NATIONAL QUALITY FORUM

Measure Submission and Evaluation Worksheet 5.0

This form contains the information submitted by measure developers/stewards, organized according to NQF's measure evaluation criteria and process. The evaluation criteria, evaluation guidance documents, and a blank online submission form are available on the submitting standards web page.

NQF #: 0256   **NQF Project:** Renal Endorsement Maintenance 2011
(for Endorsement Maintenance Review) **Original Endorsement Date:** Nov 15, 2007 **Most Recent Endorsement Date:** Nov 15, 2007
BRIEF MEASURE INFORMATION
De.1 Measure Title: Hemodialysis Vascular Access- Minimizing use of catheters as Chronic Dialysis Access
Co.1.1 Measure Steward: Centers for Medicare & Medicaid Services
De.2 Brief Description of Measure: Percentage of patients on maintenance hemodialysis during the last HD treatment of study period with a chronic catheter continuously for 90 days or longer prior to the last hemodialysis session.
2a1.1 Numerator Statement: Patients who were continuously using a chronic catheter as hemodialysis access for 90 days or longer prior to the last hemodialysis session during the study period.
2a1.4 Denominator Statement: Patients on maintenance hemodialysis during the last HD treatment of study period.
2a1.8 Denominator Exclusions: Patients on acute hemodialysis, peritoneal dialysis, or patients <18 years of age.
1.1 Measure Type: Process **2a1. 25-26 Data Source:** Administrative claims, Electronic Clinical Data **2a1.33 Level of Analysis:** Facility **1.2-1.4 Is this measure paired with another measure?** No **De.3 If included in a composite, please identify the composite measure** (*title and NQF number if endorsed*): Hemodialysis Vascular Access- Maximizing Placement of Arterial Venous Fistula (AVF), NQF# 0257

STAFF NOTES (*issues or questions regarding any criteria*)
Comments on Conditions for Consideration:
Is the measure untested?   Yes☐ No☐   If untested, explain how it meets criteria for consideration for time-limited endorsement:
1a. Specific national health goal/priority identified by DHHS or NPP addressed by the measure (*check De.5*): 5. Similar/related endorsed or submitted measures (*check 5.1*): Other Criteria:
Staff Reviewer Name(s):

1. IMPACT, OPPORTUNITY, EVIDENCE - IMPORTANCE TO MEASURE AND REPORT
Importance to Measure and Report is a threshold criterion that must be met in order to recommend a measure for endorsement. All three subcriteria must be met to pass this criterion. See guidance on evidence. *Measures must be judged to be important to measure and report in order to be evaluated against the remaining criteria.* (evaluation criteria)
1a. High Impact: H☐ M☐ L☐ I☐

(*The measure directly addresses a specific national health goal/priority identified by DHHS or NPP, or some other high impact aspect of healthcare.*)

De.4 Subject/Topic Areas (*Check all the areas that apply*): Renal, Renal : End Stage Renal Disease (ESRD)
De.5 Cross Cutting Areas (*Check all the areas that apply*): Population Health

1a.1 Demonstrated High Impact Aspect of Healthcare: Affects large numbers, A leading cause of morbidity/mortality

1a.2 If "Other," please describe:

1a.3 Summary of Evidence of High Impact (*Provide epidemiologic or resource use data*):
Numerous studies demonstrate that the long-term use of venous catheters as HD access is associated with greater morbidity and higher mortality. Whereas it has 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, whether or not diabetes mellitus was present. Higher case-mix adjusted mortality rates have been seen for HD patients dialyzing in facilities having greater catheter use. Furthermore, much of the 30-40% higher mortality rates for HD patients in the US versus those in 5 European (EUR) countries between 1996-2008 appears to be explained by differences in vascular access use between these two regions, with catheter and graft use being substantially greater in the US than in EUR overall during this time period.
Catheter use is also associated with the highest total costs for HD patients, with an estimate of $79,364 as compared to AV fistulas at just under $60,000 for a year of treatment (USRDS, 2009).

1a.4 Citations for Evidence of High Impact cited in 1a.3: 1. National Kidney Foundation: DOQI Clinical Practice Guidelines for Vascular Access. http://www.kidney.org/Professionals/kdoqi/guideline_upHD_PD_VA/index.htm
2. U.S. Renal Data System, USRDS 2009 Annual Data Report: Atlas of Chronic Kidney Disease and End-Stage Renal Disease in the United States, National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2009.

1b. Opportunity for Improvement: H☐ M☐ L☐ I☐
(*There is a demonstrated performance gap - variability or overall less than optimal performance*)

1b.1 Briefly explain the benefits (improvements in quality) envisioned by use of this measure:
Based upon the most recent data from the CMS Fistula First Breakthrough Initiative (FFBI), 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 24% by May 2007. Furthermore, the percentage of maintenance HD patients using a catheter for >90 days has declined as well over this time period from nearly 12% to 9.5-10%. Continued monitoring of chronic catheter use is needed to sustain this trend.

1b.2 Summary of Data Demonstrating Performance Gap (*Variation or overall less than optimal performance across providers*):
[*For Maintenance – Descriptive statistics for performance results for this measure - distribution of scores for measured entities by quartile/decile, mean, median, SD, min, max, etc.*]
Analysis of CROWNWeb data from January 2010 indicated the mean percentage of patients dialyzing with a catheter >= 90 days was 5% (SD=7%). Distribution: Min=0%, Max=47%, 1st quartile=0%, median=2%, 3rd quartile=9%. These results indicate that on average, 5% of patients at facilities are dialyzing with a catheter with some facilities dialyzing a larger percent of patients with a catheter.

1b.3 Citations for Data on Performance Gap: [*For Maintenance – Description of the data or sample for measure results reported in 1b.2 including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included*]
Performance gap analyses were performed using CROWNWeb data from January 2010. There were 3,436 facilities and a total of 293,694 patients in this reporting month. Mean number of patients per facility was 84 (SD=52).

1b.4 Summary of Data on Disparities by Population Group: [*For Maintenance –Descriptive statistics for performance results for this measure by population group*]
For each population group analysis, the percent of patients (e.g. percent of females) was divided into quintiles and the performance

measure was calculated for each quintile. The range in percent of patients dialyzing with a catheter >= 90 days across quintiles is presented below. Except for the percent of black, white, and Native American patients in the facility, the test for trend for these disparities in performance were statistically significant though the ranges were small.

Population Group (Range):
Females (4.6%-6.0%)
Black (5.3%-6.0%)
White (5.3%-5.6%)
Native American (5.2%-5.7%)
Asian (4.3%-6.2%)
Hispanic (4.4%-6.1%)
Age (4.8%-6.2%)

1b.5 Citations for Data on Disparities Cited in 1b.4: [*For Maintenance – Description of the data or sample for measure results reported in 1b.4 including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included*]
CROWNWeb data from July 2009-December 2009 were analyzed. The number of facilities ranged from 3,398-3,453 and the total number of patients per month ranged from 263,743 - 290,713.

1c. Evidence (*Measure focus is a health outcome OR meets the criteria for quantity, quality, consistency of the body of evidence.*) Is the measure focus a health outcome? Yes☐ No☐ __If not a health outcome__, rate the body of evidence.

Quantity: H☐ M☐ L☐ I☐   Quality: H☐ M☐ L☐ I☐   Consistency: H☐ M☐ L☐ I☐

Quantity	Quality	Consistency	Does the measure pass subcriterion1c?
M-H	M-H	M-H	Yes☐
L	M-H	M	Yes☐ IF additional research unlikely to change conclusion that benefits to patients outweigh harms: otherwise **No**☐
M-H	L	M-H	Yes☐ IF potential benefits to patients clearly outweigh potential harms: otherwise **No**☐
L-M-H	L-M-H	L	No ☐

Health outcome – rationale supports relationship to at least one healthcare structure, process, intervention, or service	Does the measure pass subcriterion1c? Yes☐ IF rationale supports relationship

1c.1 Structure-Process-Outcome Relationship (*Briefly state the measure focus, e.g., health outcome, intermediate clinical outcome, process, structure; then identify the appropriate links, e.g., structure-process-health outcome; process- health outcome; intermediate clinical outcome-health outcome*):
The measure focus is the process of measuring catheter use at facilities. The process leads to improvement in mortality as follows:

Measure Catheter Rate --> Assess value --> Identify problems --> Decrease Catheter Rate --> Impact on mortality

1c.2-3 Type of Evidence (*Check all that apply*):
Clinical Practice Guideline

1c.4 Directness of Evidence to the Specified Measure (*State the central topic, population, and outcomes addressed in the body of evidence and identify any differences from the measure focus and measure target population*):
The body of evidence shows a relationship between low catheter use and improved mortality and morbidity. This measure focus is on measuring catheter use in ESRD patients on HD.

1c.5 Quantity of Studies in the Body of Evidence (*Total number of studies, not articles*): 41

1c.6 Quality of Body of Evidence (*Summarize the certainty or confidence in the estimates of benefits and harms to patients across studies in the body of evidence resulting from study factors. Please address: a) study design/flaws; b)*

directness/indirectness of the evidence to this measure (e.g., interventions, comparisons, outcomes assessed, population included in the evidence); and c) imprecision/wide confidence intervals due to few patients or events): A large body of literature exists showing strong associations between central venous catheter use in hemodialysis patients with poorer survival and greater morbidity [1-40,44]. The prevalence of numerous patient comorbidity indicators was similar in facilities with high versus low catheter use. Lower mortality has been observed with reduction in catheter use and an increase in fistula use in facility- and patient-level access use studies [7, 10, 13, 40, 41]. Furthermore, much of the 30-40% higher case-mix adjusted mortality rate for US hemodialysis patients compared to those in several European countries appears to be explained by differences in vascular access use between these two regions [2].

The overall quality of the body of evidence for this measure has not been evaluated. Furthermore, the quality of the individual studies referenced in 1c.15 has not been graded.

1c.7 Consistency of Results across Studies *(Summarize the consistency of the magnitude and direction of the effect):* Results were consistent across all studies listed in body of evidence. For example, across 8 large observational studies of prevalent hemodialysis patients, the hazard ratio of case-mix adjusted all-cause mortality ranged from 1.32 to 1.75 (median HR~1.5, $p<0.05$ in all studies) for patients dialyzing with a catheter versus a native arteriovenous (AV) fistula [1-4,8,23,26,37,44]. Catheter use in incident patients at the time of commencing hemodialysis was associated with a 1.5-2.5 fold higher HR of mortality. Furthermore, a 20% higher mortality rate was observed for every 20% greater facility percent catheter use (compared with AV fistula use)[2]; conversion from a catheter to an AV access was associated with a 31% lower mortality rate whereas conversion from an AV access to a catheter was associated with a 80-138% higher mortality rate, in incident and prevalent patients respectively [7,10,13].

1c.8 Net Benefit *(Provide estimates of effect for benefit/outcome; identify harms addressed and estimates of effect; and net benefit - benefit over harms)*:
Recent studies have shown a nearly 20% higher hazard of mortality for every 20% higher facility % catheter use [2]. Thus reducing catheter use could lead to reduced mortality rates.

1c.9 Grading of Strength/Quality of the Body of Evidence. Has the body of evidence been graded? No

1c.10 If body of evidence graded, identify the entity that graded the evidence including balance of representation and any disclosures regarding bias:

1c.11 System Used for Grading the Body of Evidence: Other

1c.12 If other, identify and describe the grading scale with definitions: Not graded.

1c.13 Grade Assigned to the Body of Evidence: An overall grade was not assigned.

1c.14 Summary of Controversy/Contradictory Evidence: No controversial or contradictory evidence was found.

1c.15 Citations for Evidence other than Guidelines*(Guidelines addressed below)*:
1) Dhingra RK, Young EW, Hulbert-Shearon TE, Leavey
SF, Port FK. Type of vascular access and mortality in U.S. hemodialysis patients. Kidney Int 2001; 60:1443-1451.
2) Pisoni RL, Arrington CJ, Albert JM, Ethier J, Kimata N, Krishnan M, et al. Facility hemodialysis vascular access use and mortality in countries participating in DOPPS: an instrumental variable analysis. Am J Kidney Dis 2009; 53:475-491.
3) Polkinghorne KR, McDonald SP, Atkins RC, Kerr PG. Vascular access and all-cause mortality: a propensity score analysis. J Am Soc
Nephrol 2004; 15:477-486.
4) Pastan S, Soucie JM, McClellan WM. Vascular access and increased risk of death among hemodialysis patients. Kidney Int 2002;
62:620-626.
5) Combe C, Pisoni RL, Port FK, Young EW, Canaud B, Mapes DL, et al. [Dialysis Outcomes and Practice Patterns Study: data on the
use of central venous catheters in chronic hemodialysis]. Nephrologie 2001; 22:379-384.
6) 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 2003; 42:1013-1019.

7) Allon M, Daugirdas J, Depner TA, Greene T, Ornt D, Schwab SJ. Effect of change in vascular access on patient mortality in hemodialysis patients. Am J Kidney Dis 2006; 47:469-477.

8) Astor BC, Eustace JA, Powe NR, Klag MJ, Fink NE, Coresh J. Type of vascular access and survival among incident hemodialysis
patients: the Choices for Healthy Outcomes in Caring for ESRD (CHOICE) Study. J Am Soc Nephrol 2005; 16:1449-1455.

9) Lacson E, Jr., Wang W, Hakim RM, Teng M, Lazarus JM. Associates of mortality and hospitalization in hemodialysis: potentially actionable laboratory variables and vascular access. Am J Kidney Dis 2009; 53:79- 90.

10) Lacson E, Jr., Wang W, Lazarus JM, Hakim RM. Change in vascular access and mortality in maintenance hemodialysis patients.
Am J Kidney Dis 2009; 54:912-921.

11) Lacson E, Jr., Wang W, Lazarus JM, Hakim RM. Hemodialysis facility-based quality-of-care indicators and facility-specific patient outcomes. Am J Kidney Dis 2009; 54:490-497.

12) Lacson E, Jr., Lazarus JM, Himmelfarb J, Ikizler TA, Hakim RM. Balancing Fistula First with Catheters Last. Am J Kidney Dis 2007; 50:379-395.

13) Bradbury BD, Chen F, Furniss A, Pisoni RL, Keen M, Mapes D, et al. Conversion of vascular access type among incident hemodialysis patients: description and association with mortality. Am J Kidney Dis 2009; 53:804-814.

14) Collins AJ, Foley RN, Gilbertson DT, Chen SC. The state of chronic kidney disease, ESRD, and morbidity and mortality in the first
year of dialysis. Clin J Am Soc Nephrol 2009; 4 Suppl 1:S5-11.

15) Goncalves EA, Andreoli MC, Watanabe R, Freitas MC, Pedrosa AC, Manfredi SR, et al. Effect of temporary catheter and late referral on hospitalization and mortality during the first year of hemodialysis treatment. Artif Organs 2004; 28:1043-1049.

16) Hakim RM. Reducing early mortality in hemodialysis patients. Curr Opin Nephrol Hypertens 2008; 17:595-599.

17) Hakim RM, Himmelfarb J. Hemodialysis access failure: a call to action--revisited. Kidney Int 2009; 76:1040-1048.

18) Higuera F, Rosenthal VD, Duarte P, Ruiz J, Franco G, Safdar N. The effect of process control on the incidence of central venous
catheter-associated bloodstream infections and mortality in intensive care units in Mexico. Crit Care Med 2005; 33:2022-2027.

19) Hung AM, Ikizler TA. Hemodialysis central venous catheters as a source of inflammation and its implications. Semin Dial 2008; 21:401-404.

20) Inrig JK, Reed SD, Szczech LA, Engemann JJ, Friedman JY, Corey GR, et al. Relationship between clinical outcomes and vascular
access type among hemodialysis patients with Staphylococcus aureus bacteremia. Clin J Am Soc Nephrol 2006; 1:518-524.

21) Inrig, J.K., et al., Mortality by dialysis modality among patients who have end-stage renal disease and are awaiting renal transplantation. Clin J Am Soc Nephrol, 2006. 1(4): p. 774-9.

22) Lee, T., J. Barker, and M. Allon, Tunneled catheters in hemodialysis patients: reasons and subsequent outcomes. Am J Kidney Dis, 2005. 46(3): p. 501-8.

23) Lorenzo, V., et al., Predialysis nephrologic care and a functioning arteriovenous fistula at entry are associated with better survival in incident hemodialysis patients: an observational cohort study. Am J Kidney Dis, 2004. 43(6): p. 999-1007.

24) Mendelssohn, D.C., et al., A practice-related risk score (PRS): a DOPPS-derived aggregate quality index for haemodialysis facilities. Nephrol Dial Transplant, 2008. 23(10): p. 3227-33.

25) Port, F.K., et al., DOPPS estimates of patient life years attributable to modifiable hemodialysis practices in the United States. Blood Purif, 2004. 22(1): p. 175-80.

26) Moist, L.M., et al., Increased hemodialysis catheter use in Canada and associated mortality risk: data from the Canadian Organ Replacement Registry 2001-2004. Clin J Am Soc Nephrol, 2008. 3(6): p. 1726- 32.

27) Mokrzycki, M.H., et al., Tunnelled haemodialysis catheter bacteraemia: risk factors for bacteraemia recurrence, infectious complications and mortality. Nephrol Dial Transplant, 2006. 21(4): p. 1024-31.

28) Oliver, M.J., et al., Late creation of vascular access for hemodialysis and increased risk of sepsis. J Am Soc Nephrol, 2004. 15 (7): p. 1936-42.

29) Ribot, S., S.W. Siddiqi, and C. Chen, Right heart complications of dual lumen tunneled venous catheters in hemodialysis patients. Am J Med Sci, 2005. 330(4): p. 204-8.

30) Sands, J.J., Increasing AV fistulae and decreasing dialysis catheters: two aspects of improving patient outcomes. Blood Purif, 2007. 25(1): p. 99-102.

31) Sands, J.J., Vascular access: the past, present and future. Blood Purif, 2009. 27(1): p. 22-7.

32) Sikaneta, T., et al., The Toronto Western Hospital catheter: one center´s experience and review of the literature. Int J Artif

Organs, 2006. 29(1): p. 59-63.

33) Suresh, V., et al., Bacterial meningitis--complication from a dialysis catheter. Clin Nephrol, 2006. 65(6): p. 457-9.

34) Thomson, P.C., et al., Vascular access in haemodialysis patients: a modifiable risk factor for bacteraemia and death. QJM, 2007. 100(7): p. 415-22.

35) Siempos, II, et al., Impact of catheter-related bloodstream infections on the mortality of critically ill patients: a meta-analysis. Crit Care Med, 2009. 37(7): p. 2283-9.

36) Wasse, H., Catheter-related mortality among ESRD patients. Semin Dial, 2008. 21(6): p. 547-9.

37) Wasse, H., R.A. Speckman, and W.M. McClellan, Arteriovenous fistula use is associated with lower cardiovascular mortality compared with catheter use among ESRD patients. Semin Dial, 2008. 21(5): p. 483-9.

38) Weijmer, M.C., M.G. Vervloet, and P.M. ter Wee, Prospective follow-up of a novel design haemodialysis catheter; lower infection rates and improved survival. Nephrol Dial Transplant, 2008. 23(3): p. 977-83.

39) Taylor, G.D., et al., Central venous catheters as a source of hemodialysis-related bacteremia. Infect Control Hosp Epidemiol, 1998. 19(9): p. 643-6.

40) Wasse, H., et al., Predictors of delayed transition from central venous catheter use to permanent vascular access among ESRD patients. Am J Kidney Dis, 2007. 49(2): p. 276-83.

41) Wolfe, R.A., et al., Decreases in catheter use are associated with decreases in mortality for dialysis facilities during 2000-03. J Am Soc Nephrol Dial Transplant, 2005. 16: p. 95A.

42) USRDS, 2009 Annual Report, vol 2, Chapter 11, pg. 341.

43) National Kidney Foundation: KDOQI Clinical Practice Guidelines for Vascular Access. Update 2006.

44) Foley RN, Chen SC, Collins AJ: Hemodialysis access at initiation in the United States, 2005 to 2007: still "catheter first". Hemodial Int 13:533–542, 2009.

1c.16 Quote verbatim, <u>the specific guideline recommendation</u> *(Including guideline # and/or page #)*:
Less than 10% of chronic maintenance hemodialysis patients should be maintained on catheters as their permanent chronic dialysis access. In this context, chronic catheter access is defined as the use of a dialysis catheter for more than 3 months in the absence of a maturing permanent access.

1c.17 Clinical Practice Guideline Citation: National Kidney Foundation: DOQI Clinical Practice Guidelines for Vascular Access. Update 2006.

1c.18 National Guideline Clearinghouse or other URL:
http://www.kidney.org/Professionals/kdoqi/guideline_upHD_PD_VA/index.htm

1c.19 Grading of Strength of Guideline Recommendation. Has the recommendation been graded? No

1c.20 If guideline recommendation graded, identify the entity that graded the evidence including balance of representation and any disclosures regarding bias:

1c.21 System Used for Grading the Strength of Guideline Recommendation: Other

1c.22 If other, identify and describe the grading scale with 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.

1c.23 Grade Assigned to the Recommendation: KDOQI Guideline 8.1.2.2 was graded B.

1c.24 Rationale for Using this Guideline Over Others: No other guidelines available.

Based on the NQF descriptions for rating the evidence, what was the <u>developer's assessment</u> of the quantity, quality, and consistency of the body of evidence?
1c.25 Quantity: High   **1c.26** Quality: High **1c.27** Consistency: High

Was the threshold criterion, *Importance to Measure and Report*, met?
(*1a & 1b must be rated moderate or high and 1c yes*)   Yes☐ No☐
Provide rationale based on specific subcriteria:

For a new measure if the Committee votes NO, then STOP.
For a measure undergoing endorsement maintenance, if the Committee votes NO because of 1b. (no opportunity for improvement), it may be considered for continued endorsement and all criteria need to be evaluated.

2. RELIABILITY & VALIDITY - SCIENTIFIC ACCEPTABILITY OF MEASURE PROPERTIES

Extent to which the measure, <u>as specified</u>, produces consistent (reliable) and credible (valid) results about the quality of care when implemented. **(<u>evaluation criteria</u>)**
Measure testing must demonstrate adequate reliability and validity in order to be recommended for endorsement. Testing may be conducted for data elements and/or the computed measure score. Testing information and results should be entered in the appropriate field. Supplemental materials may be referenced or attached in item 2.1. See guidance on measure testing.

S.1 Measure Web Page *(In the future, NQF will require measure stewards to provide a URL link to a web page where current detailed specifications can be obtained)*. Do you have a web page where current detailed specifications for <u>this</u> measure can be obtained? Yes

S.2 If yes, provide web page URL: http://www.arborresearch.org/ESRD_QMS.aspx

2a. RELIABILITY. Precise Specifications and Reliability Testing: H☐ M☐ L☐ I☐

2a1. Precise Measure Specifications. (*The measure specifications precise and unambiguous.*)

2a1.1 Numerator Statement *(Brief, narrative description of the measure focus or what is being measured about the target population, e.g., cases from the target population with the target process, condition, event, or outcome)*:
Patients who were continuously using a chronic catheter as hemodialysis access for 90 days or longer prior to the last hemodialysis session during the study period.

2a1.2 Numerator Time Window *(The time period in which the target process, condition, event, or outcome is eligible for inclusion)*:
For the ESRD CPM, we propose a one month time period. However, if the measure is adapted by other organizations for other purposes, there is no technical problem with using longer evaluation periods.

2a1.3 Numerator Details *(All information required to identify and calculate the cases from the target population with the target process, condition, event, or outcome such as definitions, codes with descriptors, and/or specific data collection items/responses)*:
The numerator will be determined by counting the patients in the denominator who were on maintenance hemodialysis with a chronic catheter continuously for 90 days or longer prior to the last hemodialysis session of the month ("Access Type for Dialysis" = "Catheter" AND "Date Access Type for Dialysis Changed" is blank or, if populated, is more than 90 days prior to the last hemodialysis session of the month).

2a1.4 Denominator Statement *(Brief, narrative description of the target population being measured)*:
Patients on maintenance hemodialysis during the last HD treatment of study period.

2a1.5 Target Population Category *(Check all the populations for which the measure is specified and tested if any)*: Adult/Elderly Care

2a1.6 Denominator Time Window *(The time period in which cases are eligible for inclusion)*:
For the ESRD CPM, we propose a one month time period. However, if the measure is adapted by other organizations for other purposes, there is no technical problem with using longer evaluation periods.

2a1.7 Denominator Details (*All information required to identify and calculate the target population/denominator such as definitions, codes with descriptors, and/or specific data collection items/responses)*:
The patient's age will be determined by subtracting the patient's date of birth from the first day of the reporting month.

Hemodialysis patients are defined as follows: "Admit Date" to the specified facility is prior or equal to the first day of the study period, AND the patient has not been discharged ("Discharge Date" is null or blank), OR "Discharge Date" from the facility is greater than or equal to the last day of the study period AND "Treatment Dialysis Broad Start Date" is prior or equal to the first day of the study period, AND "Dialysis Broad Type of Treatment" = 'HD', AND "Primary Dialysis Setting" ='Dialysis Facility/Center' or 'Home' on the last day of the study period, AND "Date Regular Chronic Dialysis Began" is prior to the first day of the study period.

The denominator will include all patients at least 18 years old who are determined to be in-center hemodialysis or home hemodialysis patients.

2a1.8 Denominator Exclusions *(Brief narrative description of exclusions from the target population)*:
Patients on acute hemodialysis, peritoneal dialysis, or patients <18 years of age.

2a1.9 Denominator Exclusion Details *(All information required to identify and calculate exclusions from the denominator such as definitions, codes with descriptors, and/or specific data collection items/responses)*:
See above denominator details.

2a1.10 Stratification Details/Variables *(All information required to stratify the measure results including the stratification variables, codes with descriptors, definitions, and/or specific data collection items/responses)*:
No stratification is required for this measure.

2a1.11 Risk Adjustment Type *(Select type. Provide specifications for risk stratification in 2a1.10 and for statistical model in 2a1.13)*: No risk adjustment or risk stratification   **2a1.12 If "Other," please describe:**

2a1.13 Statistical Risk Model and Variables *(Name the statistical method - e.g., logistic regression and list all the risk factor variables. Note - risk model development should be addressed in 2b4.)*:
No risk adjustment necessary.

2a1.14-16 Detailed Risk Model Available at Web page URL (or attachment). Include coefficients, equations, codes with descriptors, definitions, and/or specific data collection items/responses. Attach documents only if they are not available on a webpage and keep attached file to 5 MB or less. NQF strongly prefers you make documents available at a Web page URL. Please supply login/password if needed:

2a1.17-18. Type of Score: Rate/proportion

2a1.19 Interpretation of Score *(Classifies interpretation of score according to whether better quality is associated with a higher score, a lower score, a score falling within a defined interval, or a passing score)*: Better quality = Lower score

2a1.20 Calculation Algorithm/Measure Logic*(Describe the calculation of the measure score as an ordered sequence of steps including identifying the target population; exclusions; cases meeting the target process, condition, event, or outcome; aggregating data; risk adjustment; etc.)*:
For this measure calculation, the numerator will be divided by the denominator.

Calculation of the numerator and denominator is described below.

The patient's age will be determined by subtracting the patient's date of birth from the first day of the reporting month.

Hemodialysis patients are defined as follows: "Admit Date" to the specified facility is prior or equal to the first day of the study

period, AND the patient has not been discharged ("Discharge Date" is null or blank), OR "Discharge Date" from the facility is greater than or equal to the last day of the study period AND "Treatment Dialysis Broad Start Date" is prior or equal to the first day of the study period, AND "Dialysis Broad Type of Treatment" = 'HD', AND "Primary Dialysis Setting" ='Dialysis Facility/Center' or 'Home' on the last day of the study period, AND "Date Regular Chronic Dialysis Began" is prior to the first day of the study period.

The denominator will include all patients at least 18 years old who are determined to be in-center hemodialysis or home hemodialysis patients.

The numerator will be determined by counting the patients in the denominator who were on maintenance hemodialysis with a chronic catheter continuously for 90 days or longer prior to the last hemodialysis session of the month ("Access Type for Dialysis" = "Catheter" AND "Date Access Type for Dialysis Changed" is blank or, if populated, is more than 90 days prior to the last hemodialysis session of the month).

2a1.21-23 Calculation Algorithm/Measure Logic Diagram URL or attachment:
Attachment
Appendix C CPM Calculation Flow charts_Catheter.pdf

2a1.24 Sampling (Survey) Methodology. If measure is based on a sample (or survey), provide instructions for obtaining the sample, conducting the survey and guidance on minimum sample size (response rate):
N/A

2a1.25 Data Source *(Check all the sources for which the measure is specified and tested)*. If other, please describe:
 Administrative claims, Electronic Clinical Data

2a1.26 Data Source/Data Collection Instrument (*Identify the specific data source/data collection instrument, e.g. name of database, clinical registry, collection instrument, etc.*): CROWNWeb is the primary data source. However, this measure can be collected through Medicare claims data (since July 2010) and Fistula First Breakthrough Initiative data (though the definition of the measure is slightly different).

2a1.27-29 Data Source/data Collection Instrument Reference Web Page URL or Attachment: URL
http://www.projectcrownweb.org

2a1.30-32 Data Dictionary/Code Table Web Page URL or Attachment:
URL
http://projectcrownweb.org/crown/index.php?page=Public_Documents&subPage=Release_Documents

2a1.33 Level of Analysis (*Check the levels of analysis for which the measure is specified and tested)*:   Facility

2a1.34-35 Care Setting *(Check all the settings for which the measure is specified and tested)*: Dialysis Facility

2a2. Reliability Testing. (*Reliability testing was conducted with appropriate method, scope, and adequate demonstration of reliability.*)

2a2.1 Data/Sample *(Description of the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included)*:
CROWNWeb data from August 2009-December 2009 were analyzed. The number of facilities ranged from 3,415-3,453. The total number of patients per month ranged from 263,743 - 290,713.

2a2.2 Analytic Method *(Describe method of reliability testing & rationale)*:
Reliability was assessed by calculating facility-level month-to-month correlations. Pearson correlation coefficients were calculated between the current performance month and previous month for reporting months August 2009 through October 2010.

2a2.3 Testing Results *(Reliability statistics, assessment of adequacy in the context of norms for the test conducted)*:

Reliability of this measure has been consistently high. Correlation coefficients ranged from 0.93 to 0.95. The lowest correlation was observed in the last reporting month. In 2010, correlations from month-to-month were still high (range: 0.91-0.95), thus indicating the data elements for this measure are reliable.

2b. VALIDITY. Validity, Testing, <u>including all Threats to Validity</u>: H☐ M☐ L☐ I☐

2b1.1 Describe how the measure specifications *(measure focus, target population, and exclusions)* are consistent with the evidence cited in support of the measure focus (*criterion 1c*) and identify any differences from the evidence:
The target population in the validity analysis was all ESRD patients on HD who are reported in CROWNWeb in 2009. The population and results from the validity analyses performed were consistent with the evidence provided. The validity analyses showed that relative to facilities with the highest performances scores, the Standardized Mortality Ratio (SMR) increased as performance scores decreased.

2b2. Validity Testing. (*Validity testing was conducted with appropriate method, scope, and adequate demonstration of validity.*)

2b2.1 Data/Sample *(Description of the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included)*:
2009 CROWNWeb data (August - December) were used to calculate monthly performance scores, and the SHR was calculated using 2009 Medicare-paid dialysis claims and the Medical Evidence Form (Form CMS-2728).

2b2.2 Analytic Method *(Describe method of validity testing and rationale; if face validity, describe systematic assessment)*:
Validity was assessed using Poisson regression models to measure the association between facility level quintiles of performance scores and the 2009 SHR. Facility-level performance scores were divided into quintiles and the relative risk (RR) of hospitalization was calculated for each quintile. The highest 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 hospitalization.

Association with the 2009 SMR was also examined; while an increase in mortality was not found to be statistically significant, an association with hospital admission rates shows that catheter usage is associated with significant patient morbidity.

2b2.3 Testing Results *(Statistical results, assessment of adequacy in the context of norms for the test conducted; if face validity, describe results of systematic assessment)*:
Quintiles of the performance scores were defined as follows:

Q1 &Q2: 0-0%, RR(CI)= 0.97 (0.95, 1.00), p = 0.02

Q3: 0%-<6%, RR(CI)= 0.89 (0.86, 0.91), p <0.001

Q4: 6%-<11%, RR(CI)= 0.96 (0.93, 0.98), p = 0.001

Q5: 11%-<58%, RR(CI)= 1.00(ref)

Overall results from the Poisson model indicated that the percent of patients dialyzing with a catheter >= 90 days was significantly associated with SHR (p<0.001). These findings confirm the association between low catheter use and lower hospital admissions.

POTENTIAL THREATS TO VALIDITY. (*<u>All</u> potential threats to validity were appropriately tested with adequate results.*)

2b3. Measure Exclusions. (*Exclusions were supported by the clinical evidence in 1c or appropriately tested with results demonstrating the need to specify them.*)

2b3.1 Data/Sample for analysis of exclusions *(Description of the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included)*:
CROWNWeb data from July through December 2009 included up to 3495 facilities per month with an average of 80 patients per facility. The total number of patients per month ranged from 267,515 - 290,713. The number of exclusions per month ranged from 2,322 to 1,732 among HD records.
This measure is intended for adult hemodialysis patients. No further exclusions are made.

2b3.2 Analytic Method (*Describe type of analysis and rationale for examining exclusions, including exclusion related to patient*

preference):

2b3.3 Results *(Provide statistical results for analysis of exclusions, e.g., frequency, variability, sensitivity analyses):*

2b4. Risk Adjustment Strategy. (*For outcome measures, adjustment for differences in case mix (severity) across measured entities was appropriately tested with adequate results.*)

2b4.1 Data/Sample *(Description of the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included)*:
No risk adjustment is performed for this measure.

2b4.2 Analytic Method (*Describe methods and rationale for development and testing of risk model or risk stratification including selection of factors/variables)*:
N/A

2b4.3 Testing Results *(Statistical risk model: Provide quantitative assessment of relative contribution of model risk factors; risk model performance metrics including cross-validation discrimination and calibration statistics, calibration curve and risk decile plot, and assessment of adequacy in the context of norms for risk models. Risk stratification: Provide quantitative assessment of relationship of risk factors to the outcome and differences in outcomes among the strata)*:
N/A

2b4.4 If outcome or resource use measure is not risk adjusted, provide rationale and analyses to justify lack of adjustment: Disparities by population group were not observed (see results in Section 1b.4). Furthermore, there is no evidence suggesting this
measure should be risk adjusted.

2b5. Identification of Meaningful Differences in Performance. (*The performance measure scores were appropriately analyzed and discriminated meaningful differences in quality.*)

2b5.1 Data/Sample *(Describe the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included)*:
Analyses were performed using CROWNWeb data from January 2010. There were 3,436 facilities and a total of 293,694 patients in this reporting month. Mean number of patients per facility was 84 (SD=52).

2b5.2 Analytic Method *(Describe methods and rationale to identify statistically significant and practically/meaningfully differences in performance)*:
Facility-level percents of patients with dialyzing with a catheter >=90 days were calculated as the number of patients within the facility reported to be dialyzing with a catheter >=90 days divided by the total number of HD patients in the facility. The mean, SD, and quartiles also were calculated.

2b5.3 Results *(Provide measure performance results/scores, e.g., distribution by quartile, mean, median, SD, etc.; identification of statistically significant and meaningfully differences in performance)*:
 Analysis of CROWNWeb data from January 2010 indicated the mean percentage of patients dialyzing witha catheter >=90 days was 5% (SD=7%).
Distribution: Min=0%, Max=47%, 1st quartile=0%, median=2%, 3rd quartile=9%. These results indicate that on average, 5% of patients are dialyzing with a catheter >=90 days, with some facilities dialyzing a larger percent of patients with a catheter >=90 days.

2b6. Comparability of Multiple Data Sources/Methods. (*If specified for more than one data source, the various approaches result in comparable scores.*)

2b6.1 Data/Sample *(Describe the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included)*:
Multiple data sources were not used.

2b6.2 Analytic Method *(Describe methods and rationale for testing comparability of scores produced by the different data sources specified in the measure)*:
N/A

2b6.3 Testing Results *(Provide statistical results, e.g., correlation statistics, comparison of rankings; assessment of adequacy in the context of norms for the test conducted)*:
N/A

2c. Disparities in Care: H☐ M☐ L☐ I☐ NA☐ *(If applicable, the measure specifications allow identification of disparities.)*

2c.1 If measure is stratified for disparities, provide stratified results *(Scores by stratified categories/cohorts)*: This measure is not stratified.

2c.2 If disparities have been reported/identified (e.g., in 1b), but measure is not specified to detect disparities, please explain:
No disparities have been identified.

2.1-2.3 Supplemental Testing Methodology Information:

Steering Committee: Overall, was the criterion, *Scientific Acceptability of Measure Properties*, met?
(*Reliability and Validity must be rated moderate or high*) Yes☐ No☐
Provide rationale based on specific subcriteria:

If the Committee votes No, STOP

3. USABILITY

Extent to which intended audiences (e.g., consumers, purchasers, providers, policy makers) can understand the results of the measure and are likely to find them useful for decision making. (**evaluation criteria**)

C.1 Intended Purpose/ Use *(Check all the purposes and/or uses for which the measure is intended)*: Public Reporting, Quality Improvement (Internal to the specific organization), Quality Improvement with Benchmarking (external benchmarking to multiple organizations)

3.1 Current Use *(Check all that apply; for any that are checked, provide the specific program information in the following questions)*: Public Reporting, Quality Improvement (Internal to the specific organization)

3a. Usefulness for Public Reporting: H☐ M☐ L☐ I☐
(*The measure is meaningful, understandable and useful for public reporting.*)

3a.1. Use in Public Reporting - disclosure of performance results to the public at large *(If used in a public reporting program, provide name of program(s), locations, Web page URL(s)).* If not publicly reported in a national or community program, state the reason AND plans to achieve public reporting, potential reporting programs or commitments, and timeline, e.g., within 3 years of endorsement: [*For __Maintenance__ – If not publicly reported, describe progress made toward achieving disclosure of performance results to the public at large and expected date for public reporting; provide rationale why continued endorsement should be considered.*]
Quality measure results will be evaluated for future public reporting on Medicare's Dialysis Facility Compare website.

3a.2.Provide a rationale for why the measure performance results are meaningful, understandable, and useful for public reporting. Unsefulness was demonstrated (e.g., focus group, cognitive testing), describe the data, method, and results: This measure has been reported in previous ESRD CPM Annual Reports. Healthcare providers and patients can easily understand the meaning of this measure.

3.2 Use for other Accountability Functions (payment, certification, accreditation). If used in a public accountability program,

provide name of program(s), locations, Web page URL(s): This measure is not used for other Accountability Functions.

3b. Usefulness for Quality Improvement: H☐ M☐ L☐ I☐
(*The measure is meaningful, understandable and useful for quality improvement.*)

3b.1. Use in QI. If used in quality improvement program, provide name of program(s), locations, Web page URL(s):
[*For Maintenance – If not used for QI, indicate the reasons and describe progress toward using performance results for improvement*].
This measure is not currently used in a quality improvement program. However,in previous years, this measure was reported in ESRD CPM Annual Reports. The ESRD CPM Project was a national effort designed to assist dialysis providers to improve patient care and outcomes.

3b.2. Provide rationale for why the measure performance results are meaningful, understandable, and useful for quality improvement. Underline usefulness was demonstrated *(e.g., QI initiative),* describe the data, method and results:
See response in 3a.2.

Overall, to what extent was the criterion, *Usability*, met? H☐ M☐ L☐ I☐
Provide rationale based on specific subcriteria:

4. FEASIBILITY

Extent to which the required data are readily available, retrievable without undue burden, and can be implemented for performance measurement. **(evaluation criteria)**

4a. Data Generated as a Byproduct of Care Processes: H☐ M☐ L☐ I☐

4a.1-2 How are the data elements needed to compute measure scores generated? *(Check all that apply).*
Data used in the measure are:
generated by and used by healthcare personnel during the provision of care, e.g., blood pressure, lab value, medical condition, Coded by someone other than person obtaining original information (e.g., DRG, ICD-9 codes on claims), Abstracted from a record by someone other than person obtaining original information (e.g., chart abstraction for quality measure or registry)

4b. Electronic Sources: H☐ M☐ L☐ I☐

4b.1 Are the data elements needed for the measure as specified available electronically *(Elements that are needed to compute measure scores are in defined, computer-readable fields)*: ALL data elements in electronic health records (EHRs)

4b.2 If ALL data elements are not from electronic sources, specify a credible, near-term path to electronic capture, OR provide a rationale for using other than electronic sources:

4c. Susceptibility to Inaccuracies, Errors, or Unintended Consequences: H☐ M☐ L☐ I☐

4c.1 Identify susceptibility to inaccuracies, errors, or unintended consequences of the measurement identified during testing and/or operational use and strategies to prevent, minimize, or detect. If audited, provide results:
There are no potential barriers to retrieving data necessary for the measure, and there are no data availability issues.

4d. Data Collection Strategy/Implementation: H☐ M☐ L☐ I☐

A.2 Please check if either of the following apply (*regarding proprietary measures*):
4d.1 Describe what you have learned/modified as a result of testing and/or operational use of the measure regarding data collection, availability of data, missing data, timing and frequency of data collection, sampling, patient confidentiality, time and cost of data collection, other feasibility/implementation issues *(e.g., fees for use of proprietary measures)*:
Since this measure has been collected for several years as part of the CPM project, facilities are familiar with the data required for this measure, and data are readily available. It is unlikely that data elements will be susceptible to inaccuracies, errors, or unintended consequences.

Overall, to what extent was the criterion, *Feasibility*, met? H☐ M☐ L☐ I☐
Provide rationale based on specific subcriteria:

OVERALL SUITABILITY FOR ENDORSEMENT

Does the measure meet all the NQF criteria for endorsement? Yes☐ No☐ Rationale:

If the Committee votes No, STOP.
If the Committee votes Yes, the final recommendation is contingent on comparison to related and competing measures.

5. COMPARISON TO RELATED AND COMPETING MEASURES

If a measure meets the above criteria and there are endorsed or new related measures (either the same measure focus or the same target population) or competing measures (both the same measure focus and the same target population), the measures are compared to address harmonization and/or selection of the best measure before a final recommendation is made.

5.1 If there are related measures *(either same measure focus or target population)* or competing measures *(both the same measure focus and same target population)*, list the NQF # and title of all related and/or competing measures:
0251 : Vascular Access—Functional Arteriovenous Fistula (AVF) or AV Graft or Evaluation by Vascular Surgeon for Placement
0257 : Hemodialysis Vascular Access- Maximizing Placement of Arterial Venous Fistula (AVF)
0262 : Vascular Access—Catheter Vascular Access and Evaluation by Vascular Surgeon for Permanent Access.

5a. Harmonization

5a.1 If this measure has EITHER the same measure focus OR the same target population as NQF-endorsed measure(s): Are the measure specifications completely harmonized?

5a.2 If the measure specifications are not completely harmonized, identify the differences, rationale, and impact on interpretability and data collection burden:

5b. Competing Measure(s)

5b.1 If this measure has both the same measure focus and the same target population as NQF-endorsed measure(s): Describe why this measure is superior to competing measures *(e.g., a more valid or efficient way to measure quality);* OR provide a rationale for the additive value of endorsing an additional measure. *(Provide analyses when possible)*:

CONTACT INFORMATION

Co.1 Measure Steward (Intellectual Property Owner): Centers for Medicare & Medicaid Services, 7500 Security Boulevard , Mail Stop S3-01-02, Baltimore, Maryland, 21244-1850

Co.2 Point of Contact: Edward Q., Garcia III, MHS, Health Policy Analyst, MMSNQF@hsag.com, 410-786-6738-

Co.3 Measure Developer if different from Measure Steward: Arbor Research/UM-KECC, 340 East Huron St., Suite 300, Ann Arbor, Michigan, 48104

Co.4 Point of Contact: Claudia, Dahlerus, Claudia.Dahlerus@arborresearch.org, 734-665-4108-

Co.5 Submitter: Thomas, Dudley, Thomas.Dudley@cms.hhs.gov, 410-786-1442-, Centers for Medicare & Medicaid Services

Co.6 Additional organizations that sponsored/participated in measure development:

Co.7 Public Contact: ESRD Quality Measures, Help Desk, ESRD_quality_measures@arborresearch.org, 877-665-1680-, Arbor Research Collaborative for Health

ADDITIONAL INFORMATION

Workgroup/Expert Panel involved in measure development
Ad.1 Provide a list of sponsoring organizations and workgroup/panel members' names and organizations. Describe the members' role in measure development.
Clinical and data technical expert panels (TEP) were held in September and October 2006, respectively. Since 2006, no TEPs have been held for adult hemodialysis adequacy measures.

Ad.2 If adapted, provide title of original measure, NQF # if endorsed, and measure steward. Briefly describe the reasons for adapting the original measure and any work with the original measure steward: No changes to this measure title are requested.

Measure Developer/Steward Updates and Ongoing Maintenance
Ad.3 Year the measure was first released: 2007
Ad.4 Month and Year of most recent revision: 11, 2007
Ad.5 What is your frequency for review/update of this measure? Every 3 years
Ad.6 When is the next scheduled review/update for this measure? 06, 2013

Ad.7 Copyright statement:

Ad.8 Disclaimers:

Ad.9 Additional Information/Comments: This form was revised on November 9, 2011. The items revised were 1c.6, 1c.7, 1c.11, 1c.15, 1c.21 1c.22, 1c.23, 2a1.3, 2a1.7, 2a1.9, 2a1.20, 2b2.1, 2b.2.2, and 2b2.3.

Specific CROWNWeb data fields/numbers and the relevant response options were identified in the measure specifications. Additional information regarding the quality of the body of evidence and consistency of results across studies was added. Text regarding the validity testing has been revised to show that better performance is associated with better outcomes.

Date of Submission (*MM/DD/YY*): 06/23/2011

Vascular Access
CPM II: Minimizing Use of Catheters as Chronic Hemodialysis (HD) Access
Numerator: Maintenance HD patients dialyzed continuously with a catheter ≥90 days prior to the last HD treatment of the month
Denominator: All adult patients (≥ 18 years old) on maintenance HD during last HD treatment of the month. Including home hemodialysis.
Exclusion: Pediatric patients. Peritoneal dialysis patients. Acute HD. Transient dialysis patients and kidney transplant patients.

```
                            ( Start )
                                |
                              < DOB >
                                |
  A  <-- missing/invalid --  Calculate age:  -- <18 -->  B
                            studystart - DOB
                                |
                               18+
                                |
  A  <-- missing/invalid --     HD          -- No -->  B
                            (Model = 1,3)   (MODAL = 2)
                                |
                               Yes
                                |
  A  <-- missing/invalid --   Catheter      -- Not Catheter -->  B
                            (CURACCTYPE=6)   (CURACCTYPE =
                                |             1, 2, 3, 4, 5, 7, 9)
                               Yes
                                |
  A  <-- missing/invalid --  Catheter in Use
                              90+ Days
                             (CATHUSED90)
                                |
                         Calculate Measure:
                      Catheter 90+ Days = Yes
                       (CATHUSED90 = 1) = Yes
                      Catheter 90+ Days = No
                       (CATHUSED90 = 2, 9) = No
```

A   Excluded due to missing/invalid data

B   Exclude for failing to meet inclusion criteria