

NATIONAL QUALITY FORUM

TO: Perinatal and Reproductive Health Endorsement Maintenance Steering Committee

FR: Reva Winkler, MD, MPH; Suzanne Theberge, MPH

SU: Evaluation of related and/or competing measures

DA: November 18, 2011

NQF has developed guidance for Steering Committees to select among related and competing measures (attachment 1). During the preliminary reviews, Workgroup #3 identified four related measures that address hospital-acquired infections:

- **478: Nosocomial Blood Stream Infections in Neonates (NQI #3) (AHRQ)**
- **1731: Health Care-Associated Bloodstream Infections in Newborns (Joint Commission)**
- **303: Late sepsis or meningitis in neonates (risk-adjusted) (VON)**
- **304: Late sepsis or meningitis in Very Low Birth Weight (VLBW) neonates (risk-adjusted) (VON)**

Measures 478 and 1731 are intended to address the same topic and population. AHRQ and the Joint Commission have worked together to harmonize the measures to the extent possible. According to the Joint Commission's submission "the fundamental differences are that measure 0478 has been developed to collect all data elements using administrative data [compared to the Joint Commission that uses medical record abstraction through vendors.] Such an approach has led in some cases to loss of specificity available through review of the medical record. The two measures have been harmonized to the extent possible; however, there are intrinsic differences." The submission form for 1731 compares the codes included in 478 and 1731.

Additionally, NQF is reviewing a measure for central-line associated blood stream infection (CLABSI) for adults and NICUs (attachment 2), in another project that is a related measure:

PSM-001-10 National Healthcare Safety Network (NHSN) Central line-associated Bloodstream Infection (CLABSI) Outcome Measure:

Description: Standardized Infection Ratio (SIR) of healthcare-associated, central line-associated bloodstream infections (CLABSI) will be calculated among patients in the following patient care locations:

- **Intensive Care Units (ICUs)**
- **Specialty Care Areas (SCAs) - adult and pediatric: long term acute care, bone marrow transplant, acute dialysis, hematology/oncology, and solid organ transplant locations**
- **other inpatient locations. (Data from these locations are reported from acute care general hospitals (including specialty hospitals), freestanding long term acute care hospitals, rehabilitation hospitals, and behavioral health hospitals. Only locations where patients reside overnight are included, i.e., inpatient locations.**

At the November 29-30, 2011 meeting the Steering Committee will further evaluate these similar measures to select the measure that best meets the measure evaluation criteria.

Principles for Selection of Best in Class

The Consensus Standards Approval Committee (CSAC) has identified the following principles for selection of best in class:

1. The endorsement of multiple competing measures should be by exception with adequate justification.
2. NQF prefers endorsement of measures that include the broadest possible target patient population for whom the measure is appropriate.
3. NQF prefers endorsement of measures that assess performance scores at the broadest level of analysis (e.g., for as many possible individuals and entities) for which the measure is appropriate.
4. If a single measure cannot accommodate the inclusion of all relevant patient populations or entities for performance measurement, a second measure could be considered for endorsement. The two measures should be harmonized to the extent possible.
5. When best in class is not clear, it may be appropriate to endorse more than one competing measure. At the time of initial endorsement, NQF should identify analyses needed to conduct a rigorous evaluation of the use and usefulness of the measures. This information should be provided by the developers to support best-in-class determination at the time of three-year maintenance.

Side-by-side comparison of related measures

Description

PSM-001-10 CLABSI (CDC)	BSI – 478(AHRQ) and 1731(JC)	Sepsis -303 and 304 (VON)
Standardized Infection Ratio (SIR) of healthcare-associated, central line-associated bloodstream infections (CLABSI) will be calculated among patients in the following patient care locations: NICU	478 (AHRQ) Percentage of high-risk newborn discharges with an ICD-9-CM diagnosis code of bloodstream infection 1731 (JC) This measure assesses the number of staphylococcal and gram negative septicemias or bacteremias in high-risk newborns.	303: Standardized rate and standardized morbidity ratio for nosocomial bacterial infection after day 3 of life for very low birth weight infants, other infants who are admitted to a neonatal intensive care unit within 28 days of birth and other infants who die in a hospital within 28 days of birth.

Discussion question:

- How much overlap exists among these measures?

Numerator/Case Finding

PSM-001-10 CLABSI (CDC)	BSI – 478(AHRQ) and 1731(JC)	Sepsis -303 and 304 (VON)
Total number of observed healthcare-associated CLABSI among patients in ICUs, NICUs, SCAs and other acute care	478 (AHRQ): Discharges among cases meeting the inclusion and exclusion rules for the denominator with an ICD-9-CM	303: Eligible infants with one or more of the following criteria: Criterion 1: Bacterial Pathogen. A bacterial pathogen is recovered from

<p>hospital locations where patients reside overnight. 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</p>	<p>code for bloodstream infection in any secondary diagnosis field</p> <p>1731 (JC): This measure assesses the number of staphylococcal and gram negative septicemias or bacteremias in high-risk newborns. Cases are eligible for the numerator population with ICD-9-CM Other Diagnosis Code for septicemias OR one or more ICD-9-CM Other Diagnosis Codes for newborn septicemia or bacteremia and one diagnosis code for newborn bacteremia.</p>	<p>a blood and/or cerebral spinal fluid culture obtained after Day 3 of life. OR Criterion 2: Coagulase Negative Staphylococcus. The infant has all 3 of the following:</p> <ol style="list-style-type: none"> 1. Coagulase negative staphylococcus is recovered from a blood culture <ul style="list-style-type: none"> obtained from either a central line, or peripheral blood sample and/or is recovered from cerebrospinal fluid obtained by lumbar puncture, ventricular tap or ventricular drain. 2. One or more signs of generalized infection (such as apnea, temperature instability, feeding intolerance, worsening respiratory distress or hemodynamic instability). 3. Treatment with 5 or more days of intravenous antibiotics after the above <ul style="list-style-type: none"> cultures were obtained. If the infant died, was discharged, or transferred prior to the completion of 5 days of intravenous antibiotics, this condition would still be met if the intention were to treat for 5 or more days.
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Denominator

PSM-001-10 CLABSI (CDC)	BSI – 478(AHRQ) and 1731(JC)	Sepsis -303 and 304 (VON)
<p>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.</p>	<p>478 (AHRQ) : All newborns and outborns with</p> <ol style="list-style-type: none"> 1) Birth weight 500 to 1499g OR 2) Gestational age between 24 and 30 weeks OR 3) Birth weight greater than or equal to 1500g AND <ul style="list-style-type: none"> - in-hospital death OR - operating room procedure OR - mechanical ventilation OR - age in days less than 2 AND <p>transferred from another health care facility</p>	<p>303:Eligible infants who are in the reporting hospital after day 3 of life:</p> <p>Infants in the reporting hospital after day 3 of life or readmitted after day three of life are included if they meet any of the following criteria:</p> <ol style="list-style-type: none"> 1. Any infant who is born at the reporting hospital and whose birth weight is between 401 and 1500 grams or whose gestational age is between 22 weeks 0 days and 29 weeks 6 days (inclusive) is included,

	<p>1731 (JC): Liveborn newborns with birth weight between 500 and 1499g OR Birth Weight between 500 and 1499g OR an ICD-9-CM Other Diagnosis Codes for birth weight = 1500g as defined in Appendix A, Table 11.15, 11.16 or 11.17 OR Birth Weight = 1500g who experienced one or more of the following:</p> <ul style="list-style-type: none"> o Experienced death o ICD-9-CM Principal Procedure Code or ICD-9-CM Other Procedure Codes for major surgery as defined in Appendix A, Table 11.18 o ICD-9-CM Principal Procedure Code or ICD-9-CM Other Procedure Codes for mechanical ventilation as defined in Appendix A, Table 11.19 o Transferred in from another acute care hospital or health care setting within 2 days of birth. 	<p>regardless of where in the hospital the infant receives care.</p> <p>2. Any outborn infant who is admitted to any location in the reporting hospital within 28 days of birth, without first having gone home, and whose birth weight is between 401 and 1500 grams or whose gestational age is between 22 weeks 0 days and 29 weeks 6 days (inclusive) is included, regardless of where in the hospital the infant receives care.</p> <p>3. Any infant whose birth weight is over 1500 grams and who is admitted to a Neonatal Intensive Care Unit (NICU) in the reporting hospital within the first 28 days of life without first having gone home is included, regardless of gestational age. A NICU is any location within the hospital in which newborn infants receive continuous positive airway pressure (CPAP) or intermittent mandatory ventilation (IMV).</p> <p>4. Any infant whose birth weight is over 1500 grams and who dies at any location in the reporting hospital within 28 days of birth without first having gone home is included. This includes inborn and outborn infants.</p>
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Discussion questions:

- **How similar/different are the measured populations?**
- **Which measure captures the broadest population?**

Exclusions

<u>PSM-001-10 CLABSI (CDC)</u>	<u>BSI – 478(AHRQ) and 1731(JC)</u>	<u>Sepsis -303 and 304 (VON)</u>
1. Pacemaker wires and other nonlumened devices inserted into central blood vessels or the heart are excluded as central lines	<u>478 (AHRQ)</u> Exclude cases: <ul style="list-style-type: none"> • with principal diagnosis code of sepsis or secondary diagnosis code present on admission 	<u>303:</u> Exclude patients who do not meet eligibility criteria for birth weight, gestational age or NICU admission. Exclude infants who

<p>2. Peripheral intravenous lines are excluded from this measure</p>	<ul style="list-style-type: none"> • with birth weight less than 500 grams • with length of stay less than 2 days • with missing data for (SEX=missing), age (AGE=missing), quarter (DQTR=missing), year (YEAR=missing) or principal diagnosis (DX1=missing) <p>1731 (JC) ICD-9-CM Principal Diagnosis Code for sepsis as defined in Appendix A, Table 11.10.2</p> <ul style="list-style-type: none"> • ICD-9-CM Principal Diagnosis Code for liveborn newborn as defined in Appendix A, Table 11.10.3 AND ICD-9-CM Other Diagnosis Codes for newborn septicemia or bacteremia as defined in Appendix A, Table 11.10 • ICD-9-CM Other Diagnosis Codes for birth weight < 500g as defined in Appendix A, Table 11.20 OR Birth Weight < 500g • Length of Stay < 2 days OR > 120 days 	<p>are discharged home, transferred or die prior to day 3 of life.</p>
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Risk adjustment

<u>PSM-001-10 CLABSI (CDC)</u>	<u>BSI – 478(AHRQ) and 1731(JC)</u>	<u>Sepsis -303 and 304 (VON)</u>
<p>CLABSI rates per 1000 central line device days provide adjustment for the influence of length of stay and central line utilization stratified by patient care locations.</p>	<p>478 (AHRQ): Statistical risk model -- The predicted value for each case is computed using a hierarchical model (logistic regression with hospital random effect) and covariates for gender, birthweight (500g groups), modified CMS DRG, congenital anomalies, transfer-in status and the availability of point of origin.</p>	<p>303 and 304: Each measure has a distinct risk model: The risk adjustment process begins by using logistic regression to model the dichotomous measure with several case mix variables: gestational age and its quadratic term, APGAR score at 1 minute, maternal race, infant gender, multiple birth (Yes/No), vaginal delivery (Yes/No), birth location (Inborn/Outborn), major birth defect (Yes/No) and small for gestational age (Yes/No). An estimate is made of the "systematic variation" associated</p>
	<p>1731 (JC) Statistical risk model - Logistic regression Model Risk Factors: Intercept Intercept Birth Weight 1250g to 2499g</p>	

	Birth Weight 1000 to 1249g Birth Weight 500 to 999g Modified DRG Newborn Transfers Out or Died Congenital Anomaly Gastrointestinal Anomaly Congenital Anomaly Cardiovascular Anomaly Congenital Anomaly Other Anomaly Out-born Birth Newborns Transfers In	with the hospital standardized morbidity ratios (SMRs) using the method suggested by Martuzzi and Hills (Martuzzi M and Hills M,
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Level of analysis

<u>PSM-001-10 CLABSI (CDC)</u>	<u>BSI – 478(AHRQ) and 1731(JC)</u>	<u>Sepsis -303 and 304 (VON)</u>
Facility/Agency, Population : National, Population : states	<u>478 (AHRQ)</u> Facility <u>1731 (JC)</u> Facility, Population : National	<u>303 and 304:</u> Facility

Data source

<u>PSM-001-10 CLABSI (CDC)</u>	<u>BSI – 478(AHRQ) and 1731(JC)</u>	<u>Sepsis -303 and 304 (VON)</u>
NHSN Primary BSI collection form NHSN Denominator for NICU form	<u>478 (AHRQ):</u> Administrative claims <u>1731 (JC)</u> Data are collected using contracted Performance Measurement Systems (vendors) that develop data collection tools based on the measure specifications.	<u>303 and 304:</u> VON Registry

Type of Score

<u>PSM-001-10 CLABSI (CDC)</u>	<u>BSI – 478(AHRQ) and 1731(JC)</u>	<u>Sepsis -303 and 304 (VON)</u>
Ratio	<u>478 (AHRQ)</u> Rate/proportion <u>1731 (JC)</u> Rate/proportion	<u>303 and 304:</u> Adjusted rate and standardized morbidity ratio (observed minus expected cases are also reported)

Discussion question:

- Are certain methods of scoring more useful/meaningful?

Current performance

<u>PSM-001-10 CLABSI (CDC)</u>	<u>BSI – 478(AHRQ) and 1731(JC)</u>	<u>Sepsis -303 and 304 (VON)</u>		
<u>2009 National data: Ratio</u> <table border="1" style="width: 100%;"> <tr> <td style="width: 80%;"><=750 grams</td> <td style="width: 20%;">3.3</td> </tr> </table>	<=750 grams	3.3	<u>478 (AHRQ)</u> Risk adjusted rate per 1,000	<u>303:</u> In 2009 at 293 hospitals in the Vermont Oxford Network
<=750 grams	3.3			

751-1000 grams	2.8	<p>discharges:</p> <table border="1"> <thead> <tr> <th></th> <th>Estimate</th> <th>SE</th> <th>p</th> </tr> </thead> <tbody> <tr> <td>value</td> <td></td> <td></td> <td></td> </tr> <tr> <td>Northeast c</td> <td>43.494</td> <td>1.623</td> <td></td> </tr> <tr> <td>Midwest</td> <td>37.175</td> <td>1.580</td> <td></td> </tr> <tr> <td></td> <td>0.005</td> <td></td> <td></td> </tr> <tr> <td>South</td> <td>68.833</td> <td>1.101</td> <td></td> </tr> <tr> <td></td> <td>0.000</td> <td></td> <td></td> </tr> <tr> <td>West</td> <td>56.902</td> <td>1.508</td> <td></td> </tr> <tr> <td></td> <td>0.000</td> <td></td> <td></td> </tr> </tbody> </table> <p>1731 (JC) Based on 4 quarters of data reported to The Joint Commission, PC-04 has an aggregate performance rate of 0.3 %, indicating a potential performance gap of 0.3% if the optimal rate was 0%.</p>		Estimate	SE	p	value				Northeast c	43.494	1.623		Midwest	37.175	1.580			0.005			South	68.833	1.101			0.000			West	56.902	1.508			0.000			<p>expanded database for all NICU admission, of the 123,000 infants of all birth weights enrolled 4% had a hospital acquired bacterial infection. There was marked variation in rates among hospitals with the following distribution by percentiles:</p> <table border="1"> <thead> <tr> <th>10th</th> <th>25th</th> <th>50th</th> <th>75th</th> <th>90th</th> </tr> </thead> <tbody> <tr> <td>0.4</td> <td>1.4</td> <td>2.9</td> <td>5.2</td> <td>8.5</td> </tr> </tbody> </table>	10 th	25th	50th	75th	90th	0.4	1.4	2.9	5.2	8.5
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ATTACHMENT 1 – GUIDANCE ON RELATED AND COMPETING MEASURES

5. Comparison to Related or Competing Measures [Definitions-Table11](#) [Guidance-Figure 1](#)

If a measure meets the above criteria and there are endorsed or new related measures (either the same measure focus or the same target population) or competing measures (both the same measure focus and the same target population), the measures are compared to address harmonization and/or selection of the best measure.

5a. The measure specifications are harmonized¹⁸ with related measures;

OR

the differences in specifications are justified. [Guidance-Table 13](#)

5b. The measure is superior to competing measures (e.g., is a more valid or efficient way to measure); [Guidance-Table 12](#)

OR

multiple measures are justified.

Note

18. Measure harmonization refers to the standardization of specifications for related measures with the same measure focus (e.g., *influenza immunization* of patients in hospitals or nursing homes); related measures with the same target population (e.g., eye exam and HbA1c for *patients with diabetes*); or definitions applicable to many measures (e.g., age designation for children) so that they are uniform or compatible, unless differences are justified (e.g., dictated by the evidence). The dimensions of harmonization can include numerator, denominator, exclusions, calculation, and data source and collection instructions. The extent of harmonization depends on the relationship of the measures, the evidence for the specific measure focus, and differences in data sources.

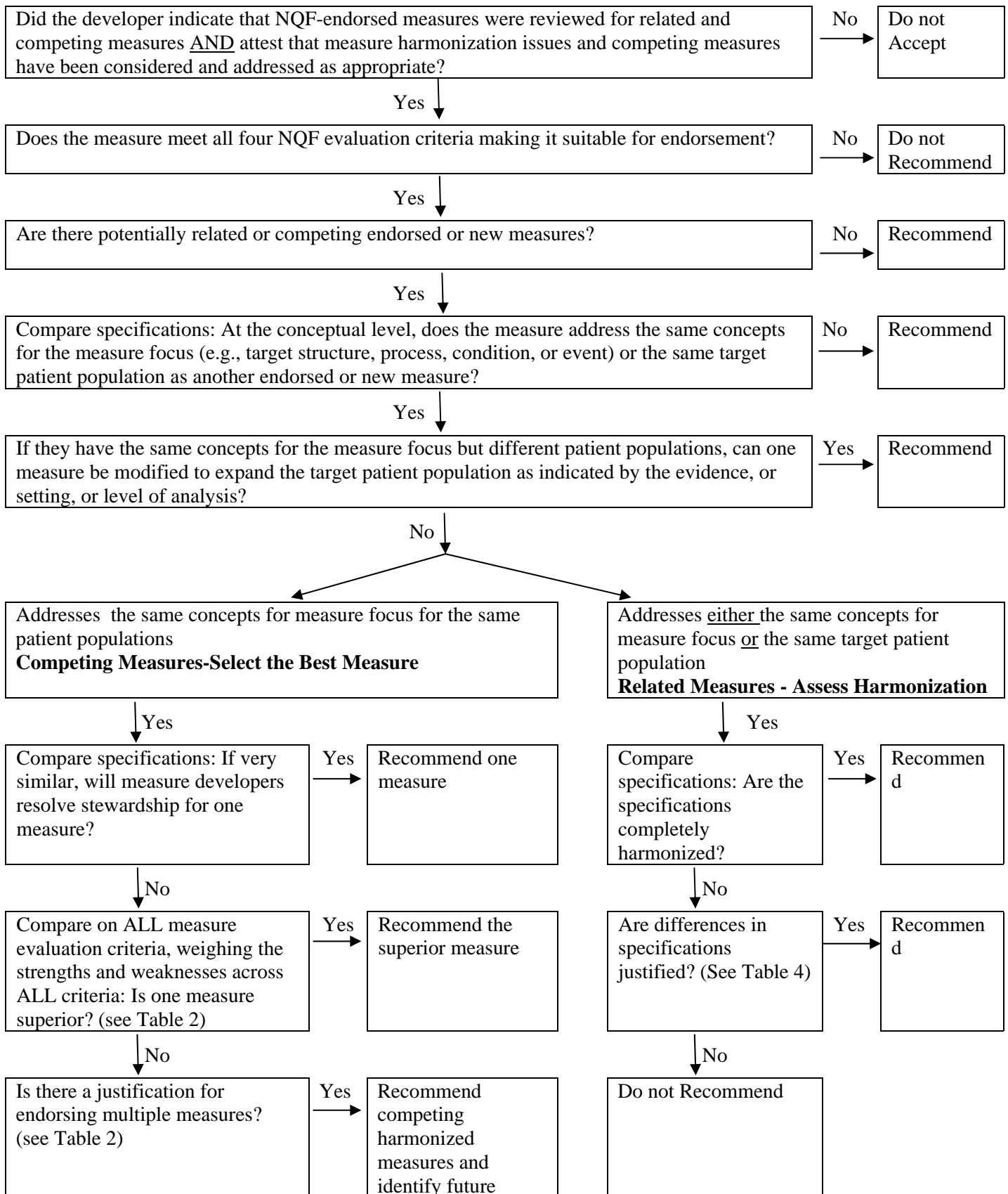
Guidance on Evaluating Related and Competing Measures

For more information, see full report: [Guidance for Measure Harmonization](#).

Table 11: Related versus Competing Measures

	Same concepts for measure focus— target process, condition, event, outcome	Different concepts for measure focus—target process, condition, event, outcome
Same target patient population	Competing measures—Select best measure from competing measures or justify endorsement of additional measure(s).	Related measures—Harmonize on target patient population or justify differences.
Different target patient population	Related measures—Combine into one measure with expanded target patient population or justify why different harmonized measures are needed.	Neither harmonization nor competing measure issue

Figure 1: Addressing Competing Measures and Harmonization of Related Measures in the NQF Evaluation Process



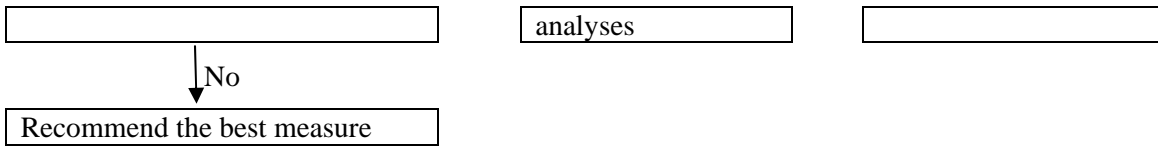


Table 12: Evaluating Competing Measures for Superiority or Justification for Multiple Measures

Steps	Evaluate Competing Measures
1. Determine if need to compare measures for superiority	Work through the steps in the algorithm (Figure 1) to determine if need to evaluate competing measures for superiority (i.e., two or more measures address the same concepts for measure focus for the same patient populations)
2. Assess Competing Measures for Superiority by weighing the strengths and weaknesses across ALL NQF evaluation criteria	<p>Because the competing measures have already been determined to have met NQF’s criteria for endorsement, the assessment of competing measures must include <u>weighing the strengths and weaknesses across ALL the criteria</u> and involves more than just comparing ratings. (For example, a decision is not based on just the differences in scientific acceptability of measure properties without weighing the evaluation of importance to measure and report, usability, and feasibility as well.)</p> <p>Impact, Opportunity, and Evidence—Importance to Measure and Report: Competing measures generally will be the same in terms of the measure focus addressing a high-impact aspect of healthcare (1a) and evidence for the focus of measurement (1c). However, due to differences in measure construction, they could differ on alignment with national health goals/priorities or opportunity for improvement.</p> <ul style="list-style-type: none"> • Compare measures on alignment with national health goals/priorities (1a) • Compare measures on opportunity for improvement (1b) <p>Reliability and Validity—Scientific Acceptability of Measure Properties:</p> <ul style="list-style-type: none"> • Compare evidence of reliability (2a1-2a2) • Compare evidence of validity, including threats to validity (2b1-2b6) <p>Untested measures cannot be considered superior to tested measures because there would be no empirical evidence on which to compare reliability and validity. (However, a new measure, when tested, could ultimately demonstrate superiority over an endorsed measure and the NQF endorsement maintenance cycles allow for regular submission of new measures.)</p> <p>Compare and identify differences in specifications <u>All else being equal on the criteria and subcriteria, the preference is for:</u></p> <ul style="list-style-type: none"> • Measures specified for the broadest application (target patient population as indicated by the evidence, settings, level of analysis) • Measures that address disparities in care when appropriate <p>Usability:</p> <ul style="list-style-type: none"> • Compare evidence of use and usefulness for public reporting, including availability of data for reporting performance results • Compare evidence of use and usefulness for quality improvement <p><u>All else being equal on the criteria and subcriteria, the preference is for:</u></p> <ul style="list-style-type: none"> • Measures that are publicly reported • Measures with the widest use (e.g., settings, numbers of entities reporting performance results)

Steps	Evaluate Competing Measures
	<ul style="list-style-type: none"> • Measures that are in use over those without evidence of use <p>Feasibility:</p> <ul style="list-style-type: none"> • Compare the ease of data collection/availability of required data • Compare the potential for inaccuracies, errors, and unintended consequences <p><u>All else being equal on the criteria and subcriteria, the preference is for:</u></p> <ul style="list-style-type: none"> • Measures based on data from electronic sources • Clinical data from EHRs • Measures that are freely available <p>After weighing the strengths and weaknesses across ALL criteria, identify if one measure is clearly superior and provide the rationale based on the NQF criteria.</p>
<p>3.If a competing measure does not have clear superiority, assess justification for multiple measures</p>	<p>If a competing measure does not have clear superiority, is there a justification for endorsing multiple measures? Does the added value offset any burden or negative impact?</p> <p>Identify the value of endorsing competing measures Is an additional measure necessary?</p> <ul style="list-style-type: none"> • to change to EHR-based measurement; • to have broader applicability (if one measure cannot accommodate all patient populations; settings, e.g., hospital, home health; or levels of analysis, e.g., clinician, facility; etc.); • to increase availability of performance results (if one measure cannot be widely implemented, e.g., if measures based on different data types increase the number of entities for whom performance results are available) <p>Note: Until clinical data from electronic health records (EHRs) are widely available for performance measurement, endorsement of competing measures based on different data types (e.g., claims and EHRs) may be needed to achieve the dual goals of 1) advocating widespread access to performance data and 2) migrating to performance measures based on EHRs. EHRs are the preferred source for clinical record data, but measures based on paper charts or data submitted to registries may be needed in the transition to EHR-based measures.</p> <p>Is an additional measure unnecessary?</p> <ul style="list-style-type: none"> • primarily for unique developer preferences <p>Identify the burden of endorsing competing measures Do the different measures affect interpretability across measures? Does having more than one endorsed measure increase the burden of data collection?</p> <p>Determine if the added value of endorsing competing measures offsets any burden or negative impact?</p> <ul style="list-style-type: none"> • If yes, recommend competing measures for endorsement (if harmonized) and provide the rationale for recommending endorsement of multiple competing measures. Also, identify analyses needed to conduct a rigorous evaluation of the use and usefulness of the measures at the time of endorsement maintenance. • If no, recommend the best measure for endorsement and provide rationale.

Table 13: Sample Considerations to Justify Lack of Measure Harmonization

Related Measures	Lack of Harmonization	Assess Justification for Conceptual Differences	Assess Justification for Technical Differences
Same measure focus (numerator); different target population (denominator)	Inconsistent measure focus (numerator)	The evidence for the measure focus is different for the different target population so that one measure cannot accommodate both target populations. Evidence should always guide measure specifications.	<ul style="list-style-type: none"> • Differences in the available data drive differences in the technical specifications for the measure focus. • Effort has been made to reconcile the differences across measures but important differences remain.
Same target population (denominator); different measure focus (numerator)	Inconsistent target population (denominator) and/or exclusions	The evidence for the different measure focus necessitates a change in the target population and/or exclusions. Evidence should always guide measure specifications.	<ul style="list-style-type: none"> • Differences in the available data drive differences in technical specifications for the target population. • Effort has been made to reconcile the differences across measures but important differences remain.
For any related measures	Inconsistent scoring/computation	The difference does not affect interpretability or burden of data collection. If it does, it adds value that outweighs any concern regarding interpretability or burden of data collection.	The difference does not affect interpretability or burden of data collection. If it does, it adds value that outweighs any concern regarding interpretability or burden of data collection.

ATTACHMENT 2

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 #: 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 line-associated bloodstream infections (CLABSI) will be calculated among patients in the following patient care locations:
<ul style="list-style-type: none"> • Intensive Care Units (ICUs) • Specialty Care Areas (SCAs) - adult and pediatric: long term acute care, bone marrow transplant, acute dialysis, hematology/oncology, and solid organ transplant locations • other inpatient locations. (Data from these locations are reported from acute care general hospitals (including specialty hospitals), freestanding long term acute care hospitals, rehabilitation hospitals, and behavioral health hospitals. Only locations where patients reside overnight are included, i.e., inpatient locations.
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
A.1 Do you attest that the measure steward holds intellectual property rights to the measure and the	Y <input type="checkbox"/>
	N <input type="checkbox"/>

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

ATTACHMENT 2

right to use aspects of the measure owned by another entity (e.g., risk model, code set)? Yes A.2 Indicate if Proprietary Measure (as defined in measure steward agreement): A.3 Measure Steward Agreement: Government entity and in the public domain - no agreement necessary A.4 Measure Steward Agreement attached:	
B. The measure owner/steward verifies there is an identified responsible entity and process to maintain and update the measure on a schedule that is commensurate with the rate of clinical innovation, but at least every 3 years. Yes, information provided in contact section	B Y <input type="checkbox"/> N <input type="checkbox"/>
C. The intended use of the measure includes both public reporting and quality improvement. ► Purpose:	C Y <input type="checkbox"/> N <input type="checkbox"/>
D. The requested measure submission information is complete. Generally, measures should be fully developed and tested so that all the evaluation criteria have been addressed and information needed to evaluate the measure is provided. Measures that have not been tested are only potentially eligible for a time-limited endorsement and in that case, measure owners must verify that testing will be completed within 12 months of endorsement. D.1 Testing: 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 <input type="checkbox"/> N <input type="checkbox"/>
(for NQF staff use) Have all conditions for consideration been met? Staff Notes to Steward (if submission returned):	Met Y <input type="checkbox"/> N <input type="checkbox"/>
Staff Notes to Reviewers (issues or questions regarding any criteria):	
Staff Reviewer Name(s):	

TAP/Workgroup Reviewer Name:	
Steering Committee Reviewer Name:	
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. (evaluation criteria)</i> 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 needed. 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 C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/>
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.	

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).

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<p>(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.</p>	
<p>1b. Opportunity for Improvement</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>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.</p>	<p>1b C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/></p>
<p>1c. Outcome or Evidence to Support Measure Focus</p> <p>1c.1 Relationship to Outcomes (For non-outcome measures, briefly describe the relationship to desired outcome. For outcomes, describe why it is relevant to the target population): 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.</p> <p>1c.2-3. Type of Evidence: Evidence-based guideline, Expert opinion, Meta-analysis, Randomized controlled trial, Systematic synthesis of research</p> <p>1c.4 Summary of Evidence (as described in the criteria; for outcomes, summarize any evidence that healthcare services/care processes influence the outcome): 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.</p> <p>1c.5 Rating of strength/quality of evidence (also provide narrative description of the rating and by whom): 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.</p> <p>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.</p>	<p>1c C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/></p>

Comment [kP2]: 1b. Demonstration of quality problems and opportunity for improvement, i.e., data demonstrating considerable variation, or overall poor performance, in the quality of care across providers and/or population groups (disparities in care).

Comment [k3]: 1 Examples of data on opportunity for improvement include, but are not limited to: prior studies, epidemiologic data, measure data from pilot testing or implementation. If data are not available, the measure focus is systematically assessed (e.g., expert panel rating) and judged to be a quality problem.

Comment [k4]: 1c. The measure focus is:
 •an outcome (e.g., morbidity, mortality, function, health-related quality of life) that is relevant to, or associated with, a national health goal/priority, the condition, population, and/or care being addressed;
 OR
 •if an intermediate outcome, process, structure, etc., there is evidence that supports the specific measure focus as follows:
 oIntermediate outcome - evidence that the measured intermediate outcome (e.g., blood pressure, Hba1c) leads to improved health/avoidance of harm or cost/benefit.
 oProcess - evidence that the measured clinical or administrative process leads to improved health/avoidance of harm and if the measure focus is on one step in a multi-step care process, it measures the step that has the greatest effect on improving the specified desired outcome(s).
 oStructure - evidence that the measured structure supports the consistent delivery of effective processes or access that lead to improved health/avoidance of harm or cost/benefit. ... [1]

Comment [k5]: 4 Clinical care processes typically include multiple steps: assess → identify problem/potential problem → choose/plan intervention (with patient input) → provide intervention → evaluate impact on health status. If the measure focus is one step in such a multi-step process, the step with the greatest effect on the desired outcome should be selected as the focus of measurement. For example, although assessment of immunization status and recommending immunization are necessary steps, they are not sufficient to achieve the desired impact on health status - patients must be vaccinated to achieve ... [2]

Comment [k6]: 3 The strength of the body of evidence for the specific measure focus should be systematically assessed and rated (e.g., USPSTF grading system <http://www.ahrq.gov/clinic/uspstf07/methods/benefit.htm>). If the USPSTF grading system was not used, the grading system is explained including how it relates to the USPSTF grades or why it does not. However, evidence is not limited to quantitative studies and the best type of evidence depends upon the question being studied (e.g., randomized controlled trials appropriate for studying drug efficacy are not well suited for complex system ... [3])

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<p>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. 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.</p> <p>1c.7 Summary of Controversy/Contradictory Evidence: None</p> <p>1c.8 Citations for Evidence (<i>other than guidelines</i>):</p> <p>1c.9 Quote the Specific guideline recommendation (<i>including guideline number and/or page number</i>): See 1c.10</p> <p>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</p> <p>1c.11 National Guideline Clearinghouse or other URL:</p> <p>1c.12 Rating of strength of recommendation (<i>also provide narrative description of the rating and by whom</i>): see 1c.6</p> <p>1c.13 Method for rating strength of recommendation (<i>If different from USPSTF system, also describe rating and how it relates to USPSTF</i>):</p> <p>1c.14 Rationale for using this guideline over others:</p>	
TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for <i>Importance to Measure and Report</i>?	1
Steering Committee: Was the threshold criterion, <i>Importance to Measure and Report</i>, met? Rationale:	1 Y <input type="checkbox"/> N <input type="checkbox"/>
2. SCIENTIFIC ACCEPTABILITY OF MEASURE PROPERTIES	
Extent to which the measure, <u>as specified</u> , produces consistent (reliable) and credible (valid) results about the quality of care when implemented. (evaluation criteria)	Eval Rating
2a. MEASURE SPECIFICATIONS	
S.1 Do you have a web page where current detailed measure specifications can be obtained? S.2 If yes, provide web page URL:	
2a. Precisely Specified	
2a.1 Numerator Statement (<i>Brief, text description of the numerator - what is being measured about the target population, e.g. target condition, event, or outcome</i>): Total number of observed healthcare-associated CLABSI among patients in ICUs, NICUs, SCAs and other acute care hospital locations where patients reside overnight.	2a-spec C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/>
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	

Comment [k7]: USPSTF grading system <http://www.ahrq.gov/clinic/uspstf/grades.htm>: A - The USPSTF recommends the service. There is high certainty that the net benefit is substantial. B - The USPSTF recommends the service. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial. C - The USPSTF recommends against routinely providing the service. There may be considerations that support providing the service in an individual patient. There is at least moderate certainty that the net benefit is small. Offer or provide this service only if other considerations support the offering or providing the service in an individual patient. D - The USPSTF recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits. I - The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.

Comment [KP8]: 2a. The measure is well defined and precisely specified so that it can be implemented consistently within and across organizations and allow for comparability. The required data elements are of high quality as defined by NOF's Health Information Technology Expert Panel (HITEP) .

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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

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[*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 in inpatient locations.

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

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birthweight.
 c. In SCAs, because of differing infection risks, the number of patients with temporary central lines and those with permanent central lines is collected daily, at the same time each day, during the month. If a patient has both a temporary and permanent line, count the day only as a temporary line day.
 4. See 2a.3 for definitions of CDC location, location, and location of attribution.
 5. 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 -
 a. 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.
 b. Graduate: Hospital is used by the medical school for graduate trainings only (residency and/or fellowships).
 c. 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
 2. Peripheral intravenous lines are excluded from this measure

2a.10 Denominator Exclusion Details (All information required to collect exclusions to the denominator, including all codes, logic, and definitions):
 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.
 2. NICU location catheters are stratified by two types, central and umbilical lines. Numerator and denominator information is further stratified by five birthweight categories.
 3. SCA location central lines are stratified by two types, temporary and permanent.

2a.12-13 Risk Adjustment Type: Risk-adjustment devised specifically for this measure/condition

2a.14 Risk Adjustment Methodology/Variables (List risk adjustment variables and describe conceptual models, statistical models, or other aspects of model or method):
 CLABSI rates per 1000 central line device days provide adjustment for the influence of length of stay and central line utilization stratified by patient care locations. 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: Better quality = Lower score

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

The SIR is calculated as follows:

1. Identify the number of CLABSI in each location type
2. Total these numbers for an observed number of CLABSIs
3. Obtain the expected number of CLABSIs in the same location types from a standard population (i.e., using the NHSN data report <http://www.cdc.gov/nhsn/PDFs/dataStat/2009NHSNReport.PDF>) by multiplying the number of central line days observed by the expected CLABSI rate for that location and dividing by 1000
4. 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 ("3" above).
6. Result = SIR

2a.22 Describe the method for discriminating performance (e.g., significance testing):

Performance evaluation can be conducted through at least 2 processes. First an SIR can be compared to the

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.

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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 *(Identify the specific data source/data collection instrument, e.g. name of database, clinical registry, collection instrument, etc.):*

- NHSN Primary BSI collection form
- NHSN Denominator for ICU form
- NHSN Denominator for NICU form
- NHSN Denominator for Specialty Care Area Form

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)*
Facility/Agency, Population : National, Population : states

2a.36-37 Care Settings *(Check the setting(s) for which the measure is specified and tested)*
Behavioral health/psychiatric unit, Hospice, Hospital, Long Term Acute Care Hospital, Nursing home (NH) /Skilled Nursing Facility (SNF), Rehabilitation Facility

2a.38-41 Clinical Services *(Healthcare services being measured, check all that apply)*

TESTING/ANALYSIS

2b. Reliability testing

2b.1 Data/sample *(description of data/sample and size):* The standard population's CLABSI rates used in the SIR calculations are from 16 different types of ICUs, two types of NICUs, 5 types of SCAs, and 21 other inpatient locations. The numerators of the adult and pediatric ICUs range from 23 to 1683 CLABSI and the denominators range from 17,223 to 986,982 central line days, with 11 of the 16 adult and pediatric ICUs having greater than 160,000 up to nearly 990,000 central line 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 days. The Level III NICU umbilical line-associated BSIs range from 28 to 129, while the denominators range from 29,492 to 45,568 umbilical catheter days. For SCAs, the CLABSI numerators associated with temporary central lines range from 47 to 260 with denominators ranging from 10,287 to 149,298. For SCAs, the CLABSI numerators associated with permanent central lines range from 11 to 235 with denominators ranging from 3,953 to 95,535. For other inpatient locations, the CLABSI numerators range from 0 to 733 with denominators ranging from 255 to 618,196. 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].

While CLABSI reporting is greatest in ICUs, there are a number of facilities reporting CLABSI data in non-ICU locations and the number is growing. In 2010, over 925 acute care facilities reported at least one month's

Comment [KP10]: 2b. Reliability testing demonstrates the measure results are repeatable, producing the same results a high proportion of the time when assessed in the same population in the same time period.

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CLABSI data in a non-ICU location and 205 of those locations were new for NHSN CLABSI reporting in 2010. 83 long-term acute care facilities reported at least one month of CLABSI data in 2010 and 17 of those locations were new for NHSN CLABSI reporting in that year.

NHSN NICU Birthweight Categories:
 less than or equal to 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 (*reliability statistics, assessment of adequacy in the context of norms for the test conducted*):

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).

1 state has independently completed and reported validity testing in their state HAI report. Those reports can be found at the following URLs:

Pennsylvania:
www.portal.state.pa.us/portal/server.pt/.../padoh_2009_hai_report_pdf

Additionally, CLABSI in other inpatient locations were validated by Pennsylvania in 12 hospitals that were low and high outliers by SIR. The audit period covered data reported during Jan. 1-Dec. 31, 2009. 26 previously reported CLABSI cases were reviewed as well as 70 positive blood cultures that were not reported as CLABSI. Overall, 90.6% specificity and 90.4% sensitivity was found between facility and auditor CLABSI determinations, with a positive predictive value of 73.1% and negative predictive value of 97.1%. This audit, the first such performed for this state, was intentionally targeted to facilities that were at the top and bottom of the Pennsylvania SIR range, which may be associated with the less than ideal accuracy scores seen and thus may not reflect the majority of the hospitals. Another audit is being planned to review an additional 10% sample of PA hospitals.

Validity testing has begun through CDC's Emerging Infections Program in July, 2010 in one state and in 2 states in August 2010. Additional testing 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.

Validity testing has begun in July, 2010 in one state and in 2 states in August, 2010 and is expected to begin

2c
 C
 P
 M
 N

Comment [k11]: 8 Examples of reliability testing include, but are not limited to: inter-rater/abstractor or intra-rater/abstractor studies; internal consistency for multi-item scales; test-retest for survey items. Reliability testing may address the data items or final measure score.

Comment [KP12]: 2c. Validity testing demonstrates that the measure reflects the quality of care provided, adequately distinguishing good and poor quality. If face validity is the only validity addressed, it is systematically assessed.

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<p>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.</p> <p>2c.2 Analytic Method (<i>type of validity & rationale, method for testing</i>): 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 through NHSN.</p> <p>2c.3 Testing Results (<i>statistical results, assessment of adequacy in the context of norms for the test conducted</i>):</p>	
<p>2d. Exclusions Justified</p> <p>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.</p> <p>2d.2 Citations for Evidence:</p> <p>2d.3 Data/sample (<i>description of data/sample and size</i>):</p> <p>2d.4 Analytic Method (<i>type analysis & rationale</i>):</p> <p>2d.5 Testing Results (<i>e.g., frequency, variability, sensitivity analyses</i>):</p>	<p>2d</p> <p>C <input type="checkbox"/></p> <p>P <input type="checkbox"/></p> <p>M <input type="checkbox"/></p> <p>N <input type="checkbox"/></p> <p>NA <input type="checkbox"/></p>
<p>2e. Risk Adjustment for Outcomes/ Resource Use Measures</p> <p>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, two types of NICUs, 5 types of SCAs, and 21 other inpatient locations. The numerators of the adult and pediatric ICUs range from 23 to 1683 CLABSI and the denominators range from 17,223 to 986,982 central line days, with 11 of the 16 adult and pediatric ICUs having greater than 160,000 up to nearly 990,000 central line 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 days. The Level III NICU umbilical line-associated BSIs range from 28 to 129, while the denominators range from 29,492 to 45,568 umbilical catheter days. For SCAs, the CLABSI numerators associated with temporary central lines range from 47 to 260 with denominators ranging from 10,287 to 149,298. For SCAs, the CLABSI numerators associated with permanent central lines range from 11 to 235 with denominators ranging from 3,953 to 95,535. For other inpatient locations, the CLABSI numerators range from 0 to 733 with denominators ranging from 255 to 618,196. 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].</p> <p>While CLABSI reporting is greatest in ICUs there are a number of facilities reporting CLABSI data in non-ICU locations. Currently over 925 acute care facilities have reported at least one month's CLABSI data in a non-ICU location and for long-term acute care facilities this number is 83. Therefore, we conclude for most of both ICU and non-ICU 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.]</p> <p>2e.2 Analytic Method (<i>type of risk adjustment, analysis, & rationale</i>):</p>	<p>2e</p> <p>C <input type="checkbox"/></p> <p>P <input type="checkbox"/></p> <p>M <input type="checkbox"/></p> <p>N <input type="checkbox"/></p> <p>NA <input type="checkbox"/></p>

Comment [k13]: 9 Examples of validity testing include, but are not limited to: determining if measure scores adequately distinguish between providers known to have good or poor quality assessed by another valid method; correlation of measure scores with another valid indicator of quality for the specific topic; ability of measure scores to predict scores on some other related valid measure; content validity for multi-item scales/tests. Face validity is a subjective assessment by experts of whether the measure reflects the quality of care (e.g., whether the proportion of patients with BP < 140/90 is a marker of quality). If face validity is the only validity addressed, it is systematically assessed (e.g., ratings by relevant stakeholders) and the measure is judged to represent quality care for the specific topic and that the measure focus is the most important aspect of quality for the specific topic.

Comment [KP14]: 2d. Clinically necessary measure exclusions are identified and must be:
 •supported by evidence of sufficient frequency of occurrence so that results are distorted without the exclusion;
 AND
 •a clinically appropriate exception (e.g., contraindication) to eligibility for the measure focus;
 AND
 •precisely defined and specified:
 –if there is substantial variability in exclusions across providers, the measure is specified so that exclusions are computable and the effect on the measure is transparent (i.e., impact clearly delineated, such as number of cases excluded, exclusion rates by type of exclusion);
 if patient preference (e.g., informed decision-making) is a basis for exclusion, there must be evidence that it strongly impacts performance on the measure and the measure must be specified so that the information about { ... [4]

Comment [k15]: 10 Examples of evidence that an exclusion distorts measure results include, but are not limited to: frequency of occurrence, sensitivity analyses with and without the exclusion, and variability of exclusions across providers.

Comment [KP16]: 2e. For outcome measures and other measures (e.g., resource use) when indicated:
 •an evidence-based risk-adjustment strategy (e.g., risk models, risk stratification) is specified and is based on patient clinical factors that influence the measured outcome (but not disparities in care) and are present at start of care; Error! Bookmark not defined. OR
 rationale/data support no risk adjustment.

Comment [k17]: 13 Risk models should not obscure disparities in care for populations by including factors that are associated with differences/inequalities in care such as race, socioeconomic status, gender (e.g., poorer treatment outcomes of African American men with prostate cancer, inequalities in treatment for CVD risk factors between men and women). It is preferable to stratify measures by race and socioeconomic status rather than adjusting out differences.

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<p>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 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.</p> <p>2e.3 Testing Results (risk model performance metrics):</p> <p>2e.4 If outcome or resource use measure is not risk adjusted, provide rationale:</p>	
<p>2f. Identification of Meaningful Differences in Performance</p> <p>2f.1 Data/sample from Testing or Current Use (description of data/sample and size): SIRs have been used as metrics for identifying differences in performance by state.</p> <p>2f.2 Methods to identify statistically significant and practically/meaningfully differences in performance (type of analysis & rationale): 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.</p> <p>2f.3 Provide Measure Scores from Testing or Current Use (description of scores, e.g., distribution by quartile, mean, median, SD, etc.; identification of statistically significant and meaningfully differences in performance): 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).</p>	<p>2f C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/></p>
<p>2g. Comparability of Multiple Data Sources/Methods</p> <p>2g.1 Data/sample (description of data/sample and size):</p> <p>2g.2 Analytic Method (type of analysis & rationale):</p> <p>2g.3 Testing Results (e.g., correlation statistics, comparison of rankings):</p>	<p>2g C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/> NA <input type="checkbox"/> <input type="checkbox"/></p>
<p>2h. Disparities in Care</p> <p>2h.1 If measure is stratified, provide stratified results (scores by stratified categories/cohorts):</p> <p>2h.2 If disparities have been reported/identified, but measure is not specified to detect disparities, provide follow-up plans:</p>	<p>2h C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/> NA <input type="checkbox"/> <input type="checkbox"/></p>
<p>TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for Scientific Acceptability of Measure Properties?</p>	<p>2</p>
<p>Steering Committee: Overall, to what extent was the criterion, Scientific Acceptability of Measure Properties, met? Rationale:</p>	<p>2 C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/></p>

Comment [KP18]: 2f. Data analysis demonstrates that methods for scoring and analysis of the specified measure allow for identification of statistically significant and practically/clinically meaningful differences in performance.

Comment [k19]: 14 With large enough sample sizes, small differences that are statistically significant may or may not be practically or clinically meaningful. The substantive question may be, for example, whether a statistically significant difference of one percentage point in the percentage of patients who received smoking cessation counseling (e.g., 74% v. 75%) is clinically meaningful; or whether a statistically significant difference of \$25 in cost for an episode of care (e.g., \$5,000 v. \$5,025) is practically meaningful. Measures with overall poor performance may not demonstrate much variability across providers.

Comment [KP20]: 2g. If multiple data sources/methods are allowed, there is demonstration they produce comparable results.

Comment [KP21]: 2h. If disparities in care have been identified, measure specifications, scoring, and analysis allow for identification of disparities through stratification of results (e.g., by race, ethnicity, socioeconomic status, gender); OR rationale/data justifies why stratification is not necessary or not feasible.

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3. USABILITY		Eval Rating
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 Rating
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). <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 time. A Centers for Disease Control and Prevention report on HAIs with SIRs for individual U.S. states was published in May, 2010 and is available for viewing on the NHSN website at http://www.cdc.gov/nhsn/index.html A second report in this series was published in March, 2011, and can be found at http://www.cdc.gov/HAI/pdfs/stateplans/state-specific-hai-sir-july-dec2009r.pdf Additionally, the CDC also published the first national report of HAIs using the SIR metric which included not only data from intensive care unit (ICU) locations but also data from non-ICU locations and long-term acute-care units (LTAC a type of SCA). That report, published in March, 2011, can be found at http://www.cdc.gov/HAI/pdfs/stateplans/SIR-2010_JunDec2009.pdf Precedence has also been set for using SIRs for public reporting of HAIs by several states. Such states include Pennsylvania (two reports may be found at http://www.portal.health.state.pa.us/portal/server.pt/community/healthcare_associated_infections/14234 Tennessee (2 reports may be found at http://health.state.tn.us/Downloads/TN_HAI_Report_2008_Jan_Dec_final.pdf and http://health.state.tn.us/Downloads/TROHAI08022010.pdf), and South Carolina (http://www.scdhec.gov/health/disease/hai/reports.htm). Specific to CLABSI surveillance, six states currently require some reporting of CLABSIs from locations outside the ICU. California, Nevada and Pennsylvania reporting requirements have included CLABSI data from all non-ICU locations since 2010, 2010, and 2008 respectively. South Carolina began requiring some non-ICU locations in certain hospitals to report CLABSI surveillance data in January of 2008 and as of 2009 require all non-ICU locations except neonatal step down units (i.e. Level II) to report CLABSI data. While there has been limited use of CLABSI surveillance in LTAC, the state mandates speak to the increasing importance of using this measure for public reporting.		
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). <u>If not used for QI</u> , state the plans to achieve use for QI within 3 years): See 3a.2		
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 C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/>
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:		
(for NQF staff use) Notes on similar/related endorsed or submitted measures:		
3b. Harmonization		3b
If this measure is related to measure(s) already endorsed by NQF (e.g., same topic, but different target)		C <input type="checkbox"/>

Comment [KP22]: 3a. Demonstration that information produced by the measure is meaningful, understandable, and useful to the intended audience(s) for both public reporting (e.g., focus group, cognitive testing) and informing quality improvement (e.g., quality improvement initiatives). An important outcome that may not have an identified improvement strategy still can be useful for informing quality improvement by identifying the need for and stimulating new approaches to improvement.

Comment [KP23]: 3b. The measure specifications are harmonized with other measures, and are applicable to multiple levels and settings.

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population/setting/data source or different topic but same target population): 3b.2 Are the measure specifications harmonized? If not, why?	P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/> NA <input type="checkbox"/>
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 <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/> NA <input type="checkbox"/>
TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for Usability?	3
Steering Committee: Overall, to what extent was the criterion, Usability, met? Rationale:	3 C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/>
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 <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/>
4b. Electronic Sources 4b.1 Are all the data elements available electronically? (elements that are needed to compute measure scores are in defined, computer-readable fields, e.g., electronic health record, electronic claims) 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-associated bloodstream infections). This will serve as a test project for other HAI surveillance.	4b C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/>
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 <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/> NA <input type="checkbox"/>
4d. Susceptibility to Inaccuracies, Errors, or Unintended Consequences 4d.1 Identify susceptibility to inaccuracies, errors, or unintended consequences of the measure and describe how these potential problems could be audited. If audited, provide results. 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	4d C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/>

Comment [k24]: 16 Measure harmonization refers to the standardization of specifications for similar measures on the same topic (e.g., influenza immunization of patients in hospitals or nursing homes), or related measures for the same target population (e.g., eye exam and HbA1c for patients with diabetes), or definitions applicable to many measures (e.g., age designation for children) so that they are uniform or compatible, unless differences are dictated by the evidence. The dimensions of harmonization can include numerator, denominator, exclusions, and data source and collection instructions. The extent of harmonization depends on the relationship of the measures, the evidence for the specific measure focus, and differences in data sources.

Comment [KP25]: 3c. Review of existing endorsed measures and measure sets demonstrates that the measure provides a distinctive or additive value to existing NQF-endorsed measures (e.g., provides a more complete picture of quality for a particular condition or aspect of healthcare, is a more valid or efficient way to measure).

Comment [KP26]: 4a. For clinical measures, required data elements are routinely generated concurrent with and as a byproduct of care processes during care delivery. (e.g., BP recorded in the electronic record, not abstracted from the record later by other personnel; patient self-assessment tools, e.g., depression scale; lab values, meds, etc.)

Comment [KP27]: 4b. The required data elements are available in electronic sources. If the required data are not in existing electronic sources, a credible, near-term path to electronic collection by most providers is specified and clinical data elements are specified for transition to the electronic health record.

Comment [KP28]: 4c. Exclusions should not require additional data sources beyond what is required for scoring the measure (e.g., numerator and denominator) unless justified as supporting measure validity.

Comment [KP29]: 4d. Susceptibility to inaccuracies, errors, or unintended consequences and the ability to audit the data items to detect such problems are identified.

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<p>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/hospit-acquired_infection.pdf, p20).</p>	
<p>4e. Data Collection Strategy/Implementation</p> <p>4e.1 Describe what you have learned/modified as a result of testing and/or operational use of the measure regarding data collection, availability of data/missing data, timing/frequency of data collection, patient confidentiality, time/cost of data collection, other feasibility/ implementation issues: 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.</p> <p>4e.2 Costs to implement the measure (costs of data collection, fees associated with proprietary measures): We have estimated the time for identifying and reporting a CLABSI to be 30 minutes, and 2.5 hours per selected location 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 medical 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. Fewer patients may have central lines in non-ICU areas, but the population is less homogenous and it may take longer to identify patient with central lines in these areas.</p> <p>4e.3 Evidence for costs: See OMB submission number 0920-0666, expires 03-31-2011 (labor cost adjusted for inflation).</p> <p>4e.4 Business case documentation:</p>	<p>4e C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/></p>
<p>TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for Feasibility?</p>	<p>4</p>
<p>Steering Committee: Overall, to what extent was the criterion, Feasibility, met? Rationale:</p>	<p>4 C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/></p>
<p style="text-align: center;">RECOMMENDATION</p>	
<p>(for NQF staff use) Check if measure is untested and only eligible for time-limited endorsement.</p>	<p>Time-limited <input type="checkbox"/></p>
<p>Steering Committee: Do you recommend for endorsement? Comments:</p>	<p>Y <input type="checkbox"/> N <input type="checkbox"/> A <input type="checkbox"/></p>
<p style="text-align: center;">CONTACT INFORMATION</p>	
<p>Co.1 Measure Steward (Intellectual Property Owner)</p>	

Comment [KP30]: 4e. Demonstration that the data collection strategy (e.g., source, timing, frequency, sampling, patient confidentiality, etc.) can be implemented (e.g., already in operational use, or testing demonstrates that it is ready to put into operational use).

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<p>Co.1 Organization Centers for Disease Control and Prevention, 1600 Clifton Rd, NE, Mailstop A-24, Atlanta, Georgia, 30333</p>
<p>Co.2 Point of Contact Daniel, Pollock, MD, Medical Epidemiologist, dpollock@cdc.gov, 404-639-4237-</p>
<p>Measure Developer If different from Measure Steward</p> <p>Co.3 Organization Centers for Disease Control and Prevention, 1600 Clifton Rd, NE, Mailstop A-24, Atlanta, Georgia, 30333</p>
<p>Co.4 Point of Contact Daniel, Pollock, MD, Medical Epidemiologist, dpollock@cdc.gov, 404-639-4237-</p>
<p>Co.5 Submitter If different from Measure Steward POC Daniel, Pollock, MD, Medical Epidemiologist, dpollock@cdc.gov, 404-639-4237-, Centers for Disease Control and Prevention</p>
<p>Co.6 Additional organizations that sponsored/participated in measure development</p>
<p>ADDITIONAL INFORMATION</p>
<p>Workgroup/Expert Panel involved in measure development Ad.1 Provide a list of sponsoring organizations and workgroup/panel members' names and organizations. Describe the members' role in measure development.</p>
<p>Ad.2 If adapted, provide name of original measure: NQF # 0139 Central line associated bloodstream infection Ad.3-5 If adapted, provide original specifications URL or attachment http://www.cdc.gov/nhsn/PDFs/pscManual/4PSC_CLABScurrent.pdf</p>
<p>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</p>
<p>Ad.10 Copyright statement:</p>
<p>Ad.11 Disclaimers:</p>
<p>Ad.12 -14 Additional Information web page URL or attachment: Attachment NQF CLABSI-Additional information042310.docx</p>
<p>Date of Submission (MM/DD/YY): 04/23/2010</p>

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.

4 Clinical care processes typically include multiple steps: assess → identify problem/potential problem → choose/plan intervention (with patient input) → provide intervention → evaluate impact on health status. If the measure focus is one step in such a multi-step process, the step with the greatest effect on the desired outcome should be selected as the focus of measurement. For example, although assessment of immunization status and recommending immunization are necessary steps, they are not sufficient to achieve the desired impact on health status - patients must be vaccinated to achieve immunity. This does not preclude consideration of measures of preventive screening interventions where there is a strong link with desired outcomes (e.g., mammography) or measures for multiple care processes that affect a single outcome.

3 The strength of the body of evidence for the specific measure focus should be systematically assessed and rated (e.g., USPSTF grading system <http://www.ahrq.gov/clinic/uspstf07/methods/benefit.htm>). If the USPSTF grading system was not used, the grading system is explained including how it relates to the USPSTF grades or why it does not. However, evidence is not limited to quantitative studies and the best type of evidence depends upon the question being studied (e.g., randomized controlled trials appropriate for studying drug efficacy are not well suited for complex system changes). When qualitative studies are used, appropriate qualitative research criteria are used to judge the strength of the evidence.

2d. Clinically necessary measure exclusions are identified and must be:

- supported by evidence of sufficient frequency of occurrence so that results are distorted without the exclusion;
AND
- a clinically appropriate exception (e.g., contraindication) to eligibility for the measure focus;
AND
- precisely defined and specified:
 - if there is substantial variability in exclusions across providers, the measure is specified so that exclusions are computable and the effect on the measure is transparent (i.e., impact clearly delineated, such as number of cases excluded, exclusion rates by type of exclusion);

if patient preference (e.g., informed decision-making) is a basis for exclusion, there must be evidence that it strongly impacts performance on the measure and the measure must be specified so that the information about patient preference and the effect on the measure is transparent (e.g., numerator category computed separately, denominator exclusion category computed separately).