use. If a catheter has been observed for three consecutive months (i.e., in the reporting month and the immediate two preceding months) at the same facility, the reporting month is counted in the numerator. Access Type ID "16" represents AV Fistula combined with a Catheter, "18" represents AV Graft combined with a Catheter, "19" represents Catheter only, "20" represents Port access only, "21" represents other/unknown, and "·" represents missing. If a patient changes dialysis facilities, the counting of the three consecutive complete months restarts at the new facility.

Denominator Statement S.7.

All patients at least 18 years old as of the first day of the reporting month who are determined to be maintenance hemodialysis patients (in-center and home HD) for the complete reporting month at the same facility.

Target Population Category S.8.

Populations at Risk

Denominator Details S.9.

For each patient, we identify the dialysis provider at each month using a combination of Medicare-paid dialysis claims, the Medical Evidence Form (Form CMS-2728), and data from CROWNWeb. These sources

are used to identify patients that are receiving in-center or home hemodialysis for the entire reporting month. Patients are required to have been treated by the same facility for the complete month in order to be assigned to that facility for the reporting month.

To be included in the denominator for a particular reporting month, the patient must be receiving home or in-center hemodialysis for the complete reporting month at the facility, and be at least 18 years old as of the first day of the month.

The monthly patient count at a facility includes all eligible prevalent and incident patients. The number of patient-months over a time period is the sum of patients reported for the months covered by the time period. An individual patient may contribute up to 12 patient-months per year.

Denominator Exclusions (NQF Includes "Exceptions" in the "Exclusion" Field) S.10.

Exclusions that are implicit in the denominator definition include:

- Pediatric patients (<18 years old)
- Patients on Peritoneal Dialysis
- Patient-months under in-center or home hemodialysis for less than a complete reporting month at the same facility

In addition, the following exclusions are applied to the denominator:

Patients with a catheter that have limited life expectancy:

- 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

Denominator Exclusion Details (NQF Includes "Exceptions" in the "Exclusion" Field) S.11.

Determination of peritoneal dialysis treatment modality is derived from a combination of Medicare-paid dialysis claims, the Medical Evidence Form (Form CMS-2728), and data from CROWNWeb. These sources also determine patient assignment to the facility. Patients not treated by the facility for the entire month are excluded for that reporting month.

The patient's age is determined by subtracting the patient's date of birth from the first day of the reporting month. Patients that are < 18 years old as of the first day of the reporting month are excluded.

For the exclusion of catheter patients with limited life expectancy, catheter use in the reporting month is defined as the CROWNWeb "Access Type ID" having any of the following values: (16,18,19,20,21,"·"), where Access_Type_ID "16" represents AV Fistula combined with a Catheter, "18" represents AV Graft combined with a Catheter, "19" represents Catheter only, "20" represents Port access only, "21" represents other/unknown, and "·" represents missing.

Hospice status is determined from a separate CMS file that contains final action claims submitted by Hospice providers. Once a beneficiary elects Hospice, all Hospice related claims will be found in this file, regardless if the beneficiary is in Medicare fee-for-service or in a Medicare managed care plan. Patients are identified as receiving hospice care if they have any final action claims submitted to Medicare by hospice providers in the current month.

Diagnoses of metastatic cancer, end stage liver disease, or coma in the past 12 months were determined from Medicare claim types. Medicare claims include inpatient hospitalizations, outpatient claims (including dialysis claims), and physician services. Claims from providers, such as laboratories, that report diagnosis codes when testing for the presence of a condition are excluded. A detailed list of ICD-9/ICD-10 diagnostic codes used to identify these comorbidities is included in the attached data dictionary code table (excel file)

Stratification Details/Variables S.12.

N/A

Risk Adjustment Type S.13. No risk adjustment or risk stratification

Statistical Risk Model and Variables S.14. N/A

Detailed Risk Model Specifications S.15. N/A

Type of Score S.16. Rate/proportion

Interpretation of Score S.17. Better quality = Lower score

Calculation Algorithm/Measure Logic S.18. See calculation flowchart in Appendix.

Calculation Algorithm/Measure Logic Diagram URL or Attachment S.19.

Available in attached appendix

Sampling S.20. N/A

Survey/Patient-Reported Data S.21. N/A

Missing Data S.22.

We count patients with missing vascular access type in both the denominator and the numerator. Therefore missing vascular access type is counted as a catheter. For comorbidities used to determine the exclusions, if the patient had missing comorbidity values in the preceding 12 months of Medicare claims, we assume this patient did not have the comorbidity in that reporting month. The same methodology is applied to the hospice exclusion.

Data Source S.23.

Administrative claims, Electronic Clinical Data

Data Source or Collection Instrument S.24.

CROWNWeb, Medicare Claims and the CMS Medical Evidence form 2728 are used as the data sources for establishing the denominator. CROWNWeb is the data source for establishing the numerator. Medicare claims are used for the comorbidity conditions exclusion criteria.

Data Source or Collection Instrument (Reference) S.25.

No data collection instrument provided

Level of Analysis S.26. Facility

Care Setting S.27. Dialysis Facility

Composite Performance Measure S.28. N/A

Project Title:

End-Stage Renal Disease Vascular Access Measure Development

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Measure Name

Hemodialysis Vascular Access: Long-term Catheter Rate

Type of Measure

Intermediate Outcome

Importance

1a—Opportunity for Improvement1a.1. This is a Measure ofIntermediate clinical outcome (*e.g., lab value*): catheter 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. Long term catheter use is associated with the highest mortality risk while arteriovenous fistula use has the lowest mortality risk. 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 assessing long term catheter use at chronic dialysis facilities. This process leads to improvement in mortality as follows:

Measure long term catheter rate \rightarrow Assess value \rightarrow Identify patients who do not have an AV Fistula or AV graft \rightarrow Evaluation for an AV fistula or graft by a qualified dialysis vascular access provider \rightarrow Increase Fistula/Graft Rate \rightarrow Lower catheter rate \rightarrow Lower patient mortality.

1a.3.1. Source of Systematic Review Clinical Practice Guideline recommendation

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 \boxtimes Yes \rightarrow complete section 1a.7

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

1a.5.1.Recommendation Citation N/A

1a.5.2.Specific Recommendation N/A

1a.5.3. Grade N/A 1a.5.4. Grades and Associated Definitions N/A

1a.5.5. Methodology Citation N/A

1a.6.—Other Systematic Review of the Body of Evidence 1a.6.1. Review Citation N/A

1a.6.2. Methodology Citation N/A

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, specifically over catheters as the means of vascular access. The review 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

		Methadologic Quality		
Outcome	Population	Well designed and analyzed (little if any potential bias)	Some problems in design and/or analysis (some notential bias)	Poorly designed and/or analyzed (large potential bias)
		<u>c</u> :		bidby
Health Outcomes	Target Population	Strong	Moderately Strong	Weak
Health Outcomes	Other than target population	Moderately Strong	Moderately Strong	Weak
Surrogate Measure	Target Population	Moderately Strong	Weak	Weak
Surrogate Measure	Other than target	Weak	Weak	Weak
	population			

<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 associated with using an AV fistula or graft such as reduced mortality and morbidity relative to using a tunneled catheter. Specifically, AV fistula have:

- Lowest Cost¹⁻³: Compared to catheters, Medicare expenditures for AVF are approximately \$17,000 less per person per year.
- Lowest rates of infection: AV fistula have the lowest rates of infection followed by AV grafts and then tunneled dialysis catheters⁴. Vascular access infections are common, and represent the second most common cause of death for patients receiving hemodialysis.⁵
- Lowest mortality and hospitalization: Patients using catheters (RR=2.3) and grafts (RR=1.47) have a greater mortality risk than patients dialyzed with fistulae⁶⁻⁹. Other studies have also found that use of fistulae reduces mortality and morbidity¹⁰⁻¹² compared to AV grafts or catheters.

References:

- 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
- 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
- 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
- 4. Nassar GM, Ayus JC: Infectious complications of the hemodialysis access. Kidney Int 60:1-13, 2001
- 5. 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
- 6. 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
- 7. Woods JD, Port FK: The impact of vascular access for haemodialysis on patient morbidity and mortality. Nephrol Dial Transplant 12:657-659, 1997
- 8. 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
- 9. 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
- 10. 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
- 11. 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
- 12. 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

1a.7.8. Benefits Over Harms

Unintended consequences of catheter avoidance strategies were not well studied at the time when the clinical practice guidelines were developed. More recently, members of the dialysis community have voiced concern that an aggressive agenda to create AVF in most all patients would lead to unnecessary surgery for some patients that have a high risk of mortality either before starting dialysis or within the first year of treatment. Despite these concerns, the overall risk associated with AV fistula creation to avoid long term catheter use are considered to be small and overshadowed by the long-term benefits outlined above for fistula use.

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.

Impact: Adds the patient's perspective to the discussion on vascular access options.

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.

Impact: Updates primary and secondary patency rates of AVF for more contemporary cohorts of dialysis patients. The lower success rates suggests that some patients may not realize the full benefits of AVF that have been previously reported in the KDOQI systematic review.

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.

Impact: Highlights that not all older patients may benefit from an AVF.

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.

Impact: Certain patient groups, such as women with diabetes, have lower reported success rates of AVF creation and may have equivalent outcomes with an AVG.

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.

Impact: Opinion piece on changes in the Fistula First initiative reflecting the implementation of the current NQF endorsed fistula and catheter vascular access measures in the CMS Quality Incentive Program (QIP). The empahsis of the opinion piece suggests a greater shift to catheter avoidance versus only prioritizing promotion of fistula 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.

Selection of healthier patients for arteriovenous fistula (AVF) placement may explain higher observed catheter-associated mortality among elderly hemodialysis patients. A proportional hazard model was used to examine 117,277 incident hemodialysis patients aged 67-90 years from USRDS for the association of initial vascular access type and 5-year mortality after accounting for health status. 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>.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.

Impact: Underscores the need to adjust for patient characteristics and comorbidities when evaluating the association between vascular access type and outcomes such as mortality.

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.*

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.

Impact: Despite longstanding KDOQI guidelines, many patients still start hemodialysis with a tunneled catheter and experience higher rates of infectious complications compared to those with an AVF.

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.

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. This systematic review of cohort studies evaluates the associations between type of vascular access (arteriovenous fistula, arteriovenous graft, and central venous catheter) and risk for death, infection, and major cardiovascular events. 67 (62 cohort studies comprising 586,337 participants)studies were selected. 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% Cl=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.

Impact: This study emphasizes that the body of evidence is consistent in the magnitude and direction of effect with regards to the benefits of AVF over central venous catheter.

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.*

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.

Impact: Outlines the importance of considering patient factors in vascular access options for elderly patients.

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.*

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.

Impact: Risks and benefits of arteriovenous fistulas, relative to arteriovenous grafts, and central venous catheters need to be considered, particularly carefully in older patients and those with poor prognosis (limited life expectancy).

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.*

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 three months), while CVC usage in the first three months 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 three months, 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.

Impact: Emphasizes that catheter avoidance should receive more attention than simply increasing the proportion of patients with an AVF.

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.

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.

Impact: An individualized approach to vascular access decisions that relies on both quantitative assessment of benefits and harms, as well as patient preference, can lead to treatement decisions that contradict practice guidelines.

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.*

The excess morbidity and mortality related to catheter utilization at and immediately following dialysis initiation may simply be a proxy for poor prognosis. This study examined hospitalization burden related to vascular access (VA) type among incident patients who received some predialysis care using the DOPPS patient cohort (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. 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 VArelated hospitalizations with graft use. 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.

Impact: Additional support for the association between catheter use and risk of hospitalization, particularly infection related hospitalizations.

1a.8.—Other Source of Evidence N/A 1a.8.1. Process Used N/A 1a.8.2. Citation N/A

1b.—Evidence to Support Measure Focus

1b.1. Rationale

Based upon data from the CMS Fistula First/Catheter Last initiative, a gradual trend towards lower catheter use has been observed among prevalent maintenance HD patients in the US, declining from approximately 28% in 2006 to approximately 18% by August 2015. Furthermore, the percentage of maintenance HD patients using a catheter for at least three months has declined as well over this time period from nearly 12% to 10.8%. Continued monitoring of chronic catheter use is needed to sustain this trend.

This measure is intended to be jointly reported with the Hemodialysis Vascular Access- Standardized Fistula Rate. These two vascular access quality measures, when used together, consider Arterial Venous (AV) fistula

use as a positive outcome and prolonged use of a tunneled catheter as a negative outcome. With the growing recognition that some patients have exhausted options for an arteriovenous fistula, or have comorbidities that may limit the success of AVF creation, joint reporting of the measures accounts for all three vascular access options. The fistula measure adjusts for patient factors where fistula placement may be either more difficult or not appropriate and acknowledges that in certain circumstances an AV graft may be the best access option. This paired incentive structure that relies on both measures reflects consensus best practice, and supports maintenance of the gains in vascular access success achieved via the Fistula First/Catheter Last Project over the last decade.

1b.2. Performance Scores

Analysis of CROWNWeb data from January 2014- December 2014 indicated the facility-level mean percentage of patient-months with a long-term catheter was 11.6% (SD=6.6%). Distribution: Min=0%, 1st quartile=7.0%, median=10.5%, 3rd quartile=14.9%, Max=58.2%.

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 the data from Jan-Dec 2014, age, sex, race, ethnicity and dialysis vintage were evaluated in a logistic regression model for long- term catheter use. Below we report the odds ratios for these patient characteristics. Age, sex, race, ethnicity and dialysis vintage are all statistically significant predictors of long-term catheter use. The analysis results indicate potential disparity in prolonged use of a tunneled catheter among these groups. Specifically, females are about 55% more likely to have a long-term catheter as males. Individuals 75 years of age and older were 14% more likely to have a long-term catheter and younger individuals 18-25 years of age were 46% more likely to have a long-term catheter when compared to patients 60-75 years of age. Those whose race is reported as "Other" were less likely to have a long-term catheter when compared to patients 60-75 years and whose duration of ESRD are 9+ year were almost four times and 26% more likely to have a long-term catheter of ESRD < 1 year and whose duration of ESRD are 9+ year were almost four times and 26% more likely to have a long-term catheter, respectively. Patients whose duration of ESRD are 1-<5 years. In the absence of biological effects explaining these differences, risk adjustment for these demographic factors could potentially mask disparities in care.

Odds ratio of having a catheter for at least three months:

Age:

For the 18-<25 age group, the Odds Ratio (95% CI) is 1.46 (1.12, 1.90), P-value is 0.005. For the 25-<59 age group, the Odds Ratio (95% CI) is 1.06 (1.00, 1.121), P-value is 0.057. The 60-<75 age group was used as the reference group. For the 75+ age group, the Odds Ratio (95% CI) is 1.14 (1.07, 1.23), P-value is <.0001.

Sex:

For Female: the Odds Ratio (95% CI) is 1.55 (1.47, 1.63), P-value is <.0001. Male was used as the reference group.

Race:

White was used as the reference group. For Black: the Odds Ratio (95% CI) is 0.98 (0.91, 1.05), P-value is 0.586. For Other race: the Odds Ratio (95% CI) is 0.77 (0.67, 0.88), P-value is <.0001. Ethnicity:

For Hispanic: the Odds Ratio (95% Cl) is 0.81 (0.74, 0.89), P-value is <.0001. Non-Hispanic was used as the reference group.

Duration of ESRD: For <1 year: the Odds Ratio was 3.97 (3.78, 4.18), P-value is <.0001. 1-<5 years was used as the reference group. For 5-<9 years: the Odds Ratio was 0.92 (0.84, 1.00), P-value is 0.041. For 9+ years: the Odds Ratio was 1.26 (1.15, 1.38), P-value is <.0001.

IN RESPONSE TO THE REQUIREMENTS FOR THE SDS TRIAL PERIOD* *placing these results here per instructions from NQF staff, as the measure is not risk adjusted.

We performed the following analyses specifically to address the requirement for the NQF Trial Period for assessment of sociodemographic factors as potential risk adjustors. Sociodemographic factors included in the analysis were based on conceptual criteria and empirically demonstrated findings in the literature, which have shown that differences in long-term (= three months) catheter use exist among racial minorities, women and the poor. In addition, the particular patient and area level SDS/SES variables tested were based on availability of data for the analyses. We were able to acquire individual and area-level variables included in the Area Deprivation Index (ADI) developed by Singh and colleagues at the University of Wisconsin (Singh, GK. Area deprivation and widening inequalities in US mortality, 1969–1998. Am J Public Health. 2003;93(7):1137–1143).

The results below show the parameter estimates for patient- and area-level variables based on a logistic regression model for long-term catheter use (at least three months) that included these variables.

Sex:

For Female: The Odds Ratio is 1.47, and the P-value is <.0001. Male was used as the reference group.

Race: White was used as the reference group. For Black: The Odds Ratio is 0.87, and the P-value is <.0001. For Other: The Odds Ratio is 0.73, and the P-value is <.0001.

Ethnicity: For Hispanic: The Odds Ratio is 0.77, and the P-value is <.0001. Non-Hispanic was used as the reference group.

Employment Status: Employed was used as the reference group. For Unemployed: The Odds Ratio is 1.36, and the P-value is <.0001. For Other: The Odds Ratio is 1.37, and the P-value is <.0001.

Medicare Coverage:

Medicare as primary w/o Medicaid was used as the reference group. Medicare as primary with Medicaid: The Odds Ratio is 0.66, and the P-value is <.0001. Medicare as secondary/Medicare HMO: The Odds Ratio is 0.94, and the P-value is 0.060. For Non-Medicare/missing: The Odds Ratio is 1.41, and the P-value is <.0001.

ADI (zipcode-level):

Unemployment rate (%): The Odds Ratio is 0.997, and the P-value is 0.690.

Median family income: The Odds Ratio is 1.002, and the P-value is 0.881.

Families below the poverty level (%): The Odds Ratio is 0.999, and the P-value is 0.876.

Single-parent households with children <18 (%): The Odds Ratio is 0.998, and the P-value is 0.488.

Home ownership rate (%): The Odds Ratio is 0.997, and the P-value is 0.019.

Median home value: The Odds Ratio is 0.948, and the P-value is 0.052.

Median monthly mortgage: The Odds Ratio is 1.154, and the P-value is 0.058.

Median gross rent: The Odds Ratio is 0.887, and the P-value is 0.205.

Population (aged 25+) without High School diploma (%): The Odds Ratio is 0.997, and the P-value is 0.390.

Income disparity: The Odds Ratio is 1.003, and the P-value is 0.944.

Patient-level SDS/SES: Compared to males, females were more likely to have long-term catheter use (OR=1.47, p<0.01). Hispanics were less likely to have long-term catheter use (OR=0.77, p<0.01), compared to non-Hispanics. Compared to white patients, black patients and patients reporting other race were less likely to have long-term catheter use (OR=0.87, p<0.01; OR=0.73, p<0.01). As for employment status, unemployed patients and those with unknown or "other" status patients were more likely to have long-term catheter use (OR=1.36; p<0.01; OR=1.37; p<0.01), compared to employed patients. Note that for employment categories, the "Other" category represents diverse patient groups with regards to SDS/SES, such as students, homemakers, and those who are retired. Compared to Medicare only patients, patients with both Medicare and Medicaid and patients with Medicare as secondary/Medicare HMO were less likely to have long-term catheter use (OR=0.66, p<0.01; OR=0.94, p=0.06), and patients with no Medicare/missing were more likely to have long-term catheter use (OR=1.41, p<0.01). This latter result suggests that patients without Medicare coverage/missing are likely to have no insurance coverage and be in poorer health due to reduced access to health care.

Area-level SDS/SES: Area-level effects were all very small, and only three were statistically significant (p<0.05).

These analyses indicate that patient-level, but not area-level, variables for SDS/SES affect long-term catheter use. However, patient-level SDS/SES variables are not included as risk adjustment factors in the measure due to the absence of a convincing biological or clinical rationale that warrants accounting for different outcomes on the basis of race, sex, and the other patient-level SDS/SES factors tested. Area-level factors of SDS/SES are not included as adjustments due to the absence of clinically meaningful or statistically observed differences in long-term catheter use with these adjustment factors.

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 long-term use of central venous catheters for HD access is associated with greater morbidity and higher mortality. Whereas catheters have the advantage of immediate use without need for maturation time, as enumerated in the Kidney Disease Outcomes Quality Initiative (KDOQI) guidelines, the long-term use of catheters is associated with substantially higher rates of infection-related complications and increased risk for central venous thrombosis, stenosis and occlusion. Numerous studies have shown that patients receiving dialysis using catheters have been found to have greater mortality risk than patients dialyzed with fistulas or grafts, whether or not diabetes mellitus was present. Higher case-mix adjusted mortality rates have been for HD patients dialyzing in facilities having greater catheter use.

1c.4. Citations

 National Kidney Foundation: DOQI Clinical Practice Guidelines for Vascular Access. http://www.kidney.org/professionals/KDOQI/guidelines_commentaries
 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.

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 the month from January 2014-December 2014 were included in the analyses. The number of facilities per month ranged from 5,736-5,871 and the total number of patient-months ranged from 344,945- 363,257.
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

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

validity testing reported here.

There were a total of 4,274,619 eligible patient-months. Among those patient-months over the whole year, the average age was 62.7 years, 43.79% of patient-months were female, 56.27% were white, 37.05% were black, 6.68% reported race as "other", 18.41% were Hispanic and 46.37% had type II diabetes as the primary cause of ESRD.

1.7. Sample Differences, if Applicable N/A

1.8 What were the patient-level sociodemographic (SDS) variables that were available and analyzed in the data or sample used?

Patient level:

- Employment status 6 months prior to ESRD
- Race
- Sex
- Ethnicity
- Medicare coverage*

*Assessed at a specific time point (e.g., at the reporting month). Medicare coverage in model was defined as:

- 1. Medicare as primary and Medicaid
- 2. Medicare as primary and NO Medicaid
- 3. Medicare as secondary or Medicare HMO (e.g. Medicare Advantage)
- 4. Non-Medicare/missing

Data on patient level SDS/SES factors obtained from Medicare claims and administrative data.

ZIP code level – Area Deprivation Index (ADI) elements from Census data:

- Unemployment rate (%)
- Median family income
- Income disparity
- Families below the poverty level (%)
- Single-parent households with children <18 years old (%)
- Home ownership rate (%)
- Median home value
- Median monthly mortgage
- Median gross rent
- Population (aged 25+) with <9 years of education (%)
- Population (aged 25+) without high school diploma (%)

NOTE: As this measure is not risk adjusted, the analysis results and interpretation for the above SDS factors are included in the response to question **1b.4** (Disparities) in the submission form.

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-facility variation (σ_b^2) and the within-facility variation ($\sigma_{t,w}^2$) in the measure is

determined. The inter-unit reliability (IUR) measures the proportion of the total variation of a measure (i.e., $\sigma_b^2 + \sigma_{t,w}^2$) that is attributable to the between-facility variation, the true signal reflecting the differences across facilities. 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. 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.

Here we describe our approach to calculating IUR. Let $T_1,...,T_N$ be the annual catheter rate for N facilities. To generate re-sampled data, we randomly draw patients from the national population B times (we set B=100). Using each re-sampled dataset, for the *i*th facility, we calculate an annual catheter rate $(T_{i,1}^*,...,T_{i,B}^*)$ 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 catheter rate, where n_i is the number of subjects in the *i*th facility. Calling on formulas from the one-way ANOVA, the total variation in the annual catheter rate (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 the overall weighted average of catheter rate is $\overline{T} = \sum n_i T_{i/\Sigma} n_{i,i}$, and

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

is approximately the average facility size (number of patients per facility). Thus, the IUR = $\sigma_b^2 / (\sigma_b^2 + \sigma_{t,w}^2)$ can be estimated by $(s_t^2 - s_{t,w}^2)/s_t^2$.

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

2a2.3. Statistical Results from Reliability Testing

The IUR is 0.765, which indicates that 76.5% of the variation in the annual long-term catheter rate can be attributed to between-facility differences in performance (signal) and about 23.5% to the within-facility variation (noise).

2a2.4. Interpretation The result of IUR testing 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 of <u>performance measure score</u> as an indicator of quality or resource use (*i.e., is an accurate reflection of performance on quality or resource use and can distinguish good from poor performance*)

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 (Q1 to Q5), and the relative risk (RR) of mortality (and hospitalization, separately) was calculated for each quintile, using the combined Q1 and Q2 as the reference group. Thus, a RR>1.0 would indicate a higher relative risk of mortality or hospitalization, compared to the lowest performance score quintiles.

In 2015 a vascular access TEP was convened to provide input on the development of access measures, and specifically input on exclusions for both catheter and fistula measures, and for fistula, risk adjustment factors to be considered. The TEP felt that minimizing catheter use is paramount and that while catheters may potentially be acceptable for some patients, they addressed this through identifying patient level exclusion criteria rather than risk adjustment. The candidate catheter measure was reviewed and validated by the Technical Expert Panel (TEP) in 2015.

2b2.3. Statistical Results from Validity Testing Quintiles of the performance scores were defined as follows:

Q1*: 0.0%-<6.24%

Q2*: 6.24%-<9.12%

Q3: 9.12-<12.00%

Q4: 12.00%-<16.21%

Q5: 16.21%-<58.16%

*Q1 and Q2 as Reference

Results from the Poisson model indicated that the percent of patient-months with a long-term catheter was significantly associated with the risks of mortality and hospitalization.

For the 2014 SMR, the relative risk of mortality increased as the performance measure quintile increased from the reference group (combined Q1 and Q2). For quintile 3, RR=1.03 (95% CI: 1.01, 1.05; p=0.006), quintile 4, RR=1.03 (95% CI: 1.01, 1.05; p=0.008), and quintile 5, RR=1.09 (95% CI: 1.07, 1.12; p<0.001).

Similarly for the 2014 SHR, the relative risk of hospitalization increased as the performance measure quintile increased from the reference group (combined Q1 and Q2). For quintile 3, RR=1.08 (95% CI: 1.08, 1.08; p<0.001), quintile 4, RR=1.10 (95% CI: 1.10, 1.10; p<0.001), and quintile 5, RR=1.16 (95% CI: 1.15, 1.16; p<0.001).

2b2.4. Interpretation

Results of the Poisson regression suggest the predictive relationship of higher catheter use with higher mortality and hospitalization, as measured by the respective standardized mortality and hospitalization rates, compared to facilities with a lower proportion of patients with a long-term catheter.

2b3—Exclusion Analysis

2b3.1. Method of Testing Exclusion The following exclusions are applied to the denominator:

Patients with a catheter that have limited life expectancy. Limited life expectancy is defined as:

- 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 mean percentage of patient-months with a catheter for at least three months with and without the patient-month exclusions are calculated and compared.

2b3.2. Statistical Results From Testing Exclusion

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 1: Percent of patient-months at risk excluded

Year	Before Exclusion	After Exclusion	Percent
2014	4,314,450	4,274,619	0.92%

Table 2: Number and percent of unique patients excluded

Year	Before Exclusion	After Exclusion	Percent
2014	468,910	457,902	2.35%

Table 3: Distribution of performance scores before and after the exclusion

Catheter Rate	N	Mean	Standard Deviation	Minimum	Maximum
Before					
exclusion	5928	0.121	0.068	0.000	0.597
After exclusion	5928	0.118	0.066	0.000	0.582

Figure 1: Scatterplot – Facility Catheter Rate with and without Exclusions



Figure 2. Distribution of Excluded Patients at the facility level for 2014



2b3.3. Interpretation

The exclusion criteria are necessary since the percentage of patients excluded at each facility is not evenly distributed across facilities (Distribution shown in the boxplot). 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 0.993 (p-value <0.0001) between the mean percentage of patient months with a long-term catheter 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

2b4.1. Method of controlling for differences No risk adjustment or stratification

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

Risk adjustment is not appropriate for this measure because of the primary goal of disincentivizing catheter use for incident and particularly prevalent dialysis patients. This measure was reviewed by the 2015 vascular access TEP which also did not recommend risk adjustment.

The TEP felt that minimizing catheter use is paramount and that while catheters may potentially be acceptable for some patients, they addressed this through identifying patient level exclusion criteria rather than risk adjustment, so as not to penalize providers that treat patients that have limited life expectancy or limit those patients' access to care.

Consistent with the TEP's concerns, potential risk adjustors in a catheter measure would apply to a large portion of both incident and prevalent ESRD patients, and therefore may not function as a disincentive to reduce catheter use, which is the intent of the measure. Applying the exclusions more appropriately accounts for conditions in a very specific subset of patients where a catheter may be the only or an acceptable access type. Additionally, the fistula measure (intended to be reported with the catheter measure) includes risk adjustment based on the TEP's recommendation that facility success in fistula use (versus graft or catheter) will be limited in patients with certain comorbidities and other patient characteristics.

2b4.3. Conceptual, Clinical, and Statistical Methods N/A

<mark>2b4.4a. Statistical Results</mark> N/A

2b4.4b. Statistical Results for SDS factors N/A

2b4.5. Method Used to Develop the Statistical Model or Stratification Approach $\ensuremath{\mathsf{N/A}}$

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

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

N/A

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

2b4.9. Results of Risk stratification Analysis N/A

2b4.10. Interpretation N/A

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 using patient level analyses. For each facility, the proportion of patient-months with catheter \geq three months, calculated at the year-level, was compared to the overall national distribution.

Note that the monthly based measure is a simple average of binary outcomes across individuals in the facility, for which the binary outcome equals 0 if no catheter is present, and equals 1 if a catheter ≥ three months is present. The differences in proportions can be compared using Fisher's Exact tests or its normal approximation. The yearly based measure, however, is not a simple average of binary outcomes and we instead used a re-sampling based exact test, with re-sampling generated from the population distribution of the patient level outcomes. Due to the non-symmetric structure of the measure distributions, a one-sided test with significance level 0.025 is used (corresponding to a cutoff=0.05 in a two-sided test). To calculate the p-value, we assess the probability that patients in each facility would experience a number of events (i.e., months dialyzing with catheter ≥ three months) more extreme than what was actually observed if the null hypothesis were true, where the null hypothesis is that a patient in each facility will follow the overall national distribution.

2b5.2. Statistical Results

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

Category	Number of facilities	Percent of facilities
As expected	5,211	87.9%
Worse than expected	717	12.1%

2b5.3. Interpretation

For the annual percentage of patients with a long-term catheter as the performance measure, 5,211 (87.9%) facilities have achieved expected performance, and 717 (12%) facilities have performed worse than expected (higher catheter rate).

In general, lower rates of catheter use for three months or more represent better quality of care. This analysis demonstrates both practical and statistically significant differences in performance across facilities based on their proportion of patient months with a catheter for three months or greater.

2b6—Comparability of performance scores

2b6.1. Method of testing conducted to demonstrate comparability N/A

2b6.2. Statistical Results N/A

2b6.3. Interpretation N/A

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

3b.3. If this is an eMeasure, provide a summary of the feasibility assessment $\ensuremath{\mathsf{N/A}}$

3c.1. Describe what you have learned or modified as a result of testing $\ensuremath{\mathsf{N/A}}$

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 Planned- Public Reporting, Payment Program

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. Upon endorsement, CMS will consider retiring the currently endorsed measure of catheter use (#0256) in favor of this new measure for implementation in a future performance year for the ESRD QIP and reporting period for Dialysis Facility Compare at the next available opportunity.

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 this catheter measure. Once implemented facility performance on the measure can be evaluated to determine if the measure has supported and detected quality improvement in reducing prolonged catheter use, while accounting for patients where a long-term catheter may be an appropriate vascular access choice.

Related and Competing Measures

5—Relation to Other NQF-Endorsed Measures Yes

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

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

2594 : Optimal End Stage Renal Disease (ESRD) Starts

5.1b. If the measures are not NQF-endorsed, indicate the measure title $\ensuremath{\mathsf{N/A}}$

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 including AV fistula use, AV graft use or referral to a vascular surgeon (or other qualified physician) if using a long-term catheter. It is a referral process measure for those patients with a catheter. This has the potential for facilities to score well on the measure even if they have patients with a 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 catheter measure to function as a more direct disincentive to prolonged catheter use, consistent with the concerns and recommendations made by the vascular access TEP. 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 prolonged catheter use. These suggest fundamental differences in measure target populations, setting and intent that cannot be harmonized. Additionally, the measure is limited to incident patients, while the long-term catheter rate measure 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 Sophia Co.1.3. Last Name Chan Co.1.4. Email Address sophia.chan@cms.hhs.gov Co.1.5. Phone Number N/A

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 734-548-3057

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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Ad.2. Year the Measure Was First Released 2016

Ad.3. Month and Year of Most Recent Revision 04, 2016

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? 04, 2017

Ad.6. Copyright Statement N/A

Ad.7. Disclaimers

Ad.8. Additional Information/Comments N/A

Data Dictionary

Variable	Primary Data Source	
Facility CCN #	CMS data sources ^{*1}	
Reporting year and month	CROWNWeb	
Vascular Access Type	CROWNWeb	
Date of Birth	CMS data sources ^{*1}	
Date of First ESRD	Medical Evidence Form (CMS-2728)	
Age at the first day of reporting month	CMS data sources ^{*1}	
Hospice_status in the current month *4	CMS Hospice file ^{*2}	
Metastatic Cancer reported on Medicare Claims in past 12 months ^{*4}	Medicare Claims ^{*3}	
End-Stage Liver Disease reported on Medicare Claims in past 12 months ^{*4}	Medicare Claims ^{*3}	
Coma or Anoxic Brain Damage reported on Medicare Claims in past 12 months *4	Medicare Claims ^{*3}	

*1. Multiple data sources include CMS Consolidated Renal Operations in a Web-enabled Network (CROWNWeb), the CMS Annual Facility Survey (Form CMS-2744), Medicare dialysis and hospital payment records, the CMS Medical Evidence Form (Form CMS-2728), transplant data from the Organ Procurement and Transplant Network (OPTN), the Death Notification Form (Form CMS-2746), the Dialysis Facility Compare (DFC) and the Social Security Death Master File.

Unique patients are identified byusing a combination of SSN, first name, surname, sex, Medicare claim number and birth date. A matching process is performed to ensure that minor typos and misspellings do not cause a patient record to fall out of their history. The matching process is able to successfully match 99.5% of patients. The remaining patients have incomplete or incorrect data that does not allow them to be matched.

*2. Hospice information comes from CMS hospice file that contains final action claims submitted by Hospice providers. Once a beneficiary elects Hospice, all Hospice related claims will be found in this file, regardless if the beneficiary is in Medicare fee-for-service or in a Medicare managed care plan.

*3. Medicare claims include Part A claims such as inpatient admissions and Part B claims such as outpatient claims (including dialysis claims) and physician services. Claims from providers, such as laboratories, that report diagnosis codes when testing for the presence of a condition are excluded.

*4. Exclusion factors: A detailed list of ICD-9 diagnostic codes used to identify exclusion comorbidities is included in this file (See Tab ICD-9 to 10 Exclusions).

ICD-9 to 10 Mapping: Exclusions

ICD9DX	ICD9::ICD9DX_desc	ICD10CM	ICD	L0::ICD10CM_desc
1960	Secondary and unspecified malignant neoplasm of lymph nodes of head, fac	C770	C770	Secondary and unspecified malignant neoplasm of lymph nodes of head, face and neck
1961	Secondary and unspecified malignant neoplasm of intrathoracic lymph node	C771	C771	Secondary and unspecified malignant neoplasm of intrathoracic lymph nodes
1962	Secondary and unspecified malignant neoplasm of intra-abdominal lymph n	C772	C772	Secondary and unspecified malignant neoplasm of intra-abdominal lymph nodes
1965	Secondary and unspecified malignant neoplasm of lymph nodes of inguinal	C774	C774	Secondary and unspecified malignant neoplasm of inguinal and lower limb lymph nodes
1966	Secondary and unspecified malignant neoplasm of intrapelvic lymph nodes	C775	C775	Secondary and unspecified malignant neoplasm of intrapelvic lymph nodes
1968	Secondary and unspecified malignant neoplasm of lymph nodes of multiple	C778	C778	Secondary and unspecified malignant neoplasm of lymph nodes of multiple regions
1970	Secondary malignant neoplasm of lung	C7800	C7800	Secondary malignant neoplasm of unspecified lung
1971	Secondary malignant neoplasm of mediastinum	C781	C781	Secondary malignant neoplasm of mediastinum
1972	Secondary malignant neoplasm of pleura	C782	C782	Secondary malignant neoplasm of pleura
1973	Secondary malignant neoplasm of other respiratory organs	C7839	C7839	Secondary malignant neoplasm of other respiratory organs
1974	Secondary malignant neoplasm of small intestine including duodenum	C784	C784	Secondary malignant neoplasm of small intestine
1975	Secondary malignant neoplasm of large intestine and rectum	C785	C785	Secondary malignant neoplasm of large intestine and rectum
1976	Secondary malignant neoplasm of retroperitoneum and peritoneum	C786	C786	Secondary malignant neoplasm of retroperitoneum and peritoneum
1977	Coordery molignest peoplesm of other disective errors and splean	C787	C787	Secondary malignant neoplasm of liver and intrahepatic bile duct
1978	Secondary malignant neoplasm of other digestive organs and spleen	C7890	C7890	Secondary malignant neoplasm of other directive ergans
1090	Secondary malignant neoplasm of bidney	C7000	C7000	Secondary malignant neoplasm of uncredified kidney and renal polyic
1001	Secondary malignant neoplasm of other urinary organs	C7900	C7011	Secondary malignant neoplasm of bladder
1001	Secondary malignant neoplasm of other urinary organs	C7010	C7010	Secondary malignant neoplasm of other urinary organs
1983	Secondary malignant neoplasm of brain and spinal cord	C7931	C7931	Secondary malignant neoplasm of brain
1984	Secondary malignant neoplasm of other parts of pervous system	C7932	C7932	Secondary malignant neoplasm of cerebral meninges
1984	Secondary malignant neoplasm of other parts of nervous system	C7949	C7949	Secondary malignant neoplasm of other parts of nervous system
1985	Secondary malignant neoplasm of bone and bone marrow	C7951	C7951	Secondary malignant neoplasm of bone
1985	Secondary malignant neoplasm of bone and bone marrow	C7952	C7952	Secondary malignant neoplasm of bone marrow
1986	Secondary malignant neoplasm of ovary	C7960	C7960	Secondary malignant neoplasm of unspecified ovary
1987	Secondary malignant neoplasm of adrenal gland	C7970	C7970	Secondary malignant neoplasm of unspecified adrenal gland
19889	Secondary malignant neoplasm of other specified sites	C7989	C7989	Secondary malignant neoplasm of other specified sites
1990	Disseminated malignant neoplasm without specification of site	C800	C800	Disseminated malignant neoplasm, unspecified
20400	Acute lymphoid leukemia, without mention of having achieved remission	C9100	C9100	Acute lymphoblastic leukemia not having achieved remission
20401	Acute lymphoid leukemia, in remission	C9101	C9101	Acute lymphoblastic leukemia, in remission
20402	Acute lymphoid leukemia, in relapse	C9102	C9102	Acute lymphoblastic leukemia, in relapse
20500	Acute myeloid leukemia, without mention of having achieved remission	C9200	C9200	Acute myeloblastic leukemia, not having achieved remission
20500	Acute myeloid leukemia, without mention of having achieved remission	C9240	C9240	Acute promyelocytic leukemia, not having achieved remission
20500	Acute myeloid leukemia, without mention of having achieved remission	C9250	C9250	Acute myelomonocytic leukemia, not having achieved remission
20501	Acute myeloid leukemia, in remission	C9201	C9201	Acute myeloblastic leukemia, in remission
20501	Acute myeloid leukemia, in remission	C9241	C9241	Acute promyelocytic leukemia, in remission
20501	Acute myeloid leukemia, in remission	C9251	C9251	Acute myelomonocytic leukemia, in remission
20502	Acute myeloid leukemia, in relapse	C9202	C9202	Acute myeloblastic leukemia, in relapse
20502	Acute myeloid leukemia, in relapse	C9242	C9242	Acute promyelocytic leukemia, in relapse
20502	Acute myeloid leukemia, in relapse	C9252	C9252	Acute myelomonocytic leukemia, in relapse
20600	Acute monocytic leukemia, without mention of having achieved remission	C9300	C9300	Acute monoblastic/monocytic leukemia, not having achieved remission
20601	Acute monocytic leukemia, in remission	C9301	C9301	Acute monoblastic/monocytic leukemia, in remission
20602	Acute monocytic leukemia, in relapse	C9302	C9302	Acute monoblastic/monocytic leukemia, in relapse
20700	Acute erythremia and erythroleukemia, without mention of having achieved	C9400	C9400	Acute erythroid leukemia, not having achieved remission
20701	Acute erythremia and erythroleukemia, in remission	C9401	C9401	Acute erythroid leukemia, in remission
20702	Acute erythremia and erythroleukemia, in relapse	C9402	C9402	Acute erythroid leukemia, in relapse
20800	Acute leukemia of unspecified cell type, without mention of having achieved	C9500	C9500	Acute leukemia of unspecified cell type not having achieved remission
20801	Acute leukemia of unspecified cell type, in remission	C9501	C9501	Acute leukemia of unspecified cell type, in remission
20802	Acute leukemia of unspecified cell type, in relapse	C9502	C9502	Acute leukemia of unspecified cell type, in relapse
20970	Secondary neuroendocrine tumor, unspecified site	C7B00	C7B00	Secondary carcinoid tumors, unspecified site
20971	Secondary neuroendocrine tumor of distant lymph nodes	C7B01	C7B01	Secondary carcinoid tumors of distant lymph nodes
20972	Secondary neuroendocrine tumor of liver	C7B02	C7B02	Secondary carcinoid tumors of liver
20973	Secondary neuroendocrine tumor of bone	C7B03	C7B03	Secondary carcinoid tumors of bone
20974	Secondary neuroendocrine tumor of peritoneum	C7B04	C7B04	Secondary carcinoid tumors of peritoneum
20975	Secondary Merkel cell carcinoma	C7B1	C7B1	Secondary Merkel cell carcinoma
20979	Secondary neuroendocrine tumor of other sites	C7B09	C7809	Secondary carcinoid tumors of other sites
20979	Secondary neuroendocrine tumor of other sites	C7B8	C788	Other secondary neuroendocrine tumors
3/81	Anovic brain damage	6931	6931	Anoxic brain damage, not elsewhere classified
2/8/	Compression of brain	6935	6025	Compression of brain
2404	Compression of Brain	C036	6036	Compression of Sham
45.00	Cerebral veriese with blooding	19501	19501	Celebrar evenia
4500	Esophageal varices with bleeding	10500	10500	Esophageal varices with bleeding
4501	Esophageal varices without mention of bleeding	18500	18500	Esophageal varices without bleeding
45620	Esophageal varices in diseases classified elsewhere, with bleeding	18511	18511	Secondary esophageal varices with bleeding
45621	Esophageal varices in diseases classified elsewhere, without mention of blee	18510	18510	Secondary esophageal varices without bleeding
5722	Hepatic encephalopathy	к/290	K7290	Hepatic failure, unspecified without coma
5722	Hepatic encephalopathy	K7291	K7291	Hepatic failure, unspecified with coma
5723	Portal hypertension	K766	K766	Portal hypertension
5724	Hepatorenal syndrome	K767	K767	Hepatorenal syndrome
5728	Other sequelae of chronic liver disease	K7210	K7210	Chronic hepatic failure without coma
5728	Other sequelae of chronic liver disease	K7290	K7290	Hepatic failure, unspecified without coma
5735	Hepatopulmonary syndrome	K7681	K7681	Hepatopulmonary syndrome
78001	Coma	R4020	R4020	Unspecified coma
78003	Persistent vegetative state	R403	R403	Persistent vegetative state

APPENDIX

Hemodialysis Vascular Access: Long-Term Catheter Rate

S.19: Calculation Algorithm/Measure Logic Diagram Hemodialysis Vascular Access: Long-term Catheter Rate



*Multiple data sources include CMS Consolidated Renal Operations in a Web-enabled Network (CROWNWeb), the CMS Annual Facility Survey (Form CMS-2744), Medicare dialysis and hospital payment records, the CMS Medical Evidence Form (Form CMS-2728), transplant data from the Organ Procurement and Transplant Network (OPTN), the Death Notification Form (CMS-2746), the Dialysis Facility Compare (DFC) and the Social Security Death Master File.

**Access_Type_id "16" represents AV Fistula combined with a Catheter, "19" represents AV Graft combined with a Catheter, "19" represents Catheter only, "20" represents Port access only, "21" represents other/unknown, and "." represents missing.