

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 #: 0251 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: Vascular Access—Functional Arteriovenous Fistula (AVF) or AV Graft or Evaluation by Vascular Surgeon for Placement
Co.1.1 Measure Steward: Kidney Care Quality Alliance
De.2 Brief Description of Measure: Percentage of end stage renal disease (ESRD) patients aged 18 years and older receiving hemodialysis during the 12-month reporting period and on dialysis >90 days who: (1) have a functional autogenous AVF (defined as two needles used or a single-needle device [NOT one needle used in a two-needle device]) (computed and reported separately); (2) have a functional AV graft (computed and reported separately); or (3) have a catheter but have been seen/evaluated by a vascular surgeon, other surgeon qualified in the area of vascular access, or interventional nephrologist trained in the primary placement of vascular access for a functional autogenous AVF or AV graft at least once during the 12-month reporting period (computed and reported separately).
Reporting should be stratified by incident versus prevalent patients, as defined by USRDS.
2a1.1 Numerator Statement: Number of patients from the denominator who: (1) have a functional autogenous AVF (defined as two needles used or a single-needle device) (computed and reported separately); or (2) have a functional AV graft (computed and reported separately); or (3) have a catheter but have been seen/evaluated by a vascular surgeon, other surgeon qualified in the area of vascular access, or interventional nephrologist trained in the primary placement of vascular access for a functional autogenous AVF (defined as two needles used or a single needle device) or AV graft at least once during the 12-month reporting period (computed and reported separately).
Reporting should be stratified by incident versus prevalent patients, as defined by USRDS.
2a1.4 Denominator Statement: All ESRD patients aged 18 years and older receiving hemodialysis during the 12-month reporting period and on dialysis for greater than 90 days.
This measure includes both in-center and home hemodialysis patients.
2a1.8 Denominator Exclusions: Patients enrolled in hospice.
1.1 Measure Type: Outcome 2a1. 25-26 Data Source: Electronic Clinical Data : Electronic Health Record, Paper Records 2a1.33 Level of Analysis: Clinician : Individual
1.2-1.4 Is this measure paired with another measure? No
De.3 If included in a composite, please identify the composite measure (<i>title and NQF number if endorsed</i>): Not applicable.

STAFF NOTES <i>(issues or questions regarding any criteria)</i>
Comments on Conditions for Consideration:
Is the measure untested? Yes <input type="checkbox"/> No <input type="checkbox"/> 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 <i>(check De.5)</i> : 5. Similar/related endorsed or submitted measures <i>(check 5.1)</i> : 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 . <i>Measures must be judged to be important to measure and report in order to be evaluated against the remaining criteria. (evaluation criteria)</i>
1a. High Impact: H <input type="checkbox"/> M <input type="checkbox"/> L <input type="checkbox"/> I <input type="checkbox"/> <i>(The measure directly addresses a specific national health goal/priority identified by DHHS or NPP, or some other high impact aspect of healthcare.)</i>
De.4 Subject/Topic Areas <i>(Check all the areas that apply)</i> : Renal, Renal : End Stage Renal Disease (ESRD) De.5 Cross Cutting Areas <i>(Check all the areas that apply)</i> : Access, Care Coordination, Disparities, Functional Status, Patient and Family Engagement, Safety, Safety : Complications, Safety : Healthcare Associated Infections
1a.1 Demonstrated High Impact Aspect of Healthcare: Affects large numbers, A leading cause of morbidity/mortality, Frequently performed procedure, High resource use, Patient/societal consequences of poor quality, Severity of illness
1a.2 If "Other," please describe:
1a.3 Summary of Evidence of High Impact <i>(Provide epidemiologic or resource use data)</i> : In 2008, the adjusted incident rate of end-stage renal disease (ESRD) cases in the United States was 350.8 per million population, and the adjusted rate of prevalent cases rose 1.9 percent to 1,699 per million population. This rate is nearly 20 percent greater than that seen in 2000, and the annual rate of increase has remained between 1.9 and 2.3 percent since 2003. Total Medicare costs rose nearly 11 percent in 2008—up from a 7 percent rise the previous year—to \$454 billion. ESRD costs rose 13.2 percent to \$26.8 billion, and accounted for 5.9 percent of the Medicare budget.(1)
Vascular access-related complications are a major cause of excessive morbidity, mortality, and healthcare costs in the ESRD population. The three types of vascular access used by most dialysis patients are arteriovenous fistulas (AVFs), arteriovenous grafts, and central venous catheters. Of these, AVFs have superior longevity, fewer complications (e.g., stenosis and infection), and are associated with the lowest mortality and costs.(2-6) Numerous peer-review studies have demonstrated a graded mortality risk dependent on vascular access type in hemodialysis patients, with the highest risk associated with central venous catheters, followed by AV grafts and then AVFs.(7-9) For instance, a recent retrospective cohort study of a random sample of 4,532 incident U.S. hemodialysis patients that participated in the Dialysis Outcomes and Practice Patterns Study (DOPPS) examined vascular access conversions during the first year on dialysis therapy or the effect of converting to and from a catheter on subsequent mortality risk. Conversion to a permanent access was associated with an adjusted mortality hazard ratio of 0.69 (95% confidence interval, 0.55 to 0.85). The effect was similar for conversion to an AVF or AVG, and persisted across demographic groups and facilities with different conversion practices. Conversely, conversion from a permanent vascular access to a catheter was associated with an adjusted mortality hazard ratio of 1.81 (95% confidence interval, 1.22 to 2.68).(7) In a similar study, investigators again examined DOPPS data for trends in vascular access and outcomes from 1996 to 2007. Compared to patients using an AVF, patients with a catheter displayed significantly lower mean Kt/V levels, and native AVF use was associated with improved dialysis adequacy and better patient outcomes. AV grafts were found to be a better alternative than catheters for patients

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where the creation of an attempted AVF failed or could not be created for different reasons.(8) A third study examined trends in type of vascular access and survival using 1,084 incident hemodialysis patients enrolled in the Choices for Healthy Outcomes in Caring for ESRD (CHOICE) Study. Annual mortality rates were found to be 11.7% for patients using an AVF, 14.2% for those with an AVG, and 16.1% for catheter patients. Adjusted relative hazards of death compared with AVF were 1.5 (95% confidence interval, 1.0 to 2.2) for catheters and 1.2 (0.8 to 1.8) for AVG.(9) Additionally, in June 2009, Kidney Care Partners (KCP) launched its Performance Excellence and Accountability in Kidney Care (PEAK) campaign, a voluntary quality improvement initiative with a goal to reduce mortality among first-year patients—those at greatest risk—by 20 percent by the end of 2012. While USRDS has reported that mortality rates for patients in their first year of dialysis have remained unchanged at approximately 30 percent since 1999, data received from the Centers for Medicare and Medicaid Services (CMS) through September 2010 indicate that the first-year mortality rate—including the 90-day and 120-day mortality rates—have been on the decline since the launch of PEAK in June 2009. Analyses demonstrate a clear association between this reduction and a concomitant decline in catheter use in these patients. (10)

These findings strongly support existing clinical practice guidelines and the underlying construct of the KCOA vascular access measures—i.e., that the use of venous catheters should be minimized and permanent access maximized to reduce the frequency of access complications and to improve patient survival. In particular, we note that the original KCOA measure specifications were modified in response to the NQF Steering Committee's comment that referral was not sufficient and that the patient must be seen/evaluated for AVF placement.

1a.4 Citations for Evidence of High Impact cited in 1a.3: 1. U.S. Renal Dialysis System, USRDS 2010 Annual Data Report: Atlas of Chronic Kidney Disease and End-Stage Renal Disease in the United States. 2010.

2. Port F, Pisoni R, Bommer J, et al. Improving outcomes for dialysis patients in the international Dialysis Outcomes and Practice Patterns Study. *Clin J Am Soc Nephrol.* 2006;1:246-55.

3. Wasse H, Kutner N, Zhang R, and Huang Y. Association of initial hemodialysis vascular access with patient-reported health status and quality of life. *Clin J Am Soc Nephrol.* 2007;2:708-14.

4. Bradbury B, Fissell R, Albert J, et al. Predictors of early mortality among incident U.S. hemodialysis patients in the Dialysis Outcomes and Practice Patterns Study (DOPPS). *Clin J Am Soc Nephrol.* 2007;2:89-99.

5. Allon M. Current management of vascular access. *Clin J Am Soc Nephrol.* 2007;2:786-800.

6. Ravani P, Spergel LM, Asif A, et al. Clinical epidemiology of arteriovenous fistula in 2007. *J Nephrol.* 2007;20:141-9.

7. Bradbury B et al. Conversion of vascular access type among incident hemodialysis patients: description and association with mortality. *Am J Kidney Dis.* 2009;53(5):804-14.

8. Ethier J et al. Vascular access use and outcomes: an international perspective from the Dialysis Outcomes and Practice Patterns Study (DOPPS). *Nephrol Dial Transplant.* 2008;23(10):3219-26.

9. Astor B et al. Type of vascular access and survival among incident hemodialysis patients: the Choices for Health Outcomes in Caring for ESRD (CHOICE) Study. *J Am Soc Nephrol.* 2005;16(5):1449-55.

10. Performance Excellence and Accountability in Kidney Care (PEAK). PEAK Campaign Progress. Available at: <http://www.kidneycarequality.com/CampProg.htm>. Accessed 06/06/11.

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:

The measure will reduce the frequency of vascular access-related complications and will improve patient survival by promoting AVF and/or AV graft placement and discouraging central venous catheter use.

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.*]

Facility Testing:

KCOA tested its ESRD measures through a prospective cohort study on a nationally drawn sample of 53 dialysis facilities containing a mix of for-profit and not-for-profit providers; hospital-affiliated and freestanding facilities within large, small, and independent dialysis organizations; urban, suburban, and rural settings; and facilities both with and without electronic health records (EHRs). Approximately 25 patients per facility were sought, resulting in a final sample size of 1,115 patients. Both facility and patient samples were structured to be generally representative of the national industry profile as identified by the United States Renal Data Systems (USRDS) 2007 Annual Data Report. Because of the measure's intended use via CROWNWeb, facility records were used as the data source, and standardized, paper-based data collection sheets constructed from the endorsed specifications were employed during data collection.

Vascular access data were provided for the 1,057 hemodialysis patients included in the study sample. The vascular access profile for the study population on hemodialysis was as follows:

- Functional AVF = 621 patients (58.8%)
- Catheter only = 306 (28.9%)
- AV graft only = 99 (9.4%)
- AVF with catheter = 26 (2.5%)
- AV graft with catheter = 5 (0.5%)

Facilities reported that 291 (86.4%) of the 337 patients who did NOT have a permanent access at the commencement of the study (September 1, 2008) had been evaluated by a vascular or other qualified surgeon for placement of permanent access by the conclusion of the study (August 31, 2009). Of these, 20 did not have documentation of the evaluation—a requirement to receive credit for the measure. The data elements collected thus permit calculation of performance for the measure as follows:

Performance Rate =

$$\frac{([\text{Patients With AVF}] + [\text{Patients With AV graft}] + [\text{Patients without AVF or AV graft seen by surgeon for permanent access}] - [\text{Patients seen but without documentation}])}{([\text{Total patients on hemodialysis >90 days}] - [\text{Patients enrolled in hospice}])} = \frac{(621 + 99 + 291 - 20)}{(1,057 - 1)} = 93.8\%$$

The performance for each individual facility in the pilot ranged from 41% to 100%, with a mean performance of 93.8%.

Physician Office Testing:

To test the measure in physician offices, Kidney Care Partners (KCP) contracted with the Iowa Foundation for Medical Care (IFMC). IFMC was under an existing contract with the American Medical Association Physician Consortium for Performance Improvement (AMA PCPI)/Renal Physicians Association (RPA) to perform on-site feasibility and implementation testing of several AMA PCPI/RPA measures, and both organizations generously permitted KCOA to “piggy-back” onto the AMA PCPI/RPA testing visits. At the time KCOA engaged IFMC, it had already obtained consent from four nephrology practice sites that would consist of a nephrology practice alpha site local to IFMC and three sites distributed geographically across the United States (Iowa, Nevada, Texas, and Pennsylvania) of various practice sizes (5.25 to 62 physicians) and medical record types (two EHR, one paper but by the time of visit transitioning to EHR, and one hybrid). Each site was asked to pull in advance the records of the first 35 adult hemodialysis patients seen on or after July 1, 2007; IFMC requested what it referred to as an oversample of five patients in an effort to ensure a remaining sample of 30 patients. Additionally, following the alpha site, the following were stipulated:

- Patient had two face-to-face office visits between July 1, 2007 and June 30, 2008, or if not seen in the office twice, it was determined he/she was receiving ongoing care from the office practice by looking first at the medical reviews resulting in an annual History and Physical, then supplementing using the monthly billings until the office reached the total of 35 ESRD patients. E&M service codes included: 99201, 99202, 99203, 99204, 99205, 99212, 99213, 99214, 99215, 99241, 99242, 99243, 99244, or 99245.
- ESRD patients can be identified with an ICD-9 code of 585.6 or an ICD-10 code of N18.0 and G-codes or CPT codes descriptive

of hemodialysis.

- Hemodialysis = G0314, G0315, G0316, G0317, G0318, G0319, 90935, 90937.

Facilities were asked to pull the records in advance of the IFMC visit because IFMC and AMA PCPI/RPA had previously identified the need for both patient's physician office and dialysis organization records to collect necessary data elements. Physician offices were, therefore, requested to secure copies of the necessary facility records in advance of the IFMC visit.

The three nephrology office sites, in addition to the alpha site, were visited by a two-person IFMC abstractor team to conduct feasibility and reliability testing. Using the KCQA data collection tool, the two abstractors individually abstracted each medical record, compared the results, and evaluated the mismatches. Mismatch codes, previously developed by IFMC for reliability testing of project abstraction, were used to classify the reason determined for each mismatch.

Physician office performance measure results were calculated based on the data collected by IFMC. As with testing in facilities, a performance gap is demonstrated, with a mean performance rate of 72 percent. (NOTE: This rate reflects the measure scores giving credit only for patients with or evaluated for a functional AVF. The rate incorporating AV grafts as an acceptable alternative to AVFs cannot be calculated on the physician office data as IFMC only categorized patients according to AVF status (y/n). Data on AV graft status was not collected.)

Conclusions: The findings from both the facility and physician office testing indicate that contrary to current clinical practice guidelines and recommendations, a considerable proportion of hemodialysis patients continue to be dialyzed via access types other than AVFs and AV grafts, and that provider performance varies widely in this aspect of care. The results identify an important gap in clinical performance.

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] Kidney Care Quality Alliance. KCQA Performance Measures Pilot Testing Results: Report to the National Quality Forum. February 2010.

1b.4 Summary of Data on Disparities by Population Group: [*For Maintenance* –Descriptive statistics for performance results for this measure by population group]

KCOA tested its ESRD measures through a prospective cohort study on a nationally drawn sample of 53 dialysis facilities. Approximately 25 patients per facility were sought, resulting in a final sample size of 1,115 patients. Both facility and patient samples were structured to be generally representative of the national industry profile as identified by the United States Renal Data Systems (USRDS) 2007 Annual Data Report. As minimal patient data was sought to protect confidentiality and the collection of race/ethnicity information was not necessary to test the measure's data elements for reliability and validity, an examination of the data for disparities trends was not conducted. However, CMS Clinical Performance Measures (CPM) data for 2007 indicate that catheter use continues to be significantly more common in women than in men (22.9 and 13.3 percent, respectively). And while the overall AVF use increased from 50.3 to 55.0 percent between 2006 and 2007, rates were lower in patients aged 44 years and older (52.1 percent), in females (44.3 percent), and in African American patients (47.2 percent).(1)

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]

U.S. Renal Dialysis System, USRDS 2010 Annual Data Report: Atlas of Chronic Kidney Disease and End-Stage Renal Disease in the United States. 2010.

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 <input type="checkbox"/>

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L	M-H	M	Yes <input type="checkbox"/> IF additional research unlikely to change conclusion that benefits to patients outweigh harms: otherwise No <input type="checkbox"/>
M-H	L	M-H	Yes <input type="checkbox"/> IF potential benefits to patients clearly outweigh potential harms: otherwise No <input type="checkbox"/>
L-M-H	L-M-H	L	No <input type="checkbox"/>
Health outcome – rationale supports relationship to at least one healthcare structure, process, intervention, or service		Does the measure pass subcriterion 1c? Yes <input type="checkbox"/> IF rationale supports relationship	
<p>1c.1 Structure-Process-Outcome Relationship (<i>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</i>):</p> <p>ANTECEDENTS: A graded morbidity and mortality risk dependent on vascular access type has been identified in hemodialysis patients, with catheters carrying the highest risk, followed by AV grafts, then AVFs >> PROCESS: Assessment of the proportion of a provider's hemodialysis patient population being dialyzed via an AVF or AV graft >> Identification of hemodialysis patients with vascular access types other than AVF or AV graft >> Evaluation of all hemodialysis patients without a functional autogenous AVF (defined as two needles used or a single-needle device) or AV graft for evaluation by a vascular or other surgeon qualified in the area of vascular access for a functional AVF or AV graft >> OUTCOME: Placement of an AVF or AV graft in all candidate patients as appropriate >> Increased overall AVF and AV graft rates >> Reduced overall morbidity and mortality in hemodialysis patients.</p> <p>1c.2-3 Type of Evidence (<i>Check all that apply</i>): Clinical Practice Guideline, Systematic review of body of evidence (other than within guideline development)</p> <p>1c.4 Directness of Evidence to the Specified Measure (<i>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</i>): Central Topic: Promotion of AVF and AV graft vascular access in chronic hemodialysis patients. Population: Adult ESRD hemodialysis patients in the United States. Outcomes Addressed: • Proportion of chronic hemodialysis patients with a functional autogenous AVF (defined as two needles used or a single needle device) or functional AV graft • Referral to and physical evaluation by a vascular or other surgeon qualified in the area of vascular access of all chronic hemodialysis patients without a functional autogenous AVF or functional AV graft Differences Between Measure Focus and Measure Target Population: None.</p> <p>1c.5 Quantity of Studies in the Body of Evidence (<i>Total number of studies, not articles</i>): The body of evidence presented in Section 1c.6 cites nine peer-reviewed publications encompassing 15 clinical studies.</p> <p>1c.6 Quality of Body of Evidence (<i>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</i>): With the advent of the National Kidney Foundation's (NKF) Kidney Dialysis Outcome and Quality Initiative (KDOQI) and CMS' Fistula First National Vascular Access Improvement Initiative, much emphasis has been placed on increasing AVF use in hemodialysis patients recent years. Accordingly, the body of related evidence is vast. We limit our focus to the peer-reviewed literature that informed the 2006 KDOQI Clinical Practice Guidelines for Vascular Access, as the recommendations contained therein served as the foundation for this measure. The following is a summary of the body of evidence upon which the relevant KDOQI guidelines are based, consisting of seven studies and two review articles that together encompass more than 300,000 hemodialysis patients in the United States, the United Kingdom, and Canada. KDOQI grades the strength of its recommendation to use AVFs over other forms of vascular access in chronic hemodialysis patients as "B", indicating that the recommendation is based on moderately strong evidence that the</p>			

practice improves health outcomes.

Summary of Body of Evidence:

As noted in the KDOQI guidelines, AVFs are preferred over all other forms of access because of their functional advantages and lower complications rates. Specifically, AVFs have the lowest rate of thrombosis (1) and require the fewest interventions (1,2), and thus provide longer survival of the access.(1-4) The number of access events is three- to seven-fold greater in prosthetic bridge grafts than in native AVFs.(1,2,4) As a result, costs of implantation and access maintenance are the lowest for AVFs.(4-6) Moreover, vascular access infections in hemodialysis patients are common, can be severe, and contribute to infection being the second leading cause of death in patients with CKD stage 5.(7) AVFs have been demonstrated to have lower rates of infection than grafts, which, in turn, are less prone to infection than percutaneous catheters and subcutaneous port catheter systems.(8) Consequently, AVFs are associated with increased survival and lower hospitalization rates than either AV grafts or catheters.(9) Research indicates that patients dialyzed via catheters and grafts have a greater mortality risk (relative risk = 2.3 and 1.47, respectively) than patients dialyzed with AVFs (9), and epidemiological evidence confirms that greater use of AVFs reduces morbidity and mortality.(9–12)

Study Design/Flaws:

We note that there are no randomized clinical trials (RCTs) comparing the three available vascular access types or demonstrating the superiority of AVFs, as a treatment/placebo RCT in that regard would be unethical given the known risks of catheters. Despite this, we have provided evidence demonstrating that AVFs have superior longevity, fewer complications, and are associated with the lowest mortality and costs.

1c.7 Consistency of Results across Studies (*Summarize the consistency of the magnitude and direction of the effect*): The studies cited in Section 1c.6. consistently demonstrate that AVFs have the lowest complications rate (1), the lowest costs of implantation and maintenance (4-6), require the fewest interventions (1,2), provide longer survival of the access (1-4), and are associated with increased survival and lower hospitalization rates than either AV grafts or catheters.(9)

1c.8 Net Benefit (*Provide estimates of effect for benefit/outcome; identify harms addressed and estimates of effect; and net benefit - benefit over harms*):

Research has clearly and consistently illustrated the net benefit of AVF use over other vascular access options. The studies cited in Section 1c.6. demonstrate that AVFs have the lowest complications rate (1), the lowest costs of implantation and maintenance (4-6), require the fewest interventions (1,2), provide longer survival of the access (1-4), and are associated with increased survival and lower hospitalization rates than either AV grafts or catheters.(9)

1c.9 Grading of Strength/Quality of the Body of Evidence. Has the body of evidence been graded? **Yes**

1c.10 If body of evidence graded, identify the entity that graded the evidence including balance of representation and any disclosures regarding bias: The KDOQI guidelines are based on a systematic review of the literature available at the time of publication. In developing the KDOQI clinical practice guidelines, the National Kidney Foundation (NKF) utilizes experts to decide which recommendations are supported by evidence and which are supported by consensus of the Work Group opinion. Evidence-based guideline recommendations are graded as strong, moderate, or weak in an approach consistent with the USPSTF and GRADE grading methods. Guidelines are assigned a grade of "A", "B", or "C" depending whether the recommendation is based on strong, moderately strong, or weak evidence that the practice improves health outcomes:

- 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 C = "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."

NKF notes that it makes every effort to avoid any actual or potential conflicts of interest that may arise as a result of an outside

relationship or a personal, professional, or business interest of a member of the Work Group. Specifically, all members of the Work Group are required to complete, sign, and submit a Disclosure Questionnaire showing all such relationships that might be perceived as real or potential conflicts of interest. All affiliations are published in their entirety at the end of the publication in the Biographical Sketch section of the Work Group members. Support for the development of the KDOQI Clinical Practice Guidelines and Clinical Practice Recommendations for Hemodialysis Vascular Access 2006 was provided by: Amgen, Inc., Baxter Healthcare Corporation, Fresenius USA, Inc., Genentech, Inc., and Watson Pharmaceuticals, Inc.

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

1c.12 If other, identify and describe the grading scale with definitions:

1c.13 Grade Assigned to the Body of Evidence: KDOQI grades the strength of its recommendation to use AVFs over other forms of vascular access in chronic hemodialysis patients as “B”.

1c.14 Summary of Controversy/Contradictory Evidence: We note that there are no randomized clinical trials (RCTs) comparing the three available vascular access types or demonstrating the superiority of AVFs, as a treatment/placebo RCT in that regard would be unethical given the known risks of catheters. Despite this, we have provided evidence demonstrating that fistulas have superior longevity, fewer complications, and are associated with the lowest mortality and costs.

1c.15 Citations for Evidence other than Guidelines (*Guidelines addressed below*):

1. Perera G, Mueller M, Kubaska S, Wilson S, Lawrence P, Fujitani R. Superiority of autogenous arteriovenous hemodialysis access: maintenance of function with fewer secondary interventions. *Ann Vasc Surg.* 2004;18:66–73.
2. Huber T, Carter J, Carter R, Seeger J. Patency of autogenous and polytetrafluoroethylene upper extremity arteriovenous hemodialysis accesses: a systematic review. *J Vasc Surg.* 2003;38:1005–11.
3. Pisoni R, Young E, Dykstra D, et al. Vascular access use in Europe and the United States: results from the DOPPS. *Kidney Int.* 2002;61:305–16.
4. Mehta S. Statistical summary of clinical results of vascular access procedures for haemodialysis, in Sommer BG, Henry ML (eds): *Vascular Access for Hemodialysis-II* (ed 2). Chicago, IL, Gore, 1991, pp 145–57.
5. The Cost Effectiveness of Alternative Types of Vascular access and the Economic Cost of ESRD. Bethesda, MD, National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, 1995, pp 139–57.
6. Eggers P, Milam R. Trends in vascular access procedures and expenditures in Medicare’s ESRD program, in Henry ML (ed): *Vascular Access for Hemodialysis-VII*. Chicago, IL, Gore, 2001, pp 133–43.
7. Gulati S, Sahu K, Avula S, Sharma R, Ayyagiri A, Pandey C. Role of vascular access as a risk factor for infections in hemodialysis. *Ren Fail.* 2003;25:967–73.
8. Nassar G and Ayus J. Infectious complications of the hemodialysis access. *Kidney Int.* 2001;60:1–13.
9. Dhingra R, Young E, Hulbert-Shearon T, Leavey S, and Port F. Type of vascular access and mortality in U.S. hemodialysis patients. *Kidney Int.* 2001;60:1443–51.
10. Woods J and Port F. The impact of vascular access for haemodialysis on patient morbidity and mortality. *Nephrol Dial Transplant.* 1997;12:657–9.
11. Xue J, Dahl D, Ebben J, and Collins A. The association of initial hemodialysis access type with mortality outcomes in elderly Medicare ESRD patients. *Am J Kidney Dis.* 2003;42:1013–19.
12. Polkinghorne K, McDonald S, Atkins R, and Kerr P. Vascular access and all-cause mortality: a propensity score analysis. *J Am*

Soc Nephrol. 2004;15:477–86.

1c.16 Quote verbatim, the specific guideline recommendation (Including guideline # and/or page #):
KDOQI Clinical Practice Guidelines and Recommendations for Vascular Access:

Guideline 2.1: A structured approach to the type and location of long-term hemodialysis access should help optimize access survival and minimize complications. The order of preference for vascular access in patients with kidney failure who choose hemodialysis as their initial mode of KRT should be (in descending order of preference):

- 2.1.1 Preferred: Fistula. (B)
- 2.1.2 Acceptable: AV graft 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)

1c.17 **Clinical Practice 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. 2006;48(suppl 1):S1-S322.

1c.18 **National Guideline Clearinghouse or other URL:**
<http://www.guideline.gov/content.aspx?id=10017&search=vascular+access>

1c.19 **Grading of Strength of Guideline Recommendation.** Has the recommendation been graded? Yes

1c.20 **If guideline recommendation graded, identify the entity that graded the evidence including balance of representation and any disclosures regarding bias:** The KDOQI guidelines are based on a systematic review of the literature available at the time of publication. In developing the KDOQI clinical practice guidelines, the National Kidney Foundation (NKF) utilizes experts to decide which recommendations are supported by evidence and which are supported by consensus of the Work Group opinion. Evidence-based guideline recommendations are graded as strong, moderate, or weak in an approach consistent with the USPSTF and GRADE grading methods. Guidelines are assigned a grade of "A", "B", or "C" depending whether the recommendation is based on strong, moderately strong, or weak evidence that the practice improves health outcomes: • 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 C = "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." NKF notes that it makes every effort to avoid any actual or potential conflicts of interest that may arise as a result of an outside relationship or a personal, professional, or business interest of a member of the Work Group. Specifically, all members of the Work Group are required to complete, sign, and submit a Disclosure Questionnaire showing all such relationships that might be perceived as real or potential conflicts of interest. All affiliations are published in their entirety at the end of the publication in the Biographical Sketch section of the Work Group members. Support for the development of the KDOQI Clinical Practice Guidelines and Clinical Practice Recommendations for Hemodialysis Vascular Access 2006 was provided by: Amgen, Inc., Baxter Healthcare Corporation, Fresenius USA, Inc., Genentech, Inc., and Watson Pharmaceuticals, Inc.

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

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

1c.23 **Grade Assigned to the Recommendation:** KDOQI grades the strength of its recommendation to use permanent access types instead of other forms of vascular access in chronic hemodialysis patients as "B".

1c.24 **Rationale for Using this Guideline Over Others:** The KDOQI guidelines present the most up-to-date summary of available

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knowledge in the field of hemodialysis vascular access. KDOQI has provided evidence-based clinical practice guidelines for, all stages of chronic kidney disease (CKD) and related complications since 1997 and is recognized throughout the world for improving the diagnosis and treatment of kidney disease.

Based on the NQF descriptions for rating the evidence, what was the developer’s assessment of the quantity, quality, and consistency of the body of evidence?

1c.25 Quantity: **High** 1c.26 Quality: **Moderate** 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, as specified, produces consistent (reliable) and credible (valid) results about the quality of care when implemented. (evaluation criteria)

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 this measure can be obtained? **Yes**

S.2 If yes, provide web page URL: <http://www.kidneycarepartners.org>

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):

Number of patients from the denominator who:

(1) have a functional autogenous AVF (defined as two needles used or a single-needle device) (computed and reported separately); or

(2) have a functional AV graft (computed and reported separately); or

(3) have a catheter but have been seen/evaluated by a vascular surgeon, other surgeon qualified in the area of vascular access, or interventional nephrologist trained in the primary placement of vascular access for a functional autogenous AVF (defined as two needles used or a single needle device) or AV graft at least once during the 12-month reporting period (computed and reported separately).

Reporting should be stratified by incident versus prevalent patients, as defined by USRDS.

2a1.2 **Numerator Time Window** (The time period in which the target process, condition, event, or outcome is eligible for inclusion): 12-month reporting period.

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 necessary data elements are to be collected via the Centers for Medicare and Medicaid (CMS) CROWNWeb data repository when functional, as indicated by the measure’s inclusion in CMS’s list of Phase III ESRD Clinical Performance Measures in effect April 1, 2008.

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1. Access type (select one):

- AVF with 2 needles used or single needle device --> END.
- AV graft with 2 needles used --> END.
- AVF with AV graft --> END.
- AVF with catheter --> GO TO 2.
- AV graft with catheter --> GO TO 2.
- Catheter --> GO TO 2.
- Other/unknown --> GO TO 2.

2. Vascular access referral status (select one):

- Patient referred to a vascular surgeon, other surgeon qualified in the area of vascular access, or interventional nephrologist trained in the primary placement of vascular access for an AVF or AV graft during the 12-month reporting period --> GO TO 3.
- Patient NOT referred to a vascular surgeon, other surgeon qualified in the area of vascular access, or interventional nephrologist trained in the primary placement of vascular access for an AVF or AV graft during the 12-month reporting period --> END.

3. Vascular access evaluation status (select one):

- Patient seen/evaluated by a vascular surgeon, other surgeon qualified in the area of vascular access, or interventional nephrologist trained in the primary placement of vascular access for an AVF or AV graft during the 12-month reporting period --> GO TO 4.
- Patient NOT seen/evaluated by a vascular surgeon, other surgeon qualified in the area of vascular access, or interventional nephrologist trained in the primary placement of vascular access for an AVF or AV graft during the 12-month reporting period --> END.

4. Type of documentation of the surgical evaluation in facility's medical records/CROWNWeb (select one):

- No documentation --> END.
- A note or letter prepared by the primary nephrologist --> GO TO 5.
- A note or letter prepared by the vascular surgeon, other surgeon qualified in the area of vascular access, or interventional nephrologist trained in the primary placement of vascular access --> GO TO 5.
- A note prepared by facility personnel --> GO TO 5.

5. Date of the surgical evaluation: (MM/YYYY) --> GO TO 6.

6. If permanent access was not placed, the reason for this decision --> END.

2a1.4 Denominator Statement (*Brief, narrative description of the target population being measured*):

All ESRD patients aged 18 years and older receiving hemodialysis during the 12-month reporting period and on dialysis for greater than 90 days.

This measure includes both in-center and home hemodialysis patients.

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

2a1.6 Denominator Time Window (*The time period in which cases are eligible for inclusion*):

12-month reporting period.

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 necessary data elements are to be collected via the CMS CROWNWeb data repository when functional, as indicated by the measure's inclusion in CMS's list of Phase III ESRD Clinical Performance Measures in effect April 1, 2008.

The denominator population consists of all ESRD patients receiving hemodialysis for a given nephrologist. Data elements required to identify the denominator population:

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- Patient diagnosis = ESRD
- AND
- Patient primary type of dialysis = hemodialysis
- AND
- Patient's date of birth
- AND
- Date regular chronic dialysis began
- AND
- Nephrologist's name

2a1.8 Denominator Exclusions (*Brief narrative description of exclusions from the target population*):
Patients enrolled in hospice.

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*):
Identify all patients in the denominator enrolled in hospice.

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*):
Not applicable.

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.*):
Not applicable.

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 = Higher 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.*):

DENOMINATOR

Include in the denominator all patients for a given nephrologist who meet the following criteria in the most recent month of the 12-month study period and who are not enrolled in hospice:

1. Diagnosis = ESRD

AND

2. Primary type of dialysis = hemodialysis or home hemodialysis

AND

3. Age = >18 years or older as of the first day of the most recent month of the reporting period. (Patient's age is or shall be determined by subtracting the patient's date of birth from the first day of the most recent month of the reporting period.)

AND

4. Time on dialysis = >90 days as of the first day of the most recent month of the reporting period. (Patient's time on dialysis is or shall be determined by subtracting the patient's Date Regular Chronic Dialysis Began from the first day of the most recent month of the reporting period. Patients on dialysis <90 days are excluded so that emergent patients and patients requiring only transient dialysis are not encompassed, as permanent access would not be appropriate in these populations.)

NUMERATOR

Include in the numerator all patients from the denominator who meet the following criteria:

1. Access Type = Functional autogenous AVF (defined as 2 needles used or single-needle device)

OR

2. Access type = Functional AV graft

OR

3. Access type = AVF combined with AV graft

OR

4. Access type (select one):

- AVF with a catheter
- AV graft with a catheter
- Catheter
- Other/unknown

AND

2. Patient referred to a vascular surgeon, other surgeon qualified in the area of vascular access, or interventional nephrologist trained in the primary placement of vascular access for an AVF or AV graft during the 12-month reporting period

AND

3. Patient seen/evaluated by a vascular surgeon, other surgeon qualified in the area of vascular access, or interventional nephrologist trained in the primary placement of vascular access for an AVF or AV graft during the 12-month reporting period

AND

4. Facility medical records contain the following types of documentation of the surgical evaluation:

- A note or letter prepared by the primary nephrologist OR
- A note or letter prepared by the vascular surgeon, other surgeon qualified in the area of vascular access, or interventional nephrologist trained in the primary placement of vascular access OR
- A note prepared by facility personnel

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<p>AND</p> <ul style="list-style-type: none">• Date of the surgical evaluation: (MM/YYYY) <p>AND</p> <ul style="list-style-type: none">• If permanent access was not placed, the reason for this decision <p>2a1.21-23 Calculation Algorithm/Measure Logic Diagram URL or attachment: Attachment txKCQACalcAlgorithmAVF11-07-11NQFrecs.pdf</p>
<p>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): Not applicable.</p>
<p>2a1.25 Data Source (<i>Check all the sources for which the measure is specified and tested</i>). If other, please describe: Electronic Clinical Data : Electronic Health Record, Paper Records</p> <p>2a1.26 Data Source/Data Collection Instrument (<i>Identify the specific data source/data collection instrument, e.g. name of database, clinical registry, collection instrument, etc.</i>): All data elements for the measure can be collected using the KCOA Vascular Access Data Collection Form (attached), which reflect the data elements to be included in CROWNWeb.</p> <p>2a1.27-29 Data Source/data Collection Instrument Reference Web Page URL or Attachment: Attachment fmKCQADataFormVascAccess11-07-11NQFrecs.pdf</p> <p>2a1.30-32 Data Dictionary/Code Table Web Page URL or Attachment: Attachment txKCQADataDictionaryAVF11-07-11NQFrecs.pdf</p> <p>2a1.33 Level of Analysis (<i>Check the levels of analysis for which the measure is specified and tested</i>): Clinician : Individual</p> <p>2a1.34-35 Care Setting (<i>Check all the settings for which the measure is specified and tested</i>): Ambulatory Care : Clinician Office, Dialysis Facility</p>
<p>2a2. Reliability Testing. (<i>Reliability testing was conducted with appropriate method, scope, and adequate demonstration of reliability.</i>)</p>
<p>2a2.1 Data/Sample (<i>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</i>): Facility Testing: KCOA tested its ESRD measures through a one-year prospective cohort study on a nationally drawn sample of 53 dialysis facilities containing a mix of for-profit and not-for-profit providers; hospital-affiliated and freestanding facilities within large, small, and independent dialysis organizations; urban, suburban, and rural settings; and facilities both with and without electronic health records (EHRs). Approximately 25 patients per facility were sought, resulting in a final sample size of 1,115 patients. Of these, 1,057 were hemodialysis patients and were thus included in the vascular access measures' denominator populations. Both facility and patient samples were structured to be generally representative of the national industry profile as identified by the United States Renal Data Systems (USRDS) 2007 Annual Data Report. Facility records were used as the data source, given CMS's intent to include the measure in its Phase III Clinical Performance Measures, which involve CROWNWeb electronic transmission of data from facility medical records. Because CROWNWeb was not operational at the time, standardized, paper-based data collection sheets were constructed from the endorsed specifications and were employed during data collection for the testing.</p> <p>Physician Office Testing: To test the measure in physician offices, KCP contracted with IFMC, which was under an existing contract with the AMA PCPI/RPA to perform on-site feasibility and implementation testing of several AMA PCPI/RPA measures and had thus already obtained</p>

consent from four nephrology practice sites that would consist of a nephrology practice alpha site local to IFMC and three sites distributed geographically across the United States (Iowa, Nevada, Texas, and Pennsylvania) of various practice sizes (5.25 to 62 physicians), and medical record types (two EHR, one paper but by the time of visit transitioning to EHR, and one hybrid). Each site was asked to pull in advance the records of the first 35 adult hemodialysis patients seen on or after July 1, 2007; IFMC requested what it referred to as an oversample of five patients in an effort to ensure a remaining sample of 30 patients. The facilities within which the sample patients received care were asked to pull the records in advance of the IFMC visit because IFMC and AMA PCPI/RPA had previously identified the need for both patient's physician office and dialysis organization records to collect necessary data elements. Physician offices were, therefore, requested to secure copies of the necessary facility records in advance of the IFMC visit.

(IFMC noted that it is a Quality Improvement Organization that serves as a health oversight agency for CMS and is therefore authorized to have access to personal health information (PHI). It further noted that PHI may be disclosed to it without patient authorization under the HIPAA Privacy Rule at 45 CFR***164.512(d).)

2a2.2 Analytic Method (*Describe method of reliability testing & rationale*):

Facility Testing:

Following the data collection period, on-site data-integrity audits were performed at 11 of the 53 facilities (21%). Audit sites were selected to provide a cross-section of facilities reflective of the sample profile. Selection criteria included geographic location, facility type (e.g., for-profit vs. not-for-profit, urban vs. rural), and EHR use. Pertinent data were reabstracted from the patients' medical records and were compared to the information submitted by the facility throughout the pilot to assess the measure's reliability.

Physician Office Testing:

The three nephrology office sites, in addition to the alpha site, were visited by a two-person IFMC abstractor team to conduct feasibility and reliability testing. Using the KCQA data collection tool, the two abstractors individually abstracted each medical record, compared the results, and evaluated the mismatches. Mismatch codes, previously developed by IFMC for reliability testing of project abstraction, were used to classify the reason determined for each mismatch.

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

Facility Testing:

Inter-rater reliability was assessed during the on-site audits through a direct comparison of data submitted by the facilities throughout the pilot to data reabstracted by the auditor(s). (See Table 1 [Measure Performance, Submitted vs. Reabstracted Data] in the accompanying Attachment A.) Reliability was quantitatively summarized using Cohen's Kappa with confidence intervals. The resulting Kappa statistic for the Functional AVF or Evaluation by Vascular Surgeon for Placement measure was found to be 0.8880 with a 95% confidence interval of 0.7484-1.000. (See Table 2 [Measure Aggregate Reliability] in Attachment A.) Based on the literature, this value indicates "almost perfect agreement" and excellent reproducibility for the measure. In addition to the Kappa value, the percent agreement between the auditor and facility abstractors (i.e., the reliability percentage) was calculated and was found to be excellent at 96.9%. (See Table 3 [Measure Reliability Percentage and Error Type] in Attachment A.) These two values demonstrate that the KCQA measure is reliable.

Physician Office Testing:

To determine whether the ESRD measure definitions and specifications, as prepared by KCQA, yield stable, consistent measurements when applied in the physician office setting, inter-rater reliability was also assessed by IFMC. As in the facility setting, the resulting Kappa statistic indicates excellent reproducibility at 0.9152 with a 95% confidence interval of 0.8349-0.9964. (See Table 4 [Kappa Statistics with Confidence Intervals, Physician Office Setting] in Attachment A.)

2b. VALIDITY. Validity, Testing, including all Threats to Validity: 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 measure focus and target population are consistent with the evidence cited in Section 1c; no differences have been identified. In both the body of evidence and the measure specifications, the target population is adult ESRD patients on chronic hemodialysis, the central topic is the promotion of permanent vascular access placement to improve patient outcomes.

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

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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*):

KCOA tested its ESRD measures through a one-year prospective cohort study on a nationally drawn sample of 53 dialysis facilities. Approximately 25 patients per facility were sought, resulting in a final sample size of 1,115 patients, including 1,057 hemodialysis patients. Both facility and patient samples were structured to be generally representative of the national industry profile as identified in the USRDS 2007 Annual Data Report.

2b2.2 Analytic Method (*Describe method of validity testing and rationale; if face validity, describe systematic assessment*):

Validity refers to the degree to which a performance measure truly measures what it was intended to measure (i.e., construct validity) and the degree to which the conclusions drawn from a test would hold for other persons, places, and times (external validity).

Construct Validity:

A test is said to have construct validity when it measures a construct (or theory) accurately. For the KCOA performance measures, the construct being tested is that the measures will accurately assess and depict a dialysis facility's practices. In claiming construct validity, we would thus be asserting that our pilot test confirmed that KCOA's two vascular access measures do in fact effectively portray a facility's vascular access practices. Specifically, KCOA asserts the measures meet the following types of construct validity: face validity and content validity:

- A measure is said to have face validity when it appears to be valid—i.e., on its “face” it seems like a good translation of the construct being tested. Face validity uses common-sense rules—for example, to assess a facility's vaccination practices, a measure should quantify its vaccination rate. While face validity is the weakest means of demonstrating construct validity, its strength can be improved by making the process more systematic—for instance, by utilizing a panel of experts to confirm that the measure appears to be a proper translation of the construct.
- Content validity centers on a measure's ability to include or represent all of the content of the construct in question. Content under-representation occurs when important areas are missed, and construct-irrelevant variation occurs when irrelevant factors contaminate the measure. Determination of content validity requires agreement among experts in the field in question. Thus, while face validity can be established by one person, content validity must be determined by a panel.

The KCOA measures have both face and content validity based on the following: The measures were deemed appropriate and valid by (1) expert opinion within the KCP and KCOA; (2) expert opinion within the NQF ESRD TAPs, Steering Committee, and the CSAC, all of which advanced the measures to the next stage of the CDP; and (3) broad agreement as demonstrated through the NQF review and voting processes.

External Validity:

A test is said to have external validity when results can be reliably generalized to the larger relevant population. External validity can be improved by employing appropriate methods to draw the sampling model from a population. For instance, when feasible, random selection should be utilized over a nonrandom procedure. Likewise, researchers should work to assure that respondents participate and that dropout rates are minimized.

KCOA posits that external validity has been met through the diligence with which the original sampling schema was crafted to reflect the national industry and patient vintage and access profiles. Because the sample is representative of the U.S. dialysis population, results can be generalized with confidence.

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*):

External Validity:

External validity of the KCOA measures was established through the meticulous construction of patient and facility samples, modeled to reflect the national industry and patient vintage and access profiles as per the 2007 USRDS Annual Data Report of Chronic Kidney Disease & End-Stage Renal Disease, the most current volume available at the time the sample was constructed. Because the sample is representative of the U.S. dialysis population, results can be generalized with confidence.

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Facility Sampling: In the United States, dialysis services are provided at more than 4,800 sites (freestanding non-profit and for-profit centers, hospital-based, and government-affiliated entities—i.e., Department of Veterans Affairs or state/county/city-run). Based on the industry profile in the 2007 U.S. Renal Data System (USRDS), a recruitment list of 71 facilities that mirrored this profile was identified so as to reach a target of 60 facilities, from which we assumed additional attrition might occur during the one-year course of data collection. Department of Veterans Affairs (VA)-affiliated and other public facilities were excluded to streamline the facility recruitment process. (VA and other public facilities represent less than two percent of dialysis sites, and less than one percent of the patient population.) Based on the USRDS data, the following target facility distribution was constructed:

- 60% from for-profit large dialysis organizations (LDO),
- 15% from non-profit LDOs,
- 20% from for-profit non-LDOs, and
- 5% from non-profit non-LDOs.

Ultimately, 53 facilities participated in the pilot. The final facility sample contained a mix of both for-profit and not-for-profit providers; hospital-affiliated and freestanding facilities within large, small, and independent dialysis organizations; urban, suburban, and rural settings; and facilities both with and without electronic medical records, and was generally representative of the national industry profile. The facility distribution in the final sample was:

- 59% from for-profit LDOs,
- 8% from non-profit LDOs,
- 21% from for-profit non-LDOs, and
- 13% from non-profit non-LDOs.

Additionally, KCP members represent approximately 85% of the community; the final sample contained facilities involved with KCP members (47 facilities; 89%) and those not (6 facilities; 11%).

Patient Sampling: Twenty-five patients per facility were sought, and three primary patient-related variables were identified: dialysis type (hemodialysis, peritoneal dialysis, or home hemodialysis), vintage on dialysis, and vascular access type. Per the 2007 USDRS report, approximately 94.5 percent of patients are on in-center hemodialysis, 5 percent on peritoneal dialysis, and 0.5 percent on home hemodialysis. The sample at the outset of the study was 92.6 percent in-center hemodialysis, 4.8 percent peritoneal dialysis, and 2.7 percent home hemodialysis. At the study's conclusion, the profile was 92.1 percent in-center hemodialysis 5.2 percent peritoneal dialysis, and 2.7 percent home hemodialysis. (The slight overrepresentation of home hemodialysis patients resulted from the participation of a facility caring exclusively for home-based hemodialysis patients. We also note that the 2007 USRDS atlas reports on data as of the end of 2005. In fact, the home hemodialysis population has been growing, and is currently estimated by community members to be 1-2%. Thus, the actual sample more accurately reflects the current situation. Regardless, nothing in the current literature indicated this small sampling difference from the national norm would have any impact on the pilot test results, and so the pilot proceeded with the original sample rather than exclude the facility with only home hemodialysis and/or attempt to replace it.)

With respect to vintage, patients were characterized as less than 90 days, 90 days to one year, and less than one year as appropriately reflecting the relevant populations to follow the performance specified by the vascular access measures. Again, the original sample was constructed to mirror the national distribution. Based on USRDS data, this equated to 6, 11, and 8 patients per facility, respectively as of September 1, 2008.

Data collection for patients with a functional AVF (defined as using two needles in the fistula) was considerably easier than for patients without and so facilities were not permitted to self-identify patients based on AVF status. To obtain sufficient sample size to analyze the underlying purpose of the two vascular access measures, facilities were asked to select 13 patients on hemodialysis who did not have a functional AVF at the study onset.

The initial patient sample size equated to 1,325 adult patients (25 patients/53 facilities), but was reduced to 1,295 because some facilities did not have enough patients of a given type. This number was reduced to 1,115 by the study's conclusion due to patient death, transplantation, or patient transfer out of the participating facility.

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Face Validity:

The KCQA measures have face validity based on the following: The measures were deemed appropriate and valid by (1) expert opinion within the KCP and KCQA; (2) expert opinion within the NQF ESRD TAPs, Steering Committee, and the CSAC, all of which advanced the measures (in some cases with recommended changes adopted by KCQA) to the next stage of the CDP; and (3) broad agreement as demonstrated through the NQF review and voting processes.

Content Validity:

The KCQA measures have content validity based on the following: The measures were deemed appropriate and valid by: (1) consensus of KCQA's expert panel; and (2) consensus of NQF's ESRD Technical Advisory Panels and Steering Committee.

POTENTIAL THREATS TO VALIDITY. (*All 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*):

KCQA tested its ESRD measures through a one-year prospective cohort study on a nationally drawn sample of 53 dialysis facilities. Approximately 25 patients per facility were sought, resulting in a final sample size of 1,115 patients, including 1,057 hemodialysis patients. Both facility and patient samples were structured to be generally representative of the national industry profile as identified in the USRDS 2007 Annual Data Report.

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

Facility Testing:

Following the data collection period, on-site data-integrity audits were performed at 11 of the 53 facilities (21%). Audit sites were selected to provide a cross-section of facilities reflective of the sample profile. Selection criteria included geographic location, facility type (e.g., for-profit vs. not-for-profit, urban vs. rural), and EHR use. Pertinent data were reabstracted from the patients' medical records and were compared to the information submitted by the facility throughout the pilot to assess the measure's reliability.

Physician Office Testing:

The three nephrology office sites, in addition to the alpha site, were visited by a two-person IFMC abstractor team to conduct feasibility and reliability testing. Using the KCQA data collection tool, the two abstractors individually abstracted each medical record, compared the results, and evaluated the mismatches. Mismatch codes, previously developed by IFMC for reliability testing of project abstraction, were used to classify the reason determined for each mismatch.

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

Inter-rater reliability could not be calculated for the measure exclusion due to small numbers. Specifically, only one hospice patient was included among the 1,057 hemodialysis patients in the facility sample and none were identified in the physician office sample.

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*):

Not applicable.

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

Not applicable.

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*

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relationship of risk factors to the outcome and differences in outcomes among the strata):

Not applicable.

2b4.4 If outcome or resource use measure is not risk adjusted, provide rationale and analyses to justify lack of adjustment: This measure assesses provider adherence to established clinical guidelines and recommendations. Permanent vascular access types have long been recognized as superior to catheters and have been demonstrated to minimize patient morbidity and mortality rates and improve outcomes. As ALL adult chronic hemodialysis patients should be dialyzed via a permanent access when feasible, and ALL patients without a functional autogenous AVF (defined as two needles used or a single-needle device) or an AV graft should be seen/evaluated by a vascular or other surgeon qualified in the area of vascular access for placement, risk adjustment of this measure is inappropriate.

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*):

As previously described, KCOA tested its ESRD measures through a year-long prospective cohort study on a nationally drawn sample of 53 dialysis facilities containing a mix of for-profit and not-for-profit providers; hospital-affiliated and freestanding facilities within large, small, and independent dialysis organizations; urban, suburban, and rural settings; and facilities both with and without electronic health records (EHRs). Approximately 25 patients per facility were sought, resulting in a final sample size of 1,115 patients. Of these, 1,057 were hemodialysis patients and were thus included in the vascular access measures' denominator populations. Both facility and patient samples were structured to be generally representative of the national industry profile as identified by the USRDS 2007 Annual Data Report. Facility records were used as the data source, given CMS's intent to include the measure in its Phase III Clinical Performance Measures, which involve CROWNWeb electronic transmission of data from facility medical records. Because CROWNWeb was not operational at the time, standardized, paper-based data collection sheets were constructed from the endorsed specifications and were employed during data collection for the testing.

2b5.2 Analytic Method (*Describe methods and rationale to identify statistically significant and practically/meaningfully differences in performance*):

The data elements necessary for measure calculation were collected from the 53 participating facilities on the 1,057 hemodialysis patient included in the study sample. Performance rate was calculated using the following formula:

Performance Rate =
([Patients with AVF] + [Patients with AV graft] + [Patients without AVF or AV graft seen by surgeon for placement] – [Patients seen but without medical record documentation]) ÷ ([Total patients on hemodialysis >90 days] – [Patients enrolled in hospice])

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*):

The vascular access profile for the 1,057 hemodialysis patients included in the pilot sample was as follows:

- Functional AVF = 621 patients (58.8%)
- Catheter only = 306 (28.9%)
- AV graft only = 99 (9.4%)
- AVF with catheter = 26 (2.5%)
- AV graft with catheter = 5 (0.5%)

Facilities reported that 291 (86.4%) of the 337 patients who did NOT have a functional permanent access at the commencement of the study (September 1, 2008) had been evaluated by a vascular or other qualified surgeon for placement of permanent access by the conclusion of the study (August 31, 2009). Of these, 20 did not have documentation of the evaluation—a requirement to receive credit for the measure. The data elements collected thus permit calculation of performance for the measure as follows:

Performance Rate =
([Patients with AVF] + [Patients with AV graft] + [Patients without AVF or AV graft seen by surgeon for placement] – [Patients seen but without medical record documentation]) ÷ ([Total patients on hemodialysis > 90 days] – [Patients enrolled in hospice])
= (621 + 99 + 291 – 20) ÷ (1,057 – 1) = 93.8%

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The performance for each individual facility in the pilot ranged from 41% to 100%, with a mean performance of 93.8%. These findings indicate that, contrary to current clinical practice guidelines and recommendations, a considerable proportion of hemodialysis patients continue to be dialyzed via catheters without evaluation as to whether permanent access placement should occur, and that facility performance varies widely in this aspect of care. The results identify an important gap and meaningful differences in patient care.

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):

Not applicable.

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

The necessary data elements are to be collected via the CMS CROWNWeb data repository when functional.

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):

Not applicable.

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): CMS Clinical Performance Measures (CPM) data for 2007 indicate that AVF and catheter rates vary by race/ethnicity and gender (1). The measure could be reported in a stratified manner to monitor disparities.

Citation:

U.S. Renal Dialysis System, USRDS 2010 Annual Data Report: Atlas of Chronic Kidney Disease and End-Stage Renal Disease in the United States. 2010.

2c.2 If disparities have been reported/identified (e.g., in 1b), but measure is not specified to detect disparities, please explain:

The measure could be reported in a stratified manner to monitor the disparities in AVF and catheter rates by race/ethnicity and gender.

2.1-2.3 Supplemental Testing Methodology Information:

Attachment

tbKCQAAAttachmentAAVF06-07-11FINAL.pdf

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): Payment Program, Public Health/Disease Surveillance, Public Reporting, Quality Improvement (Internal to the specific organization), Quality Improvement with Benchmarking (external benchmarking to multiple organizations)

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3.1 **Current Use** (Check all that apply; for any that are checked, provide the specific program information in the following questions): Public Health/ Disease Surveillance, Quality Improvement with Benchmarking (external benchmarking to multiple organizations), 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.]

The measure is intended to be used by CMS for its public reporting and payment initiatives once CMS brings CROWNWeb fully online.

3a.2. **Provide a rationale for why the measure performance results are meaningful, understandable, and useful for public reporting.** If usefulness was demonstrated (e.g., focus group, cognitive testing), describe the data, method, and results: While measure results have not been tested for interpretability in public reporting, the Kidney Care Partners' dialysis patient group members support the measure and concur that the availability of performance data on this measure is an important indicator of quality of care and that the measure will be readily interpreted by dialysis patients. Additionally, as part of the CMS Fistula First Initiative, patients are familiar with the underlying concept of the importance of using permanent access types instead of catheters, which is the central goal of the KCOA 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): The measure is intended to be used by CMS for its public reporting and payment initiatives.

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].

The measure is intended to be used by CMS for its public reporting and payment initiatives, and data will be collected via the CROWNWeb data repository. The ESRD Conditions for Coverage (section B494.180 [h]) state that data collected through CROWNWeb are to be used in a national ESRD information system and in compilations relevant to performance assessment and quality improvement.

3b.2. **Provide rationale for why the measure performance results are meaningful, understandable, and useful for quality improvement.** If usefulness was demonstrated (e.g., QI initiative), describe the data, method and results: On-site interviews of participating facility personnel were conducted during the data integrity audits. Neither facility management nor the staff responsible for collecting and entering the necessary data elements reported any difficulty comprehending the measure concepts and or data elements and agreed that the measure is an important indicator or quality that will be useful for quality improvement.

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).

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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*): Some data elements are in electronic sources

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: The necessary data elements are to be collected via the Centers for Medicare and Medicaid (CMS) CROWNWeb data repository when functional, as indicated by the measure's inclusion in CMS's list of Phase III ESRD Clinical Performance Measures in effect April 1, 2008.

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:
 Percent agreement between the auditor and facility abstractors (i.e., the reliability percentage) was assessed during the on-site audits through a direct comparison of data submitted by the facilities throughout the pilot to data reabstracted by the auditor(s). (See Table 3 [Measure Reliability Percentage and Error Type] in Attachment A.) This marker of accuracy was found to be excellent at 96.9%, indicating minimal susceptibility to inaccuracies and errors.

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*):

As the reliability analyses indicated, the measure is specified in a manner that permits it to be reliably applied. Additionally, during the course of the pilot and during the on-site interviews, facility personnel did not report any difficulty with the measure concepts or data elements. All data elements are derived from only the facility records and do not require a review of the nephrologist's office records. The burden of manual data collection to collect all KCOA measures ranged from 1 to 15 minutes per patient once facilities became familiar with the data collection forms after the first quarter.

We do not minimize this time commitment, but note that the CROWNWeb interface will reduce the burden and that batch electronic processing for dialysis organizations with integrated EHRs will significantly minimize burden. Nevertheless, for facilities relying on manual data entry into CROWNWeb from paper-based records, we recognize the measures are feasible, but do impose a burden to comply with the data needs.

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

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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:

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): [Kidney Care Quality Alliance, 2550 M Street, NW, Washington, District Of Columbia, 20037](#)

Co.2 Point of Contact: [Lisa, McGonigal, MD, MPH, lmcgon@msn.com, 203-298-0567-](#)

Co.3 Measure Developer if different from Measure Steward: [Kidney Care Quality Alliance, 2550 M Street, NW, Washington, District Of Columbia, 20037](#)

Co.4 Point of Contact: [Lisa, McGonigal, MD, MPH, lmcgon@msn.com, 203-298-0567-](#)

Co.5 Submitter: [Lisa, McGonigal, MD, MPH, lmcgon@msn.com, 203-298-0567-, Kidney Care Quality Alliance](#)

Co.6 Additional organizations that sponsored/participated in measure development:
Not applicable.

Co.7 Public Contact: [Lisa, McGonigal, MD, MPH, lmcgon@msn.com, 203-298-0567-, Kidney Care Quality Alliance](#)

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.

[KCQA Clinical Measures Work Group Members \(developed measures\):](#)

1. William Haley, MD — Mayo Clinic
2. John Burkart, MD — GatesMcDonald Health Plus
3. Al Collins, MD — University of Minnesota
4. Charlie McAllister, MD — DaVita, Inc.
5. Jerry Yee, MD — Henry Ford Hospital

[KCQA Clinical Measures Task Group Members \(approved measures\):](#)

1. Charlie McAllister, MD—DaVita, Inc.
2. Raymond M. Hakim, MD, PhD — Fresenius Medical Care

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3. Alan Kliger — Yale University
4. Ed Jones — Renal Physicians Association
5. Allen Nissenson — DaVita, Inc.
6. William Goodman — Amgen, Inc.
7. William Haley, MD — Mayo Clinic
8. Robert Provenzano — DaVita, Inc.
9. Gail Wick — American Nephrology Nurses Association
10. Rulan Parekh — American Kidney Fund

Kidney Care Quality Alliance Steering Committee Members (oversaw testing):

- Raymond M. Hakim, MD, PhD (Co-Chair) — Fresenius Medical Care
- Gail S. Wick, BSN, RN, CNN (Co-Chair) — American Nephrology Nurses Association
- Dolph Chianchiano, JD — National Kidney Foundation
- Richard S. Goldman, MD — Renal Physicians Association
- Barbara Fivush, MD — American Society of Pediatric Nephrology
- Maureen Michael, BSN, MBA — National Renal Administrators Association
- Allen Nissenson, MD — DaVita
- Barry M. Straube, MD — Centers for Medicare and Medicaid Services (Liaison Member)

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: [Not applicable.](#)

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: [10, 2011](#)

Ad.5 What is your frequency for review/update of this measure? [As needed with changes or additions to the evidence base, but at minimum every three years.](#)

Ad.6 When is the next scheduled review/update for this measure? [10, 2013](#)

Ad.7 Copyright statement: [© 2010 Kidney Care Quality Alliance. All Rights Reserved.](#)

Ad.8 Disclaimers:

Ad.9 Additional Information/Comments: <http://www.kidneycarepartners.com>

Date of Submission (MM/DD/YY): [10/05/2011](#)

KCQA VASCULAR ACCESS DATA COLLECTION FORM

1. AVF Access or Evaluation by Vascular Surgeon for Placement

2. Catheter Vascular Access and Evaluation by Vascular Surgeon for Permanent Access

VASCULAR ACCESS INFORMATION
<p>1. How long has the patient been on hemodialysis as of the final day of the 12-month reporting period?</p> <p><input type="checkbox"/> < 90 days → End.</p> <p><input type="checkbox"/> 90 days - 1 year → Go to question 2.</p> <p><input type="checkbox"/> > 1 year → Go to question 2.</p>
<p>2. Did the patient have a functional autogenous AVF (using 2 needles in the fistula) during the last hemodialysis session?</p> <p><input type="checkbox"/> Yes → Go to question 5.</p> <p><input type="checkbox"/> No → Go to question 3.</p>
<p>3. Indicate the patient's vascular access method during the last hemodialysis session:</p> <p><input type="checkbox"/> AV graft only (using 2 needles in graft) → Go to question 4.</p> <p><input type="checkbox"/> AVF with catheter (used simultaneously during session) → Go to question 4.</p> <p><input type="checkbox"/> AV graft with catheter (used simultaneously during session) → Go to question 4.</p> <p><input type="checkbox"/> Catheter only → Go to question 4.</p>
<p>4. Has the patient been seen by a vascular surgeon or other surgeon qualified in the area of vascular access for evaluation for permanent vascular access during the 12-month reporting period?</p> <p><input type="checkbox"/> Yes → Answer questions 4.a. through 4.c., then go to question 5.</p> <p><input type="checkbox"/> No → Go to question 5.</p> <p><input type="checkbox"/> Unknown → Go to question 5.</p> <p>4.a. If yes, indicate the type of documentation in the <u>facility's</u> medical record:</p> <p><input type="checkbox"/> No documentation in the <u>facility's</u> medical record.</p> <p>Verification that the patient was assessed by a vascular surgeon or other surgeon qualified in the area of vascular access and the reason permanent access was <u>not</u> placed (check all that apply):</p> <p><input type="checkbox"/> A note or letter prepared by the nephrologist.</p> <p><input type="checkbox"/> A note or letter prepared by the vascular or other qualified surgeon.</p> <p><input type="checkbox"/> A note prepared by the facility.</p> <p style="margin-left: 40px;">Date of assessment: ____ / ____ (mm) (yyyy)</p> <p>Verification that the patient was assessed by a vascular surgeon or other surgeon qualified in the area of vascular access indicating that permanent access <u>was</u> placed (check all that apply):</p> <p><input type="checkbox"/> A note or letter prepared by the nephrologist.</p> <p><input type="checkbox"/> A note or letter prepared by the vascular or other qualified surgeon.</p> <p><input type="checkbox"/> A note prepared by the facility.</p> <p style="margin-left: 40px;"><input type="checkbox"/> AVF placed OR <input type="checkbox"/> AV graft placed. Date of placement: ____ / ____ (mm) (yyyy)</p> <p>4.b. Name of vascular or other qualified surgeon: _____</p> <p>4.c. Name of nephrologist: _____</p>
<p>5. Is the patient enrolled in hospice?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown</p>

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ATTACHMENT A: TABLES

Table 1. Measure Performance, Submitted vs. Reabstracted Data, Facility Setting

MEASURE	SUBMITTED DATA	REABSTRACTED DATA
Functional AVF or Evaluation by Vascular Surgeon for Placement	82.7% (162 of 196)	84.7% (166 of 196)

Table 2. Measure Aggregate Reliability, Facility Setting

MEASURE	Y/Y	Y/N	N/Y	N/N	KAPPA	95% CI
Functional AVF or Evaluation by Vascular Surgeon for Placement	161	5	1	29	0.8880	0.7484-1.000

X/Z=aditor/facility so that Y/N are false negatives and N/Y are false positives

Table 3. Measure Reliability Percentage and Error Type, Facility Setting

MEASURE	REABSTRACTION UNIVERSE	TOTAL DISCORDANCE	RELIABILITY PERCENTAGE	DISCORDANCE CODES*							
				1	2	3	4	5	6	7	
Functional AVF or Evaluation by Vascular Surgeon for Placement	196	6	96.9%	1	5						

* Reason for Discrepancies: 1=Data entry/transcription error; 2=Information missed; 3=Illegible document; 4=Conflicting information; 5=Unclear element definition; 6=Not following definition; 7=Other/not determined.

Table 4. Kappa Statistics with Confidence Intervals, Physician Office Setting

MEASURE	Y/Y	Y/N	N/Y	N/N	KAPPA	95% CI
Functional AVF Access or Evaluation by Vascular Surgeon for Placement	70	4	0	33	0.9152	0.8340-0.9964

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CALCULATION ALGORITHM

The measure score is calculated by dividing the total number of patients included in the numerator by the total number of patients included in the denominator.

IDENTIFICATION OF DENOMINATOR CASES

To identify patients in the denominator, first calculate the following:

- Patient age = (Date of first day of most recent month of study period)– (Patient’s Date of Birth)
- Patient time on dialysis = (Date of first day of most recent month of study period)–(Patient’s Date Regular Chronic Dialysis Began)

Include in the denominator all patients for a given nephrologist who meet the following criteria in the most recent month of the 12-month study period:

1. Diagnosis = ESRD
AND
2. Primary type of dialysis = hemodialysis or home hemodialysis
AND
3. Age = ≥ 18 years
AND
4. Time on dialysis = > 90 days

IDENTIFICATION OF NUMERATOR CASES

Include in the numerator all patients from the denominator who meet the following criteria:

1. Access type = AVF with 2 needles
OR
1. Access type (select one):
 - AV fistula combined with an AV graft
 - AV fistula with a catheter
 - AV graft with 2 needles
 - AV graft combined with a catheter
 - Catheter
 - Other/unknown

AND

2. Patient referred to a vascular surgeon or other surgeon qualified in the area of vascular access for an AVF during the 12-month reporting period

AND

3. Patient seen/evaluated by a vascular surgeon or other surgeon qualified in the area of vascular access for an AVF during the 12-month reporting period

AND

4. Facility medical records contain the following types of documentation of the surgical evaluation:
 - A note or letter prepared by the nephrologist OR
 - A note or letter prepared by the vascular or other qualified surgeon OR
 - A note prepared by facility personnel

AND

- Date of the surgical evaluation: (MM/YYYY)

AND

- If permanent access was not placed, the reason for this decision

MEASURE SCORE CALCULATION

Performance Rate = (Patients with a functional AVF + Patients without a functional AVF who have been seen/evaluated by a vascular or other surgeon qualified in the area of vascular access for a functional AVF during the 12-month reporting period WITH documentation of the evaluation in the facility medical records) ÷ (Total ESRD patients \geq 18 years of age receiving HD during the 12-month reporting period and on dialysis >90 days)

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DATA DICTIONARY

The necessary data elements for the Vascular Access—Functional AVF or Evaluation by Vascular Surgeon for Placement measure are to be collected via the CMS CROWNWeb data repository when functional. With the release of the new CPT-II codes, it appears the measure could perhaps be collected using administrative data—CPT and ICD-9 and ICD-10 codes—which are supplied here; the measure has not been tested in this manner.

Diagnosis/Procedure	ICD-9 Codes	ICD-10 Codes	G Codes	CPT Codes	E/M Codes
DENOMINATOR					
ESRD	585.6				
Hemodialysis/Home Hemodialysis			G0312, G0315, G0316, G0317, G1308	Procedure codes: 90935, 90937	
NUMERATOR					
AVF with 2 needles				CPT II: 4052F	
AVF with catheter				CPT II: 4054F	
AVF with AV graft				CPT II: 4053F	
AV Graft with 2 needles				CPT II: 4053F	
AV Graft with catheter				CPT II: 4054F	
Catheter				CPT II: 4054F	
Referral to vascular or other surgeon for AVF				CPT II: 4051F	
Seen/evaluated by vascular or other surgeon for AVF					99241-99245