

# 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 #: 1453      NQF Project: End Stage Renal Disease
<b>MEASURE DESCRIPTIVE INFORMATION</b>
De.1 Measure Title: <b>Clinically Confirmed Infection (rate)</b>
De.2 Brief description of measure: <b>Six-month rolling average rate of clinically confirmed infection with IV antibiotic therapy among adult chronic HD patients (Express as: rate per 1000 HD patient days)</b>
1.1-2 Type of Measure: <b>Process</b> De.3 If included in a composite or paired with another measure, please identify composite or paired measure <b>Clinically Confirmed Infection (percentage)</b>
De.4 National Priority Partners Priority Area: <b>Population health</b> De.5 IOM Quality Domain: <b>Safety</b> De.6 Consumer Care Need: <b>Living with illness</b>

<b>CONDITIONS FOR CONSIDERATION BY NQF</b>	
Four conditions must be met before proposed measures may be considered and evaluated for suitability as voluntary consensus standards:	<b>NQF Staff</b>
<p>A. The measure is in the public domain or an intellectual property (<a href="#">measure steward agreement</a>) is signed. <i>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.</i></p> <p>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)? <b>Yes</b></p> <p>A.2 Indicate if Proprietary Measure (as defined in measure steward agreement):</p> <p>A.3 Measure Steward Agreement: <b>Government entity and in the public domain - no agreement necessary</b></p> <p>A.4 Measure Steward Agreement attached:</p>	<p><b>A</b></p> <p>Y <input type="checkbox"/></p> <p>N <input type="checkbox"/></p>
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	<p><b>B</b></p> <p>Y <input type="checkbox"/></p>

every 3 years. <a href="#">Yes, information provided in contact section</a>	N <input type="checkbox"/>
C. The intended use of the measure includes <u>both</u> public reporting <u>and</u> quality improvement. ► <b>Purpose:</b> <a href="#">Public reporting</a> , <a href="#">Internal quality improvement</a>	C Y <input type="checkbox"/> N <input type="checkbox"/>
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: <a href="#">No, testing will be completed within 12 months</a> D.2 Have NQF-endorsed measures been reviewed to identify if there are similar or related measures? <a href="#">Yes</a>	D Y <input type="checkbox"/> N <input type="checkbox"/>
<b>(for NQF staff use)</b> Have all conditions for consideration been met? Staff Notes to Steward (if submission returned):	Met Y <input type="checkbox"/> N <input type="checkbox"/>
Staff Notes to Reviewers (issues or questions regarding any criteria): Staff Reviewer Name(s):	

TAP/Workgroup Reviewer Name:	
Steering Committee Reviewer Name:	
<b>1. IMPORTANCE TO MEASURE AND REPORT</b>	
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. <i>Measures must be judged to be important to measure and report in order to be evaluated against the remaining criteria.</i> (evaluation criteria) <b>1a. High Impact</b>	<a href="#">Eval Rating</a>
<b>(for NQF staff use)</b> <a href="#">Specific NPP goal</a> :	
1a.1 Demonstrated High Impact Aspect of Healthcare: <a href="#">Affects large numbers, Leading cause of morbidity/mortality, Severity of illness, Patient/societal consequences of poor quality</a> 1a.2 1a.3 Summary of Evidence of High Impact: <a href="#">Infection-related death is the 2nd most common cause of death among chronic hemodialysis patients after cardiovascular-related causes [1, 2]. Infection-related hospitalizations are associated with high health care costs [3-7]. Furthermore, the rates of infection-related hospitalization vary substantially across dialysis units. Whereas IV Antibiotic Therapy (rate) provides a measure of overall suspected infections based upon whether a patient was prescribed an antibiotic, Clinically Confirmed Infection (percentage) and Clinically Confirmed Infection (rate) were recommended to provide a more reliable measure of infection [i.e., an infection which has been clinically established]. Furthermore, the frequency of infection severity is poorly understood among hemodialysis patients, and was viewed by the clinical Technical Expert Panel (C-TEP) as an important factor for understanding the nature of infections experienced by hemodialysis patients and the percentage of suspected infections that are confirmed by a clinician. The collection of this data element will make it possible to more accurately characterize the nature and severity of infections on a national level [e.g., positive blood culture plus symptoms of clinical sepsis versus soft-tissue infection without symptoms of clinical sepsis, etc], and relate these to mortality, morbidity, health care costs, and the focus of quality improvement programs. Furthermore, 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.</a>	1a C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/>

**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).

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:**
- 1) U.S. Renal Data System, USRDS 2009 Annual Data Report: Atlas of End-Stage Renal Disease in the United States, National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2009.
  - 2) 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.
  - 3) 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.
  - 4) Engemann JJ, Friedman JY, Reed SD, Griffiths RI, Szczech LA, Kaye KS, et al. Clinical outcomes and costs due to Staphylococcus aureus bacteremia among patients receiving long-term hemodialysis. Infect Control Hosp Epidemiol 2005; 26:534-539.
  - 5) 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.
  - 6) Ramanathan V, Chiu EJ, Thomas JT, Khan A, Dolson GM, Darouiche RO. Healthcare costs associated with hemodialysis catheter-related infections: a single-center experience. Infect Control Hosp Epidemiol 2007; 28:606-609.
  - 7) Reed SD, Friedman JY, Engemann JJ, Griffiths RI, Anstrom KJ, Kaye KS, et al. Costs and outcomes among hemodialysis-dependent patients with methicillin-resistant or methicillin-susceptible Staphylococcus aureus bacteremia. Infect Control Hosp Epidemiol 2005; 26:175-183.

**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 clinically confirmed infection, 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:**

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**

1b  
C   
P   
M   
N

1c  
C

**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.

**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): Infection-related death is the 2nd most common cause of death among chronic hemodialysis patients after cardiovascular-related causes [1, 2]. Infection-related hospitalizations are associated with high health care costs [3-7]. Furthermore, the rates of infection-related hospitalization vary substantially across dialysis units. Whereas IV Antibiotic Therapy (rate) provides a measure of overall suspected infections based upon whether a patient was prescribed an antibiotic, Clinically Confirmed Infection (percentage) and Clinically Confirmed Infection (rate) were recommended to provide a more reliable measure of infection [i.e., an infection which has been clinically established]. Furthermore, the frequency of infection severity is poorly understood among hemodialysis patients, and was viewed by the C-TEP as an important factor for understanding the nature of infections experienced by hemodialysis patients and the percentage of suspected infections that are confirmed by a clinician. The collection of this data element will make it possible to more accurately characterize the nature and severity of infections on a national level and relate these to mortality, morbidity, health care costs, and the focus of quality improvement programs. Furthermore, 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.

P   
M   
N

**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., mammography) or measures for multiple care processes that affect a single outcome.

The proposed scheme described above provides an overview of the overall proposed scheme for monitoring dialysis access-related infection in hemodialysis patients, with this particular measure contributing to element 1c in this overall schema to provide the rate of clinically confirmed infection with new IV antibiotic therapy among all chronic HD patients.

**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 hemodialysis 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 hemodialysis 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, 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 Kidney Disease Outcomes Quality Initiative (NKF KDOQI) and Centers for Disease Control and Prevention (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.

**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.

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

**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. Furthermore, clinical confirmation of whether a suspected infection was confirmed and whether the confirmed infection was vascular access-related is expected to vary across physicians with some degree of subjectivity thus resulting in some variability in findings due to differences in interpretation of patient symptoms and laboratory findings. In addition, when some, but not all, blood cultures are indicated to be positive for an infection, variation in concluding whether blood cultures were positive for an infection is recognized as well thus leading to variability for indicating whether a suspected infection was clinically confirmed.

- 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, I.I., et al., Impact of catheter-related bloodstream infections on the mortality of critically ill patients: a meta-analysis. *Crit Care Med*, 2009. 37(7): p. 2283-9.
- 36) Wasse, H., Catheter-related mortality among ESRD patients. *Semin Dial*, 2008. 21(6): p. 547-9.
- 37) Wasse, H., R.A. Speckman, and W.M. McClellan, Arteriovenous fistula use is associated with lower cardiovascular mortality compared with catheter use among ESRD patients. *Semin Dial*, 2008. 21(5): p. 483-9.
- 38) Weijmer, M.C., M.G. Vervloet, and P.M. ter Wee, Prospective follow-up of a novel design haemodialysis catheter: lower infection rates and improved survival. *Nephrol Dial Transplant*, 2008. 23(3): p. 977-83.
- 39) Taylor, G.D., et al., Central venous catheters as a source of hemodialysis-related bacteremia. *Infect Control Hosp Epidemiol*, 1998. 19(9): p. 643-6.
- 40) Wasse, H., et al., Predictors of delayed transition from central venous catheter use to permanent vascular access among ESRD patients. *Am J Kidney Dis*, 2007. 49(2): p. 276-83.
- 41) Wolfe, R.A., et al., Decreases in catheter use are associated with decreases in mortality for dialysis facilities during 2000-03. *J Am Soc Nephrol Dial Transplant*, 2005. 16: p. 95A.
- 42) Beathard, G.A. and A. Urbanes, Infection associated with tunneled hemodialysis catheters. *Semin Dial*, 2008. 21(6): p. 528-38.
- 43) Collins, A.J., et al., Excerpts from the US Renal Data System 2009 Annual Data Report. *Am J Kidney Dis*. 55(1 Suppl 1): p. S1-420, A6-7.
- 44) Butterly, D.W. and S.J. Schwab, Dialysis access infections. *Curr Opin Nephrol Hypertens*, 2000. 9(6): p. 631-5.
- 45) Fluck, R., et al., UK Renal Registry 11th Annual Report (December 2008): Chapter 12 Epidemiology of Methicillin Resistant *Staphylococcus aureus* bacteraemia amongst patients receiving Renal Replacement Therapy in England in 2007. *Nephron Clin Pract*, 2009. 111 Suppl 1: p. c247-56.
- 46) Rehman, R., R.J. Schmidt, and A.H. Moss, Ethical and legal obligation to avoid long-term tunneled

- catheter access. *Clin J Am Soc Nephrol*, 2009. 4(2): p. 456-60.
- 47) Engemann, J.J., et al., Clinical outcomes and costs due to *Staphylococcus aureus* bacteremia among patients receiving long-term hemodialysis. *Infect Control Hosp Epidemiol*, 2005. 26(6): p. 534-9.
- 48) Ramanathan, V., et al., Healthcare costs associated with hemodialysis catheter-related infections: a single-center experience. *Infect Control Hosp Epidemiol*, 2007. 28(5): p. 606-9.
- 49) Lok, C.E., Avoiding trouble down the line: the management and prevention of hemodialysis catheter-related infections. *Adv Chronic Kidney Dis*, 2006. 13(3): p. 225-44.
- 50) Lok, C.E., et al., Trisodium citrate 4%--an alternative to heparin capping of haemodialysis catheters. *Nephrol Dial Transplant*, 2007. 22(2): p. 477-83.
- 51) Rabindranath, K.S., et al., Systematic review of antimicrobials for the prevention of haemodialysis catheter-related infections. *Nephrol Dial Transplant*, 2009. 24(12): p. 3763-74.
- 52) Peterson, W.J., et al., Treatment of dialysis catheter-related *Enterococcus* bacteremia with an antibiotic lock: a quality improvement report. *Am J Kidney Dis*, 2009. 53(1): p. 107-11.
- 53) Beathard, G.A., Catheter management protocol for catheter-related bacteremia prophylaxis. *Semin Dial*, 2003. 16(5): p. 403-5.
- 54) Allon, M., Prophylaxis against dialysis catheter-related bacteremia with a novel antimicrobial lock solution. *Clin Infect Dis*, 2003. 36(12): p. 1539-44.
- 55) Allon, M., Prophylaxis against dialysis catheter-related bacteremia: a glimmer of hope. *Am J Kidney Dis*, 2008. 51(2): p. 165-8.
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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

<p>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</p> <p>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</p> <p>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).</p> <p>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.</p> <p><b>1c.10 Clinical Practice Guideline Citation:</b> 1) Kidney Disease: Improving Global Outcomes (KDIGO) Clinical Practice Guidelines for Vascular Access (2006) <a href="http://www.kidney.org/professionals/kdoqi/guideline_uphd_pd_va/index.htm">http://www.kidney.org/professionals/kdoqi/guideline_uphd_pd_va/index.htm</a> 2) O'Grady NP, Alexander M, Dellinger EP, Gerberding JL, Heard SO, Maki DG, et al. CDC Guidelines for the Prevention of Intravascular Catheter-Related Infections. 2002. 3) Mactier R, Hoenich N, Breen C. UK Renal Association. Guideline for Haemodialysis. 2007.</p> <p><b>1c.11 National Guideline Clearinghouse or other URL:</b> <a href="http://www.qualitymeasures.ahrq.gov">http://www.qualitymeasures.ahrq.gov</a></p> <p><b>1c.12 Rating of strength of recommendation</b> (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.</p> <p><b>1c.13 Method for rating strength of recommendation</b> (If different from <a href="#">USPSTF system</a>, also describe rating and how it relates to USPSTF): USPSTF</p> <p><b>1c.14 Rationale for using this guideline over others:</b> N/A</p>	
<p><b>TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for Importance to Measure and Report?</b></p>	<p>1</p>
<p><b>Steering Committee: Was the threshold criterion, Importance to Measure and Report, met? Rationale:</b></p>	<p>1 Y <input type="checkbox"/> N <input type="checkbox"/></p>
<p><b>2. SCIENTIFIC ACCEPTABILITY OF MEASURE PROPERTIES</b></p>	
<p>Extent to which the measure, <u>as specified</u>, produces consistent (reliable) and credible (valid) results about the quality of care when implemented. (<a href="#">evaluation criteria</a>)</p>	<p><a href="#">Eval Rating</a></p>
<p><b>2a. MEASURE SPECIFICATIONS</b></p>	
<p><b>S.1 Do you have a web page where current detailed measure specifications can be obtained?</b> <b>S.2 If yes, provide web page URL:</b></p>	<p>2a-specs C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/></p>
<p><b>2a. Precisely Specified</b></p> <p><b>2a.1 Numerator Statement</b> (Brief, text description of the numerator - what is being measured about the target population, e.g. target condition, event, or outcome):</p>	<p><input type="checkbox"/></p>

**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.

**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).

<p>Number of months that hemodialysis (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 the infection was clinically confirmed.</p> <p><b>2a.2 Numerator Time Window</b> (<i>The time period in which cases are eligible for inclusion in the numerator</i>): Six months ending with the current reporting month.</p> <p><b>2a.3 Numerator Details</b> (<i>All information required to collect/calculate the numerator, including all codes, logic, and definitions</i>):                  A month is included in the numerator if a patient from the denominator was prescribed IV antibiotic therapy for a newly suspected infection during the month (RQMT_1319 and RQMT_1323), the infection was clinically confirmed (RQMT_1312), the date that the patient was prescribed IV antibiotic therapy falls within the parameters of the reporting period (RQMT_1534), and this date occurred when the patient was considered to be a chronic hemodialysis patient.</p>
<p><b>2a.4 Denominator Statement</b> (<i>Brief, text description of the denominator - target population being measured</i>):                  All adult (18+) chronic maintenance HD patient days during the six-month period ending with the current reporting month.</p> <p><b>2a.5 Target population gender:</b> Female, Male  <b>2a.6 Target population age range:</b> Adults 18 years or older.</p> <p><b>2a.7 Denominator Time Window</b> (<i>The time period in which cases are eligible for inclusion in the denominator</i>):                  Six months ending with the current reporting month.</p> <p><b>2a.8 Denominator Details</b> (<i>All information required to collect/calculate the denominator - the target population being measured - including all codes, logic, and definitions</i>):                  Patient days are included in the denominator from a patient who is &gt;= 18 years old at the start of the six-month reporting period, on chronic hemodialysis and at the facility. 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 hemodialysis if HD treatment start date is on or before the last day of the six-month reporting period and the patient was receiving hemodialysis 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.</p> <p>The number of days in the denominator is calculated by summing the number of chronic hemodialysis days during the reporting period that a patient meets the above inclusion criteria.</p>
<p><b>2a.9 Denominator Exclusions</b> (<i>Brief text description of exclusions from the target population</i>): Patients less than 18 years old.</p> <p><b>2a.10 Denominator Exclusion Details</b> (<i>All information required to collect exclusions to the denominator, including all codes, logic, and definitions</i>):                  None</p>
<p><b>2a.11 Stratification Details/Variables</b> (<i>All information required to stratify the measure including the stratification variables, all codes, logic, and definitions</i>):                  This measure can be stratified by vascular access type (fistula/graft/catheter).</p>
<p><b>2a.12-13 Risk Adjustment Type:</b> No risk adjustment necessary</p> <p><b>2a.14 Risk Adjustment Methodology/Variables</b> (<i>List risk adjustment variables and describe conceptual models, statistical models, or other aspects of model or method</i>):                  N/A</p> <p><b>2a.15-17 Detailed risk model available</b> Web page URL or attachment:</p>

**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.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*):  
 Patient days are included in the denominator from a patient who is >= 18 years old at the start of the six-month reporting period, on chronic hemodialysis and at the facility. 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 hemodialysis if HD treatment start date is on or before the last day of the six-month reporting period and the patient was receiving hemodialysis 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.

The number of days in the denominator is calculated by summing the number of chronic hemodialysis days during the reporting period that a patient meets the above inclusion criteria.

A month is included in the numerator if a patient from the denominator was prescribed IV antibiotic therapy for a newly suspected infection during the month (RQMT\_1319 and RQMT\_1323), the infection was clinically confirmed (RQMT\_1312), the date that the patient was prescribed IV antibiotic therapy falls within the parameters of the reporting period (RQMT\_1534), and this date occurred when the patient was considered to be a chronic hemodialysis patient.

**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 monthly episodes of clinically confirmed infection with IV antibiotic therapy per 1000 hemodialysis 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 clinical data

**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 (Consolidated Renal Operations in a Web Enabled Network)

**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](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**

<p><b>2b. Reliability testing</b></p> <p>2b.1 Data/sample (description of data/sample and size): N/A</p> <p>2b.2 Analytic Method (type of reliability &amp; rationale, method for testing): N/A</p> <p>2b.3 Testing Results (reliability statistics, assessment of adequacy in the context of norms for the test conducted): N/A</p>	<p>2b</p> <p>C <input type="checkbox"/></p> <p>P <input type="checkbox"/></p> <p>M <input type="checkbox"/></p> <p>N <input type="checkbox"/></p>
<p><b>2c. Validity testing</b></p> <p>2c.1 Data/sample (description of data/sample and size): N/A</p> <p>2c.2 Analytic Method (type of validity &amp; rationale, method for testing): Face validity is the only validity assessed, therefore testing is not applicable.</p> <p>2c.3 Testing Results (statistical results, assessment of adequacy in the context of norms for the test conducted): N/A</p>	<p>2c</p> <p>C <input type="checkbox"/></p> <p>P <input type="checkbox"/></p> <p>M <input type="checkbox"/></p> <p>N <input type="checkbox"/></p>
<p><b>2d. Exclusions Justified</b></p> <p>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 &lt; 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.</p> <p>2d.2 Citations for Evidence: N/A</p> <p>2d.3 Data/sample (description of data/sample and size): N/A</p> <p>2d.4 Analytic Method (type analysis &amp; rationale): N/A</p> <p>2d.5 Testing Results (e.g., frequency, variability, sensitivity analyses): N/A</p>	<p>2d</p> <p>C <input type="checkbox"/></p> <p>P <input type="checkbox"/></p> <p>M <input type="checkbox"/></p> <p>N <input type="checkbox"/></p> <p>NA <input type="checkbox"/></p>
<p><b>2e. Risk Adjustment for Outcomes/ Resource Use Measures</b></p> <p>2e.1 Data/sample (description of data/sample and size): N/A</p> <p>2e.2 Analytic Method (type of risk adjustment, analysis, &amp; rationale): N/A</p> <p>2e.3 Testing Results (risk model performance metrics): N/A</p> <p>2e.4 If outcome or resource use measure is not risk adjusted, provide rationale: There are no compelling reasons to risk adjust measure.</p>	<p>2e</p> <p>C <input type="checkbox"/></p> <p>P <input type="checkbox"/></p> <p>M <input type="checkbox"/></p> <p>N <input type="checkbox"/></p> <p>NA <input type="checkbox"/></p>
<p><b>2f. Identification of Meaningful Differences in Performance</b></p> <p>2f.1 Data/sample from Testing or Current Use (description of data/sample and size): N/A</p> <p>2f.2 Methods to identify statistically significant and practically/meaningfully differences in performance (type of analysis &amp; rationale):</p>	<p>2f</p> <p>C <input type="checkbox"/></p> <p>P <input type="checkbox"/></p> <p>M <input type="checkbox"/></p> <p>N <input type="checkbox"/></p>

**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 ... [1])

**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 ... [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.

**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 ... [3]

**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 ... [4])

**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 ... [5]

N/A	
2f.3 Provide Measure Scores from Testing or Current Use ( <i>description of scores, e.g., distribution by quartile, mean, median, SD, etc.; identification of statistically significant and meaningful differences in performance</i> ): N/A	
2g. Comparability of Multiple Data Sources/Methods	
2g.1 Data/sample ( <i>description of data/sample and size</i> ): N/A	2g C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/> NA <input type="checkbox"/>
2g.2 Analytic Method ( <i>type of analysis &amp; rationale</i> ): N/A	
2g.3 Testing Results ( <i>e.g., correlation statistics, comparison of rankings</i> ): N/A	
2h. Disparities in Care	
2h.1 If measure is stratified, provide stratified results ( <i>scores by stratified categories/cohorts</i> ): N/A	2h C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/> NA <input type="checkbox"/>
2h.2 If disparities have been reported/identified, but measure is not specified to detect disparities, provide follow-up plans: N/A	
TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for <i>Scientific Acceptability of Measure Properties</i> ?	2
Steering Committee: Overall, to what extent was the criterion, <i>Scientific Acceptability of Measure Properties</i> , met? Rationale:	2 C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/>
<b>3. USABILITY</b>	
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. ( <a href="#">evaluation criteria</a> )	Eval Rating
3a. Meaningful, Understandable, and Useful Information	
3a.1 Current Use: Testing not yet completed	3a C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/>
3a.2 Use in a public reporting initiative (disclosure of performance results to the public at large) ( <i>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</i> ): 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 ( <i>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</i> ): CDC National Healthcare Safety Network (NHSN), Dialysis Event (DE) <a href="http://www.cdc.gov/nhsn/psc_da_de.html">http://www.cdc.gov/nhsn/psc_da_de.html</a>	
Testing of Interpretability ( <i>Testing that demonstrates the results are understood by the potential users for public reporting and quality improvement</i> )	
3a.4 Data/sample ( <i>description of data/sample and size</i> ): Thirty-two dialysis facilities provided hemodialysis reported adverse events related to infection to the CDC in 2006. These facilities submitted data on 28,047 patient-months.	
3a.5 Methods ( <i>e.g., focus group, survey, QI project</i> ): Staff from the participating dialysis facilities monitored and reported vascular access type, new IV	

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.

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 the 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.	
<b>3a.6 Results (qualitative and/or quantitative results and conclusions):</b> 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 <u>endorsed</u> or submitted measures:	
<b>3b. Harmonization</b> If this measure is related to measure(s) already <u>endorsed by NQF</u> (e.g., same topic, but different target population/setting/data source <u>or</u> different topic but same target population): 3b.2 Are the measure specifications <u>harmonized</u> ? If not, why?	<b>3b</b> C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/> NA <input type="checkbox"/>
<b>3c. Distinctive or Additive Value</b> 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	<b>3c</b> C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/> NA <input type="checkbox"/>
TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for <i>Usability</i> ?	3
Steering Committee: Overall, to what extent was the criterion, <i>Usability</i> , met? Rationale:	3 C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/>
<b>4. FEASIBILITY</b>	
Extent to which the required data are readily available, retrievable without undue burden, and can be implemented for performance measurement. ( <u>evaluation criteria</u> )	<u>Eval Rating</u>
<b>4a. Data Generated as a Byproduct of Care Processes</b>	<b>4a</b> C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/>
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)	
<b>4b. Electronic Sources</b>	<b>4b</b> C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/>
4b.1 Are all the data elements available electronically? ( <i>elements that are needed to compute measure scores are in defined, computer-readable fields, e.g., electronic health record, electronic claims</i> ) Yes	

**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).

**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.

4b.2 If not, specify the near-term path to achieve electronic capture by most providers.	
<p><b>4c. Exclusions</b></p> <p>4c.1 Do the specified exclusions require additional data sources beyond what is required for the numerator and denominator specifications? No</p> <p>4c.2 If yes, provide justification.</p>	<p>4c</p> <p>C <input type="checkbox"/></p> <p>P <input type="checkbox"/></p> <p>M <input type="checkbox"/></p> <p>N <input type="checkbox"/></p> <p>NA <input type="checkbox"/></p>
<p><b>4d. Susceptibility to Inaccuracies, Errors, or Unintended Consequences</b></p> <p>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 clinically confirmed which will have a degree of subjectivity.</p>	<p>4d</p> <p>C <input type="checkbox"/></p> <p>P <input type="checkbox"/></p> <p>M <input type="checkbox"/></p> <p>N <input type="checkbox"/></p>
<p><b>4e. Data Collection Strategy/Implementation</b></p> <p>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.</p> <p>4e.2 Costs to implement the measure (costs of data collection, fees associated with proprietary measures): N/A</p> <p>4e.3 Evidence for costs: N/A</p> <p>4e.4 Business case documentation: Infection has been shown to be associated with high costs to the health care system and is strongly related to mortality and morbidity in hemodialysis patients. Reducing infection rates is expected to have a high impact on reducing health care costs.</p>	<p>4e</p> <p>C <input type="checkbox"/></p> <p>P <input type="checkbox"/></p> <p>M <input type="checkbox"/></p> <p>N <input type="checkbox"/></p>
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:	<p>4</p> <p>C <input type="checkbox"/></p> <p>P <input type="checkbox"/></p> <p>M <input type="checkbox"/></p> <p>N <input type="checkbox"/></p>
<b>RECOMMENDATION</b>	
(for NQF staff use) Check if measure is untested and only eligible for time-limited endorsement.	<p>Time-limited</p> <p><input type="checkbox"/></p>
Steering Committee: Do you recommend for endorsement? Comments:	<p>Y <input type="checkbox"/></p> <p>N <input type="checkbox"/></p> <p>A <input type="checkbox"/></p>
<b>CONTACT INFORMATION</b>	

**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).

<p><b>Co.1 Measure Steward (Intellectual Property Owner)</b>  <b>Co.1 Organization</b>                  Centers for Medicare &amp; Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland, 21244</p>
<p><b>Co.2 Point of Contact</b>                  Thomas, Dudley, <a href="mailto:Thomas.Dudley@cms.hhs.gov">Thomas.Dudley@cms.hhs.gov</a>, 410-786-1442-</p>
<p><b>Measure Developer If different from Measure Steward</b>  <b>Co.3 Organization</b>                  Arbor Research/UM-KECC, 315 W. Huron Street, Ann Arbor, Michigan, 48103</p>
<p><b>Co.4 Point of Contact</b>                  Adrienne, Janney, <a href="mailto:adrienne.janney@arborresearch.org">adrienne.janney@arborresearch.org</a>, 734-665-4108-</p>
<p><b>Co.5 Submitter If different from Measure Steward POC</b>                  Thomas, Dudley, <a href="mailto:Thomas.Dudley@cms.hhs.gov">Thomas.Dudley@cms.hhs.gov</a>, 410-786-1442-, Centers for Medicare &amp; Medicaid Services</p>
<p><b>Co.6 Additional organizations that sponsored/participated in measure development</b></p>
<p><b>ADDITIONAL INFORMATION</b></p>
<p><b>Workgroup/Expert Panel involved in measure development</b>  <b>Ad.1 Provide a list of sponsoring organizations and workgroup/panel members' names and organizations. Describe the members' role in measure development.</b>                  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 &amp; 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)</p>
<p><b>Ad.2 If adapted, provide name of original measure:</b>  <b>Ad.3-5 If adapted, provide original specifications URL or attachment</b></p>
<p><b>Measure Developer/Steward Updates and Ongoing Maintenance</b>  <b>Ad.6 Year the measure was first released:</b>  <b>Ad.7 Month and Year of most recent revision:</b>  <b>Ad.8 What is your frequency for review/update of this measure?</b> <a href="#">Three years</a>  <b>Ad.9 When is the next scheduled review/update for this measure?</b> <a href="#">2013</a></p>
<p><b>Ad.10 Copyright statement/disclaimers:</b></p>
<p><b>Ad.11 -13 Additional Information web page URL or attachment:</b></p>
<p><b>Date of Submission (MM/DD/YY):</b> <a href="#">12/21/2010</a></p>

**Page 12: [1] Comment [k13]** **Karen Pace** **10/5/2009 8:59:00 AM**

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.

**Page 12: [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).

**Page 12: [3] 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 12: [4] 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 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.

**Page 12: [5] 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.