

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 #: 1469 NQF Project: End Stage Renal Disease	
MEASURE DESCRIPTIVE INFORMATION	
De.1 Measure Title: Clinically Confirmed Access-Related Infection (rate)	
De.2 Brief description of measure: Clinically confirmed infection: 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) Specific access types: Six-month rolling average rate for access-related infection with IV antibiotic therapy, among adult chronic hemodialysis (HD) patients using an arteriovenous fistula for HD access (Express as: rate per 1000 HD fistula days) Six-month rolling average rate for access-related infection with IV antibiotic therapy, among adult chronic hemodialysis (HD) patients using an arteriovenous graft for HD access (Express as: rate per 1000 HD graft days) Six-month rolling average rate for access-related infection with IV antibiotic therapy, among adult chronic hemodialysis (HD) patients using a catheter for HD access (Express as: rate per 1000 HD catheter days)	
1.1-2 Type of Measure: Process	
De.3 If included in a composite or paired with another measure, please identify composite or paired measure	
De.4 National Priority Partners Priority Area: Population health	
De.5 IOM Quality Domain: Safety	
De.6 Consumer Care Need: Living with illness	

CONDITIONS FOR CONSIDERATION BY NQF	
Four conditions must be met before proposed measures may be considered and evaluated for suitability as voluntary consensus standards:	NQF Staff
A. The measure is in the public domain or an intellectual property (measure steward agreement) is signed.	A

<p><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)? Yes</p> <p>A.2 Indicate if Proprietary Measure (as defined in measure steward agreement):</p> <p>A.3 Measure Steward Agreement: Government entity and in the public domain - no agreement necessary</p> <p>A.4 Measure Steward Agreement attached:</p>	<p>Y <input type="checkbox"/></p> <p>N <input type="checkbox"/></p>
<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 every 3 years. Yes, information provided in contact section</p>	<p>B</p> <p>Y <input type="checkbox"/></p> <p>N <input type="checkbox"/></p>
<p>C. The intended use of the measure includes both public reporting and quality improvement.</p> <p>► Purpose: Public reporting, Internal quality improvement</p>	<p>C</p> <p>Y <input type="checkbox"/></p> <p>N <input type="checkbox"/></p>
<p>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.</p> <p>D.1 Testing: No, testing will be completed within 12 months</p> <p>D.2 Have NQF-endorsed measures been reviewed to identify if there are similar or related measures? Yes</p>	<p>D</p> <p>Y <input type="checkbox"/></p> <p>N <input type="checkbox"/></p>
<p>(for NQF staff use) Have all conditions for consideration been met?</p> <p>Staff Notes to Steward (if submission returned):</p>	<p>Met</p> <p>Y <input type="checkbox"/></p> <p>N <input type="checkbox"/></p>
<p>Staff Notes to Reviewers (issues or questions regarding any criteria):</p> <p>Staff Reviewer Name(s):</p>	

TAP/Workgroup Reviewer Name:	
Steering Committee Reviewer Name:	
1. IMPORTANCE TO MEASURE AND REPORT	
<p>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.</p> <p><i>Measures must be judged to be important to measure and report in order to be evaluated against the remaining criteria. (evaluation criteria)</i></p> <p>1a. High Impact</p>	Eval Rating
(for NQF staff use) Specific NPP goal:	
<p>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</p> <p>1a.2</p> <p>1a.3 Summary of Evidence of High Impact: The clinical Technical Expert Panel (C-TEP) felt it was very important to determine rates of infection associated with different types of vascular access used for HD particularly since prior studies have shown much higher rates of access-related infection for central venous catheters versus native arteriovenous fistulae or prosthetic grafts. 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</p>	<p>1a</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 [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).

consequences of a dialysis access-related infection. Use of various insertion/exit site disinfection procedures and various anti-microbial lock solutions in the care of catheters along with other vascular access-related infection control practices have led to substantially reduced rates of access-related infection in numerous studies [1-45]. Routinely monitoring access-related infection rates by vascular access type will provide important feedback to dialysis facilities, health policy makers, and infection-control experts regarding the effectiveness of ongoing infection control practices and impact of future changes in practice upon these types of infection rates.

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.
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 - 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.
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 - 13) Beathard GA. Catheter management protocol for catheter-related bacteremia prophylaxis. *Semin Dial* 2003; 16:403-405.
 - 14) Allon M. Prophylaxis against dialysis catheter-related bacteremia with a novel antimicrobial lock solution. *Clin Infect Dis* 2003; 36:1539-1544.

- 15) Allon M. Prophylaxis against dialysis catheter-related bacteremia: a glimmer of hope. *Am J Kidney Dis* 2008; 51:165-168.
- 16) Allon M. Treatment guidelines for dialysis catheter-related bacteremia: an update. *Am J Kidney Dis* 2009; 54:13-17.
- 17) 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.
- 18) 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.
- 19) 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.
- 20) 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.
- 21) Winnett G, Nolan J, Miller M, Ashman N. Trisodium citrate 46.7% selectively and safely reduces staphylococcal catheter-related bacteraemia. *Nephrol Dial Transplant* 2008; 23:3592-3598.
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- 32) Manierski C, Besarab A. Antimicrobial locks: putting the lock on catheter infections. *Adv Chronic Kidney Dis* 2006; 13:245-258.
- 33) 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.
- 34) McCann M, Moore ZE. Interventions for preventing infectious complications in haemodialysis patients with central venous catheters. *Cochrane Database Syst Rev*:CD006894.
- 35) 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.
- 36) 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.
- 37) 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.
- 38) 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.
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- 40) 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.
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51) Aslam S, Trautner BW, Ramanathan V, Darouiche RO. Pilot trial of N-acetylcysteine and tigecycline as a catheter-lock solution for treatment of hemodialysis catheter-associated bacteremia. Infect Control Hosp Epidemiol 2008; 29:894-897.

1b. Opportunity for Improvement

1b.1 Benefits (improvements in quality) envisioned by use of this measure: Infection-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.

The Clinical Technical Expert Panel (C-TEP) felt it was very important to determine rates of infection associated with different types of vascular access used for HD particularly since prior studies have shown much higher rates of access-related infection for central venous catheters versus native arteriovenous fistulae or prosthetic grafts. 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 [2,8-51]. Routinely monitoring access-related infection rates by vascular access type will provide important feedback to dialysis facilities, health policy makers, and infection control experts regarding the effectiveness of ongoing infection control practices and impact of future changes in practice upon these types of infection rates. Furthermore, these national data will also serve to provide additional insights regarding aspects of access-related infections associated with the use of arteriovenous fistulae since information in this regard is much more limited than currently exists for use of central venous catheters for vascular access.

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

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

1b
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<p>bacteremia by access type: AV fistulae, AV grafts and catheters.</p> <p>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.</p> <p>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.</p> <p>1b.4 Summary of Data on disparities by population group: N/A</p> <p>1b.5 Citations for data on Disparities: N/A</p>	
<p>1c. Outcome or Evidence to Support Measure Focus</p> <p>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]. The rates of infection-related hospitalization vary substantially across dialysis units. Clinically confirmed infection including specific access types was 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. In addition, routinely monitoring access-related infection rates by vascular access type will provide important feedback to dialysis facilities, health policy makers, and infection-control experts regarding the effectiveness of ongoing infection control practices and impact of future changes in practice upon these types of infection rates. The collection of these data elements 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. 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> <p>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, 2a and 2b in this overall schema to provide the rate of clinically confirmed infection with new IV antibiotic therapy among all chronic HD patients.</p> <p>1c.2-3. Type of Evidence: Cohort study, Observational study, Evidence-based guideline, Randomized controlled trial, Meta-analysis</p> <p>1c.4 Summary of Evidence (as described in the criteria; for outcomes, summarize any evidence that healthcare services/care processes influence the outcome): A large body of literature exists showing strong associations between central venous catheter use in HD patients with poorer survival and greater morbidity [1-40]. Recent studies have shown a nearly 20% higher hazard of mortality for every 20% higher facility % catheter use [2]. The prevalence of numerous patient comorbidity indicators was similar in facilities with high versus low catheter use. Lower mortality has been observed with reduction in catheter use in facility- and patient-level access use studies [7, 10, 13, 40, 41]. Furthermore, much of the 30-40% higher case-mix adjusted mortality rate for US HD patients compared to those in several European countries appears to be explained by differences in vascular access use between these two regions [2]. Rates of access-related infection, including septicemia, have been shown to be</p>	<p>1c C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/></p>

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

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 the National Kidney Foundation (NKF) Kidney Disease Outcomes Quality Initiative (KDOQI) and Centers for Disease Control (CDC) guideline committees. The magnitude and certainty of net benefit are expected to be moderate to high with low to no risks to patients in facilities reporting these data for purposes of quality measurement/monitoring.

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

1c.7 Summary of Controversy/Contradictory Evidence: 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.

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.

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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.

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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. Center for Disease Control and Prevention (CDC) Guidelines for Prevention of IV Catheter Related Infections (2002)

1. Surveillance

A. Conduct surveillance in ICUs and other patient populations to determine CRBSI rates, monitor trends in those rates, and assist in identifying lapses in infection control practices (3,12,16,247-250). Category IA

B. Express ICU data as the number of catheter-associated BSIs per 1,000 catheter-days for both adults and children and stratify by birth weight categories for neonatal ICUs to facilitate comparisons with national data in comparable patient populations and healthcare settings (3,12,16,247-250). Category IB

C. Investigate events leading to unexpected life-threatening or fatal outcomes. This includes any process variation for which a recurrence would likely present an adverse outcome (13).

3. UK-Renal Association Guideline for Haemodialysis Vascular Access (2007)

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

1c.10 Clinical Practice Guideline Citation: 1) Kidney Disease: Improving Global Outcomes (KDIGO) Clinical Practice Guidelines for Vascular Access (2006)

http://www.kidney.org/professionals/kdoqi/guideline_uphd_pd_va/index.htm

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1c.11 National Guideline Clearinghouse or other URL: <http://www.qualitymeasures.ahrq.gov>

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

The certainty of net benefit is moderate to high, and the magnitude of the net benefit is expected to be moderate to substantial yielding a USPSTF Grade B level of recommendation. This is consistent with strength of recommendations from the following: (1) National Kidney Foundation KDOQI guideline (2006) 8.3.3.1 (shown above): Rates the strength of this guideline recommendation as Grade B: It is recommended that clinicians routinely follow the guideline for eligible patients. There is moderately strong evidence that the practice improves health outcomes. (2) CDC for Surveillance (guidelines shown above): Rates the evidence for this guideline as Category IA. Strongly recommended for implementation and strongly supported by well-designed experimental, clinical, or epidemiologic studies.

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

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.

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 <i>Importance to Measure and Report</i> ?	1
Steering Committee: Was the threshold criterion, <i>Importance to Measure and Report</i> , met? Rationale:	1 Y <input type="checkbox"/> N <input type="checkbox"/>
2. SCIENTIFIC ACCEPTABILITY OF MEASURE PROPERTIES	
Extent to which the measure, <u>as specified</u> , produces consistent (reliable) and credible (valid) results about the quality of care when implemented. (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	
<p>2a.1 Numerator Statement (<i>Brief, text description of the numerator - what is being measured about the target population, e.g. target condition, event, or outcome</i>): Clinically confirmed infection: 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 and related to the dialysis access.</p> <p>Specific access types: Number of months that HD patients initiated a new IV antibiotic therapy for a newly suspected infection that was clinically confirmed during the six-month period ending with the current reporting month and for which the infection was related to the fistula/graft/catheter used as HD access.</p> <p>2a.2 Numerator Time Window (<i>The time period in which cases are eligible for inclusion in the numerator</i>): Six months ending with the current reporting month (for all access types)</p> <p>2a.3 Numerator Details (<i>All information required to collect/calculate the numerator, including all codes, logic, and definitions</i>): Clinically confirmed infection: 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, RQMT_1534, and RQMT_1323), the infection was clinically confirmed (RQMT_1312), the infection was related to the dialysis access (RQMT_1315), the date that the patient was prescribed IV antibiotic therapy falls within the parameters of the reporting period, and this date occurred when the patient was considered to be a chronic hemodialysis patient.</p> <p>Specific access types: A month is included in the numerator if a patient in the denominator had been prescribed an IV antibiotic during the month for a newly suspected infection (RQMT_1319, RQMT_1534, and RQMT_1323) that was clinically confirmed (RQMT_1312) and related to the fistula used as HD access (RQMT_1315 and RQMT_1314), the date that the patient was prescribed IV antibiotic therapy falls within the parameters of the reporting period, and this date occurred when the patient was considered to be a chronic HD patient.</p> <p>A month is included in the numerator if a patient in the denominator had been prescribed an IV antibiotic during the month for a newly suspected infection (RQMT_1319, RQMT_1534, and RQMT_1323) that was clinically confirmed (RQMT_1312) and related to the graft used as HD access (RQMT_1315 and RQMT_1314), the date that the patient was prescribed IV antibiotic therapy falls within the parameters of the reporting period, and this date occurred when the patient was considered to be a chronic HD patient.</p>	<p>2a-specs C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/></p>

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) .

A month is included in the numerator if a patient in the denominator had been prescribed an IV antibiotic during the month for a newly suspected infection (RQMT_1319, RQMT_1534, and RQMT_1323) that was clinically confirmed (RQMT_1312) and related to the catheter used as HD access (RQMT_1315 and RQMT_1314), the date that the patient was prescribed IV antibiotic therapy falls within the parameters of the reporting period, and this date occurred when the patient was considered to be a chronic HD patient.

2a.4 Denominator Statement (*Brief, text description of the denominator - target population being measured*):

Clinically confirmed infection:

All adult (18+) chronic maintenance HD patient days during the six-month period ending with the current reporting month.

Specific access types:

All adult (18+) chronic maintenance HD fistula/graft/catheter days 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 (for all access types)

2a.8 Denominator Details (*All information required to collect/calculate the denominator - the target population being measured - including all codes, logic, and definitions*):

Clinically confirmed infection:

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.

Specific access types:

Fistula 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 HD at the facility, and access type for dialysis is an arteriovenous fistula at any time during 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 be using a fistula if access type for HD any time during the six-month reporting period is an arteriovenous fistula with two needles and the date access type changed to a fistula is on or before the last day of the reporting period.

The number of fistula days in the denominator is calculated by summing the number of days during the reporting period that a patient meets the above inclusion criteria and was using a fistula during the six-month reporting period.

Graft 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 HD at the facility, and access type for dialysis is an arteriovenous graft

at any time during 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 be using a graft if access type for HD any time during the six-month reporting period is an arteriovenous graft with two needles and the date access type changed to a graft is on or before the last day of the reporting period.

The number of graft days in the denominator is calculated by summing the number of days during the reporting period that a patient meets the above inclusion criteria and was using a graft during the six-month reporting period.

Catheter 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 HD at the facility, and access type for dialysis is a catheter at any time during 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 be using a catheter if access type for HD any time during the six-month reporting period is a catheter with two needles and the date access type changed to a catheter is on or before the last day of the reporting period.

The number of catheter days in the denominator is calculated by summing the number of days during the reporting period that a patient meets the above inclusion criteria and was using a catheter during the six-month reporting period.

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

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 as noted in the numerator and denominator statements.

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

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

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

2a.18-19 Type of Score: Rate/proportion

2a.20 Interpretation of Score: Better quality = Lower score

2a.21 Calculation Algorithm (Describe the calculation of the measure as a flowchart or series of steps):
Clinically confirmed infection:

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

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.

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, RQMT_1534, and RQMT_1323), the infection was clinically confirmed (RQMT_1312), the infection was related to the dialysis access (RQMT_1315), the date that the patient was prescribed IV antibiotic therapy falls within the parameters of the reporting period, and this date occurred when the patient was considered to be a chronic hemodialysis patient.

Specific access types:

Fistula days are included in the denominator from a patient who is \geq 18 years old at the start of the six-month reporting period, on chronic HD at the facility, and access type for dialysis is an arteriovenous fistula at any time during 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 be using a fistula if access type for HD any time during the six-month reporting period is an arteriovenous fistula with two needles and the date access type changed to a fistula is on or before the last day of the reporting period.

The number of fistula days in the denominator is calculated by summing the number of days during the reporting period that a patient meets the above inclusion criteria and was using a fistula during the six-month reporting period.

A month is included in the numerator if a patient in the denominator had been prescribed an IV antibiotic during the month for a newly suspected infection (RQMT_1319, RQMT_1534, and RQMT_1323) that was clinically confirmed (RQMT_1312) and related to the fistula used as HD access (RQMT_1315 and RQMT_1314), the date that the patient was prescribed IV antibiotic therapy falls within the parameters of the reporting period, and this date occurred when the patient was considered to be a chronic HD patient.

Graft days are included in the denominator from a patient who is \geq 18 years old at the start of the six-month reporting period, on chronic HD at the facility, and access type for dialysis is an arteriovenous graft at any time during 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 be using a graft if access type for HD any time during the six-month reporting period is an arteriovenous graft with two needles and the date access type changed to a graft is on or before the last day of the reporting period.

The number of graft days in the denominator is calculated by summing the number of days during the reporting period that a patient meets the above inclusion criteria and was using a graft during the six-month reporting period.

A month is included in the numerator if a patient in the denominator had been prescribed an IV antibiotic during the month for a newly suspected infection (RQMT_1319, RQMT_1534, and RQMT_1323) that was

clinically confirmed (RQMT_1312) and related to the graft used as HD access (RQMT_1315 and RQMT_1314), the date that the patient was prescribed IV antibiotic therapy falls within the parameters of the reporting period, and this date occurred when the patient was considered to be a chronic HD patient.

Catheter 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 HD at the facility, and access type for dialysis is an catheter at any time during 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 be using a catheter if access type for HD any time during the six-month reporting period is a catheter with two needles and the date access type changed to a catheter is on or before the last day of the reporting period.

The number of catheter days in the denominator is calculated by summing the number of days during the reporting period that a patient meets the above inclusion criteria and was using a catheter during the six-month reporting period.

A month is included in the numerator if a patient in the denominator had been prescribed an IV antibiotic during the month for a newly suspected infection(RQMT_1319, RQMT_1534, and RQMT_1323) that was clinically confirmed (RQMT_1312) and related to the catheter used as HD access(RQMT_1315 and RQMT_1314), the date that the patient was prescribed IV antibiotic therapy falls within the parameters of the reporting period, and this date occurred when the patient was considered to be a chronic HD 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 infections per 1000 HD/fistula/graft/catheter 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

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 C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/>
2b.3 Testing Results (reliability statistics, assessment of adequacy in the context of norms for the test conducted): N/A	
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 C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/>
2c.3 Testing Results (statistical results, assessment of adequacy in the context of norms for the test conducted): N/A	
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 <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/> NA <input type="checkbox"/>
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 C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/> NA <input type="checkbox"/>
2e.4 If outcome or resource use measure is not risk adjusted, provide rationale: There are no compelling reasons to risk adjust measure.	
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 C <input type="checkbox"/> P <input type="checkbox"/>

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 ... [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 factors that influence the measured out... [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 men with prostate cancer, inequalities in treat... [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.

<p>2f.2 Methods to identify statistically significant and practically/meaningfully differences in performance (type of analysis & rationale): N/A</p> <p>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</p>	<p>M <input type="checkbox"/></p> <p>N <input type="checkbox"/></p>
<p>2g. Comparability of Multiple Data Sources/Methods</p> <p>2g.1 Data/sample (description of data/sample and size): N/A</p> <p>2g.2 Analytic Method (type of analysis & rationale): N/A</p> <p>2g.3 Testing Results (e.g., correlation statistics, comparison of rankings): N/A</p>	<p>2g</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>2h. Disparities in Care</p> <p>2h.1 If measure is stratified, provide stratified results (scores by stratified categories/cohorts): N/A</p> <p>2h.2 If disparities have been reported/identified, but measure is not specified to detect disparities, provide follow-up plans: N/A</p>	<p>2h</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>TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for Scientific Acceptability of Measure Properties?</p>	<p>2</p>
<p>Steering Committee: Overall, to what extent was the criterion, Scientific Acceptability of Measure Properties, met? Rationale:</p>	<p>2</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>3. USABILITY</p>	
<p>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)</p>	<p>Eval Rating</p>
<p>3a. Meaningful, Understandable, and Useful Information</p> <p>3a.1 Current Use: Testing not yet completed</p> <p>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.</p> <p>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</p> <p>Testing of Interpretability (Testing that demonstrates the results are understood by the potential users for public reporting and quality improvement)</p> <p>3a.4 Data/sample (description of data/sample and size): 32 dialysis facilities provided hemodialysis reported adverse events related to infection to the CDC in 2006. These facilities submitted data on 28,047 patient-months.</p>	<p>3a</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 [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.

<p>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 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.</p> <p>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.</p>	
<p>3b/3c. Relation to other NQF-endorsed measures</p> <p>3b.1 NQF # and Title of similar or related measures:</p>	
<p>(for NQF staff use) Notes on similar/related <u>endorsed</u> or submitted measures:</p>	
<p>3b. Harmonization 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 or different topic but same target population):</p> <p>3b.2 Are the measure specifications <u>harmonized</u>? If not, why?</p>	<p>3b</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>3c. Distinctive or Additive Value 3c.1 Describe the distinctive, improved, or additive value this measure provides to existing NQF-endorsed measures:</p> <p>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</p>	<p>3c</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>TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for <i>Usability</i>?</p>	<p>3</p>
<p>Steering Committee: Overall, to what extent was the criterion, <i>Usability</i>, met? Rationale:</p>	<p>3</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>
4. FEASIBILITY	
<p>Extent to which the required data are readily available, retrievable without undue burden, and can be implemented for performance measurement. (evaluation criteria)</p>	<p>Eval Rating</p>
<p>4a. Data Generated as a Byproduct of Care Processes</p>	<p>4a</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>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)</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>4b. Electronic Sources</p>	<p>4b</p> <p>C <input type="checkbox"/></p>

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.

<p>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</p> <p>4b.2 If not, specify the near-term path to achieve electronic capture by most providers.</p>	<p>P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/></p>
<p>4c. Exclusions</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 C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/> NA <input type="checkbox"/></p>
<p>4d. Susceptibility to Inaccuracies, Errors, or Unintended Consequences</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 access-related which will have a degree of subjectivity.</p>	<p>4d C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/></p>
<p>4e. Data Collection Strategy/Implementation</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 (<i>costs of data collection, fees associated with proprietary measures</i>): N/A</p> <p>4e.3 Evidence for costs: N/A</p> <p>4e.4 Business case documentation: Dialysis access-related infection, particularly for catheters, has been shown to be associated with 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.</p>	<p>4e C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/></p>
<p>TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for <i>Feasibility</i>?</p>	<p>4</p>
<p>Steering Committee: Overall, to what extent was the criterion, <i>Feasibility</i>, met? Rationale:</p>	<p>4 C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/></p>
<p>RECOMMENDATION</p>	
<p>(for NQF staff use) Check if measure is untested and only eligible for time-limited endorsement.</p>	<p>Time-limited <input type="checkbox"/></p>
<p>Steering Committee: Do you recommend for endorsement? Comments:</p>	<p>Y <input type="checkbox"/> N <input type="checkbox"/> A <input type="checkbox"/></p>

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).

CONTACT INFORMATION
<p>Co.1 Measure Steward (Intellectual Property Owner) Co.1 Organization Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland, 21244</p> <p>Co.2 Point of Contact Thomas, Dudley, Thomas.Dudley@cms.hhs.gov, 410-786-1442-</p>
<p>Measure Developer If different from Measure Steward Co.3 Organization Arbor Research/UM-KECC, 315 W. Huron Street, Ann Arbor, Michigan, 48103</p> <p>Co.4 Point of Contact Adrienne, Janney, adrienne.janney@arborresearch.org, 734-665-4108-</p>
<p>Co.5 Submitter If different from Measure Steward POC Thomas, Dudley, Thomas.Dudley@cms.hhs.gov, 410-786-1442-, Centers for Medicare & Medicaid Services</p>
<p>Co.6 Additional organizations that sponsored/participated in measure development</p>
ADDITIONAL INFORMATION
<p>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)</p>
<p>Ad.2 If adapted, provide name of original measure: Ad.3-5 If adapted, provide original specifications URL or attachment</p>
<p>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</p>
<p>Ad.10 Copyright statement/disclaimers:</p>
<p>Ad.11 -13 Additional Information web page URL or attachment:</p>
<p>Date of Submission (MM/DD/YY): 12/21/2010</p>

Page 18: [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 18: [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 18: [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 18: [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.