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.

<u>Note</u>: 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 #: PSM-001-10 NQF Project: Patient Safety Measures

MEASURE DESCRIPTIVE INFORMATION

De.1 Measure Title: National Healthcare Safety Network (NHSN) Central line-associated Bloodstream Infection (CLABSI) Outcome Measure

De.2 Brief description of measure: Standardized Infection Ratio (SIR) of healthcare-associated, central lineassociated bloodstream infections (CLABSI) among patients in intensive care units (ICUs) and Neonatal Intensive Care Units (NICUs)

1.1-2 Type of Measure: Outcome **De.3** If included in a composite or paired with another measure, please identify composite or paired measure

De.4 National Priority Partners Priority Area: Safety **De.5** IOM Quality Domain: Safety **De.6** Consumer Care Need:

CONDITIONS FOR CONSIDERATION BY NQF

Four conditions must be met before proposed measures may be considered and evaluated for suitability as voluntary consensus standards:	NQF Staff
 A. The measure is in the public domain or an intellectual property (measure steward agreement) is signed. <i>Public domain only applies to governmental organizations. All non-government organizations must sign a measure steward agreement even if measures are made publicly and freely available.</i> 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 (<i>as defined in measure steward agreement</i>): A.3 Measure Steward Agreement: Government entity and in the public domain - no agreement necessary A.4 Measure Steward Agreement attached: 	A Y N
B. The measure owner/steward verifies there is an identified responsible entity and process to maintain and	В

update the measure on a schedule that is commensurate with the rate of clinical innovation, but at least every 3 years. Yes, information provided in contact section	Y N
C. The intended use of the measure includes <u>both</u> public reporting <u>and</u> quality improvement. Purpose: Public reporting, Internal quality improvement	
	C Y□ N□
D. The requested measure submission information is complete. Generally, measures should be fully developed and tested so that all the evaluation criteria have been addressed and information needed to evaluate the measure is provided. Measures that have not been tested are only potentially eligible for a time-limited endorsement and in that case, measure owners must verify that testing will be completed within 12 months of endorsement.	
D.1Testing: Yes, fully developed and tested D.2 Have NQF-endorsed measures been reviewed to identify if there are similar or related measures? Yes	D Y N
(for NQF staff use) Have all conditions for consideration been met? Staff Notes to Steward (<i>if submission returned</i>):	Met Y N
Staff Notes to Reviewers (issues or questions regarding any criteria):	
Staff Reviewer Name(s):	

TAP/Workgroup Reviewer Name:	
Steering Committee Reviewer Name:	
1. IMPORTANCE TO MEASURE AND REPORT	
Extent to which the specific measure focus is important to making significant gains in health care quality (safety, timeliness, effectiveness, efficiency, equity, patient-centeredness) and improving health outcomes for a specific high impact aspect of healthcare where there is variation in or overall poor performance. <i>Measures must be judged to be important to measure and report in order to be evaluated against the remaining criteria.</i> (evaluation criteria) 1a. High Impact	Eval Ratin g
(for NQF staff use) Specific NPP goal:	
 1a.1 Demonstrated High Impact Aspect of Healthcare: Affects large numbers, Leading cause of morbidity/mortality, Patient/societal consequences of poor quality, Frequently performed procedure 1a.2 1a.3 Summary of Evidence of High Impact: (1)An estimated 248,000 bloodstream infections occur in U.S. hospitals each year. It is believed that a large proportion of these are associated with the presence of a central vascular catheter, though this is an area where more study is needed1. For the purposes of NHSN, such infections are termed central line-associated bloodstream infections (CLABSI). Bloodstream infections are usually serious infections typically causing a prolongation of hospital stay and increased cost and risk of mortality. (2) A range of estimates for the attributable cost of CLABSI (\$5,734 to \$22,939 in 2003 dollars) that would be representative of all hospitalized patients. 	
 1a.4 Citations for Evidence of High Impact: (1)Klevens RM, Edwards JR, et al. Estimating healthcare-associated infection and deaths in U.S. hospitals, 2002. Public Health Reports 2007; 122:160-166. (2) Scott, RD. The Direct Medical Costs of Healthcare-Associated Infections in U.S. Hospitals and the Benefits of Prevention. http://www.cdc.gov/ncidod/dhqp/pdf/Scott_CostPaper.pdf Accessed April 12, 2010. 	1a C P M N

1b. Opportunity for Improvement	
1b.1 Benefits (improvements in quality) envisioned by use of this measure: Use of this measure to track CLABSIs through a nationalized standard for HAI monitoring, leads to improved patient outcomes and provides a mechanism for identifying improvements and quality efforts. CLABSI can be prevented through proper management of the central line. Efforts to improve central line insertion and maintenance practices, with early discontinuance of lines are recommended. These efforts result in decreased morbidity and mortality and reduced healthcare costs.	
1b.2 Summary of data demonstrating performance gap (variation or overall poor performance) across providers: CLABSI infection rates vary by reporting location and patient type and in some instances by location bed size and type of medical affiliation of the facility.	
1b.3 Citations for data on performance gap: (1)Edwards JR, Peterson KD, et al. National Healthcare Safety Network (NHSN) report, data summary for 2006 through 2008, issued December 2009. Am J Infect Control 2009; 37: 783-805.	
1b.4 Summary of Data on disparities by population group: According to the cited NHSN report, CLABSI infection rates vary from a low of 0.0% per 1000 device days to a high of 11.8% per 1000 device days between all reporting critical care units1 which vary by bed size and type of medical affiliation of the facility.	
1b.5 Citations for data on Disparities: (1)Edwards JR, Peterson KD, et al. National Healthcare Safety Network (NHSN) report, data summary for 2006 through 2008, issued December 2009. Am J Infect Control 2009; 37: 783-805.	1b C P M N
1c. Outcome or Evidence to Support Measure Focus	
1c.1 Relationship to Outcomes (<i>For non-outcome measures, briefly describe the relationship to desired outcome. For outcomes, describe why it is relevant to the target population</i>): CLABSI SIRs are relevant to patient populations because prevention recommendations have been published to reduce the incidence of CLABSI. A high SIR indicates an opportunity for improvement.	
1c.2-3. Type of Evidence: Evidence-based guideline, Expert opinion, Meta-analysis, Randomized controlled trial, Systematic synthesis of research	
1c.4 Summary of Evidence (<i>as described in the criteria; for outcomes, summarize any evidence that healthcare services/care processes influence the outcome</i>): O'Grady NP, Alexander M, Dellinger EP, Gerberding JL, Heard SO, Maki DG, et al. Guidelines for the prevention of intravascular catheter-related infections. MMWR 2002;51 (No. RR-10:1-26). As in previous guidelines issued by CDC and HICPAC, each recommendation was categorized on the basis of existing scientific data, theoretical rationale, applicability, and economic impact.	
1c.5 Rating of strength/quality of evidence (<i>also provide narrative description of the rating and by whom</i>):	
As in previous guidelines issued by CDC and HICPAC, each recommendation is categorized on the basis of existing scientific data, theoretical rationale, applicability, and economic impact.	
1c.6 Method for rating evidence: The CDC/HICPAC system for categorizing recommendations is 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	1c C P M
epidemiologic studies, and a strong theoretical rationale.	N

Category IC. Required by state or federal regulations, rules, or standards. 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: None	
1c.8 Citations for Evidence (other than guidelines):	
1c.9 Quote the Specific guideline recommendation (<i>including guideline number and/or page number</i>): See 1c.10	
1c.10 Clinical Practice Guideline Citation: O'Grady NP, Alexander M, Dellinger EP, Gerberding JL, Heard SO, Maki DG, et al. Guidelines for the prevention of intravascular catheter-related infections. MMWR 2002;51 (No. RR-10:1-26). Accessed April 22, 2010, http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5110a1.htm 1c.11 National Guideline Clearinghouse or other URL:	
1c.12 Rating of strength of recommendation (<i>also provide narrative description of the rating and by whom</i>): see 1c.6	
1c.13 Method for r ating strength of recommendation (<i>If different from</i> USPSTF system, <i>also describe rating and how it relates to USPSTF</i>):	
1c.14 Rationale for using this guideline over others:	
TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for <i>Importance</i> to Measure and Report?	1
Steering Committee: Was the threshold criterion, <i>Importance to Measure and Report</i> , met? Rationale:	1 Y N
2. SCIENTIFIC ACCEPTABILITY OF MEASURE PROPERTIES	
Extent to which the measure, <u>as specified</u> , produces consistent (reliable) and credible (valid) results about the quality of care when implemented. (evaluation criteria)	Eval Ratin g
2a. MEASURE SPECIFICATIONS	
 S.1 Do you have a web page where current detailed measure specifications can be obtained? S.2 If yes, provide web page URL: 	
2a. Precisely Specified	
2a.1 Numerator Statement (Brief, text description of the numerator - what is being measured about the target population, e.g. target condition, event, or outcome): Total number of observed healthcare-associated CLABSI among patients in ICUs and NICUs	2a-
2a.2 Numerator Time Window (<i>The time period in which cases are eligible for inclusion in the numerator</i>): Cases are included if they are healthcare-associated and their infection dates are during a month in which a patient care area (location) was selected for surveillance (i.e., if CLABSI surveillance is done in a medical	specs C P M N

ICU during January, all healthcare-associated CLABSI with infection dates in January are included). With low numbers of expected infections, it will be necessary to have a data sample of sufficient size to generate meaningful SIRs, thus the time window will be a period greater than monthly.

2a.3 Numerator Details (*All information required to collect/calculate the numerator, including all codes, logic, and definitions***)**:

1. Definition of healthcare-associated Infection (HAI): Any infection reported to NHSN must meet the definition of an NHSN healthcare-associated infection, that is, a localized or systemic condition resulting from an adverse reaction to the presence of an infectious agent(s) or its toxin(s). There must be no evidence that the infection was present or incubating at the time of admission to the care setting. Clinical evidence may be derived from direct observation of the infection site or review of information in the patient chart or other clinical records. For certain, but not all, infection sites, a physician's or surgeon's diagnosis of infection derived from direct observation during a surgical operation, endoscopic examination, or other diagnostic studies or from clinical judgment may be an acceptable criterion for an NHSN infection, unless there is compelling evidence to the contrary.

2. Definition of CLABSI: Primary bloodstream infections (BSI) are laboratory-confirmed bloodstream infections (LCBI) that are not secondary to an infection meeting CDC/NHSN criteria at another body site (see criteria in Chapter 17 CDC/NHSN Surveillance Definition. Report BSIs that are central line-associated (i.e., a central line or umbilical catheter was in place at the time of, or within 48 hours before, onset of the event).

3. Definition of Central line: An intravascular catheter that terminates at or close to the heart or in one of the great vessels which is used for infusion, withdrawal of blood, or hemodynamic monitoring. The following are considered great vessels for the purpose of reporting central-line BSI and counting central-line days in the NHSN system: Aorta, pulmonary artery, superior vena cava, inferior vena cava, brachiocephalic veins, internal jugular veins, subclavian veins, external iliac veins, common femoral veins, and in neonates, the umbilical artery/vein. NOTE: Neither the insertion site nor the type of device may be used to determine if a line qualifies as a central line. The device must terminate in one of these vessels or in or near the heart to qualify as a central line.

4. Infusion: The introduction of a solution through a blood vessel via a catheter lumen. This may include continuous infusions such as nutritional fluids or medications, or it may include intermittent infusions such as flushes or IV antimicrobial administration, or blood, in the case of transfusion or hemodialysis.

5. Umbilical catheter: A central vascular device inserted through the umbilical artery or vein in a neonate.

6. Temporary central line: A non-tunneled catheter.

7. Permanent central line: Includes

o Tunneled catheters, including certain dialysis catheters o Implanted catheters (including ports)

8. CLABSI Criteria:

• Laboratory-confirmed bloodstream infection (LCBI):

Must meet one for the following criteria:

Criterion 1: Patient has a recognized pathogen cultured from one or more blood cultures and organism cultured from blood is not related to an infection at another site.

Criterion 2: Patient has at least one of the following signs or symptoms: fever (>38oC), chills, or hypotension and signs and symptoms and positive laboratory results are not related to an infection at another site and common skin contaminant (i.e., diphtheroids [Corynebacterium spp.], Bacillus [not B. anthracis] spp., Propionibacterium spp., coagulase-negative staphylococci [including S. epidermidis], viridans group streptococci, Aerococcus spp., Micrococcus spp.) is cultured from two or more blood cultures drawn on separate occasions.

Criterion 3: Patient < 1 year of age has at least one of the following signs or symptoms: fever (>38oC core) hypothermia (<36oC core), apnea, or bradycardia and signs and symptoms and positive laboratory results

are not related to an infection at another site and common skin contaminant (i.e., diphtheroids [Corynebacterium spp.], Bacillus [not B. anthracis] spp., Propionibacterium spp., coagulase-negative staphylococci [including S. epidermidis], viridans group streptococci, Aerococcus spp., Micrococcus spp.) is cultured from two or more blood cultures drawn on separate occasions.

9. CDC Location: A CDC-defined designation given to a patient care area housing patients who have similar disease conditions or who are receiving care for similar medical or surgical specialties. Each facility location that is monitored is "mapped" to one CDC Location. The specific CDC Location code is determined by the type of patients cared for in that area according to the 80% Rule. That is, if 80% of patients are of a certain type (e.g., pediatric patients with orthopedic problems) then that area is designated as that type of location (in this case, an Inpatient Pediatric Orthopedic Ward).

10. Location: The patient care area to which a patient is assigned while receiving care in the healthcare facility.

11. Location of attribution: The location to which the event is being attributed.

12. Date of event: In the case of an infection event, the date when the first signs or symptoms of infection (clinical evidence) appeared, or the date the specimen used to meet the infection criterion was collected, whichever came first.

13. Facility-specific data for individual patient locations (i.e., bedsize of location, affiliation and level of affiliation with a medical school [Teaching statuses: major, graduate, limited, not affiliated -

• Major: A hospital that is an important part of the teaching program of a medical school and the majority of medical students rotate through multiple clinical services.

• Graduate: Hospital is used by the medical school for graduate trainings only (residency and/or fellowships).

• Limited: Hospital is used in the medical school's teaching program to only a limited extent.

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

Total number of expected CLABSIs, calculated by multiplying the number of central line device days for each location under surveillance for CLABSI during the period by the CLABSI rate for the same types of locations obtained from the standard population. Central line device- day denominator data that are collected differ according to the location of the patients being monitored. See 2a.8.

2a.5 Target population gender: Female, Male

2a.6 Target population age range: Patients of all ages are included, from premature infant to adult.

2a.7 Denominator Time Window (*The time period in which cases are eligible for inclusion in the denominator***)**:

The number of central line device days for the location under surveillance for CLABSI during the period is collected. This number is multiplied by the 2006 through 2008 standard population's CLABSI rate for the same type of location to obtain the number of expected CLABSIs. The expected number of CLABSIs is the sum across all location types during the period. The expected number of CLABSIs will be influenced by the number of central line device days in the facility and the CLABSI rate in the standard population; with low numbers of expected infections, it will be necessary to have a data sample of sufficient size to generate meaningful SIRs.

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

1. Number of appropriate device days for locations under CLABSI surveillance during the period

2. CLABSI rate per 1000 device days for the same location types from the identified population (2006 through 2008; see NHSN Report at http://www.cdc.gov/nhsn/PDFs/dataStat/2009NHSNReport.PDF).

3. Definition of device days: Device days are used for denominators. Device day denominator data that are collected differ according to the location of the patients being monitored.

a. For ICUs, the number of patients with one or more central lines of any type is collected daily, at the same time each day during the month. The totals for the month are entered.

b. In NICUs, because of differing infection risks, the number of patients with central lines and those with umbilical catheters is collected daily, at the same time each day, during the month. If a patient had both an umbilical catheter and a central line, count the day only as an umbilical catheter day. For the NICU infants, patients are further stratified by birth weight in five categories since risk of BSI also varies by

 birthweight. See 2a.3 for definitions of CDC location, location, and location of attribution. Facility-specific data for individual patient locations (i.e., bedsize of location, affiliation and level of affiliation with a medical school [Teaching statuses: major, graduate, limited, not affiliated - Major: A hospital that is an important part of the teaching program of a medical school and the majority of medical students rotate through multiple clinical services. Graduate: Hospital is used by the medical school for graduate trainings only (residency and/or fellowships). Limited: Hospital is used in the medical school's teaching program to only a limited extent.
 2a.9 Denominator Exclusions (Brief text description of exclusions from the target population): 1. Pacemaker wires and other nonlumened devices inserted into central blood vessels or the heart are excluded as central lines Peripheral intravenous lines are excluded from this measure
2a.10 Denominator Exclusion Details (<i>All information required to collect exclusions to the denominator, including all codes, logic, and definitions</i>) : See 2a.9
 2a.11 Stratification Details/Variables (All information required to stratify the measure including the stratification variables, all codes, logic, and definitions): 1. Facility-specific data for individual patient locations (i.e., bedsize of location, affiliation and level of affiliation with a medical school [Teaching statuses: major, graduate, limited, not affiliated - Major: A hospital that is an important part of the teaching program of a medical school and the majority of medical students rotate through multiple clinical services. Graduate: Hospital is used by the medical school for graduate trainings only (residency and/or fellowships). Limited: Hospital is used in the medical school's teaching program to only a limited extent. NICU location catheters are stratified by two types, central and umbilical lines. Numerator and denominator information is further stratified by five birthweight categories.
2a.12-13 Risk Adjustment Type: SIR is an indirect standardization method for summarizing HAI experience across any number of stratified groups of data. CLABSI incidence rates stratified by patient care location and in some instances, location bed size and type of medical school affiliation.Example: expected numbers of CLABSI (and CLABSI rates) in an adult ICU are not the same as in an NICU.
2a.14 Risk Adjustment Methodology/Variables (<i>List risk adjustment variables and describe conceptual models, statistical models, or other aspects of model or method</i>) : CLABSI rates per 1000 central line device days are used to calculate the expected number of CLABSI for the denominator of the SIR. They are indirectly standardized rates accounting for the influence of length of stay and length of central line use, and are stratified by patient care location, adjusting for differences in patient morbidity and disease-specific variables which may influence CLABSI risk. See also 2a.4 and 2a.20.
2a.15-17 Detailed risk model available Web page URL or attachment: URL No such URL. Please see 2a.21.
 2a.18-19 Type of Score: Ratio 2a.20 Interpretation of Score: 2a.21 Calculation Algorithm (<i>Describe the calculation of the measure as a flowchart or series of steps</i>): The SIR is calculated as follows: Identify the number of CLABSI in each location type Total these numbers for an observed number of CLABSIs Obtain the number of expected number of CLABSIs in the same location types for a standard population using the NHSN data report (http://www.cdc.gov/nhsn/PDFs/dataStat/2009NHSNReport.PDF)

4. Identify the number of expected CLABSIs for the facility based on its location types and numbers of central line device days:	
a. For each location type, multiply the number of central line device days experienced, by the expected CLABSI rate for that location	
 b. Sum the number of expected CLABSIs from all locations 5. Divide the total number of observed CLABSI events ("2" above) by the "expected" number of 	
CLABSI rates ("4.c." above).	
6. Result = SIR	
(The NHSN analysis tool will perform the calculations once the patient infection data and denominator information are entered into the system.)	
2a.22 Describe the method for discriminating performance (<i>e.g.</i> , significance testing):	
Performance evaluation can be conducted through at least 2 processes. First an SIR can be compared to the nominal value of 1.0 through significance testing, i.e., P value and confidence intervals. Second,	
successive SIRs obtained for a given reporting entity can be compared to each other to assess 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):	
2a.24 Data Source (Check the source(s) for which the measure is specified and tested)	
Electronic clinical data, Electronic Health/Medical Record, Lab data, Paper medical record/flow-sheet, Special or unique data	
2a.25 Data source/data collection instrument (<i>Identify the specific data source/data collection</i>	
<i>instrument, e.g. name of database, clinical registry, collection instrument, etc.</i>): NHSN Primary BSI collection form	
NHSN Denominator for ICU form NHSN Denominator for NICU form	
0- 00 00 Data sauras (data sallastian instrument references web news UDI an attackment. UDI	
2a.26-28 Data source/data collection instrument reference web page URL or attachment: URL http://www.cdc.gov/nhsn/forms/57.108_PrimaryBSI_BLANK.pdf,	
http://www.cdc.gov/nhsn/forms/57.118_DenominatorICU_BLANK.pdf, http://www.cdc.gov/nhsn/forms/57.116_DenominatorNICU_BLANK.pdf	
2a.29-31 Data dictionary/code table web page URL or attachment: Attachment Data Dictionary-	
634076366986069304.docx	
2a.32-35 Level of Measurement/Analysis (Check the level(s) for which the measure is specified and	
tested) Population: states, Facility/Agency, Population: national	
2a.36-37 Care Settings (<i>Check the setting(s) for which the measure is specified and tested</i>) Hospital, Long term acute care hospital, Rehabilitation Facility	
2a.38-41 Clinical Services (Healthcare services being measured, check all that apply)	
TESTING/ANALYSIS	
2b. Reliability testing	ეს
2b.1 Data/sample (description of data/sample and size): The standard population's CLABSI rates used in	2b C□
the SIR calculations are from 16 different types of ICUs and two types of NICUs. The numerators of the adult and pediatric locations range from 23 to 1683 CLABSI, and the denominators range from 17,321 to	P M
986,982 central line device days, with 11 of the 16 adult and pediatric ICU locations having greater than	M N

160,879 to 986,982 central line device days. NICU CLABSI data, using Level III units as an example, are further stratified by central and umbilical lines and each of these by 5 birthweight ranges. Comparing each sub-stratification, by birthweight, the Level III NICU central line-associated BSI numerators range from 157 to 481 CLABSI. The Level III NICU denominators range from 82,677 to 122, 272 central line device days. The Level III NICU umbilical line-associated BSI numerators range from 29,492 to 45,568 umbilical catheter device days. Therefore, we conclude for most of the locations, the standard population's rates are robust enough to use for determining the expected number of CLABSI. [National Healthcare Safety Network (NHSN) report: Data summary for 2006 through 2008, issued December 2009, Am J of Infect Control 2009; 37: 783-805].	
NHSN NICU Birthweight Categories: < 750 gm 751-1000 gm 1001-1500 gm 1501-2500 gm > 2500 gm	
 2b.2 Analytic Method (type of reliability & rationale, method for testing): A SIR is identical in concept to a standardized mortality ratio (SMR) and summarizes HAI experience across any number of stratified groups of data using indirect standardization. The SMR is a widely accepted method of measurement within the public health community. An SIR is felt to be a good measurement for CLABSI experiences within facilities because it: provides a single measure that is simple to interpret for assessing CLABSI incidence problems and prevention efficacy, gives a better estimate of the infection experience when there are small numerators or denominators in some or all strata. 	
2b.3 Testing Results <i>(reliability statistics, assessment of adequacy in the context of norms for the test conducted)</i> : The final measure score (SIR) is a deterministic function that is demonstrably reliable as a result of its calculation using a 100% sample.	
 2c. Validity testing 2c.1 Data/sample (description of data/sample and size): The CLABSI data used in this measure have been endorsed by NQF in 2 other measure sets (see 3b.1) and as described in 2b.2, the SMR, upon which the SIR is based, is a widely accepted method for summarizing mortality experience. Therefore, we conclude the SIR measure has inherent face validity. However, we are undertaking validity studies beginning in July 2010 (see 2c.2). 	
 6 states have independently completed and reported validity testing in their state HAI reports. Those reports can be found at the following URLs: Connecticut - http://www.ct.gov/dph/lib/dph/government_relations/2009_reports/annual_hai_report_2009.pdf (Description of validation study is included.) Maryland -	
 http://mhcc.maryland.gov/healthcare_associated_infections/hai/clabsi_final_rpt_20100618.pdf (Description of validation study is included.) New York - 2007 annual report described methods and results for "CLABSI surveillance audit" (http://www.nyhealth.gov/statistics/facilities/hospital/hospital_acquired_infections/2008/docs/hospital-acquired_infection-full_report.pdf). Validation methods have increased in complexity, but have not been published again in great detail since the 2007 report; though the validation was briefly referred to in the 2008 and 2009 reports. They hope to publish in greater detail in their next report. 	25
 South Carolina - http://www.scdhec.gov/health/disease/hai/docs/2010%20HIDA%20Annual%20Report.pdf (Annual report makes reference to validation study but does not describe methodology or findings in-depth.) Tennessee - http://health.state.tn.us/Downloads/TN_HAI_Report_2008_Jan_Dec_final.pdf (Annual report makes reference to validation study but does not describe methodology or findings in-depth.) 	2c C P M N

• Pennsylvania - www.portal.state.pa.us/portal/server.pt//padoh_2009_hai_report_pdf (Annual Report identifies current methods of monthly internal consistency checks that are completed, as well as annual on-site facility audits that are scheduled to begin the summer of 2010.	
Validity testing has begun in July, 2010 in one state and in 2 states in August, 2010 and is expected to begin in 7 other states in August, 2010. Using ARRA funding, another state has also started validation testing in May, 2010 and 2 others are presently working on protocols to do so.	
2c.2 Analytic Method (type of validity & rationale, method for testing): To address concerns regarding validity, HHS has provided funding, utilizing Recovery Act of 2009 funds, to CDC to support 10 state Emerging Infections Programs in validating NHSN-related measures and to support reporting on HHS metrics though NHSN.	
2c.3 Testing Results (statistical results, assessment of adequacy in the context of norms for the test conducted):	
2d. Exclusions Justified	
2d.1 Summary of Evidence supporting exclusion(s): Certain devices used in a manner similar to central lines will be excluded as they do not meet the NHSN definition of a central line. Peripheral intravenous lines are excluded from this measure.	
2d.2 Citations for Evidence:	
2d.3 Data/sample (description of data/sample and size):	
2d.4 Analytic Method (type analysis & rationale):	2d C P
2d.5 Testing Results (e.g., frequency, variability, sensitivity analyses):	M N NA
2e. Risk Adjustment for Outcomes/ Resource Use Measures	
2e.1 Data/sample <i>(description of data/sample and size)</i> : The standard population's CLABSI rates used in the SIR calculations are from 16 different types of ICUs and two types of NICUs. The numerators of the adult and pediatric locations range from 23 to 1683 CLABSI, and the denominators range from 17,321 to 986,982 central line device days, with 11 of the 16 adult and pediatric ICU locations having greater than 160,879 to 986,982 central line device days. NICU CLABSI data, using Level III units as an example, are further stratified by central and umbilical lines and each of these by 5 birthweight ranges. Comparing each sub-stratification, by birthweight, the Level III NICU central line-associated BSI numerators range from 157 to 481 CLABSI. The Level III NICU denominators range from 28 to 129 CLABSI. The Level III NICU denominators range from 28 to 129 CLABSI. The Level III NICU denominators range from 28 to 129 CLABSI. The Level III NICU denominators range from 28 to 129 CLABSI. The Level III NICU denominator's rates are robust enough to use for determining the expected number of CLABSI. [National Healthcare Safety Network (NHSN) report: Data summary for 2006 through 2008, issued December 2009, Am J of Infect Control 2009; 37: 783-805.]	
2e.2 Analytic Method <i>(type of risk adjustment, analysis, & rationale)</i> : The SIR is the ratio of the observed number of CLABSI to the expected number of CLABSI. CLABSI rates per 1000 central line device days, which are used to calculate the expected number of CLABSI for the denominator of the SIR, are indirectly standardized rates accounting for the influence of length of stay and length of central line use, and are stratified by patient care location, which adjusts for differences in patient morbidity and disease-specific variables which may influence CLABSI risk. If the number of CLABSIs that is observed is the same as the number expected for a patient care location of that type and size, then the SIR will = 1.0. If the number of observed CLABSIs is less than the number expected for a patient care	2e C P M NA

location of that type and size, then the SIR will be less than 1.0. Likewise, if the number of observed CLABSIs is more than the number expected for a patient care location of that type and size, then the SIR will be greater than 1.0 (e.g., an SIR of 2.0 represents a location that has observed twice the number of expected CLABSIs for that location type). See also 2a.4 and 2a.20.	
2e.3 Testing Results (risk model performance metrics):	
2e.4 If outcome or resource use measure is not risk adjusted, provide rationale:	
2f. Identification of Meaningful Differences in Performance	
2f.1 Data/sample from Testing or Current Use (description of data/sample and size): SIRs have been used as metrics for identfying differences in performance by state.	
2f.2 Methods to identify statistically significant and practically/meaningfully differences in performance <i>(type of analysis & rationale)</i> :	
The SIR by nature identifies variation from an expected rate of occurrence of an event and a sense of the magnitude of that variation, e.g., a facility CLABSI SIR of 2.0 represents twice as many CLABSIs as expected for the patient population. Additionally, the confidence interval provides further information regarding the likelihood that the SIR occurs within a specified range. See NHSN State Report for an example.	
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):	2f C P
The SIR and 95% confidence interval will be calculated and graphically represented to show relationship to the nominal value of 1.0 (i.e., where observed equals expected).	M N
2g. Comparability of Multiple Data Sources/Methods	
2g.1 Data/sample (description of data/sample and size):	
2g.2 Analytic Method (type of analysis & rationale):	2g C P M
2g.3 Testing Results (e.g., correlation statistics, comparison of rankings):	
2h. Disparities in Care	2h
2h.1 If measure is stratified, provide stratified results (scores by stratified categories/cohorts):	C
2h.2 If disparities have been reported/identified, but measure is not specified to detect disparities, provide follow-up plans:	P M N NA
TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for <i>Scientific Acceptability of Measure Properties?</i>	2
Steering Committee: Overall, to what extent was the criterion, <i>Scientific Acceptability of Measure Properties</i> , met? Rationale:	2 C P M
	N
3. USABILITY	
Extent to which intended audiences (e.g., consumers, purchasers, providers, policy makers) can understand the results of the measure and are likely to find them useful for decision making. (evaluation criteria)	Eval Ratin g
3a. Meaningful, Understandable, and Useful Information	3a

	C
3a.1 Current Use: In use	Ρ
3a.2 Use in a public reporting initiative (disclosure of performance results to the public at large) (<i>If used in a public reporting initiative, provide name of initiative(s), locations, Web page URL(s). <u>If not publicly reported</u>, state the plans to achieve public reporting within 3 years): The SMR is a widely accepted measurement tool within the public health community and the SIR is but a variation on this method. The SIR has been available and used by NHSN member facilities for surgical site infection rate surveillance since 2005 and in NNIS facilities before that. A Centers for Disease Control and Prevention report on HAIs with SIRs for individual U.S. states is scheduled for publication in May, 2010 on the NHSN website at http://www.cdc.gov/nhsn/index.html. Precedence has been set for using SIRs for public reporting of HAIs by several states. Such states include Pennsylvania (report may be found at http://www.portal.health.state.pa.us/portal/server.pt/community/department_of_health_home/1745), Tennessee (report may be found at http://health.state.tn.us/Downloads/TN_HAI_Report_2008_Jan_Dec_final.pdf), and South Carolina (http://www.scdhec.gov/health/disease/hai/reports.htm).</i>	M N
3a.3 If used in other programs/initiatives (<i>If used in quality improvement or other programs/initiatives, name of initiative(s), locations, Web page URL(s). <u>If not used for QI</u>, state the plans to achieve use for QI within 3 years): See 3a.2</i>	
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):	
3a.6 Results (qualitative and/or quantitative results and conclusions):	
3b/3c. Relation to other NQF-endorsed measures	
3b.1 NQF # and Title of similar or related measures: NQF #0139 and and Nursing-sensitive Care (NSC-7)	
(for NQF staff use) Notes on similar/related endorsed or submitted measures:	
 3b. Harmonization If this measure is related to measure(s) already endorsed by NQF (e.g., same topic, but different target population/setting/data source or different topic but same target population): 3b.2 Are the measure specifications harmonized? If not, why? 	3b C P M M N N NA
3c. Distinctive or Additive Value 3c.1 Describe the distinctive, improved, or additive value this measure provides to existing NQF- endorsed measures:	
5.1 If this measure is similar to measure(s) already endorsed by NQF (i.e., on the same topic and the same target population), Describe why it is a more valid or efficient way to measure quality: The cited existing measures are the CLABSI rate measures. The currently proposed measure, CLABSI SIR, uses the same numerator and denominator specifications as the rate measures. As already described, SIRs are useful risk-adjusted summary metrics that complement the existing NQF-endorsed measures.	3c C P M N NA
TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for Usability?	3

ſ

	1-001-10
Steering Committee: Overall, to what extent was the criterion, Usability, met? Rationale:	3 C P M N
4. FEASIBILITY	
Extent to which the required data are readily available, retrievable without undue burden, and can be implemented for performance measurement. (evaluation criteria)	Eval Ratin g
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? Other CLABSI and central line device days must be collected by trained hospital staff from information available in clinical data sources. The standard population's CLABSI rates are available from the NHSN Report. The NHSN analysis tool will automatically calculate SIRs.	4a C P M N
4b. Electronic Sources	
4b.1 Are all the data elements available electronically? (<i>elements that are needed to compute measure scores are in defined, computer-readable fields, e.g., electronic health record, electronic claims</i>) No	
4b.2 If not , specify the near-term path to achieve electronic capture by most providers . Currently studies are underway to determine the validity of an algorithm using electronically captured data to identify one type of HAI (central line-assocaited bloodstream infections). This will serve as a test project for other HAI surveillance.	4b C P M N
4c. Exclusions	
 4c.1 Do the specified exclusions require additional data sources beyond what is required for the numerator and denominator specifications? No 4c.2 If yes, provide justification. 	4c C P M N N NA
4d. Susceptibility to Inaccuracies, Errors, or Unintended Consequences	1
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. Patient medical records and other sources of patient data must be reviewed to determine if the patient meets the necessary criteria for a healthcare-associated CLABSI. It is possible that reviewers may miss symptoms or fail to identify that patients meet criteria thereby underreporting CLABSI events. Data collectors might also intentionally underreport CLABSIs. Both of these actions would result in an SIR that is calculated to be lower than actual. Alternatively, patients may be identified as having a CLABSI when in fact they do not meet CLABSI criteria and thereby calculate an SIR that is higher than actual. In addition, it is possible SIRs may be miscalculated. The NHSN reporting tool includes business logic to minimize misclassification of CLABSI and inaccurate reporting of catheter days. In addition, site visits can be conducted to audit data validity and this has been done for other infection types by some of the states using NHSN as their mandatory reporting tool (for example, see New York's audit process summary: http://www.health.state.ny.us/statistics/facilities/hospital/hospital_acquired_infections/2008/docs/hospi tal-acquired_infection.pdf, p20).	4d C P M N
4e. Data Collection Strategy/Implementation	4e
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	C P M N

issues: CLABSI rates and SIR using the methodologies described above have been in use by hospitals participating in CDC surveillance systems since 1986, and the rate measure has been endorsed by NQF in 2 measure sets since 2004. The criteria for CLABSI were updated in January of 2010, with the removal of clinical sepsis (CSEP) as a reporting choice in NICUs. This represented a move toward more defined measures to identify bloodstream infections in the neonate.	
4e.2 Costs to implement the measure (<i>costs of data collection, fees associated with proprietary measures</i>): We have estimated the time for identifying and reporting a CLABSI to be 30 minutes, and 2.5 hours per selected ICU per month for collecting and reporting central line device days. As an example of the cost to implement the measure, if a hospital identifies and reports 4 CLABSI from 2 ICUs per month for a year, it would be 84 hours of effort. If the salary of the data collectors averaged \$36 per hour, that level of effort would cost \$3024 per year for the hospital.	
4e.3 Evidence for costs: See OMB submission number 0920-0666, expires 03-31-2011 (labor cost adjusted for inflation).	
4e.4 Business case documentation:	
TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for <i>Feasibility?</i>	4
Steering Committee: Overall, to what extent was the criterion, <i>Feasibility</i> , met? Rationale:	4 C P M N
RECOMMENDATION	
Recommendation	
(for NQF staff use) Check if measure is untested and only eligible for time-limited endorsement.	Time- limited
	-
(for NQF staff use) Check if measure is untested and only eligible for time-limited endorsement. Steering Committee: Do you recommend for endorsement?	Iimited Y N
(for NQF staff use) Check if measure is untested and only eligible for time-limited endorsement. Steering Committee: Do you recommend for endorsement? Comments: CONTACT INFORMATION	Iimited Y N
(for NQF staff use) Check if measure is untested and only eligible for time-limited endorsement. Steering Committee: Do you recommend for endorsement? Comments:	Iimited Y N
(for NQF staff use) Check if measure is untested and only eligible for time-limited endorsement. Steering Committee: Do you recommend for endorsement? Comments: CONTACT INFORMATION Co.1 Measure Steward (Intellectual Property Owner) Co.1 <u>Organization</u> Centers for Disease Control and Prevention, 1600 Clifton Rd, NE, Mailstop A-24, Atlanta, Georgia, 30333 Co.2 <u>Point of Contact</u> Daniel, Pollock, MD, Medical Epidemiologist, dpollock@cdc.gov, 404-639-4237-	Iimited Y N
(for NOF staff use) Check if measure is untested and only eligible for time-limited endorsement. Steering Committee: Do you recommend for endorsement? Comments: CONTACT INFORMATION Co.1 Measure Steward (Intellectual Property Owner) Co.1 Organization Centers for Disease Control and Prevention, 1600 Clifton Rd, NE, Mailstop A-24, Atlanta, Georgia, 30333 Co.2 Point of Contact Daniel, Pollock, MD, Medical Epidemiologist, dpollock@cdc.gov, 404-639-4237- Measure Developer If different from Measure Steward Co.3 <u>Organization</u> Centers for Disease Control and Prevention, 1600 Clifton Rd, NE, Mailstop A-24, Atlanta, Georgia, 30333 Co.4 <u>Point of Contact</u>	Iimited Y N
(for NOF staff use) Check if measure is untested and only eligible for time-limited endorsement. Steering Committee: Do you recommend for endorsement? Comments: CONTACT INFORMATION Co.1 Measure Steward (Intellectual Property Owner) Co.1 Organization Centers for Disease Control and Prevention, 1600 Clifton Rd, NE, Mailstop A-24, Atlanta, Georgia, 30333 Co.2 Point of Contact Daniel, Pollock, MD, Medical Epidemiologist, dpollock@cdc.gov, 404-639-4237- Measure Developer If different from Measure Steward Co.3 Organization Centers for Disease Control and Prevention, 1600 Clifton Rd, NE, Mailstop A-24, Atlanta, Georgia, 30333	Iimited Y N
(for NOF staff use) Check if measure is untested and only eligible for time-limited endorsement. Steering Committee: Do you recommend for endorsement? Comments: CONTACT INFORMATION Co.1 Measure Steward (Intellectual Property Owner) Co.1 Organization Centers for Disease Control and Prevention, 1600 Clifton Rd, NE, Mailstop A-24, Atlanta, Georgia, 30333 Co.2 Point of Contact Daniel, Pollock, MD, Medical Epidemiologist, dpollock@cdc.gov, 404-639-4237- Measure Developer If different from Measure Steward Co.3 <u>Organization</u> Centers for Disease Control and Prevention, 1600 Clifton Rd, NE, Mailstop A-24, Atlanta, Georgia, 30333 Co.4 <u>Point of Contact</u>	

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: NQF # 0139 Central line associated bloodstrem infection Ad.3-5 If adapted, provide original specifications URL or attachment http://www.cdc.gov/nhsn/PDFs/pscManual/4PSC_CLABScurrent.pdf

Measure Developer/Steward Updates and Ongoing Maintenance Ad.6 Year the measure was first released: 2004 Ad.7 Month and Year of most recent revision: 01, 2010 Ad.8 What is your frequency for review/update of this measure? annually and when needed Ad.9 When is the next scheduled review/update for this measure? 04, 2011

Ad.10 Copyright statement/disclaimers:

Ad.11 -13 Additional Information web page URL or attachment: Attachment NQF CLABSI-Additional information042310.docx

Date of Submission (MM/DD/YY): 08/12/2010