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 #: 1460 NQF Project: End Stage Renal Disease

<table>
<thead>
<tr>
<th>MEASURE DESCRIPTIVE INFORMATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>De.1 Measure Title: National Healthcare Safety Network (NHSN) Bloodstream Infection Measure</td>
</tr>
<tr>
<td>De.2 Brief description of measure: Number of hemodialysis outpatients with positive blood cultures per 100 hemodialysis patient-months</td>
</tr>
<tr>
<td>1.1-2 Type of Measure: Outcome</td>
</tr>
<tr>
<td>De.3 If included in a composite or paired with another measure, please identify composite or paired measure N/A</td>
</tr>
<tr>
<td>De.4 National Priority Partners Priority Area: Safety</td>
</tr>
<tr>
<td>De.5 IOM Quality Domain: Safety</td>
</tr>
<tr>
<td>De.6 Consumer Care Need: Staying healthy</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CONDITIONS FOR CONSIDERATION BY NQF</th>
</tr>
</thead>
<tbody>
<tr>
<td>Four conditions must be met before proposed measures may be considered and evaluated for suitability as voluntary consensus standards:</td>
</tr>
<tr>
<td>NQF Staff</td>
</tr>
<tr>
<td>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</td>
</tr>
<tr>
<td>A.2 Indicate if Proprietary Measure (as defined in measure steward agreement):</td>
</tr>
<tr>
<td>A.3 Measure Steward Agreement: Government entity and in the public domain - no agreement necessary</td>
</tr>
<tr>
<td>A.4 Measure Steward Agreement attached:</td>
</tr>
<tr>
<td>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</td>
</tr>
</tbody>
</table>

Rating: C=Completely; P=Partially; M=Minimally; N=Not at all; NA=Not applicable
### NQF #1460

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

#### Purpose:
- Public reporting, Internal quality improvement
- Other
- Medicare payment conditions

C. The intended use of the measure includes both public reporting and 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: Yes, fully developed and tested

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):

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

Staff Reviewer Name(s):

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### TAP/Workgroup Reviewer Name:

#### 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, Frequently performed procedure, Leading cause of morbidity/mortality, High resource use, Severity of illness, Patient/societal consequences of poor quality

1a.2

1a.3 Summary of Evidence of High Impact: In 2007, more than 340,000 patients received maintenance hemodialysis in the United States. The number of patients requiring maintenance dialysis for end stage renal disease (ESRD) continues to increase at a dramatic rate. The number of patients who will require maintenance dialysis in 2020 is projected to be 530,000. Patients who require maintenance hemodialysis are at high-risk for acquiring infections, because of their immunocompromised state, requirement for frequent and prolonged vascular access, and frequent exposure to healthcare environments, where healthcare-associated infections (HAIs) can occur. These patients typically receive hemodialysis treatments for 3-4 hours, 3 times weekly. During this time, their bloodstream is accessed for the hemodialysis procedure and they tend to be treated in close proximity with other patients, creating opportunities for infection transmission.

Infections are the second leading cause of death in this patient population and infections related to the vascular access (including bloodstream infections) are the most common type of infection experienced. A minimum of 50,000 bloodstream infections occur annually in this population. Bloodstream infections in these patients cause significant morbidity, mortality, and healthcare costs. Several studies of hemodialysis patients who were hospitalized for staphylococcus aureus bloodstream infections identified that patients required hospitalization for 9-13 days at an average cost of about $24,000 per episode. Severe complications such as...

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**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).
endocarditis and osteomyelitis occurred in 21-31% of these patients; hospital readmissions were also common and 12-week mortality following the bloodstream infection episode approached 20%.

1a.4 Citations for Evidence of High Impact:

1b. Opportunity for Improvement

1b.1 Benefits (improvements in quality) envisioned by use of this measure:
Use of this measure has been demonstrated to help identify outbreaks of bloodstream infections and to stimulate improvements in vascular access care and other infection control practices that have led to subsequent reductions in bloodstream infections. NHSN has an analytic function that allows facilities to view and analyze their own data in NHSN and produce data reports without the need for separate software packages. These features of NHSN are currently being used by multiple facilities and in several quality improvement initiatives to promote feedback of rate information to clinical staff. Such feedback has been shown to positively influence practices and infection rates. Specific improvements in quality that have been observed and are envisioned include enhanced practice in the following areas:
- Use of proper aseptic technique during catheter care;
- Use of optimal skin antiseptic solutions at catheter exit site and for hub cleansing--i.e., skin antiseptic agents that have been recommended in evidence-based guidelines from the Centers for Disease Control and Prevention (CDC) and Healthcare Infection Control Practices Advisory Committee (HICPAC) as well as the Kidney Disease Outcomes Quality Initiative (KDOQI) Vascular Access Guidelines;
- Implementation of other CDC/HICPAC and KDOQI-recommended evidence-based practices such as use of antimicrobial ointment at hemodialysis catheter exit sites;
- Increased hand hygiene adherence and proper glove use, particularly prior to vascular access care and other invasive procedures;
- Staff education and training on infection prevention.

1b.2 Summary of data demonstrating performance gap (variation or overall poor performance) across providers:
A. Substantial variability in rates of bloodstream infection (BSI) have been reported among facilities conducting BSI surveillance and among intervention trials that have described pre-intervention baseline rates of BSI. The pooled mean BSI rate for central venous catheter (CVC) patients among facilities reporting to NHSN in 2006 was 4.2 per 100 patient-months. Facilities in the 10th percentile had a rate of 0 per 100 patient-months, whereas the 90th percentile for this stratified measure was 9.4 per 100 patient-months. In another study, facilities all using a uniform method of measuring and reporting BSIs had facility-specific BSI rates that ranged from 0 to 30.8 BSIs per 100 patient-years.
B. Hospitalizations for bacteremia / septicemia among hemodialysis patients increased by 34% between 1993 and 2006. This is in marked contrast to the rate of central line associated BSIs in intensive care unit (ICU) patients during the past decade, which has declined.

1b.3 Citations for data on performance gap:

Rating: C=Completely; P=Partially; M=Minimally; N=Not at all; NA=Not applicable
Abstract presented at SHEA 2009 Annual Conference.
(http://www.cdc.gov/ncidod/dhqp/SHEA_Abstract2.html)

1b.4 Summary of Data on disparities by population group:
Older adults and blacks might be disproportionately impacted by BSIs. BSIs occur most commonly among hemodialysis patients with central venous catheters. The burden of BSI-associated morbidity and mortality is expected to be higher in these groups. CDC surveillance data demonstrate that during July 2004--June 2006, approximately 70% of invasive methicillin-resistant Staphylococcus aureus (MRSA) infections among dialysis patients occurred in persons aged >50 years. Males and blacks accounted for 57% and 56%, respectively, of the total population of dialysis patients with these infections. The majority (86%) of the infections were bloodstream infections, identified via positive blood culture. Approximately 85% of dialysis patients had an invasive device or catheter in place at the time of infection, and approximately 90% required hospitalization. The in-hospital mortality rate for MRSA-related hospitalization was 17%.

1b.5 Citations for data on Disparities:

1c. Outcome or Evidence to Support Measure Focus

1c.1 Relationship to Outcomes (For non-outcome measures, briefly describe the relationship to desired outcome. For outcomes, describe why it is relevant to the target population): This is an outcome measure. As previously described, BSIs are a leading cause of death and hospitalizations among maintenance hemodialysis patients and can lead to severe medical complications. As reported by USRDS, between 1993 and 2006, the rate of hospitalizations for bacteremia (adjusted for factors such as age, race, and cause of ESRD) among hemodialysis patients increased by 34% while the all-cause hospitalization rate in this same population remained stable. Patients with central venous catheters are at highest risk for acquiring a bloodstream infection and according to Fistula First data, approximately 20-25% of all maintenance hemodialysis patients have a central venous catheter. Thus the measure is reflective of an event with severe health consequences and close to one-quarter of all hemodialysis patients are at extremely high risk of developing this outcome.

1c.2-3. Type of Evidence: Observational study, Evidence-based guideline, Randomized controlled trial, Expert opinion, Systematic synthesis of research

1c.4 Summary of Evidence (as described in the criteria; for outcomes, summarize any evidence that healthcare services/care processes influence the outcome):
Multiple healthcare services and care processes have been shown to influence outcomes. These include: performing surveillance and data feedback to influence practices, antimicrobial ointments at hemodialysis catheter exit sites, staff education, hand hygiene, patient education, improved vascular access care and aseptic technique, and chlorhexidine for catheter exit site skin antisepsis. There is also ample evidence from the literature focused on inpatient settings describing reductions in central line-associated bloodstream infections that resulted from improved care processes. In addition to the interventions previously mentioned, these prevention trials also implemented adherence tools (e.g., catheter insertion checklist) and changes in safety culture.

1c.5 Rating of strength/quality of evidence (also provide narrative description of the rating and by whom): Multiple interventions were listed. The individual recommendations have varying levels of evidence, the highest being Category IA.

1c.6 Method for rating evidence: CDC/HICPAC recommendations are based on reviews of the evidence by an expert writing group. This information is then compiled and voted on by HICPAC. The evidence is rated as follows:

Category IA. Strongly recommended for implementation and strongly supported by well-designed experimental, clinical, or epidemiologic studies.
Category IB. Strongly recommended for implementation and supported by some experimental, clinical, or epidemiologic studies, and a strong theoretical rationale.
Category IC. Required by state or federal regulations, rules, or standards.

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:
  - Intermediate outcome - evidence that the measured intermediate outcome (e.g., bloodstream infection) is a predictor of an outcome (e.g., mortality).
  - Process - evidence that the measured process (e.g., antibiotic use) is associated with improved health/avoidance of harm or cost/benefit.
  - Patient experience - evidence that an association exists between the measure of patient experience with health care and the outcomes, values and preferences of individuals and the public.
  - Access - evidence that an association exists between access to a health service and the outcomes of, or experience with, care.

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 impact 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.

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.html). 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.
Category II. Suggested for implementation and supported by suggestive clinical or epidemiologic studies or a theoretical rationale. Unresolved issue. Represents an unresolved issue for which evidence is insufficient or no consensus regarding efficacy exists.

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

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

1c.9 **Quote the Specific guideline recommendation (including guideline number and/or page number):**

CDC. Recommendations for Preventing Transmission of Infections among Chronic Hemodialysis Patients. MMWR 2001; 50(RR05):1-43.


1c.10 **Clinical Practice Guideline Citation:**

1c.11 **National Guideline Clearinghouse or other URL:**

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

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

1c.14 **Rationale for using this guideline over others:**
Multiple guidelines are listed. All highlight the importance of basic infection control practices and vascular access care procedures to infection rates.

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

<table>
<thead>
<tr>
<th>Rating</th>
<th>1</th>
<th>Y</th>
<th>N</th>
</tr>
</thead>
</table>

**Scoring:**
- 1: Meets criterion
- 0: Does not meet criterion

**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) | 1 | Eval Rating 8 |

**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.
S.1 Do you have a web page where current detailed measure specifications can be obtained? S.2 If yes, provide web page URL:

2a. Precisely Specified

2a.1 Numerator Statement (Brief, text description of the numerator - what is being measured about the target population, e.g. target condition, event, or outcome):
The number of new positive blood culture events based on blood cultures drawn as an outpatient or within 1 calendar day after a hospital admission. A positive blood culture is considered a new event and counted only if it occurred 21 days or more after a previous positive blood culture in the same patient.

2a.2 Numerator Time Window (The time period in which cases are eligible for inclusion in the numerator):
Cases are included if the positive blood culture occurs during a month. The date of the event is based upon the date the blood culture was drawn.

2a.3 Numerator Details (All information required to collect/calculate the numerator, including all codes, logic, and definitions):
Information required: Number of positive blood culture events and event date
Definition: A positive blood culture is a blood culture that results in growth of 1 or more organisms. A new positive blood culture (not less than 21 days after a previous positive blood culture in the same patient) in a hemodialysis patient identified from blood cultures taken as an outpatient or within 1 calendar day after a hospital admission.
Data specifications: Events are counted if the following field: "patient with a positive blood culture" (on Form 57.109 under Event Details) is checked as being present.

2a.4 Denominator Statement (Brief, text description of the denominator - target population being measured):
Number of maintenance hemodialysis patients treated in the outpatient hemodialysis unit on the first 2 working days of the month.

2a.5 Target population gender: Female, Male
2a.6 Target population age range: All ages

2a.7 Denominator Time Window (The time period in which cases are eligible for inclusion in the denominator):
First 2 working days of each month
Target population is all maintenance hemodialysis patients treated in a particular month in an outpatient hemodialysis center, estimated by the number of patients treated on the first 2 working days of the month.
Data specification: The numeric value entered into the field labeled "Total patients" (on Form 57.119) is used as the denominator.

2a.8 Denominator Details (All information required to collect/calculate the denominator - the target population being measured - including all codes, logic, and definitions):
Target population is all maintenance hemodialysis patients treated on the first 2 working days of a particular month in an outpatient hemodialysis center.
Data specification: The numeric value entered into the field labeled "Total patients" (on Form 57.119) is used as the denominator.

2a.9 Denominator Exclusions (Brief text description of exclusions from the target population): Patients receiving inpatient hemodialysis are excluded

2a.10 Denominator Exclusion Details (All information required to collect exclusions to the denominator, including all codes, logic, and definitions):
The exclusion is only relevant for facilities that provide both outpatient (maintenance) and inpatient (acute or maintenance) hemodialysis. Patients who receive inpatient hemodialysis in the same facility are excluded.

2a.11 Stratification Details/Variables (All information required to stratify the measure including the stratification variables, all codes, logic, and definitions):
Both the numerator and denominator are stratified by patient vascular access type, where permanent central lines are defined as tunneled central lines (or tunneled central venous catheters) and temporary

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).

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.
central lines are defined as nontunneled central lines (or nontunneled central venous catheters).
Details of stratified measures:
1. BSI rate in CVC (central venous catheter) patients = the numerator and denominator below times 100
   1a. NUMERATOR. Events are included in the numerator if the “patient with positive blood culture” field on
   Form 57.109 is checked AND any of the following fields on Form 57.109 under ‘Vascular accesses’ are
   checked as being present: “Permanent central line”, “Temporary central line”, or “Port access device”.
   1b. DENOMINATOR. The denominator equals the sum of the numeric values entered for the following fields
   on Form 57.119: “Permanent central line”, “Temporary central line”, and “Port access device”.
2. BSI rate in AVG (arteriovenous graft) patients = the numerator and denominator below times 100
   2a. NUMERATOR. Events are included in the numerator if the “patient with positive blood culture” field on
   Form 57.109 is checked AND if the field labeled “Graft” on Form 57.109 under ‘Vascular accesses’ is checked
   as being present AND none of the following fields on the same form are checked as being present: 
   “Permanent central line”, “Temporary central line”, or “Port access device”.
   2b. DENOMINATOR. The denominator equals the numeric value entered for the field labeled, “Graft” on Form
   57.119.
3. BSI rate in AVF (arteriovenous fistula) patients = the numerator and denominator below times 100
   3a. NUMERATOR. Events are included in the numerator if the “patient with positive blood culture” field on
   Form 57.109 is checked AND if the field labeled “Fistula” on Form 57.109 under ‘Vascular accesses’ is checked
   as being present AND none of the following fields on the same form are checked as being present: 
   “Graft”, “Permanent central line”, “Temporary central line”, or “Port access device”.
   3b. DENOMINATOR. The denominator equals the numeric value entered for the field labeled, “Fistula” on Form
   57.119.

2a.12-13 Risk Adjustment Type: Other Simple Stratification

2a.14 Risk Adjustment Methodology/Variables: (List risk adjustment variables and describe conceptual
models, statistical models, or other aspects of model or method):
Both the numerator and denominator are stratified by vascular access type since vascular access type is the
single greatest risk factor for bloodstream infection in this population. The vascular access variables that are
collected and included in this analysis are: arteriovenous (AV) fistula, AV graft, permanent central line, and
temporary central line. If more than one access type is present in a patient, the bloodstream infection event
is attributed to the access type with the greatest risk (i.e., AV fistula < AV graft < permanent central line < temporary central line). During denominator collection (see URL below), the user is asked to count each
patient as having only 1 vascular access type, following the algorithm described. During numerator
collection, all vascular access types present at the time of the bloodstream infection event are reported and
the algorithm is applied during analysis of the data.

2a.15-17 Detailed risk model available Web page URL or attachment: URL
http://www.cdc.gov/nhsn/forms/57.119_DenomOutpatDialysis_BLANK.pdf

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):
1. Determine the number of bloodstream infection events in the unit for the month under surveillance (X)
2. Determine the outpatient hemodialysis facility patient census (i.e., denominator) for the month under
   surveillance (Y)
3. Divide X by Y and multiply this by 100 to determine the rate of bloodstream infections per 100 patient-
   months.
   Pooled mean rates are calculated by pooling the numerator over time (e.g., for an entire year or over
   multiple hemodialysis units) and dividing by the corresponding pooled denominator.

2a.22 Describe the method for discriminating performance (e.g., significance testing):
Rates are compared using standard significance tests for person-time rates (e.g., mid p exact test). Most
often, individual facility rates are compared to an overall pooled mean rate for all outpatient hemodialysis
facilities reporting to NHSN. In addition, rates can be tested to evaluate changes over time.

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):
This measure is not based on a sample. It represents complete information from all facilities that are
participating / reporting.
Table 1: Data Source (Check the source(s) for which the measure is specified and tested)

<table>
<thead>
<tr>
<th>Data Source</th>
<th>(Check the source(s) for which the measure is specified and tested)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Paper medical record/flow-sheet, Electronic Health/Medical Record, Lab data</td>
<td></td>
</tr>
</tbody>
</table>

Table 2: Data Source/Data Collection Instrument (Identify the specific data source/data collection instrument, e.g., name of database, clinical registry, collection instrument, etc.)

<table>
<thead>
<tr>
<th>Data Source/Data Collection Instrument</th>
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</tr>
</thead>
<tbody>
<tr>
<td>57.119 Denominators for Outpatient Dialysis</td>
<td></td>
</tr>
<tr>
<td>57.109 Dialysis Event</td>
<td></td>
</tr>
</tbody>
</table>

Table 3: Data Source/Data Collection Instrument Reference Web Page URL or Attachment

<table>
<thead>
<tr>
<th>Data Source/Data Collection Instrument Reference Web Page URL or Attachment</th>
<th>URL</th>
</tr>
</thead>
<tbody>
<tr>
<td><a href="http://www.cdc.gov/nhsn/psc_da_de.html#3">http://www.cdc.gov/nhsn/psc_da_de.html#3</a></td>
<td></td>
</tr>
</tbody>
</table>

Table 4: Data Dictionary/Code Table Web Page URL or Attachment

<table>
<thead>
<tr>
<th>Data Dictionary/Code Table Web Page URL or Attachment</th>
<th>URL</th>
</tr>
</thead>
</table>

Table 5: Level of Measurement/Analysis (Check the level(s) for which the measure is specified and tested)

<table>
<thead>
<tr>
<th>Level of Measurement/Analysis</th>
<th>(Check the level(s) for which the measure is specified and tested)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Facility/Agency, Population: national, Population: regional/network, Can be measured at all levels</td>
<td></td>
</tr>
</tbody>
</table>

Table 6: Care Settings (Check the setting(s) for which the measure is specified and tested)

<table>
<thead>
<tr>
<th>Care Settings</th>
<th>(Check the setting(s) for which the measure is specified and tested)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dialysis Facility</td>
<td></td>
</tr>
</tbody>
</table>

Table 7: Clinical Services (Healthcare services being measured, check all that apply)

<table>
<thead>
<tr>
<th>Clinical Services</th>
<th>(Healthcare services being measured, check all that apply)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinicians: Nurses, Clinicians: PA/NP/Advanced Practice Nurse, Clinicians: Physicians (MD/DO), Dialysis, Other Dialysis technicians</td>
<td></td>
</tr>
</tbody>
</table>

Table 8: Reliability Testing

<table>
<thead>
<tr>
<th>Reliability Testing</th>
<th>Data/sample (description of data/sample and size)</th>
</tr>
</thead>
<tbody>
<tr>
<td>N/A</td>
<td>The data collected for this measure represent the entire population of patients in participating facilities. There is no sampling used. Currently, there are more than 120 dialysis facilities reporting.</td>
</tr>
</tbody>
</table>

Table 9: Validity Testing

<table>
<thead>
<tr>
<th>Validity Testing</th>
<th>Data/sample (description of data/sample and size)</th>
</tr>
</thead>
<tbody>
<tr>
<td>N/A</td>
<td>A validation study was conducted of CDC’s dialysis surveillance system in 2002. At the time, this measure was collected as part of the Dialysis Surveillance Network (predecessor to the current dialysis event module in NHSN). A validation study of the BSI measure and several other data elements was conducted at 13 facilities. Twenty facilities were selected for the validation project. Participation in the study was voluntary. Thirteen of the 20 facilities opted to participate.</td>
</tr>
</tbody>
</table>

Declaring the completeness of event capture.

Were obtained from the facility and were compared with data submitted to the surveillance system to inform submitted. (2) A list of most recent positive blood culture events and other events of interest were obtained from the facility and were compared with data submitted to the surveillance system to determine the completeness of event capture.

The 2002 validation study had 2 components. (1) For each facility, a sample of events reported to the surveillance system in 2002. At the time, this measure was collected as part of the Dialysis Surveillance Network (predecessor to the current dialysis event module in NHSN). A validation study of the BSI measure and several other data elements was conducted at 13 facilities. Twenty facilities were selected for the validation project. Participation in the study was voluntary. Thirteen of the 20 facilities opted to participate.

The data collected for this measure represent the entire population of patients in participating facilities. There is no sampling used. Currently, there are more than 120 dialysis facilities reporting.

Because the data are not sampled, no formal reliability testing has been conducted. There have been some differences in pooled mean BSI rates in NHSN over time, however these changes might represent a shift in participating facilities or changes in practice over time. NHSN pooled mean BSI rate for tunneled CVC patients by timeframe (per 100 patient-months) =

1999-2005:   5.6
2006:   4.2
2007-2008: 3.9

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1999-2005:   5.6
2006:   4.2
2007-2008: 3.9
The validity of this measure will be further tested in 2010-2011 in a study designed to evaluate the validity of the measures compared to health record data available electronically and in paper records within the facility and to compare to a definition of BSI that will attempt to be more specific than the current definition. The study has been funded and is expected to begin in late 2010. It will involve data abstraction in at least 20 facilities in each of 4 geographically distinct sites in CDC’s Emerging Infections Program. The Colorado health department is also planning a validation study to compare the BSI measure in NHSN to facility medical record data.

2e. Risk Adjustment for Outcomes/ Resource Use Measures

2e.1 Data/sample (description of data/sample and size): This is not a sample but represents all of the data conducted.

2e.2 Analytic Method (type of risk adjustment, analysis, & rationale): The only risk adjustment performed is stratification of rates by vascular access type. This stratification accounts for direct contributions to risk imparted by the access type and also accounts for many other (both measured and unmeasured) factors that are correlated with vascular access type. These include variables such as age and presence of certain comorbid conditions and illness severity. Within each stratified category of patient-vascular access type, risks of bloodstream infection are more consistent and more dependent upon unmeasured) factors that are correlated with vascular access type and reviewed, 88.8% were determined to have been correctly characterized and reported.

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

2f. Identification of Meaningful Differences in Performance

2f.1 Data/sample from Testing or Current Use (description of data/sample and size): This is not a sample

Rating: C=Completely; P=Partially; M=Minimally; N=Not at all; NA=Not applicable
but represents all of the data reported by participating facilities (i.e., total population reported is used).

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

The distribution of facility-specific rates is calculated for each stratified measure and a corresponding percentile category (based on quartiles and the 1 highest and 1 lowest decile) for that facility is calculated. Some facilities utilize individualized performance targets based upon a goal rate percentile. Facility-specific stratified rates are also compared to the overall pooled mean rate for all facilities in NHSN. The difference between these two rates is assessed using standard significance tests for person-time measures (e.g., mid p exact test). A p-value of less than 0.05 is considered statistically significant.

### 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):

As described above, the distribution of facility-specific rates is calculated for each stratified measure and a corresponding percentile category (based on quartiles and the 1 highest and 1 lowest decile) for that facility is calculated. Some facilities utilize individualized performance targets based upon a goal rate percentile (e.g., 25th percentile or less). Facility-specific stratified rates are also compared to the overall pooled mean rate for all facilities in NHSN. The difference between these two rates is assessed using standard significance tests for person-time measures (e.g., mid p exact test). A p-value of less than 0.05 is considered statistically significant.

## 2g. Comparability of Multiple Data Sources/Methods

### 2g.1 Data/sample (description of data/sample and size): This is not a sample but represents all of the data reported by participating facilities (i.e., total population reported is used).

### 2g.2 Analytic Method (type of analysis & rationale):

The person-time units used in this measure (100 patient-months) can be roughly converted to different measures used in studies. Dividing the rate by 3 provides an approximate translation to a rate per 1000 patient-days. Similarly, rates per 100 patient-years can be divided by 12 to provide an estimate of the rate per 100 patient-months.

When rate units are converted in this manner, other studies and surveillance reports have documented rates that are consistent with this measure. For example, NHSN reported a pooled mean BSI rate in central venous catheter (CVC) patients of 4.2 per 100 patient-months in 2006 and 3.9 per 100 patient-months in 2007-2008. Dopirak et al. reported an overall BSI rate in CVC patients of 41.6 per 100 patient-years, which approximately translates to 3.5 per 100 patient-months.

### 2g.3 Testing Results (e.g., correlation statistics, comparison of rankings):

See above. No correlation statistics were used. Participating facilities in NHSN are different from facilities that were the data sources for other published surveillance reports or studies.

## 2h. Disparities in Care

### 2h.1 If measure is stratified, provide stratified results (scores by stratified categories/cohorts): Based on 2006 NHSN data, pooled mean stratified BSI rates (per 100 patient-months) were:

- 0.5 for AV fistula
- 0.9 for AV graft
- 4.2 for tunneled central venous catheter (CVC)
- 27.1 for non-tunneled CVC

### 2h.2 If disparities have been reported/identified, but measure is not specified to detect disparities, provide follow-up plans:

TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for Scientific Acceptability of Measure Properties?

Steering Committee: Overall, to what extent was the criterion, Scientific Acceptability of Measure Properties, met?

<table>
<thead>
<tr>
<th>Rating</th>
<th>C=Completely; P=Partially; M=Minimally; N=Not at all; NA=Not applicable</th>
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</thead>
<tbody>
<tr>
<td>2</td>
<td>C</td>
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</table>

### 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 [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.

### Rating:

C=Completely; P=Partially; M=Minimally; N=Not at all; NA=Not applicable
### 3. USABILITY

**3a. Meaningful, Understandable, and Useful Information**

3a.1 **Current Use:** In use

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):**

The state of Colorado currently mandates reporting of dialysis events, including BSIs, from all licensed outpatient dialysis facilities in the state to the National Healthcare Safety Network (NHSN). Several other states have similar legislative mandates that are not yet enforced or are planning for a similar mandate with enforcement in the future.

http://www.cdphe.state.co.us/hf/PatientSafety/HospitalReportCardInitiative/HB061045.pdf

http://www.cdphe.state.co.us/hf/PatientSafety/index.html

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):**

This measure is actively in use by more than 120 dialysis facilities nationwide. It is also a required measure (reported through NHSN) for CDC’s Hemodialysis BSI prevention collaborative (http://www.delmarvafoundation.org/providers/ambulatory/dialysis/index.html). ESRD Networks 3, 7, and 13 have recently initiated quality improvement programs that will require some or all of their ESRD facilities to report to NHSN and join the CDC prevention collaborative to prevent BSIs. CMS in its Conditions for Coverage for ESRD facilities and Interpretive Guidance requires monitoring of infection rates and recommends use of NHSN to track BSIs, other vascular access infections and related adverse events.

**Testing of Interpretability** (Testing that demonstrates the results are understood by the potential users for public reporting and quality improvement)

3a.4 **Data/sample (description of data/sample and size):**

3a.5 **Methods (e.g., focus group, survey, QI project):**

Facilities participating (approximately 20) in the CDC hemodialysis BSI prevention collaborative have been informally queried about their use of these measures, their acceptability and meaning.

3a.6 **Results (qualitative and/or quantitative results and conclusions):**

These participants have found the measure to be easily understandable and useful for quality improvement.

3b/3c. **Relation to other NQF-endorsed measures**

3b.1 **NQF # and Title of similar or related measures:**

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

3b. **Harmonization**

If this measure is related to measure(s) already endorsed by NQF (e.g., same topic, but different target population-setting/data source or different topic but same target population):

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

3c. **Distinctive or Additive Value**

Rating: C=Completely; P=Partially; M=Minimally; N=Not at all; NA=Not applicable
### 3c.1 Describe the distinctive, improved, or additive value this measure provides to existing NQF- endorsed measures:

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

N/A

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

<table>
<thead>
<tr>
<th></th>
<th>C</th>
<th>P</th>
<th>M</th>
<th>N</th>
<th>NA</th>
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<tbody>
<tr>
<td>Rationale:</td>
<td>3</td>
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</tbody>
</table>

### 4. FEASIBILITY

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

<table>
<thead>
<tr>
<th>4a. Data Generated as a Byproduct of Care Processes</th>
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</thead>
<tbody>
<tr>
<td>4a.1-2 How are the data elements that are needed to compute measure scores generated?</td>
</tr>
<tr>
<td>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)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>4b. Electronic Sources</th>
</tr>
</thead>
<tbody>
<tr>
<td>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)</td>
</tr>
<tr>
<td>Yes</td>
</tr>
<tr>
<td>4b.2 If not, specify the near-term path to achieve electronic capture by most providers.</td>
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<tr>
<th>4c. Exclusions</th>
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<tbody>
<tr>
<td>4c.1 Do the specified exclusions require additional data sources beyond what is required for the numerator and denominator specifications?</td>
</tr>
<tr>
<td>No</td>
</tr>
<tr>
<td>4c.2 If yes, provide justification.</td>
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<tr>
<th>4d. Susceptibility to Inaccuracies, Errors, or Unintended Consequences</th>
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</thead>
<tbody>
<tr>
<td>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.</td>
</tr>
<tr>
<td>Positive blood cultures are to some extent a function of blood culturing practices within hemodialysis units. This includes practices that could lead to increased contamination of cultures and whether or not antibiotics are given empirically to patients with suspected BSI without performing cultures. The suggested strategy to minimize these limitations is to assess several other measures in conjunction with BSI rate. These include rate of IV antibiotic starts and rate of vascular access-related BSI. These measures have also been submitted for consideration.</td>
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<table>
<thead>
<tr>
<th>4e. Data Collection Strategy/Implementation</th>
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<tr>
<td>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:</td>
</tr>
<tr>
<td>Positive blood cultures are a fairly objective measure and relatively simple to collect. Time and costs of data</td>
</tr>
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</table>
collection for this measure are minimal. Because these data are available electronically in most instances, CDC is working to create and validate BSI measures based upon existing electronic health record and/or laboratory data.

4e.2 Costs to implement the measure (costs of data collection, fees associated with proprietary measures): NHSN is a web-based surveillance system that is available to all US outpatient dialysis facilities free of charge.
Complete data collection and reporting for NHSN (i.e., all measures) require approximately 2 hours per month of staff time.

4e.3 Evidence for costs:
1. There is no fee for participation in the NHSN. (http://www.cdc.gov/nhsn/about.html)
2. Following CDC’s dialysis surveillance protocol requires approximately 2 hours per month of staff time.
(George A, Tokars JI, Clutterbuck EJ, et al. BMJ 2006; 332:1435-1439)

4e.4 Business case documentation:

<table>
<thead>
<tr>
<th>TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for Feasibility?</th>
</tr>
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<tbody>
<tr>
<td>1. Overall, to what extent was the criterion, Feasibility, met?</td>
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<tr>
<td>Rationale:</td>
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<tr>
<th>RECOMMENDATION</th>
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<tbody>
<tr>
<td>(for NQF staff use) Check if measure is untested and only eligible for time-limited endorsement.</td>
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| Steering Committee: Do you recommend for endorsement? |
| Comments: |
| | Y |
| | N |
| | A |

<table>
<thead>
<tr>
<th>CONTACT INFORMATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Co.1 Measure Steward (Intellectual Property Owner)</td>
</tr>
<tr>
<td>Co.1 Organization</td>
</tr>
<tr>
<td>Centers for Disease Control and Prevention, Division of Healthcare Quality Promotion, 1600 Clifton Rd., MS A-31, Atlanta, Georgia, 30333</td>
</tr>
<tr>
<td>Co.2 Point of Contact</td>
</tr>
<tr>
<td>Priti, Patel, MD, MPH, <a href="mailto:pgp0@cdc.gov">pgp0@cdc.gov</a>, 404-639-4273</td>
</tr>
<tr>
<td>Measure Developer If different from Measure Steward</td>
</tr>
<tr>
<td>Co.3 Organization</td>
</tr>
<tr>
<td>Centers for Disease Control and Prevention, Division of Healthcare Quality Promotion, 1600 Clifton Rd., MS A-31, Atlanta, Georgia, 30333</td>
</tr>
<tr>
<td>Co.4 Point of Contact</td>
</tr>
<tr>
<td>Priti, Patel, MD, MPH, <a href="mailto:pgp0@cdc.gov">pgp0@cdc.gov</a>, 404-639-4273</td>
</tr>
<tr>
<td>Co.5 Submitter If different from Measure Steward POC</td>
</tr>
<tr>
<td>Priti, Patel, MD, MPH, <a href="mailto:pgp0@cdc.gov">pgp0@cdc.gov</a>, 404-639-4273, Centers for Disease Control and Prevention</td>
</tr>
<tr>
<td>Co.6 Additional organizations that sponsored/participated in measure development</td>
</tr>
</tbody>
</table>

| ADDITIONAL INFORMATION |
| Workgroup/Expert Panel involved in measure development |
| Ad.1 | Provide a list of sponsoring organizations and workgroup/panel members’ names and organizations. Describe the members’ role in measure development. |
| 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: **1999** |
| Ad.7 Month and Year of most recent revision: **09, 2008** |
| Ad.8 What is your frequency for review/update of this measure? **Annually** |
| Ad.9 When is the next scheduled review/update for this measure? **01, 2011** |
| Ad.10 Copyright statement/disclaimers: |
| Ad.11 -13 Additional Information web page URL or attachment: Attachment 2a29 Data Dictionary.docx |
| **Date of Submission (MM/DD/YY):** **03/16/2011** |
1c. The measure focus is:

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

OR

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