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)

---

### MEASURE DESCRIPTIVE INFORMATION

<table>
<thead>
<tr>
<th>De.1 Measure Title:</th>
<th>Clinically Confirmed Infection (rate)</th>
</tr>
</thead>
<tbody>
<tr>
<td>De.2 Brief description of measure:</td>
<td>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)</td>
</tr>
<tr>
<td>1.1-2 Type of Measure:</td>
<td>Process</td>
</tr>
<tr>
<td>De.3 If included in a composite or paired with another measure, please identify composite or paired measure Clinically Confirmed Infection (percentage)</td>
<td></td>
</tr>
<tr>
<td>De.4 National Priority Partners Priority Area:</td>
<td>Population health</td>
</tr>
<tr>
<td>De.5 IOM Quality Domain:</td>
<td>Safety</td>
</tr>
<tr>
<td>De.6 Consumer Care Need:</td>
<td>Living with illness</td>
</tr>
</tbody>
</table>

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### CONDITIONS FOR CONSIDERATION BY NQF

Four conditions must be met before proposed measures may be considered and evaluated for suitability as voluntary consensus standards:

- **A.** The measure is in the public domain or an intellectual property (measure steward agreement) is signed. Public domain only applies to governmental organizations. All non-government organizations must sign a measure steward agreement even if measures are made publicly and freely available.
- **A.1** Do you attest that the measure steward holds intellectual property rights to the measure and the right to use aspects of the measure owned by another entity (e.g., risk model, code set)? **Yes**
- **A.2** Indicate if Proprietary Measure (as defined in measure steward agreement): **Y**
- **A.3** Measure Steward Agreement: Government entity and in the public domain - no agreement necessary **N**
- **A.4** Measure Steward Agreement attached: **Y**
- **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 **Y**

---

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

---
NQF #1453

C. The intended use of the measure includes both public reporting and quality improvement.

► Purpose: Public reporting, Internal quality improvement

D. The requested measure submission information is complete. Generally, measures should be fully developed and tested so that all the evaluation criteria have been addressed and information needed to evaluate the measure is provided. Measures that have not been tested are only potentially eligible for a time-limited endorsement and in that case, measure owners must verify that testing will be completed within 12 months of endorsement.

D.1 Testing: No, testing will be completed within 12 months

D.2 Have NQF-endorsed measures been reviewed to identify if there are similar or related measures?

Yes

(for NQF staff use) Have all conditions for consideration been met?

Staff Notes to Steward (if submission returned):

Met

Staff Notes to Reviewers (issues or questions regarding any criteria):

Staff Reviewer Name(s):

TAP/Workgroup Reviewer Name:

Steering Committee Reviewer Name:

1. IMPORTANCE TO MEASURE AND REPORT

Extent to which the specific measure focus is important to making significant gains in health care quality (safety, timeliness, effectiveness, efficiency, equity, patient-centeredness) and improving health outcomes for a specific high impact aspect of healthcare where there is variation in or overall poor performance. Measures must be judged to be important to measure and report in order to be evaluated against the remaining criteria.

1a. High Impact

(for NQF staff use) Specific NPP goal:

1a.1 Demonstrated High Impact Aspect of Healthcare: Affects large numbers, Leading cause of morbidity/mortality, Severity of illness, Patient/societal consequences of poor quality

1a.2

1a.3 Summary of Evidence of High Impact: 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.

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).

Staff Notes to Reviewers (issues or questions regarding any criteria):

Staff Reviewer Name(s):
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.


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 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:


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

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

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):
19) Hung AM, Ikizler TA. Hemodialysis central venous catheters as a source of inflammation and its...
46) Rehman, R., R.J. Schmidt, and A.H. Moss, Ethical and legal obligation to avoid long-term tunneled

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)

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

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)
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 epidemiological studies.

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

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

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

Steering Committee: Was the threshold criterion, Importance to Measure and Report, met? Rationale:

2. SCIENTIFIC ACCEPTABILITY OF MEASURE PROPERTIES

Extent to which the measure, as specified, produces consistent (reliable) and credible (valid) results about the quality of care when implemented. (evaluation criteria)

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.1 Precisely Specified

2a.1 Numerator Statement (Brief, text description of the numerator - what is being measured about the target population, e.g. target condition, event, or outcome):
**Number of months that 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.**

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

2a.3 **Numerator Details** *(All information required to collect/calculate the numerator, including all codes, logic, and definitions):*  
A month is included in the numerator if a patient from the denominator 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.4 **Denominator Statement** *(Brief, text description of the denominator - target population being measured):*  
All adult (18+) chronic maintenance HD patient 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.

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

2a.9 **Denominator Exclusions** *(Brief text description of exclusions from the target population):*  
Patients less than 18 years old.

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

2a.11 **Stratification Details/Variables** *(All information required to stratify the measure including the stratification variables, all codes, logic, and definitions):*  
This measure can be stratified by vascular access type (fistula/graft/catheter).

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

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

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

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**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.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
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 of analysis & rationale):
N/A

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

2e. Risk Adjustment for Outcomes/ Resource Use Measures

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

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

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

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

2f. Identification of Meaningful Differences in Performance

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

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

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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]: 2b. 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 [KP13]: 2c. 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 measures/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 meaningful indicator of quality). 10

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
- N/A

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]
<table>
<thead>
<tr>
<th>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):</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>2g.1 Data/sample (description of data/sample and size):</td>
<td>N/A</td>
</tr>
<tr>
<td>2g.2 Analytic Method (type of analysis &amp; rationale):</td>
<td>N/A</td>
</tr>
<tr>
<td>2g.3 Testing Results (e.g., correlation statistics, comparison of rankings):</td>
<td>N/A</td>
</tr>
<tr>
<td>2g. Comparability of Multiple Data Sources/Methods</td>
<td></td>
</tr>
<tr>
<td>2h. Disparities in Care</td>
<td></td>
</tr>
<tr>
<td>2h.1 If measure is stratified, provide stratified results (scores by stratified categories/cohorts):</td>
<td>N/A</td>
</tr>
<tr>
<td>2h.2 If disparities have been reported/identified, but measure is not specified to detect disparities, provide follow-up plans:</td>
<td>N/A</td>
</tr>
<tr>
<td>TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for Scientific Acceptability of Measure Properties?</td>
<td></td>
</tr>
<tr>
<td>Steering Committee: Overall, to what extent was the criterion, Scientific Acceptability of Measure Properties, met?</td>
<td></td>
</tr>
<tr>
<td>Rationale:</td>
<td></td>
</tr>
</tbody>
</table>

3. USABILITY

<table>
<thead>
<tr>
<th>3a. Meaningful, Understandable, and Useful Information</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>3a.1 Current Use: Testing not yet completed</td>
<td></td>
</tr>
<tr>
<td>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): 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></td>
<td></td>
</tr>
<tr>
<td>Testing of Interpretability (Testing that demonstrates the results are understood by the potential users for public reporting and quality improvement)</td>
<td></td>
</tr>
<tr>
<td>3a.4 Data/sample (description of data/sample and size): 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.</td>
<td></td>
</tr>
<tr>
<td>3a.5 Methods (e.g., focus group, survey, QI project): Staff from the participating dialysis facilities monitored and reported vascular access type, new IV</td>
<td></td>
</tr>
</tbody>
</table>
For vascular access infection, the pooled mean rates were 0.4, 0.9, 4.8, and 22.9 per 100 patient-months 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.

<table>
<thead>
<tr>
<th>3b/3c. Relation to other NQF-endorsed measures</th>
<th>3b</th>
<th>NQF # and Title of similar or related measures:</th>
</tr>
</thead>
</table>

(for NQF staff use) Notes on similar/related endorsed or submitted measures:

3b. Harmonization
If this measure is related to measure(s) already endorsed by NQF (e.g., same topic, but different target population/settul/different topic but same target population):

3b.2 Are the measure specifications harmonized? If not, why?

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

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

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

4. FEASIBILITY

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

4a. Data Generated as a Byproduct of Care Processes

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)

4b. Electronic Sources

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

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

4c. Exclusions

4c.1 Do the specified exclusions require additional data sources beyond what is required for the numerator and denominator specifications?

No

4c.2 If yes, provide justification.

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

4d.1 Identify susceptibility to inaccuracies, errors, or unintended consequences of the measure and describe how these potential problems could be audited. If audited, provide results.

Facilities may not be aware of IV antibiotics prescribed if patients are hospitalized. Claims data may help with auditing of this. This measure requires physician input of whether infection was clinically confirmed which will have a degree of subjectivity.

4e. Data Collection Strategy/Implementation

4e.1 Describe what you have learned/modified as a result of testing and/or operational use of the measure regarding data collection, availability of data/missing data, timing/frequency of data collection, patient confidentiality, time/cost of data collection, other feasibility/implementation issues:

Data elements were reviewed and input was received by a data technical expert panel which includes representatives from many types of US dialysis facilities. The proposed measures are based on feedback from this group regarding feasibility of data collection.

4e.2 Costs to implement the measure (costs of data collection, fees associated with proprietary measures):

N/A

4e.3 Evidence for costs:

N/A

4e.4 Business case documentation: 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.

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

Steering Committee: Overall, to what extent was the criterion, Feasibility, met?

Rationale:

4

RECOMMENDATION

(for NQF staff use) Check if measure is untested and only eligible for time-limited endorsement.

Time-limited

Steering Committee: Do you recommend for endorsement?

Comments:

Y

CONTACT INFORMATION

Rating: C=Completely; P=Partially; M=Minimally; N=Not at all; NA=Not applicable
**Co.1 Measure Steward (Intellectual Property Owner)**
- **Organization**: Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland, 21244

**Co.2 Point of Contact**
- **Thomas, Dudley**, Thomas.Dudley@cms.hhs.gov, 410-786-1442

**Co.3 Measure Developer If different from Measure Steward**
- **Organization**: Arbor Research/UM-KECC, 315 W. Huron Street, Ann Arbor, Michigan, 48103

**Co.4 Point of Contact**
- **Adrienne, Janney**, adrienne.janney@arborresearch.org, 734-665-4108

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

**Co.6 Additional organizations that sponsored/participated in measure development**

### ADDITIONAL INFORMATION

**Workgroup/Expert Panel involved 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)
- Dr. Ronald Pisoni, moderator for contractor (Arbor Research Collaborative for Health)
- Ms. Natalie Lueth, analyst for contractor (University of Michigan KECC)

**Ad.2 If adapted, provide name of original measure:**

**Ad.3-5 If adapted, provide original specifications URL or attachment**

**Measure Developer/Steward Updates and Ongoing Maintenance**
- **Ad.6 Year the measure was first released:**
- **Ad.7 Month and Year of most recent revision:**
- **Ad.8 What is your frequency for review/update of this measure?** Three years
- **Ad.9 When is the next scheduled review/update for this measure?** 2013

**Ad.10 Copyright statement/disclaimers:**

**Ad.11 -13 Additional Information web page URL or attachment:**

**Date of Submission (MM/DD/YY):** 12/21/2010
9 Examples of validity testing include, but are not limited to: determining if measure scores adequately distinguish between providers known to have good or poor quality assessed by another valid method; correlation of measure scores with another valid indicator of quality for the specific topic; ability of measure scores to predict scores on some other related valid measure; content validity for multi-item scales/tests. Face validity is a subjective assessment by experts of whether the measure reflects the quality of care (e.g., whether the proportion of patients with BP < 140/90 is a marker of quality). If face validity is the only validity addressed, it is systematically assessed (e.g., ratings by relevant stakeholders) and the measure is judged to represent quality care for the specific topic and that the measure focus is the most important aspect of quality for the specific topic.

2d. 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).

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; OR rationale/data support no risk adjustment.

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.

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.