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 #:** 1449 **NQF Project:** End Stage Renal Disease
MEASURE DESCRIPTIVE INFORMATION
De.1 **Measure Title:** Unavailable Blood Culture Results (percentage)
De.2 **Brief description of measure**: Six-month rolling average prevalence of "unavailable" blood culture results for adult chronic hemodialysis (HD) patients prescribed IV antibiotics (Express as: percentage)
1.1-2 **Type of Measure:** Structure/management 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.4 **Measure Steward Agreement attached:**	**A** **Y**☐ **N**☐
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:** Dialysis access-related infection, particularly for catheters, has been shown to be associated with high mortality and morbidity rates, and high costs to the health care system. 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]. Although nearly all of the other quality measures proposed in this area of care involve monitoring infection rates at dialysis units, this particular measure is important for monitoring the timeliness, efficiency, and level of complete reporting of infection-related measures by dialysis units. This measure will allow meaningful, reliable, and accurate national statistics to be obtained for the infection-related measures and will provide a mechanism for targeting improvements in reporting infection-related results for those dialysis units which may have high non-reporting rates. Studies have indicated that a surveillance program for bacteremia and serious infection in dialysis patients should fully involve the clinical staff and be embedded in routine daily practice with simple event driven data collection. Such a scheme when implemented in a dialysis unit has resulted in substantial reductions in bacteremia, admissions, and antibiotic usage [46]. It is likely that this proposed measure will have high impact in reliably measuring the rate of bacteremia since the latter is strongly related to mortality, morbidity, and health care costs and since the rate of infection varies greatly across	**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).

dialysis units. Thus this measure is intended as a quality control tool for monitoring and maintaining acceptable rates of infection-reporting by dialysis units and provide a means to control possible gaming of facility-level outcomes through non-reporting. This measure has been designed as a period prevalence over a 6 month period to provide for a stable estimate for the vast majority of US dialysis units. Routinely monitoring bacteremia will provide important feedback to dialysis facilities, health policy makers, and infection-control experts regarding the effectiveness of ongoing infection control practices.

The overall proposed scheme for monitoring dialysis access related infection in hemodialysis patients is described as follows:

Serious infections lead to higher hospitalization rates and poorer survival which both lead to high healthcare costs. There are three surrogate measures of serious infection: 1a) IV Antibiotic Therapy which is a surrogate for "suspected" serious infection, 1b) positive blood cultures or bacteremia, and 1c) clinical confirmation of infection. Methods of monitoring the rate of serious infection due to HD access practice include measuring the rate of 2a) clinically confirmed serious infections and 2b) serious infections with bacteremia by access type: AV fistulae, AV grafts and catheters.

1a.4 **Citations for Evidence of High Impact:** There are no studies specifically carried out regarding the relationship of monitoring the reporting of clinical confirmation of IV antibiotic therapy in dialysis patients with patient outcomes. However, there are numerous studies in the literature indicating that non-reporting of events is detrimental to being able to monitoring the occurrence of the events and instituting corrective measures. Below are examples of studies showing outcomes when infection rates have been monitored:

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.
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.
16) Yahav D, Rozen-Zvi B, Gafter-Gvili A, Leibovici L, Gafter U, Paul M. Antimicrobial lock solutions for

the prevention of infections associated with intravascular catheters in patients undergoing hemodialysis: systematic review and meta-analysis of randomized, controlled trials. Clin Infect Dis 2008; 47:83-93.
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.
21) Taylor C, Cahill J, Gerrish M, Little J. A new haemodialysis catheter-locking agent reduces infections in haemodialysis patients. J Ren Care 2008; 34:116-120.
22) Mokrzycki MH, Zhang M, Golestaneh L, Laut J, Rosenberg SO. An interventional controlled trial comparing 2 management models for the treatment of tunneled cuffed catheter bacteremia: a collaborative team model versus usual physician-managed care. Am J Kidney Dis 2006; 48:587-595.
23) Nori US, Manoharan A, Yee J, Besarab A. Comparison of low-dose gentamicin with minocycline as catheter lock solutions in the prevention of catheter-related bacteremia. Am J Kidney Dis 2006; 48:596-605.
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.
25) Mandolfo S, Borlandelli S, Elli A. Catheter lock solutions: it´s time for a change. J Vasc Access 2006; 7:99-102.
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.
31) James MT, Conley J, Tonelli M, Manns BJ, MacRae J, Hemmelgarn BR. Meta-analysis: antibiotics for prophylaxis against hemodialysis catheter-related infections. Ann Intern Med 2008; 148:596-605.
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.
46) 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.

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 unavailable blood culture results, 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.2 Summary of data demonstrating performance gap (variation or overall poor performance) across providers:
There are no preliminary data available specific to this measure. It is not known the extent to which patient or dialysis facility health records lack results of blood culture tests that have warranted IV antibiotic therapy.

1b.3 Citations for data on performance gap:
N/A

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

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

1b
C☐
P☐
M☐
N☐

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*)**:** Measuring new IV antibiotic therapy is a surrogate for suspected serious infection, such that measurement of the frequency of new IV antibiotic therapy will be used to help facilities monitor this indicator of serious infection and target ways to prevent and reduce infection which is the desired outcome. For these suspected serious infections that are indicated by IV antibiotic prescription, clinical confirmation will be used to determine the rate of confirmed infection. The proposed measure of determining the percentage of cases in which clinically confirmed infection is not available is directly related to determining the reliability of the outcome, which in this case is the rate of confirmed infection.
The proposed scheme described above provides an overview of the overall proposed scheme for monitoring dialysis access-related infection in HD patients, with this particular measure contributing to element 1c in this overall schema.

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

1c
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).

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 the outcomes, values and preferences of individuals/ the public.
oAccess – evidence that an association exists between access to a health service and the outcomes of, or experience with, care.
oEfficiency – 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.

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 strong link with desired outcomes (e.g., … [1]

controlled trial, Expert opinion, 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*)**:**
Dialysis access-related infection, particularly for catheters, has been shown to be associated with high mortality and morbidity rates, and high costs to the health care system. 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 [1-45]. Although nearly all of the other quality measures proposed in this area of care involve monitoring infection rates at dialysis units, this particular measure is important for monitoring the timeliness, efficiency, and level of complete reporting of infection-related measures by dialysis units. This measure will allow meaningful, reliable, and accurate national statistics to be obtained for the infection-related measures and will provide a mechanism for targeting improvements in reporting infection-related results for those dialysis units which may have high non-reporting rates. Studies have indicated that a surveillance program for bacteremia and serious infection in dialysis patients should fully involve the clinical staff and be embedded in routine daily practice with simple event driven data collection. Such a scheme when implemented in a dialysis unit has resulted in substantial reductions in bacteremia, admissions, and antibiotic usage. [46] It is likely that this proposed measure will have high impact in reliably measuring the rate of clinically confirmed infection since the latter is strongly related to mortality, morbidity, and health care costs and since the rate of infection varies greatly across dialysis units. Thus this measure is intended as a quality control tool for monitoring and maintaining acceptable rates of infection-reporting by dialysis units and provide a means to control possible gaming of facility-level outcomes through non-reporting. This measure has been designed as a period prevalence over a 6 month period to provide for a stable estimate for the vast majority of US dialysis units. Routinely monitoring access-related infection rates will provide important feedback to dialysis facilities, health policy makers, and infection-control experts regarding the effectiveness of ongoing infection control practices.

1c.5 Rating of strength/quality of evidence (*also provide narrative description of the rating and by whom***):**
United States Preventive Services Task Force (USPSTF) Grade B. Moderate quantity of evidence of moderate quality providing moderate certainty that the measure will be meaningfully related to the outcome of measuring rates of clinically confirmed infection with benefits perceived to outweigh harm to patients.

1c.6 Method for rating evidence: USPSTF

1c.7 Summary of Controversy/Contradictory Evidence: Some suspected serious infections may be treated only with oral antibiotics and these will not be accounted for. This limitation is perceived to be a relatively minor exclusion in view of current practice, and has been accepted to limit the data collection to intravenous antibiotic therapy which is indicated to be much more reliable, more uniform, and less burdensome than data collection that would include oral antibiotic therapy.

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

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.

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.
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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.
16) Yahav D, Rozen-Zvi B, Gafter-Gvili A, Leibovici L, Gafter U, Paul M. Antimicrobial lock solutions for the prevention of infections associated with intravascular catheters in patients undergoing hemodialysis: systematic review and meta-analysis of randomized, controlled trials. Clin Infect Dis 2008; 47:83-93.
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.
21) Taylor C, Cahill J, Gerrish M, Little J. A new haemodialysis catheter-locking agent reduces infections in haemodialysis patients. J Ren Care 2008; 34:116-120.
22) Mokrzycki MH, Zhang M, Golestaneh L, Laut J, Rosenberg SO. An interventional controlled trial comparing 2 management models for the treatment of tunneled cuffed catheter bacteremia: a collaborative team model versus usual physician-managed care. Am J Kidney Dis 2006; 48:587-595.
23) Nori US, Manoharan A, Yee J, Besarab A. Comparison of low-dose gentamicin with minocycline as catheter lock solutions in the prevention of catheter-related bacteremia. Am J Kidney Dis 2006; 48:596-605.
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.
25) Mandolfo S, Borlandelli S, Elli A. Catheter lock solutions: it´s time for a change. J Vasc Access 2006; 7:99-102.
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1c.9 Quote the Specific guideline recommendation (*including guideline number and/or page number***):**
N/A

1c.10 Clinical Practice Guideline Citation: N/A
1c.11 National Guideline Clearinghouse or other URL: N/A

1c.12 Rating of strength of recommendation (*also provide narrative description of the rating and by whom***):**
N/A

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

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

TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for *Importance to Measure and Report?*	**1**

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.

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.1 **Numerator Statement (***Brief, text description of the numerator - what is being measured about the target population, e.g. target condition, event, or outcome***):** Number of months that HD patients initiated a new IV antibiotic therapy for a newly suspected infection during the six-month period ending with the current reporting month and for which blood culture results were indicated to be "unavailable". 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***):** A month is included in the numerator if a patient from the denominator has an indication of "unavailable" regarding the results of the blood culture.	
2a.4 **Denominator Statement (***Brief, text description of the denominator - target population being measured***):** Number of months that adult (18+) HD patients initiated a new IV antibiotic therapy for a newly suspected infection during the six-month period ending with the current reporting 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***):** A month is included in the denominator from a patient who is >= 18 years old at the start of the six-month reporting period, on chronic HD, at the facility, and prescribed a new IV antibiotic therapy for a newly suspected infection (RQMT_1319 and RQMT_1323) while on chronic HD during a month within the six-month reporting period. The patient's age will be determined by subtracting the patient's date of birth from the first day of the reporting period. The patient will be considered on chronic dialysis if the date of initiating regular chronic dialysis is prior to or equal to the last day of the six-month reporting period. The patient will be considered to be on HD if HD treatment start date is on or before the last day of the six-month reporting period and the patient was receiving HD during the six-month reporting period. A patient is considered to be treated in a facility if the admit date is on or before the last day of the reporting period and the discharge date is on or after the first day of the period or discharge has not occurred. A patient will be considered to have been prescribed a new IV antibiotic therapy for a newly suspected infection if the new IV antibiotic therapy date (RQMT_1534) falls within the parameters of the patient month and occurred when the patient was considered to be a chronic HD patient. The number of months in the denominator is calculated by summing the number of total months plus fraction of months the patient received chronic HD when associated with the facility during the six-month	**2a-specs** **C☐** **P☐** **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) .

reporting period when the above inclusion criteria are met. For facility patients who are hospitalized, patients will be considered to be associated with the facility during the time of hospitalization.

2a.9 Denominator Exclusions (*Brief text description of exclusions from the target population***):** HD patients < 18 yrs old, or not prescribed an IV antibiotic.

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***):**
This measure can be stratified by vascular access type (fistula/graft/catheter).

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***):**

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***):**
A month is included in the denominator from a patient who is >= 18 years old at the start of the six-month reporting period, on chronic HD, at the facility, and prescribed a new IV antibiotic therapy for a newly suspected infection (RQMT_1319 and RQMT_1323) while on chronic HD during a month within the six-month reporting period. The patient's age will be determined by subtracting the patient's date of birth from the first day of the reporting period. The patient will be considered on chronic dialysis if the date of initiating regular chronic dialysis is prior to or equal to the last day of the six-month reporting period. The patient will be considered to be on HD if HD treatment start date is on or before the last day of the six-month reporting period and the patient was receiving HD during the six-month reporting period. A patient is considered to be treated in a facility if the admit date is on or before the last day of the reporting period and the discharge date is on or after the first day of the period or discharge has not occurred. A patient will be considered to have been prescribed a new IV antibiotic therapy for a newly suspected infection if the new IV antibiotic therapy date (RQMT_1534) falls within the parameters of the patient month and occurred when the patient was considered to be a chronic HD patient.

The number of months in the denominator is calculated by summing the number of total months plus fraction of months the patient received chronic HD when associated with the facility during the six-month reporting period when the above inclusion criteria are met. For facility patients who are hospitalized, patients will be considered to be associated with the facility during the time of hospitalization.

A month is included in the numerator if a patient from the denominator has an indication of "unavailable" regarding the results of the blood culture.

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 sum, with the result multiplied by 100 to express the facility-level measure as a percentage.

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 clinical data

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.

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.***):**
CROWNWeb

2a.26-28 Data source/data collection instrument reference web page URL or attachment: URL
http://www.projectcrownweb.org/crown/index.php

2a.29-31 Data dictionary/code table web page URL or attachment: URL
http://www.projectcrownweb.org/crown/index.php?page=Public_Documents&subPage=Release_Documents

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☐

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
C☐ P☐ M☐ N☐ NA☐

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

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.

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 patient preference and the effect on the measure is transparent (e.g., numerator category ... [2]

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.

2d.5 Testing Results *(e.g., frequency, variability, sensitivity analyses)*: N/A	
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, provide follow-up plans:** N/A	**2h** C☐ P☐ M☐ N☐ 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** C☐

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 outcome (but not disparities in care) and are present at start of care;[Error! Bookmark not defined.] OR rationale/data support no risk adjustment.

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 women). It is preferable to stratify measures by race and socioeconomic status rather than adjusting out differences.

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 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.

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.

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.

3a.1 Current Use: Testing not yet completed

P☐ M☐ N☐

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.

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
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?

3b
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

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

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).

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.	**4d** **C☐** **P☐** **M☐** **N☐**
4e. Data Collection Strategy/Implementation **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:** Treatment of infection is associated with high costs to the health care system. Reducing infection rates are expected to have a high impact on reducing health care costs. This proposed measure is designed to be informative in monitoring the unavailable results of a blood culture test	**4e** **C☐** **P☐** **M☐** **N☐**

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).

as a potential way that facilities could game the system and thereby appear to have lower rates of bacteremia. If widespread across many dialysis units, this practice likely would result in unreliable, less meaningful national statistics regarding infection rates among HD patients.	
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 Services, 7500 Security Boulevard, Baltimore, Maryland, 21244

Co.2 Point of Contact
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Measure Developer If different from Measure Steward
Co.3 Organization
Arbor Research/UM-KECC, 315 W. Huron, Ann Arbor, Michigan, 48103

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Co.5 Submitter If different from Measure Steward POC
Thomas, Dudley, Thomas.Dudley@cms.hhs.gov, 410-786-1442-, Centers for Medicare and Medicaid Services

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 [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 11: [2] 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).