NATIONAL QUALITY FORUM

Measure Evaluation 4.1
December 2009

This form contains the measure information submitted by stewards. Blank fields indicate no information was provided. Attachments also may have been submitted and are provided to reviewers. The subcriteria and most of the footnotes from the evaluation criteria are provided in Word comments within the form and will appear if your cursor is over the highlighted area. Hyperlinks to the evaluation criteria and ratings are provided in each section.

TAP/Workgroup (if utilized)**:** Complete all yellow highlighted areas of the form. Evaluate the extent to which each subcriterion is met. Based on your evaluation, summarize the strengths and weaknesses in each section.

Note: *If there is no TAP or workgroup, the SC also evaluates the subcriteria (yellow highlighted areas).*

Steering Committee: Complete all pink highlighted areas of the form. Review the workgroup/TAP assessment of the subcriteria, noting any areas of disagreement; then evaluate the extent to which each major criterion is met; and finally, indicate your recommendation for the endorsement. Provide the rationale for your ratings.

Evaluation ratings of the extent to which the criteria are met
C = Completely (unquestionably demonstrated to meet the criterion)
P = Partially (demonstrated to partially meet the criterion)
M = Minimally (addressed BUT demonstrated to only minimally meet the criterion)
N = Not at all (NOT addressed; OR incorrectly addressed; OR demonstrated to NOT meet the criterion)
NA = Not applicable (only an option for a few subcriteria as indicated)

(for NQF staff use) **NQF Review #:** 1455 **NQF Project:** End Stage Renal Disease
MEASURE DESCRIPTIVE INFORMATION
De.1 **Measure Title:** Access-related Bacteremia - using Medicare claims (rate)
De.2 **Brief description of measure***:* Overall access-related bacteremia: Six-month rolling average rate of access-related bacteremia among adult chronic hemodialysis (HD) patients (Express as: rate per 1000 HD patient days) Specific access types: Six-month rolling average rate of fistula/graft/catheter-related bacteremia among adult chronic hemodialysis (HD) patients using a fistula/graft/catheter for HD access (Express as: rate per 1000 days of fistula/graft/catheter use)
1.1-2 **Type of Measure:** Process De.3 **If included in a composite or paired with another measure, please identify composite or paired measure**
De.4 **National Priority Partners Priority Area:** Population health De.5 **IOM Quality Domain**: Safety De.6 **Consumer Care Need:** Living with illness

CONDITIONS FOR CONSIDERATION BY NQF	
Four conditions must be met before proposed measures may be considered and evaluated for suitability as voluntary consensus standards:	**NQF Staff**
A. The measure is in the public domain or an intellectual property (measure steward agreement) is signed. *Public domain only applies to governmental organizations. All non-government organizations must sign a measure steward agreement even if measures are made publicly and freely available.* A.1 **Do you attest that the measure steward holds intellectual property rights to the measure and the right to use aspects of the measure owned by another entity (e.g., risk model, code set)?** Yes A.2 **Indicate if Proprietary Measure** (*as defined in measure steward agreement*)**:** A.3 **Measure Steward Agreement:** Government entity and in the public domain - no agreement necessary	**A** **Y**☐ **N**☐

A.4 Measure Steward Agreement attached:	
B. The measure owner/steward verifies there is an identified responsible entity and process to maintain and update the measure on a schedule that is commensurate with the rate of clinical innovation, but at least every 3 years. Yes, information provided in contact section	**B** Y☐ N☐
C. The intended use of the measure includes both public reporting and quality improvement. ►**Purpose:** Public reporting, Internal quality improvement	**C** Y☐ N☐
D. The requested measure submission information is complete. Generally, measures should be fully developed and tested so that all the evaluation criteria have been addressed and information needed to evaluate the measure is provided. Measures that have not been tested are only potentially eligible for a time-limited endorsement and in that case, measure owners must verify that testing will be completed within 12 months of endorsement. D.1**Testing:** No, testing will be completed within 12 months D.2 **Have NQF-endorsed measures been reviewed to identify if there are similar or related measures?** Yes	**D** Y☐ N☐
(for NQF staff use) **Have all conditions for consideration been met?** **Staff Notes to Steward** (*if submission returned*)**:**	**Met** Y☐ N☐
Staff Notes to Reviewers (*issues or questions regarding any criteria*)**:**	
Staff Reviewer Name(s):	

TAP/Workgroup Reviewer Name:	
Steering Committee Reviewer Name:	
1. IMPORTANCE TO MEASURE AND REPORT	
Extent to which the specific measure focus is important to making significant gains in health care quality (safety, timeliness, effectiveness, efficiency, equity, patient-centeredness) and improving health outcomes for a specific high impact aspect of healthcare where there is variation in or overall poor performance. *Measures must be judged to be important to measure and report in order to be evaluated against the remaining criteria.* (evaluation criteria) **1a. High Impact**	**Eval Rating**
(for NQF staff use) **Specific NPP goal**:	
1a.1 **Demonstrated High Impact Aspect of Healthcare:** Affects large numbers, Leading cause of morbidity/mortality, Severity of illness, Patient/societal consequences of poor quality 1a.2 1a.3 **Summary of Evidence of High Impact:** Reducing dialysis access-related infection rates are expected to have a high impact on reducing health care costs, and moreover, improve patient survival and patient quality of life by decreasing the occurrence of life-threatening sepsis events which are one of the possible consequences of a dialysis access-related infection. Use of various insertion/exit site disinfection procedures and various anti-microbial lock solutions in the care of catheters along with other vascular access-related infection control practices have led to substantially reduced rates of access-related infection in numerous studies [1-45]. Routinely monitoring access-related infection rates by vascular access type will provide important feedback to dialysis facilities, health policy makers, and infection control experts regarding the effectiveness of ongoing infection control practices and impact of future changes in practice upon these types of infection rates. 1a.4 **Citations for Evidence of High Impact:** 1)Weijmer MC, Vervloet MG, ter Wee PM. Prospective follow-up of a novel design haemodialysis catheter; lower infection rates and improved survival. Nephrol Dial Transplant 2008; 23:977-983.	**1a** C☐ P☐ M☐ N☐

Comment [KP1]: 1a. The measure focus addresses:
•a specific national health goal/priority identified by NQF's National Priorities Partners; OR
•a demonstrated high impact aspect of healthcare (e.g., affects large numbers, leading cause of morbidity/mortality, high resource use (current and/or future), severity of illness, and patient/societal consequences of poor quality).

2) Collins AJ, Foley RN, Herzog C, Chavers BM, Gilbertson D, Ishani A, et al. Excerpts from the US Renal Data System 2009 Annual Data Report. Am J Kidney Dis; 55:S1-420, A426-427.
3) Lok CE. Avoiding trouble down the line: the management and prevention of hemodialysis catheter-related infections. Adv Chronic Kidney Dis 2006; 13:225-244.
4) Lok CE, Appleton D, Bhola C, Khoo B, Richardson RM. Trisodium citrate 4%--an alternative to heparin capping of haemodialysis catheters. Nephrol Dial Transplant 2007; 22:477-483.
5) Rabindranath KS, Bansal T, Adams J, Das R, Shail R, MacLeod AM, et al. Systematic review of antimicrobials for the prevention of haemodialysis catheter-related infections. Nephrol Dial Transplant 2009; 24:3763-3774.
6) Peterson WJ, Maya ID, Carlton D, Estrada E, Allon M. Treatment of dialysis catheter-related Enterococcus bacteremia with an antibiotic lock: a quality improvement report. Am J Kidney Dis 2009; 53:107-111.
7) Beathard GA. Catheter management protocol for catheter-related bacteremia prophylaxis. Semin Dial 2003; 16:403-405.
8) Allon M. Prophylaxis against dialysis catheter-related bacteremia with a novel antimicrobial lock solution. Clin Infect Dis 2003; 36:1539-1544.
9) Allon M. Prophylaxis against dialysis catheter-related bacteremia: a glimmer of hope. Am J Kidney Dis 2008; 51:165-168.
10) Allon M. Treatment guidelines for dialysis catheter-related bacteremia: an update. Am J Kidney Dis 2009; 54:13-17.
11) Weijmer MC, van den Dorpel MA, Van de Ven PJ, ter Wee PM, van Geelen JA, Groeneveld JO, et al. Randomized, clinical trial comparison of trisodium citrate 30% and heparin as catheter-locking solution in hemodialysis patients. J Am Soc Nephrol 2005; 16:2769-2777.
12) Taylor G, Gravel D, Johnston L, Embil J, Holton D, Paton S. Prospective surveillance for primary bloodstream infections occurring in Canadian hemodialysis units. Infect Control Hosp Epidemiol 2002; 23:716-720.
13) Klevens RM, Edwards JR, Andrus ML, Peterson KD, Dudeck MA, Horan TC. Dialysis Surveillance Report: National Healthcare Safety Network (NHSN)-data summary for 2006. Semin Dial 2008; 21:24-28.
14) George A, Tokars JI, Clutterbuck EJ, Bamford KB, Pusey C, Holmes AH. Reducing dialysis associated bacteraemia, and recommendations for surveillance in the United Kingdom: prospective study. BMJ 2006; 332:1435.
15) Winnett G, Nolan J, Miller M, Ashman N. Trisodium citrate 46.7% selectively and safely reduces staphylococcal catheter-related bacteraemia. Nephrol Dial Transplant 2008; 23:3592-3598.
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17) Zhang P, Yuan J, Tan H, Lv R, Chen J. Successful prevention of cuffed hemodialysis catheter-related infection using an antibiotic lock technique by strictly catheter-restricted antibiotic lock solution method. Blood Purif 2009; 27:206-211.
18) Saxena AK, Panhotra BR, Sundaram DS, Al-Hafiz A, Naguib M, Venkateshappa CK, et al. Tunneled catheters´ outcome optimization among diabetics on dialysis through antibiotic-lock placement. Kidney Int 2006; 70:1629-1635.
19) Saxena AK, Panhotra BR, Sundaram DS, Morsy MN, Al-Ghamdi AM. Enhancing the survival of tunneled haemodialysis catheters using an antibiotic lock in the elderly: a randomised, double-blind clinical trial. Nephrology (Carlton) 2006; 11:299-305.
20) Shanks RM, Sargent JL, Martinez RM, Graber ML, O´Toole GA. Catheter lock solutions influence staphylococcal biofilm formation on abiotic surfaces. Nephrol Dial Transplant 2006; 21:2247-2255.
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24) Maharaj AR, Zelenitsky SA, Vercaigne LM. Effect of an ethanol/trisodium citrate hemodialysis catheter locking solution on isolates of Candida albicans. Hemodial Int 2008; 12:342-347.
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26) Manierski C, Besarab A. Antimicrobial locks: putting the lock on catheter infections. Adv Chronic Kidney Dis 2006; 13:245-258.
27) Maya ID, Carlton D, Estrada E, Allon M. Treatment of dialysis catheter-related Staphylococcus aureus bacteremia with an antibiotic lock: a quality improvement report. Am J Kidney Dis 2007; 50:289-295.
28) McCann M, Moore ZE. Interventions for preventing infectious complications in haemodialysis patients with central venous catheters. Cochrane Database Syst Rev:CD006894.
29) Lok CE, Stanley KE, Hux JE, Richardson R, Tobe SW, Conly J. Hemodialysis infection prevention with polysporin ointment. J Am Soc Nephrol 2003; 14:169-179.
30) Jaffer Y, Selby NM, Taal MW, Fluck RJ, McIntyre CW. A meta-analysis of hemodialysis catheter locking solutions in the prevention of catheter-related infection. Am J Kidney Dis 2008; 51:233-241.
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32) Johnson DW, van Eps C, Mudge DW, Wiggins KJ, Armstrong K, Hawley CM, et al. Randomized, controlled trial of topical exit-site application of honey (Medihoney) versus mupirocin for the prevention of catheter-associated infections in hemodialysis patients. J Am Soc Nephrol 2005; 16:1456-1462.
33) Katneni R, Hedayati SS. Central venous catheter-related bacteremia in chronic hemodialysis patients: epidemiology and evidence-based management. Nat Clin Pract Nephrol 2007; 3:256-266.
34) Kim SH, Song KI, Chang JW, Kim SB, Sung SA, Jo SK, et al. Prevention of uncuffed hemodialysis catheter-related bacteremia using an antibiotic lock technique: a prospective, randomized clinical trial. Kidney Int 2006; 69:161-164.
35) Kritchevsky SB, Braun BI, Kusek L, Wong ES, Solomon SL, Parry MF, et al. The impact of hospital practice on central venous catheter associated bloodstream infection rates at the patient and unit level: a multicenter study. Am J Med Qual 2008; 23:24-38.
36) Labriola L, Crott R, Jadoul M. Preventing haemodialysis catheter-related bacteraemia with an antimicrobial lock solution: a meta-analysis of prospective randomized trials. Nephrol Dial Transplant 2008; 23:1666-1672.
37) Grudzinski L, Quinan P, Kwok S, Pierratos A. Sodium citrate 4% locking solution for central venous dialysis catheters--an effective, more cost-efficient alternative to heparin. Nephrol Dial Transplant 2007; 22:471-476.
38) Bleyer AJ. Use of antimicrobial catheter lock solutions to prevent catheter-related bacteremia. Clin J Am Soc Nephrol 2007; 2:1073-1078.
39) Broom JK, O´Shea S, Govindarajulu S, Playford EG, Hawley CM, Isbel NM, et al. Rationale and design of the HEALTHY-CATH trial: a randomised controlled trial of Heparin versus EthAnol Lock THerapY for the prevention of Catheter Associated infecTion in Haemodialysis patients. BMC Nephrol 2009; 10:23.
40) Chiou PF, Chang CC, Wen YK, Yang Y. Antibiotic lock technique reduces the incidence of temporary catheter-related infections. Clin Nephrol 2006; 65:419-422.
41) Abbas SA, Haloob IA, Taylor SL, Curry EM, King BB, Van der Merwe WM, et al. Effect of antimicrobial locks for tunneled hemodialysis catheters on bloodstream infection and bacterial resistance: a quality improvement report. Am J Kidney Dis 2009; 53:492-502.
42) Al-Hwiesh AK. Tunneled catheter-antibiotic lock therapy for prevention of dialysis catheter-related infections: a single center experience. Saudi J Kidney Dis Transpl 2008; 19:593-602.
43) Al-Hwiesh AK, Abdul-Rahman IS. Successful prevention of tunneled, central catheter infection by antibiotic lock therapy using vancomycin and gentamycin. Saudi J Kidney Dis Transpl 2007; 18:239-247.
44) Altman SD, Ross JJ, Work J. Reducing catheter infections through use of the CD-1000: a retrospective review of a unique catheter specific composite dressing. J Vasc Access 2008; 9:236-240.
45) Aslam S, Trautner BW, Ramanathan V, Darouiche RO. Pilot trial of N-acetylcysteine and tigecycline as a catheter-lock solution for treatment of hemodialysis catheter-associated bacteremia. Infect Control Hosp Epidemiol 2008; 29:894-897.

1b. Opportunity for Improvement

1b.1 Benefits (improvements in quality) envisioned by use of this measure: Infection is known to be the second leading cause of mortality among dialysis patients, and is associated with high costs and high morbidity. However, monitoring infection rates across dialysis facilities has been lacking. By measuring access-related bacteremia, dialysis facilities and quality improvement organizations will be able to more accurately characterize the nature and severity of infections on a national level and implement quality improvement programs for reducing infection rates which are expected to result in improved survival, quality of life, and reduced morbidity and health care costs for dialysis patients.

1b
C☐
P☐
M☐
N☐

Comment [KP2]: 1b. Demonstration of quality problems and opportunity for improvement, i.e., data demonstrating considerable variation, or overall poor performance, in the quality of care across providers and/or population groups (disparities in care).

1b.2 Summary of data demonstrating performance gap (variation or overall poor performance) across providers:
Preliminary analyses of Centers for Medicare & Medicaid Services (CMS) claims data show large variation in access-related infection across United States (US) dialysis facilities.

1b.3 Citations for data on performance gap:
1) Klevens RM, Edwards JR, Andrus ML, Peterson KD, Dudeck MA, Horan TC. Dialysis Surveillance Report: National Healthcare Safety Network (NHSN)-data summary for 2006. Semin Dial 2008; 21:24-28.
2) Kallen AJ, Arduino MJ, Patel PR. Preventing infections in patients undergoing hemodialysis. Expert Rev Anti Infect Ther. 2010 Jun;8(6):643-55.

1b.4 Summary of Data on disparities by population group:
N/A

1b.5 Citations for data on Disparities:
N/A

1c. Outcome or Evidence to Support Measure Focus

1c.1 Relationship to Outcomes (*For non-outcome measures, briefly describe the relationship to desired outcome. For outcomes, describe why it is relevant to the target population*)**:** This measure was proposed to base some of the calculations in the hemodialysis vascular access-related measure group only upon those cases in which the blood culture is positive for an infection. This more specific measure of bacteremia will provide meaningful comparisons over time within and between dialysis units. Furthermore, infections resulting in bacteremia often represent more severe infections with greater potential for major adverse outcomes than seen in non-bacteremic infections and therefore are another important reason for specific monitoring of this important subset of infections. In addition, routinely monitoring infection rates will provide important feedback to dialysis facilities, health policy makers, and infection-control experts regarding the effectiveness of ongoing infection control practices and impact of future changes in practice upon these types of infection rates.

1c.2-3. Type of Evidence: Cohort study, Observational study, Evidence-based guideline, Randomized controlled trial, Meta-analysis

1c.4 Summary of Evidence (*as described in the criteria; for outcomes, summarize any evidence that healthcare services/care processes influence the outcome*)**:**
A large body of literature exists showing strong associations between central venous catheter use in HD patients with poorer survival and greater morbidity [1-40]. Recent studies have shown a nearly 20% higher hazard of mortality for every 20% higher facility % catheter use [2]. The prevalence of numerous patient comorbidity indicators was similar in facilities with high versus low catheter use. Lower mortality has been observed with reduction in catheter use in facility- and patient-level access use studies [7, 10, 13, 40, 41]. Furthermore, much of the 30-40% higher case-mix adjusted mortality rate for US HD patients compared to those in several European countries appears to be explained by differences in vascular access use between these two regions [2]. Rates of access-related infection, including septicemia, have been shown to be substantially higher for patients dialyzing with a central venous catheter versus an arteriovenous fistula or graft [2, 5, 9, 14, 19, 28, 34, 36, 42, 43]. Access-related septicemia is strongly associated with poor survival, high rates of hospitalization, and high treatment costs (>$25,000 per episode) [9, 15, 18-20, 27, 44-48]. Numerous clinical trials have demonstrated large variability in access-related infection rates among facilities treating HD patients, while demonstrating large reductions in access-related infection rates through quality improvement programs focused on using certain anti-microbial lock solutions and/or other access-related infection control regimens [38, 49-91]. These trials provide strong evidence that access-related infection rates are modifiable with the possibility to reduce high rates of access-related infection to substantially lower levels. Several HD guideline committees and health care agencies have developed recommendations for either catheter use and/or access-related infection rates [92-96].

1c.5 Rating of strength/quality of evidence (*also provide narrative description of the rating and by whom***):**
The evidence pertinent to this area for quality measure monitoring is of high quantity, moderate quality,

1c
C ☐
P ☐
M ☐
N ☐

Rating: C=Completely; P=Partially; M=Minimally; N=Not at all; NA=Not applicable

Comment [k3]: 1 Examples of data on opportunity for improvement include, but are not limited to: prior studies, epidemiologic data, measure data from pilot testing or implementation. If data are not available, the measure focus is systematically assessed (e.g., expert panel rating) and judged to be a quality problem.

Comment [k4]: 1c. The measure focus is:
•an outcome (e.g., morbidity, mortality, function, health-related quality of life) that is relevant to, or associated with, a national health goal/priority, the condition, population, and/or care being addressed;
OR
•if an intermediate outcome, process, structure, etc., there is **evidence** that supports the specific measure focus as follows:
oIntermediate outcome – evidence that the measured intermediate outcome (e.g., blood pressure, Hba1c) leads to improved health/avoidance of harm or cost/benefit.
oProcess – evidence that the measured clinical or administrative process leads to improved health/avoidance of harm and
if the measure focus is on one step in a multi-step care process, it measures the step that has the greatest effect on improving the specified desired outcome(s).
oStructure – evidence that the measured structure supports the consistent delivery of effective processes or access that lead to improved health/avoidance of harm or cost/benefit.
oPatient experience – evidence that an association exists between the measure of patient experience of health care and th ... [1]

Comment [k5]: 4 Clinical care processes typically include multiple steps: assess → identify problem/potential problem → choose/plan intervention (with patient input) → provide intervention → evaluate impact on health status. If the measure focus is one step in such a multi-step process, the step with the greatest effect on the desired outcome should be selected as the focus of measurement. For example, although assessment of immunization status and recommending immunization are necessary steps, they are not sufficient to achieve the desired impact on health status – patients must be vaccinated to achieve immunity. This does not preclude consideration of measures of preventive screening interventions where there is a ... [2]

Comment [k6]: 3 The strength of the body of evidence for the specific measure focus should be systematically assessed and rated (e.g., USPSTF grading system http://www.ahrq.gov/clinic/uspstf07/methods/benefit.htm). If the USPSTF grading system was not used, the grading system is explained including how it relates to the USPSTF grades or why it does not. However, evidence is not limited to quantitative studies and the best type of evidence depends upon the question being studied (e.g., randomized controlled trials appropriate for studying drug efficacy are not well suited for complex system changes). When qualitative studies are used, appropriate qualitative research criteria are used to judge the strength of the evidence.

and of moderate to high consistency based on a review of the literature and overviews of this subject area during guideline development by National Kidney Foundation (NKF) Kidney Disease Outcomes Quality Initiative (KDOQI) and Centers for Disease Control (CDC) guideline committees. The magnitude and certainty of net benefit are expected to be moderate to high with low to no risks to patients in facilities reporting these data for purposes of quality measurement/monitoring.

1c.6 Method for rating evidence: United States Preventive Services Task Force (USPSTF) and Grading of Recommendations Assessment, Development, and Evaluation (GRADE)

1c.7 Summary of Controversy/Contradictory Evidence:

1c.8 Citations for Evidence (*other than guidelines***):**

1)Dhingra RK, Young EW, Hulbert-Shearon TE, Leavey SF, Port FK. Type of vascular access and mortality in U.S. hemodialysis patients. Kidney Int 2001; 60:1443-1451.
2) Pisoni RL, Arrington CJ, Albert JM, Ethier J, Kimata N, Krishnan M, et al. Facility hemodialysis vascular access use and mortality in countries participating in DOPPS: an instrumental variable analysis. Am J Kidney Dis 2009; 53:475-491.
3) Polkinghorne KR, McDonald SP, Atkins RC, Kerr PG. Vascular access and all-cause mortality: a propensity score analysis. J Am Soc Nephrol 2004; 15:477-486.
4) Pastan S, Soucie JM, McClellan WM. Vascular access and increased risk of death among hemodialysis patients. Kidney Int 2002; 62:620-626.
5) Combe C, Pisoni RL, Port FK, Young EW, Canaud B, Mapes DL, et al. [Dialysis Outcomes and Practice Patterns Study: data on the use of central venous catheters in chronic hemodialysis]. Nephrologie 2001; 22:379-384.
6) Xue JL, Dahl D, Ebben JP, Collins AJ. The association of initial hemodialysis access type with mortality outcomes in elderly Medicare ESRD patients. Am J Kidney Dis 2003; 42:1013-1019.
7) Allon M, Daugirdas J, Depner TA, Greene T, Ornt D, Schwab SJ. Effect of change in vascular access on patient mortality in hemodialysis patients. Am J Kidney Dis 2006; 47:469-477.
8) Astor BC, Eustace JA, Powe NR, Klag MJ, Fink NE, Coresh J. Type of vascular access and survival among incident hemodialysis patients: the Choices for Healthy Outcomes in Caring for ESRD (CHOICE) Study. J Am Soc Nephrol 2005; 16:1449-1455.
9) Lacson E, Jr., Wang W, Hakim RM, Teng M, Lazarus JM. Associates of mortality and hospitalization in hemodialysis: potentially actionable laboratory variables and vascular access. Am J Kidney Dis 2009; 53:79-90.
10) Lacson E, Jr., Wang W, Lazarus JM, Hakim RM. Change in vascular access and mortality in maintenance hemodialysis patients. Am J Kidney Dis 2009; 54:912-921.
11) Lacson E, Jr., Wang W, Lazarus JM, Hakim RM. Hemodialysis facility-based quality-of-care indicators and facility-specific patient outcomes. Am J Kidney Dis 2009; 54:490-497.
12) Lacson E, Jr., Lazarus JM, Himmelfarb J, Ikizler TA, Hakim RM. Balancing Fistula First with Catheters Last. Am J Kidney Dis 2007; 50:379-395.
13) Bradbury BD, Chen F, Furniss A, Pisoni RL, Keen M, Mapes D, et al. Conversion of vascular access type among incident hemodialysis patients: description and association with mortality. Am J Kidney Dis 2009; 53:804-814.
14) Collins AJ, Foley RN, Gilbertson DT, Chen SC. The state of chronic kidney disease, ESRD, and morbidity and mortality in the first year of dialysis. Clin J Am Soc Nephrol 2009; 4 Suppl 1:S5-11.
15) Goncalves EA, Andreoli MC, Watanabe R, Freitas MC, Pedrosa AC, Manfredi SR, et al. Effect of temporary catheter and late referral on hospitalization and mortality during the first year of hemodialysis treatment. Artif Organs 2004; 28:1043-1049.
16) Hakim RM. Reducing early mortality in hemodialysis patients. Curr Opin Nephrol Hypertens 2008; 17:595-599.
17) Hakim RM, Himmelfarb J. Hemodialysis access failure: a call to action--revisited. Kidney Int 2009; 76:1040-1048.
18) Higuera F, Rosenthal VD, Duarte P, Ruiz J, Franco G, Safdar N. The effect of process control on the incidence of central venous catheter-associated bloodstream infections and mortality in intensive care units in Mexico. Crit Care Med 2005; 33:2022-2027.
19) Hung AM, Ikizler TA. Hemodialysis central venous catheters as a source of inflammation and its implications. Semin Dial 2008; 21:401-404.
20) Inrig JK, Reed SD, Szczech LA, Engemann JJ, Friedman JY, Corey GR, et al. Relationship between

clinical outcomes and vascular access type among hemodialysis patients with Staphylococcus aureus bacteremia. Clin J Am Soc Nephrol 2006; 1:518-524.
21) Inrig, J.K., et al., Mortality by dialysis modality among patients who have end-stage renal disease and are awaiting renal transplantation. Clin J Am Soc Nephrol, 2006. 1(4): p. 774-9.
22) Lee, T., J. Barker, and M. Allon, Tunneled catheters in hemodialysis patients: reasons and subsequent outcomes. Am J Kidney Dis, 2005. 46(3): p. 501-8.
23) Lorenzo, V., et al., Predialysis nephrologic care and a functioning arteriovenous fistula at entry are associated with better survival in incident hemodialysis patients: an observational cohort study. Am J Kidney Dis, 2004. 43(6): p. 999-1007.
24) Mendelssohn, D.C., et al., A practice-related risk score (PRS): a DOPPS-derived aggregate quality index for haemodialysis facilities. Nephrol Dial Transplant, 2008. 23(10): p. 3227-33.
25) Port, F.K., et al., DOPPS estimates of patient life years attributable to modifiable hemodialysis practices in the United States. Blood Purif, 2004. 22(1): p. 175-80.
26) Moist, L.M., et al., Increased hemodialysis catheter use in Canada and associated mortality risk: data from the Canadian Organ Replacement Registry 2001-2004. Clin J Am Soc Nephrol, 2008. 3(6): p. 1726-32.
27) Mokrzycki, M.H., et al., Tunnelled haemodialysis catheter bacteraemia: risk factors for bacteraemia recurrence, infectious complications and mortality. Nephrol Dial Transplant, 2006. 21(4): p. 1024-31.
28) Oliver, M.J., et al., Late creation of vascular access for hemodialysis and increased risk of sepsis. J Am Soc Nephrol, 2004. 15(7): p. 1936-42.
29) Ribot, S., S.W. Siddiqi, and C. Chen, Right heart complications of dual lumen tunneled venous catheters in hemodialysis patients. Am J Med Sci, 2005. 330(4): p. 204-8.
30) Sands, J.J., Increasing AV fistulae and decreasing dialysis catheters: two aspects of improving patient outcomes. Blood Purif, 2007. 25(1): p. 99-102.
31) Sands, J.J., Vascular access: the past, present and future. Blood Purif, 2009. 27(1): p. 22-7.
32) Sikaneta, T., et al., The Toronto Western Hospital catheter: one center´s experience and review of the literature. Int J Artif Organs, 2006. 29(1): p. 59-63.
33) Suresh, V., et al., Bacterial meningitis--complication from a dialysis catheter. Clin Nephrol, 2006. 65(6): p. 457-9.
34) Thomson, P.C., et al., Vascular access in haemodialysis patients: a modifiable risk factor for bacteraemia and death. QJM, 2007. 100(7): p. 415-22.
35) Siempos, II, et al., Impact of catheter-related bloodstream infections on the mortality of critically ill patients: a meta-analysis. Crit Care Med, 2009. 37(7): p. 2283-9.
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1c.9 Quote the Specific guideline recommendation (*including guideline number and/or page number***):**

1. Kidney Disease Outcomes Quality Initiative (KDOQI) Clinical Practice Guidelines for Vascular Access (2006) 8.3.3.1 Catheter complications/performance should be as follows: Tunneled catheter-related infection less than 10% at 3 months and less than 50% at 1 year. (B)

2. Centers for Disease Control and Prevention (CDC) Guidelines for Prevention of IV Catheter Related Infections (2002)
I. Surveillance
A. Conduct surveillance in ICUs and other patient populations to determine CRBSI rates, monitor trends in those rates, and assist in identifying lapses in infection control practices (3,12,16,247–

250). Category IA
B. Express ICU data as the number of catheter-associated BSIs per 1,000 catheter-days for both adults and children and stratify by birth weight categories for neonatal ICUs to facilitate comparisons with national data in comparable patient populations and healthcare settings (3,12,16,247–250). Category IB
C. Investigate events leading to unexpected life-threatening or fatal outcomes. This includes any process variation for which a recurrence would likely present an adverse outcome (13).

3. UK-Renal Association Guideline for Haemodialysis Vascular Access (2007)
Guideline 7.16- HD: Vascular access- All HD units should collect and audit data on the form of vascular access in use in incident and prevalent haemodialysis patients and the rates of bacteraemia per 1000 patient days using central venous catheters, arterio-venous grafts and arterio-venous fistulae.

1c.10 Clinical Practice Guideline Citation: 1) Kidney Disease: Improving Global Outcomes (KDIGO) Clinical Practice Guidelines for Vascular Access (2006)
http://www.kidney.org/professionals/kdoqi/guideline_uphd_pd_va/index.htm
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1c.11 National Guideline Clearinghouse or other URL: http://www.qualitymeasures.ahrq.gov

1c.12 Rating of strength of recommendation (*also provide narrative description of the rating and by whom***):**
The certainty of net benefit is moderate to high, and the magnitude of the net benefit is expected to be moderate to substantial yielding a USPSTF Grade B level of recommendation. This is consistent with strength of recommendations from the following: (1) National Kidney Foundation KDOQI guideline (2006) 8.3.3.1 (shown above): Rates the strength of this guideline recommendation as 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. (2) CDC for Surveillance (guidelines shown above): Rates the evidence for this guideline as Category IA. Strongly recommended for implementation and strongly supported by well-designed experimental, clinical, or epidemiologic studies.

1c.13 Method for rating strength of recommendation (*If different from USPSTF system, also describe rating and how it relates to USPSTF)***:**
USPSTF

1c.14 Rationale for using this guideline over others:
N/A

Comment [k7]: USPSTF grading system **http://www.ahrq.gov/clinic/uspstf/grades.htm**: **A -** The USPSTF recommends the service. There is high certainty that the net benefit is substantial. **B -** The USPSTF recommends the service. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial. **C -** The USPSTF recommends against routinely providing the service. There may be considerations that support providing the service in an individual patient. There is at least moderate certainty that the net benefit is small. Offer or provide this service only if other considerations support the offering or providing the service in an individual patient. **D -** The USPSTF recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits. **I -** The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.

TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for *Importance to Measure and Report?*	**1**
Steering Committee: Was the threshold criterion, *Importance to Measure and Report***, met?** **Rationale:**	**1** **Y☐** **N☐**
2. 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)	**Eval Rating**
2a. MEASURE SPECIFICATIONS	
S.1 Do you have a web page where current detailed measure specifications can be obtained? **S.2 If yes, provide web page URL:** **2a. Precisely Specified**	**2a-specs** **C☐** **P☐**
2a.1 Numerator Statement (*Brief, text description of the numerator - what is being measured about the target population, e.g. target condition, event, or outcome***):**	**M☐** **N☐**

Comment [KP8]: 2a. The measure is well defined and precisely specified so that it can be implemented consistently within and across organizations and allow for comparability. The required data elements are of high quality as defined by NQF's Health Information Technology Expert Panel (HITEP) .

Overall access-related bacteremia: For the months in the denominator, number of months in which a monthly hemodialysis claim reported an access-related bacteremia using HCPCS modifier V8.

Specific access types: For the months in the denominator, number of months in which a monthly hemodialysis claim reported an access-related bacteremia using HCPCS modifier V8 with the particular type of access (fistula/graft/catheter) as indicated by HCPCS modifiers V5, V6, or V7 for vascular access in use at the end of the preceding month.

2a.2 **Numerator Time Window (***The time period in which cases are eligible for inclusion in the numerator***):**
Six months ending with the current reporting month

2a.3 **Numerator Details (***All information required to collect/calculate the numerator, including all codes, logic, and definitions***):**
None

2a.4 **Denominator Statement (***Brief, text description of the denominator - target population being measured***):**
Overall access-related bacteremia: All adult (18+) chronic maintenance HD patient days during the six-month period ending with the current reporting month.

Specific access types: All adult (18+) chronic maintenance HD patient days during the six-month period ending with the current reporting month with the particular type of access (fistula/graft/catheter) as indicated by HCPCS modifiers V5, V6, or V7 for vascular access in use at the end of the preceding month.

2a.5 **Target population gender:** Female, Male
2a.6 **Target population age range:** Adults 18 years or older.

2a.7 **Denominator Time Window (***The time period in which cases are eligible for inclusion in the denominator***):**
Six months ending with the current reporting month.

2a.8 **Denominator Details (***All information required to collect/calculate the denominator - the target population being measured - including all codes, logic, and definitions***):**
None

2a.9 **Denominator Exclusions (***Brief text description of exclusions from the target population***):** HD patients < 18 yrs old.

2a.10 **Denominator Exclusion Details (***All information required to collect exclusions to the denominator, including all codes, logic, and definitions***):**
None

2a.11 **Stratification Details/Variables (***All information required to stratify the measure including the stratification variables, all codes, logic, and definitions***):**
As stated in numerator and denominator statements, this measure can be stratified by type of access (fistula/graft/catheter) as indicated by HCPCS modifiers V5, V6, or V7 for vascular access in use at the end of the preceding month.

2a.12-13 **Risk Adjustment Type:** No risk adjustment necessary

2a.14 **Risk Adjustment Methodology/Variables (***List risk adjustment variables and describe conceptual models, statistical models, or other aspects of model or method***):**
N/A

2a.15-17 **Detailed risk model available Web page URL or attachment:**

2a.18-19 **Type of Score:** Rate/proportion
2a.20 **Interpretation of Score:** Better quality = Lower score
2a.21 **Calculation Algorithm (***Describe the calculation of the measure as a flowchart or series of steps***):**
Count number of days at risk during reporting period for denominator based on Medicare dialysis facility claims for hemodialysis. Count number of patient-months with an infection reported using HCPCS modifier

Comment [k9]: 11 Risk factors that influence outcomes should not be specified as exclusions.
12 Patient preference is not a clinical exception to eligibility and can be influenced by provider interventions.

V8 for numerator.

2a.22 Describe the method for discriminating performance *(e.g., significance testing)*:
The performance of the facility will be compared to State, Network and National performance. Calculation of the facility-level measure will be performed by: (a) summing the numerator values for each reporting period-eligible facility patient to obtain a facility-level numerator sum, (b) summing the denominator values for each reporting period-eligible facility patient to obtain a facility-level denominator sum, and (c) dividing the facility-level numerator sum by the facility-level denominator and multiply the result by 1000 to obtain the number of infections per 1000 days.

2a.23 Sampling (Survey) Methodology *If measure is based on a sample (or survey), provide instructions for obtaining the sample, conducting the survey and guidance on minimum sample size (response rate)*:
N/A

2a.24 Data Source (*Check the source(s) for which the measure is specified and tested)*
Electronic administrative data/claims

2a.25 Data source/data collection instrument (*Identify the specific data source/data collection instrument, e.g. name of database, clinical registry, collection instrument, etc.***):**
Medicare claims

2a.26-28 Data source/data collection instrument reference web page URL or attachment: URL
www.cms.gov/MLNMattersArticles/downloads/MM6782.pdf

2a.29-31 Data dictionary/code table web page URL or attachment: URL
www.cms.gov/MLNMattersArticles/downloads/MM6782.pdf

2a.32-35 Level of Measurement/Analysis (*Check the level(s) for which the measure is specified and tested)*
Facility/Agency

2a.36-37 Care Settings (*Check the setting(s) for which the measure is specified and tested)*
Dialysis Facility

2a.38-41 Clinical Services (*Healthcare services being measured, check all that apply*)
Dialysis

TESTING/ANALYSIS

2b. Reliability testing

2b.1 Data/sample *(description of data/sample and size)*: N/A

2b.2 Analytic Method *(type of reliability & rationale, method for testing)*:
N/A

2b.3 Testing Results *(reliability statistics, assessment of adequacy in the context of norms for the test conducted)*:
N/A

2b
C☐
P☐
M☐
N☐

2c. Validity testing

2c.1 Data/sample *(description of data/sample and size)*: N/A

2c.2 Analytic Method *(type of validity & rationale, method for testing)*:
Face validity is the only validity assessed, therefore testing is not applicable.

2c.3 Testing Results *(statistical results, assessment of adequacy in the context of norms for the test conducted)*:
N/A

2c
C☐
P☐
M☐
N☐

Comment [KP10]: 2b. Reliability testing demonstrates the measure results are repeatable, producing the same results a high proportion of the time when assessed in the same population in the same time period.

Comment [k11]: 8 Examples of reliability testing include, but are not limited to: inter-rater/abstractor or intra-rater/abstractor studies; internal consistency for multi-item scales; test-retest for survey items. Reliability testing may address the data items or final measure score.

Comment [KP12]: 2c. Validity testing demonstrates that the measure reflects the quality of care provided, adequately distinguishing good and poor quality. If face validity is the only validity addressed, it is systematically assessed.

Comment [k13]: 9 Examples of validity testing include, but are not limited to: determining if measure scores adequately distinguish between providers known to have good or poor quality assessed by another valid method; correlation of measure scores with another valid indicator of quality for the specific topic; ability of measure scores to predict scores on some other related valid measure; content validity for multi-item scales/tests. Face validity is a subjective assessment by experts of whether the measure reflects the quality of care (e.g., whether the proportion of patients with BP < 140/90 is a marker of quality). If face validity is the only validity addressed, it is systematically assessed (e.g., ratings by relevant stakeholders) and the measure is judged to represent quality care for the specific topic and that the measure focus is the most important aspect of quality for the specific topic.

2d. Exclusions Justified

2d.1 **Summary of Evidence supporting exclusion(s):**
Measures are currently limited to HD patients since a separate expert panel will be convened in the future to develop infection-related measures for patients receiving peritoneal dialysis. The measure excludes HD patients < 18 years of age because there are too few pediatric HD patients treated in dialysis units to meaningfully calculate facility-level access-related infection rates.

2d.2 **Citations for Evidence:**
N/A

2d.3 **Data/sample** *(description of data/sample and size)*: N/A

2d.4 **Analytic Method** *(type analysis & rationale)*:
N/A

2d.5 **Testing Results** *(e.g., frequency, variability, sensitivity analyses)*:
N/A

2d C☐ P☐ M☐ N☐ NA☐

2e. Risk Adjustment for Outcomes/ Resource Use Measures

2e.1 **Data/sample** *(description of data/sample and size)*: N/A

2e.2 **Analytic Method** *(type of risk adjustment, analysis, & rationale)*:
N/A

2e.3 **Testing Results** *(risk model performance metrics)*:
N/A

2e.4 **If outcome or resource use measure is not risk adjusted, provide rationale:** There are no compelling reasons to risk adjust measure.

2e C☐ P☐ M☐ N☐ NA☐

2f. Identification of Meaningful Differences in Performance

2f.1 **Data/sample from Testing or Current Use** *(description of data/sample and size)*: N/A

2f.2 **Methods to identify statistically significant and practically/meaningfully differences in performance** *(type of analysis & rationale)*:
N/A

2f.3 **Provide Measure Scores from Testing or Current Use** *(description of scores, e.g., distribution by quartile, mean, median, SD, etc.; identification of statistically significant and meaningfully differences in performance)*:
N/A

2f C☐ P☐ M☐ N☐

2g. Comparability of Multiple Data Sources/Methods

2g.1 **Data/sample** *(description of data/sample and size)*: N/A

2g.2 **Analytic Method** *(type of analysis & rationale)*:
N/A

2g.3 **Testing Results** *(e.g., correlation statistics, comparison of rankings)*:
N/A

2g C☐ P☐ M☐ N☐ NA☐

2h. Disparities in Care

2h.1 **If measure is stratified, provide stratified results** *(scores by stratified categories/cohorts)*: N/A

2h.2 **If disparities have been reported/identified, but measure is not specified to detect disparities,**

2h C☐ P☐ M☐ N☐

Comment [KP14]: 2d. Clinically necessary measure exclusions are identified and must be:
•supported by evidence of sufficient frequency of occurrence so that results are distorted without the exclusion;
AND
•a clinically appropriate exception (e.g., contraindication) to eligibility for the measure focus;
AND
•precisely defined and specified:
–if there is substantial variability in exclusions across providers, the measure is specified so that exclusions are computable and the effect on the measure is transparent (i.e., impact clearly delineated, such as number of cases excluded, exclusion rates by type of exclusion);
if patient preference (e.g., informed decision-making) is a basis for exclusion, there must be evidence that it strongly impacts performance on the measure and the measure must be specified so that the information about p ... [3]

Comment [k15]: 10 Examples of evidence that an exclusion distorts measure results include, but are not limited to: frequency of occurrence, sensitivity analyses with and without the exclusion, and variability of exclusions across providers.

Comment [KP16]: 2e. For outcome measures and other measures (e.g., resource use) when indicated:
•an evidence-based risk-adjustment strategy (e.g., risk models, risk stratification) is specified and is based on patient clinical factors that influence the measured outc ... [4]

Comment [k17]: 13 Risk models should not obscure disparities in care for populations by including factors that are associated with differences/inequalities in care such as race, socioeconomic status, gender (e.g., poorer treatment outcomes of African American men with prostate cancer, inequalities in treatment for CVD risk factors between men and w ... [5]

Comment [KP18]: 2f. Data analysis demonstrates that methods for scoring and analysis of the specified measure allow for identification of statistically significant and practically/clinically meaningful differences in performance.

Comment [k19]: 14 With large enough sample sizes, small differences that are statistically significant may or may not be practically or clinically meaningful. The substantive question may be, for example, whether a statistically significant difference of one percentage point in the percentage of patients who received smoking cessation ... [6]

Comment [KP20]: 2g. If multiple data sources/methods are allowed, there is demonstration they produce comparable results.

Comment [KP21]: 2h. If disparities in care have been identified, measure specifications, scoring, and analysis allow for identification of disparities through stratification of results (e.g., by race, ethnicity, socioeconomic status, gender);OR rationale/data justifies why stratification is not necessary or not feasible.

provide follow-up plans: N/A	**NA**☐
TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for *Scientific Acceptability of Measure Properties?*	**2**
Steering Committee: Overall, to what extent was the criterion, *Scientific Acceptability of Measure Properties*, **met?** **Rationale:**	*2* **C**☐ **P**☐ **M**☐ **N**☐
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)	**Eval Rating**
3a. Meaningful, Understandable, and Useful Information 3a.1 **Current Use:** Testing not yet completed 3a.2 **Use in a public reporting initiative (disclosure of performance results to the public at large)** (*If used in a public reporting initiative, provide name of initiative(s), locations, Web page URL(s). If not publicly reported, state the plans to achieve public reporting within 3 years*)**:** Klevens RM, Edwards JR, Andrus ML, Peterson KD, Dudeck MA, Horan TC. Dialysis Surveillance Report: National Healthcare Safety Network (NHSN)-Data Summary for 2006. Seminars in Dialysis 2008;21 (1):24-28. 3a.3 **If used in other programs/initiatives (***If used in quality improvement or other programs/initiatives, name of initiative(s), locations, Web page URL(s). If not used for QI, state the plans to achieve use for QI within 3 years***):** Centers for Disease Control and Prevention (CDC) National Healthcare Safety Network (NHSN), Dialysis Event (DE) http://www.cdc.gov/nhsn/psc_da_de.html **Testing of Interpretability** (*Testing that demonstrates the results are understood by the potential users for public reporting and quality improvement*) 3a.4 **Data/sample** *(description of data/sample and size)***:** 32 dialysis facilities provided HD reported adverse events related to infection to the CDC in 2006. These facilities submitted data on 28,047 patient-months. 3a.5 **Methods** *(e.g., focus group, survey, QI project)***:** Staff from the participating dialysis facilities monitored and reported vascular access type, new IV antimicrobial starts and positive blood cultures for patients and entered data monthly into NHSN's reporting tool. The data were accumulated from all centers and analyzed at CDC. The definition of an access-associated bloodstream infection was a microorganism identified in a blood culture where the infection source was the vascular access site. A bloodstream infection was defined as a positive blood culture report, regardless of the infection source, and included access-associated bloodstream infections. The definition of vascular access infection was either a local access infection or an access-associated bloodstream infection. 3a.6 **Results** *(qualitative and/or quantitative results and conclusions)***:** The pooled mean rates of IV antibiotic starts among patients with arteriovenous fistulas, grafts, permanent and temporary central venous catheters were 1.8, 2.4, 6.4, and 25.4 per 100 patient-months, respectively. For bloodstream infection, the pooled mean rates were 0.5, 0.9, 4.2, and 27.1 per 100 patient-months and for access-related bloodstream infection, the pooled means were 0.2, 0.4, 3.1, and 17.8 in these groups. For vascular access infection, the pooled mean rates were 0.4, 0.9, 4.8, and 22.9 per 100 patient-months respectively.	**3a** **C**☐ **P**☐ **M**☐ **N**☐
3b/3c. Relation to other NQF-endorsed measures 3b.1 **NQF # and Title of similar or related measures:**	
(for NQF staff use) **Notes on similar/related endorsed or submitted measures:**	
3b. Harmonization	**3b**

Comment [KP22]: 3a. Demonstration that information produced by the measure is meaningful, understandable, and useful to the intended audience(s) for both public reporting (e.g., focus group, cognitive testing) and informing quality improvement (e.g., quality improvement initiatives). An important outcome that may not have an identified improvement strategy still can be useful for informing quality improvement by identifying the need for and stimulating new approaches to improvement.

Comment [KP23]: 3b. The measure specifications are harmonized with other measures, and are applicable to multiple levels and settings.

If this measure is related to measure(s) already endorsed by NQF (e.g., same topic, but different target population/setting/data source or different topic but same target population):
3b.2 Are the measure specifications harmonized? If not, why?

C☐ P☐ M☐ N☐ NA☐

3c. Distinctive or Additive Value

3c.1 Describe the distinctive, improved, or additive value this measure provides to existing NQF-endorsed measures:

5.1 If this measure is similar to measure(s) already endorsed by NQF (i.e., on the same topic and the same target population), Describe why it is a more valid or efficient way to measure quality:
N/A

3c
C☐ P☐ M☐ N☐ NA☐

TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for *Usability*?

3

Steering Committee: Overall, to what extent was the criterion, *Usability*, met?
Rationale:

3
C☐ P☐ M☐ N☐

4. FEASIBILITY

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

Eval Rating

4a. Data Generated as a Byproduct of Care Processes

4a.1-2 How are the data elements that are needed to compute measure scores generated?
Data generated as byproduct of care processes during care delivery (Data are generated and used by healthcare personnel during the provision of care, e.g., blood pressure, lab value, medical condition)

4a
C☐ P☐ M☐ N☐

4b. Electronic Sources

4b.1 Are all the data elements available electronically? (*elements that are needed to compute measure scores are in defined, computer-readable fields, e.g., electronic health record, electronic claims*)
Yes

4b.2 If not, specify the near-term path to achieve electronic capture by most providers.

4b
C☐ P☐ M☐ N☐

4c. Exclusions

4c.1 Do the specified exclusions require additional data sources beyond what is required for the numerator and denominator specifications?
No

4c.2 If yes, provide justification.

4c
C☐ P☐ M☐ N☐ NA☐

4d. Susceptibility to Inaccuracies, Errors, or Unintended Consequences

4d.1 Identify susceptibility to inaccuracies, errors, or unintended consequences of the measure and describe how these potential problems could be audited. If audited, provide results.
Facilities may not be aware of IV antibiotics prescribed if patients are hospitalized. Claims data may help with auditing of this. This measure requires physician input of whether infection was access-related which will have a degree of subjectivity.

4d
C☐ P☐ M☐ N☐

4e. Data Collection Strategy/Implementation

4e
C☐

Comment [k24]: 16 Measure harmonization refers to the standardization of specifications for similar measures on the same topic (e.g., *influenza immunization* of patients in hospitals or nursing homes), or related measures for the same target population (e.g., eye exam and HbA1c for *patients with diabetes*), or definitions applicable to many measures (e.g., age designation for children) so that they are uniform or compatible, unless differences are dictated by the evidence. The dimensions of harmonization can include numerator, denominator, exclusions, and data source and collection instructions. The extent of harmonization depends on the relationship of the measures, the evidence for the specific measure focus, and differences in data sources.

Comment [KP25]: 3c. Review of existing endorsed measures and measure sets demonstrates that the measure provides a distinctive or additive value to existing NQF-endorsed measures (e.g., provides a more complete picture of quality for a particular condition or aspect of healthcare, is a more valid or efficient way to measure).

Comment [KP26]: 4a. For clinical measures, required data elements are routinely generated concurrent with and as a byproduct of care processes during care delivery. (e.g., BP recorded in the electronic record, not abstracted from the record later by other personnel; patient self-assessment tools, e.g., depression scale; lab values, meds, etc.)

Comment [KP27]: 4b. The required data elements are available in electronic sources. If the required data are not in existing electronic sources, a credible, near-term path to electronic collection by most providers is specified and clinical data elements are specified for transition to the electronic health record.

Comment [KP28]: 4c. Exclusions should not require additional data sources beyond what is required for scoring the measure (e.g., numerator and denominator) unless justified as supporting measure validity.

Comment [KP29]: 4d. Susceptibility to inaccuracies, errors, or unintended consequences and the ability to audit the data items to detect such problems are identified.

Comment [KP30]: 4e. Demonstration that the data collection strategy (e.g., source, timing, frequency, sampling, patient confidentiality, etc.) can be implemented (e.g., already in operational use, or testing demonstrates that it is ready to put into operational use).

4e.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/frequency of data collection, patient confidentiality, time/cost of data collection, other feasibility/ implementation issues: Data elements were reviewed and input was received by a data technical expert panel which includes representatives from many types of US dialysis facilities. The proposed measures are based on feedback from this group regarding feasibility of data collection. **4e.2 Costs to implement the measure** (*costs of data collection, fees associated with proprietary measures*)**:** N/A **4e.3 Evidence for costs:** N/A **4e.4 Business case documentation:** Infection, particularly for those resulting in bacteremia in association with catheter use in dialysis patients, has been shown to be associated with high costs to the health care system. Reducing infection rates are expected to have a high impact on reducing health care costs.	**P☐ M☐ N☐**
TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for *Feasibility*?	**4**
Steering Committee: Overall, to what extent was the criterion, *Feasibility*, met? **Rationale:**	**4** **C☐ P☐ M☐ N☐**
RECOMMENDATION	
(for NQF staff use) **Check if measure is untested and only eligible for time-limited endorsement.**	**Time-limited ☐**
Steering Committee: Do you recommend for endorsement? **Comments:**	**Y☐ N☐ A☐**
CONTACT INFORMATION	
Co.1 Measure Steward (Intellectual Property Owner) **Co.1 Organization** Centers for Medicare and Medicaid, 7500 Security Boulevard, Baltimore, Maryland, 21244 **Co.2 Point of Contact** Thomas, Dudley, Thomas.Dudley@cms.hhs.gov, 410-786-1442-	
Measure Developer If different from Measure Steward **Co.3 Organization** Arbor Research/UM-KECC, 315 W. Huron, Suite 360, Ann Arbor, Michigan, 48103 **Co.4 Point of Contact** Adrienne, Janney, adrienne.janney@arborresearch.org, 734-665-4108-	
Co.5 Submitter If different from Measure Steward POC Thomas, Dudley, Thomas.Dudley@cms.hhs.gov, 410-786-1442-, Centers for Medicare and Medicaid	
Co.6 Additional organizations that sponsored/participated in measure development	
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. Dr. Michael Allon, expert panel chair (University of Alabama at Birmingham) Ms. Lesley Dinwiddie (Nephrology Nurse Consulting, Nurse Consultant) Dr. Eduardo Lacson (Fresenius Medical Care) Dr. Derrick Latos (Nephrology Associates, Inc., Forum of ESRD Networks) Dr. Charmaine Lok (Toronto General Research Institute, Toronto General Hospital) Dr. Ted Steinman (Beth Israel Hospital, Harvard Medical School) Dr. Daniel Weiner (Tufts Medical Center) Ms. Raynel Wilson (ESRD Network 9 & ESRD Network 10, The Renal Network, Inc.) Dr. Ronald Pisoni, moderator for contractor (Arbor Research Collaborative for Health) Ms. Natalie Lueth, analyst for contractor (University of Michigan KECC)
Ad.2 **If adapted, provide name of original measure:** Ad.3-5 **If adapted, provide original specifications URL or attachment**
Measure Developer/Steward Updates and Ongoing Maintenance Ad.6 **Year the measure was first released:** Ad.7 **Month and Year of most recent revision:** Ad.8 **What is your frequency for review/update of this measure?** Three years Ad.9 **When is the next scheduled review/update for this measure?** 2013
Ad.10 **Copyright statement/disclaimers:**
Ad.11 -13 **Additional Information web page URL or attachment:**
Date of Submission (*MM/DD/YY*)**:** 12/21/2010

Page 5: [1] Comment [k4] **Karen Pace** **10/5/2009 8:59:00 AM**

1c. The measure focus is:

- an outcome (e.g., morbidity, mortality, function, health-related quality of life) that is relevant to, or associated with, a national health goal/priority, the condition, population, and/or care being addressed;

OR

- if an intermediate outcome, process, structure, etc., there is **evidence** that supports the specific measure focus as follows:
  - Intermediate outcome – evidence that the measured intermediate outcome (e.g., blood pressure, Hba1c) leads to improved health/avoidance of harm or cost/benefit.
  - Process – evidence that the measured clinical or administrative process leads to improved health/avoidance of harm and
    if the measure focus is on one step in a multi-step care process, it measures the step that has the greatest effect on improving the specified desired outcome(s).
  - Structure – evidence that the measured structure supports the consistent delivery of effective processes or access that lead to improved health/avoidance of harm or cost/benefit.
  - Patient experience – evidence that an association exists between the measure of patient experience of health care and the outcomes, values and preferences of individuals/ the public.
  - Access – evidence that an association exists between access to a health service and the outcomes of, or experience with, care.
  - Efficiency – demonstration of an association between the measured resource use and level of performance with respect to one or more of the other five IOM aims of quality.

Page 5: [2] Comment [k5] **Karen Pace** **10/5/2009 8:59:00 AM**

4 Clinical care processes typically include multiple steps: assess → identify problem/potential problem → choose/plan intervention (with patient input) → provide intervention → evaluate impact on health status. If the measure focus is one step in such a multi-step process, the step with the greatest effect on the desired outcome should be selected as the focus of measurement. For example, although assessment of immunization status and recommending immunization are necessary steps, they are not sufficient to achieve the desired impact on health status – patients must be vaccinated to achieve immunity. This does not preclude consideration of measures of preventive screening interventions where there is a strong link with desired outcomes (e.g., mammography) or measures for multiple care processes that affect a single outcome.

Page 13: [3] Comment [KP14] **Karen Pace** **10/5/2009 8:59:00 AM**

2d. Clinically necessary measure exclusions are identified and must be:

- supported by evidence of sufficient frequency of occurrence so that results are distorted without the exclusion;

AND

- a clinically appropriate exception (e.g., contraindication) to eligibility for the measure focus;

AND

- precisely defined and specified:
  - if there is substantial variability in exclusions across providers, the measure is specified so that exclusions are computable and the effect on the measure is transparent (i.e., impact clearly delineated, such as number of cases excluded, exclusion rates by type of exclusion);

if patient preference (e.g., informed decision-making) is a basis for exclusion, there must be evidence that it strongly impacts performance on the measure and the measure must be specified so that the information about patient preference and the effect on the measure is transparent (e.g., numerator category computed separately, denominator exclusion category computed separately).

Page 13: [4] Comment [KP16] **Karen Pace** **10/5/2009 8:59:00 AM**

2e. For outcome measures and other measures (e.g., resource use) when indicated:

- an evidence-based risk-adjustment strategy (e.g., risk models, risk stratification) is specified and is based on patient clinical factors that influence the measured outcome (but not disparities in care) and are present at start of care;**Error! Bookmark not defined.** OR

rationale/data support no risk adjustment.

Page 13: [5] Comment [k17] **Karen Pace** **10/5/2009 8:59:00 AM**

13 Risk models should not obscure disparities in care for populations by including factors that are associated with differences/inequalities in care such as race, socioeconomic status, gender (e.g., poorer treatment outcomes of

Page 13: [6] Comment [k19] **Karen Pace** **10/5/2009 8:59:00 AM**

14 With large enough sample sizes, small differences that are statistically significant may or may not be practically or clinically meaningful. The substantive question may be, for example, whether a statistically significant difference of one percentage point in the percentage of patients who received smoking cessation counseling (e.g., 74% v. 75%) is clinically meaningful; or whether a statistically significant difference of $25 in cost for an episode of care (e.g., $5,000 v. $5,025) is practically meaningful. Measures with overall poor performance may not demonstrate much variability across providers.