NATIONAL QUALITY FORUM

Measure Submission and Evaluation Worksheet 5.0

This form contains the information submitted by measure developers/stewards, organized according to NQF's measure evaluation criteria and process. The evaluation criteria, evaluation guidance documents, and a blank online submission form are available on the submitting standards web page.

NQF #: 0298 NQF Project: Infectious Disease Project

(for Endorsement Maintenance Review)

Original Endorsement Date: Most Recent Endorsement Date: Last Updated Date: Aug 03, 2012

BRIEF MEASURE INFORMATION

De.1 Measure Title: Central Line Bundle Compliance

Co.1 Measure Steward: Institute for Healthcare Improvement

De.2 Brief Description of Measure: Percentage of intensive care patients with central lines for whom all elements of the central line bundle are documented and in place.

The central line bundle elements include:

- Hand hygiene
- •Maximal barrier precautions upon insertion
- Chlorhexidine skin antisepsis
- Optimal catheter site selection, with avoidance of the femoral vein for central venous access in patients 18 years and older
- •Daily review of line necessity with prompt removal of unnecessary lines
- **2a1.1 Numerator Statement:** Number of intensive care patients with central lines for whom all elements of the central line bundle are documented and in place.

The central line bundle elements include:

- Hand hygiene
- Maximal barrier precautions upon insertion
- Chlorhexidine skin antisepsis
- Optimal catheter site selection, with avoidance of the femoral vein for central venous access in patients 18 years and older
- Daily review of line necessity with prompt removal of unnecessary lines
- 2a1.4 Denominator Statement: Total number of intensive care patients with central lines on the day of sample.
- **2a1.8 Denominator Exclusions:** Exclude patients less than 18 years of age at the date of ICU admission and patients outside the intensive care unit and patients whose lines were not placed in the intensive care unit

1.1 Measure Type: Composite

2a1. 25-26 Data Source: Paper Medical Records

2a1.33 Level of Analysis: Facility

1.2-1.4 Is this measure paired with another measure? No

De.3 If included in a composite, please identify the composite measure (title and NQF number if endorsed): 0298 Central Line Bundle Compliance

STAFF NOTES (issues or questions regarding any criteria)

Comments on Conditions for Consideration:

E.4 If component measures of the composite are aggregate-level measures, all must be either NQF-endorsed or submitted for consideration for NQF endorsement All component measures are NQF-endorsed measures

NOF #0298 Central Line Bundle Compilance, Last opdated Date: Aug 03, 2012
Is the measure untested? Yes No If untested, explain how it meets criteria for consideration for time-limited endorsement:
1a. Specific national health goal/priority identified by DHHS or NPP addressed by the measure (<i>check De.5</i>): 5. Similar/related endorsed or submitted measures (<i>check 5.1</i>): Other Criteria:
Staff Reviewer Name(s):
1. IMPACT, OPPORTUITY, EVIDENCE - IMPORTANCE TO MEASURE AND REPORT
Extent to which the specific measure focus is important to making significant gains in health care quality (safety, timeliness, effectiveness, efficiency, equity, patient-centeredness) and improving health outcomes for a specific high impact aspect of healthcare where there is variation in or overall poor performance. Measures must be judged to be important to measure and report in order to be evaluated against the remaining criteria. (composite measure evaluation criteria)
(for NQF staff use) Specific NPP goal:
1d.1 Describe the purpose/objective of the composite measure: The purpose/objective of the composite measure is to achieve high reliability/compliance with five components of the central line bundle, a group of evidence-based interventions for patients with intravascular central catheters that, when implemented together, result in better outcomes than when implemented individually. The science supporting each bundle component is sufficiently established to be considered the standard of care. Compliance with the central line bundle can be measured by simple assessment of the completion of each item. The approach has been most successful when all elements are executed together, an all-or-none strategy. 1d.2 Describe the quality construct used in developing the composite: In healthcare facilities, initial practice was that the only sterile precautions used during the insertion of a nontunneled CVC were sterile gloves and small sterile drapes. Raad, et. al. examined whether the use of maximal sterile barrier (consisting of mask, cap, sterile gloves, gown and large drape) would lower the risk of acquiring catheter-related infections. The results indicated patients whose catheters were inserted by using maximal sterile barrier precautions had a lower incidence of infection compared to control patients (p<0.05). Additionally, the catheter-related septicemia rate was 6.3 times higher in the control group (p = 0.06), Fisher's exact test). The study highlighted that cost-benefit analysis showed the use of such precautions to be highly cost-effective. It can be deduced that maximal sterile barrier precautions during the insertion of nontunneled catherters reduce the risk of catheter infection. Raad, II, Hohn DC, Gilbreath BJ, et al. Prevention of central venous catheter-related infections by using maximal sterile barrier precautions during insertion. Infect Control Hosp Epidemiol. 1004;15(4 Pt1): 231-238
1e.1 Describe how the component measures/items are consistent with and representative of the quality construct: The component measures assess the appropriate implementation of each of the elements of the central line bundle: - Hand Hygiene - Maximal barrier precautions - Chlorhexidine skin antisepsis - Optimal catheter site selection, with avoidance of using the femoral line for central venous access in adult patients - Daily review of line necessity with prompt removal of unnecessary lines Compliance with the central line bundle can be measured by a simple assessment of the completion of each item. The approach has been most successful when all elements are executed together, an "all or none" strategy.
If the component measures are combined at the patient level, complete 1a, 1b, and 1c.
If the component measures are combined at the aggregate level, skip to criterion 2, Scientific Acceptability of Measure Properties (individual measures are either NQF-endorsed or submitted individually).
1a. High Impact: H M L I (The measure directly addresses a specific national health goal/priority identified by DHHS or NPP, or some other high impact aspect of healthcare.)
De.4 Subject/Topic Areas (Check all the areas that apply): Prevention, Pulmonary/Critical Care: Critical Care

See Guidance for Definitions of Rating Scale: H=High; M=Moderate; L=Low; I=Insufficient; NA=Not Applicable Created on: 08/07/2012 at 05:39 PM

De.5 Cross Cutting Areas (Check all the areas that apply): Safety	v. Safety : Healthcare A	Associated Intections
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- 1a.1 Demonstrated High Impact Aspect of Healthcare: Affects large numbers, A leading cause of morbidity/mortality, Frequently performed procedure
- 1a.2 If "Other," please describe:
- 1a.3 Summary of Evidence of High Impact (Provide epidemiologic or resource use data):

Central venous catheters (CVCs) are being increasingly used in the inpatient and outpatient settings to provide long-term venous access. CVCs disrupt the integrity of the skin, making infection with bacteria and/or fungi possible. Infection may spread to the bloodstream (bacteremia) and hemodynamic changes and organ dysfunction (severe sepsis) may ensue possibly leading to death. Approximately 90 percent of the catheter-related bloodstream infections (BSIs) occur with CVCs. [1] In the US, 15 million CVC days (i.e., the total number of days of exposure to CVCs by all patients in the selected population during

the selected time period) occur in intensive care units each year.(1) Research indicates that the average rate of CVC-associated BSIs is 5.3 per 1000 catheter days in the ICU (2) It can be inferred that approximately 80,000 CVC-associated BSIs occur in ICUs annually in the US. The attributable cose per infection is estimated at \$34,508-\$56,000 (3,4) and the annual cost of caring for patients with CVC-associated BSIs ranges from \$296 million to \$2.3 billion. (5)

- **1a.4 Citations for Evidence of High Impact cited in 1a.3:** 1. Mermel LA. Prevention of intravascular catheter-related infections. Annals of Internal Medicine. Mar 7 2000;132(5):391-402.
- 2. CDC. National Nosocomial Infections Surveillance(NNIS) System report, data summary from October 1986-April 1998, issued June 1998. Am J Infect Control. 1998; 26: 522-523.
- 3. Rello J, Ochagavia A, Sabanes E, et al. Evaluation of outcome in intravenous catheter-related infections in critically ill patients. Am J Respir Crit Care Med, 2000; 162: 1027-1030.
- 4. Dimick JB, Pelz RK, Consunji R, et. al. Increased resource use associated with catheter-related bloodstream infection in the surgical intensive care unit. Arch Surg, 2001; 136: 229-243.
- 5. Mermel LA. Correction: catheter related bloodstream infections. Ann Intern Med. 2000; 133:395.

1b. Opportunity for Improvement: H M L I
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(There is a demonstrated performance gap - variability or overall less than optimal performance)

1b.1 Briefly explain the benefits (improvements in quality) envisioned by use of this measure:

Care bundles, in general, are groupings of best practices with respect to a disease process that individually improve care, but when applied together result in substantially greater improvement. The science supporting the bundle components is sufficiently established to be considered standard of care.

1b.2 Summary of Data Demonstrating Performance Gap (Variation or overall less than optimal performance across providers): [For <u>Maintenance</u> – Descriptive statistics for performance results <u>for this measure</u> - distribution of scores for measured entities by quartile/decile, mean, median, SD, min, max, etc.]

Application of the central line bundle has demonstrated striking reductions in the rate of central line infections in many hospitals. Berenholtz et al. demonstrated that ICUs that have implemented multifaceted interventions similar to the central line bundle have nearly eliminated CLABSIs. Additional results showing a 66% reduction in central line-associated bloodstream infection rates over an 18-month period in a state-wide effort in Michigan have recently been reported by Pronovost et al.9,10,11

- 1b.3 Citations for Data on Performance Gap: [For <u>Maintenance</u> Description of the data or sample for measure results reported in 1b.2 including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included] 9 Berenholtz SM, Pronovost PJ, Lipset PA, et al. Eliminating catheter-related bloodstream infection in the intensive care unit. Critical Care Medicine. 2004;32:2014-2020.
- 10 Pronovost P, Needham D, Berenholtz S, et al. An intervention to decrease catheter-related bloodstream infections in the ICU. N Engl J Med. 2006 Dec 28;355(26):2725-2732. Erratum in: N Engl J Med. 2007 Jun 21;356(25):2660.
- 11 Pronovost PJ, Goeschel CA, et al. Sustaining reductions in catheter related bloodstream infections in Michigan intensive care units: observational study. BMJ. 2010;340: c309.
- **1b.4 Summary of Data on Disparities by Population Group**: [For <u>Maintenance</u> –Descriptive statistics for performance results <u>for this measure</u> by population group]

NA				
1b.5 Citations for Data on Disparities Cited in 1b.4: [For <u>Maintenance</u> – Description of the data or sample for measure results reported in 1b.4 including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included] NA				
			health outcome OR meets tcome? Yes No	the criteria for quantity, quality, consistency of the body of evidence.) If not a health outcome, rate the body of evidence.
Quantity:	H M		Quality: H ML L	I ☐ Consistency: H☐ M☐ L☐ I ☐
Quantity	Quality	Consistency	Does the measure pass	subcriterion1c?
М-Н	M-H	M-H	Yes	
L	M-H	М	Yes IF additional resea	rch unlikely to change conclusion that benefits to patients outweigh harms
М-Н	L	M-H	Yes IF potential benefit	s to patients clearly outweigh potential harms
L-M-H	L-M-H	L	No 🗌	
			s relationship to at least tervention, or service	Does the measure pass subcriterion1c? Yes☐ IF rationale supports relationship
outcome, process, structure; then identify the appropriate links, e.g., structure-process-health outcome; intermediate clinical outcome-health outcome): The focus of this measure is the reliable use of maximal barrier precautions during the insertion of central lines and chlorhexidine skin antisepsis that have been shown to be associated with a reduction in central-line associated bloodstream infection (BSI) rates, respectively. The success of these interventions is perhaps due to a combination of the mindfulness that develops when regularly applying the elements of the bundle and the particular bundle elements themselves. Two studies have shown that the application of maximal barrier precautions substantially reduces the odds of developing a bloodstream infection. Mermel LA, McCormick RD, Springman SR, Maki DG. The pathogenesis and epidemiology of catheter-related infection with pulmonary artery Swan-Ganz catheters: a prospective study utilizing molecular subtyping. Am J Med. 1991;91(3B):197S-205S. Raad, II, Hohn DC, Gilbreath BJ, et al. Prevention of central venous catheter-related infections by using maximal sterile barrier precautions during insertion. Infect Control Hosp Epidemiol. 1994;15(4 Pt 1):231-238. 1c.2-3 Type of Evidence (Check all that apply): Clinical Practice Guideline, Selected individual studies (rather than entire body of evidence) 1c.4 Exclusions Justified NA 1c.5 Directness of Evidence to the Specified Measure (State the central topic, population, and outcomes addressed in the body of evidence and identify any differences from the measure focus and measure target population): 1c.6 Quantity of Studies in the Body of Evidence (Total number of studies, not articles):				
1c.6 Quantity of Studies in the Body of Evidence (Total number of studies, not articles):				
1c.7 Quality of Body of Evidence (Summarize the certainty or confidence in the estimates of benefits and harms to patients across studies in the body of evidence resulting from study factors. Please address: a) study design/flaws; b) directness/indirectness of the evidence to this measure (e.g., interventions, comparisons, outcomes assessed, population included in the evidence); and c) imprecision/wide confidence intervals due to few patients or events): A recent Compendium of Strategies to Prevent Healthcare-Associated Infections in Acute Care Hospitals, published by SHEA-IDSA (in partnership with The Joint Commission, Association for Professionals in Infection Control and Epidemiology (APIC), and the American Hospital				

Association), emphasizes the importance of reducing these infections and includes a guideline of practice recommendations to address them.7.8

- 7 Yokoe DS, Mermel LA, Classen, D, et al. A compendium of strategies to prevent healthcare-associated infections in acute care hospitals. Infect Control Hosp Epidemiol. 2008; 29:S12-S21.
- 8 Compendium of Strategies to Prevent HAIs.http://www.shea-online.org/about/compendium.cfm.
- 1c.8 Consistency of Results across Studies (Summarize the consistency of the magnitude and direction of the effect):
- 1c.9 **Net Benefit** (*Provide* estimates of effect for benefit/outcome; identify harms addressed and estimates of effect; and net benefit benefit over harms):

NA

- 1c.10 Grading of Strength/Quality of the Body of Evidence. Has the body of evidence been graded? No
- 1c.11 If body of evidence graded, identify the entity that graded the evidence including balance of representation and any disclosures regarding bias: individual elements graded using Modified HICPAC Categorization scheme for recommendations.
- 1c.12 System Used for Grading the Body of Evidence: Other
- 1c.13 **If other, identify and describe the grading scale with definitions**: individual elements graded using Modified HICPAC Categorization scheme for recommendations:

Category IA. Strongly recommended for implementation and strongly supported by well-designed experimental, clinical, or epidemiologic studies.

Category IB. Strongly recommended for implementation and supported by some experimental, clinical, or epidemiologic studies and a strong theoretical rationale; or an accepted practice (e.g., aseptic technique) supported by limited evidence.

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.

- 1c.14 Grade Assigned to the Body of Evidence: NA
- 1c.15 Summary of Controversy/Contradictory Evidence: NA
- 1c.16 Citations for Evidence other than Guidelines (Guidelines addressed below):

Infection Control and Hospital Epidemiology , Vol. 29, No. S1, A Compendium of Strategies to Prevent Healthcare-Associated Infections in Acute Care Hospitals (October 2008), pp. S22-S30

1c.17 Quote verbatim, the specific quideline recommendation (Including guideline # and/or page #):

The Centers for Disease Control and Prevention "Guidelines for the Prevention of Intravascular Catheter-Related Infections, 2011" note: individual elements of the central line bundle are included in the overall guidelines

- 1c.18 Clinical Practice Guideline Citation: Guidelines for the prevention of intravascular catheter-related infections. MMWR. 2002;51(RR10):1-26
- 1c.19 National Guideline Clearinghouse or other URL: NA
- 1c.20 Grading of Strength of Guideline Recommendation. Has the recommendation been graded? Yes
- 1c.21 If guideline recommendation graded, identify the entity that graded the evidence including balance of representation and any disclosures regarding bias: CDC Guidelines for the Prevention of Intravascular catheter-related infections, 2011 provides recommendations for each of the elements of the central line bundle, within the overall guidelines to provide evidence-based recommendations for preventing intravascular catheter-related infections. Each recommendation is categorized on the basis of existing scientific data, theoretical rationale, applicability and economic impact.
- 1c.22 System Used for Grading the Strength of Guideline Recommendation: Other

1c.23 **If other, identify and describe the grading scale with definitions**: The individual elements of the cental line bundle have been graded based on the Modified HICPAC Categorization scheme for recommendations.

Each of the elements of the bundle supported by scientific evidence - cited in Supplemental Article: SHEA/IDSA Practice Recommendations "Strategies to Prevent Central Line-Associated Bloodstream Infections in Acute Care Hospitals

- 1c.24 Grade Assigned to the Recommendation: hand hygiene Category IB; Barrier Precautions Category IB; Chlorhexidine skin antisepsis Category IB; Site Selection-avoid femoral Category IA; Prompt removal Category II
- 1c.25 Rationale for Using this Guideline Over Others: NA

Based on the NQF descriptions for rating the evidence, what was the <u>developer's assessment</u> of the quantity, quality, and consistency of the body of evidence?

- 1c.26 Quantity: High 1c.27 Quality: High 1c.28 Consistency: High
- 1c.29 Attach evidence submission form:
- 1c.30 Attach appendix for supplemental materials:

Was the threshold criterion, *Importance to Measure and Report*, met?

(1a & 1b must be rated moderate or high and 1c yes) Yes No

Provide rationale based on specific subcriteria:

For a new measure if the Committee votes NO, then STOP.

For a measure undergoing endorsement maintenance, if the Committee votes NO because of 1b. (no opportunity for improvement), it may be considered for continued endorsement and all criteria need to be evaluated.

2. RELIABILITY & VALIDITY - SCIENTIFIC ACCEPTABILITY OF MEASURE PROPERTIES

In the future, NQF will require measure stewards to provide a URL link to a web page where current detailed specifications can be obtained?

- S.1 Do you have a web page where current detailed specifications for this measure can be obtained? Yes
- S.2 If yes, provide web page URL: http://www.ihi.org/explore/CentralLineInfection/Pages/default.aspx

2a. Precisely Specified

2a.0.1 Components of the Composite. (List the components, i.e., domains/sub-composites, individual measures. If component measures are NQF-endorsed, include NQF measure number; if not NQF-endorsed, provide date of submission to NQF)

If the composite measure cannot be specified with a numerator and denominator, please consult with NQF staff.

If the component measures are combined at the aggregate level, do not include the individual measure specifications below.

2a1.1 Composite Numerator Statement (Brief, narrative description of the measure focus or what is being measured about the target population, e.g., cases from the target population with the target process, condition, event, or outcome):

Number of intensive care patients with central lines for whom all elements of the central line bundle are documented and in place.

The central line bundle elements include:

- Hand hygiene
- Maximal barrier precautions upon insertion
- Chlorhexidine skin antisepsis
- Optimal catheter site selection, with avoidance of the femoral vein for central venous access in patients 18 years and older
- Daily review of line necessity with prompt removal of unnecessary lines
- 2a1.2 **Numerator Time Window** (*The time period in which the target process, condition, event, or outcome is eligible for inclusion*): Daily for intensive care patients with central line in place
- 2a1.3 **Numerator Details** (All information required to identify and calculate the cases from the target population with the target process, condition, event, or outcome such as definitions, codes with descriptors, and/or specific data collection items/responses: Numerator = Number of patients with central lines who have all 5 components of the CL bundle documented. Sampling plan:

central line bundle compliance can be measured by selecting all patients in the unit(s) on a randomly selected day and determining central line bundle compliance. Sample should include all patients with a central line. Only patients with all 5 aspects of the central line bundle in place are recorded as being in compliance.

This is an "all or nothing" indicator. If any of the elements are not documented,

do not count the patient in the numerator. If a bundle element is contraindicated for a particular patient and this is documented appropriately, then the bundle can still be considered compliant with regards to that element.

- 2a1.4 Composite Denominator Statement (*Brief, narrative description of the target population being measured*): Total number of intensive care patients with central lines on the day of sample.
- 2a1.5 Target Population Category (Check all the populations for which the measure is specified and tested if any):
- 2a1.6 **Denominator Time Window** (*The time period in which cases are eligible for inclusion*): Total number of intensive care ICU patients with central line placed in the ICU for the duration of their central line.
- 2a1.7 **Denominator Details** (All information required to identify and calculate the target population/denominator such as definitions, codes with descriptors, and/or specific data collection items/responses):

Total number of intensive care patients with central lines on the day of sample, excluding patients whose lines were not placed in the intensive care unit and patients less than 18 years of age at the date of ICU admission.

2a1.8 **Denominator Exclusions** (Brief narrative description of exclusions from the target population):

Exclude patients less than 18 years of age at the date of ICU admission and patients outside the intensive care unit and patients whose lines were not placed in the intensive care unit

- 2a1.9 **Denominator Exclusion Details** (All information required to identify and calculate exclusions from the denominator such as definitions, codes with descriptors, and/or specific data collection items/responses):

 NA
- 2a1.10 **Stratification Details/Variables** (All information required to stratify the measure results including the stratification variables, codes with descriptors, definitions, and/or specific data collection items/responses):

 NA

If the component measures are combined at the patient level and include outcomes, complete the following

- 2a1.11 Risk Adjustment Type (Select type. Provide specifications for risk stratification in 2a1.10 and for statistical model in 2a1.13): No risk adjustment or risk stratification 2a1.12 If "Other," please describe:
- 2a1.13 **Statistical Risk Model and Variables** (Name the statistical method e.g., logistic regression and list all the risk factor variables. Note risk model development should be addressed in 2b4.):

 NA
- 2a1.14-16 **Detailed Risk Model Available at Web page URL** (or attachment). Include coefficients, equations, codes with descriptors, definitions, and/or specific data collection items/responses. Attach documents only if they are not available on a webpage and keep attached file to 5 MB or less. NQF strongly prefers you make documents available at a Web page URL. Please supply login/password if needed:

2a1.17 Type of Score:

2a1.19 **Interpretation of Score** (Classifies interpretation of score according to whether better quality is associated with a higher score, a lower score, a score falling within a defined interval, or a passing score):

- 2a1.20 Method of Scoring
- 2a1.21 If "other" scoring method, describe
- 2a1.22 Missing Component Score (Indicate how missing component scores are handled): NA
- 2a1.23 Weighting:
- 2a1.24 If differential weighting, describe:
- 2a1.25 Calculation Algorithm/Measure Logic (Describe the calculation of the measure score as an ordered sequence of steps including identifying the target population; exclusions; cases meeting the target process, condition, event, or outcome; aggregating data; risk adjustment; etc.):

NA

- 2a1.26 Calculation Algorithm/Measure Logic Diagram URL or attachment:
- 2a1.27 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):

Sampling plan: central line bundle compliance can be measured by selecting all patients in the intensive care unit(s) on a randomly selected day and determining central line bundle compliance. Sample should include all patients with a central line. Only patients with all 5 aspects of the central line bundle in place are recorded as being in compliance.

This is an "all or nothing" indicator. If any of the elements are not documented,

do not count the patient in the numerator. If a bundle element is contraindicated for a particular patient and this is documented appropriately, then the bundle can still be considered compliant with regards to that element.

- 2a1.28 **Data Source** (Check all the sources for which the measure is specified and tested). If other, please describe: Paper Medical Records
- 2a1.29 Data Source/Data Collection Instrument (Identify the specific data source/data collection instrument, e.g. name of database, clinical registry, collection instrument, etc.):
- 2a1.30-32 Data Source/data Collection Instrument Reference Web Page URL or Attachment:
- 2a1.33-35 Data Dictionary/Code Table Web Page URL or Attachment:
- 2a1.36 Level of Analysis (Check the levels of analysis for which the measure is specified and tested): Facility
- 2a1.37 Care Setting (Check all the settings for which the measure is specified and tested): Hospital/Acute Care Facility
- 2a2. **Reliability Testing**. (*Reliability testing was conducted with appropriate method, scope, and adequate demonstration of reliability*.)
- 2a2.1 Data/Sample (Description of the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included):

Currently two states include central line bundle compliance as one of the publically reported measures. Data is self-reported by hospitals, dependant on the individuals within hospitals collecting the data. No validation or reliability testing is conducted.
2a2.2 Analytic Method (Describe method of reliability testing & rationale): In 32/72 insertions, no discordant responses were recorded, while in the remaining 40 insertions, 1-3 discordant responses were recorded. Agreement, as determined by the kappa score (K), varied greately from poor (K=0.29, 95% CI-0.14-0.44 for use of impregnated catheter) to almost perfect for location of CDC insertion (K=0.89, 95% CI-0.8-0.98), but precision was poor for 6/9 variables demonstrated by wide CIs. Despite the large range of agreement over the 9 varialables, compliance differed significantly for only 1 varilable, skin preparation (90% vs 76% reported using chlorhexidine gluconate according to the collection records and progress notes respectively.) So interrater agreement varied among items examined. Despite the variability, rtes of compliance did not differ greately whehter evaluated using the nurse observations or the inserter progress ntoes, possibly due to te overall high compliance at theis facility. *Curtis AB, Smith S, Panlillo A, et al. Nurse and physician interrate agreement of practices during central venous catheter insertions. 13th Annual Scientific Meeting of the Society of Healthcare Epidemiologists of America, April, 2003. Arlington, VA.
2a2.3 Testing Results (Reliability statistics, assessment of adequacy in the context of norms for the test conducted): NA
2b. VALIDITY. Validity, Testing, including all Threats to Validity: H M L I
2b1.1 Describe how the measure specifications (measure focus, target population, and exclusions) are consistent with the evidence cited in support of the measure focus (criterion 1c) and identify any differences from the evidence: Currently two states include central line bundle compliance as one of the publically reported measures. Data is self-reported by hospitals, dependant on the individuals within hospitals collecting the data. No validation or reliability testing is conducted.
2b2. Validity Testing. (Validity testing was conducted with appropriate method, scope, and adequate demonstration of validity.)
2b2.1 Data/Sample (Description of the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included): NA
2b2.2 Analytic Method (Describe method of validity testing and rationale; if face validity, describe systematic assessment): NA
2b2.3 Testing Results (Statistical results, assessment of adequacy in the context of norms for the test conducted; if face validity, describe results of systematic assessment): NA
POTENTIAL THREATS TO VALIDITY. (All potential threats to validity were appropriately tested with adequate results.)
If the component measures are combined at the patient level, complete 2b 2b3. Measure Exclusions. (Exclusions were supported by the clinical evidence in 1c or appropriately tested with results demonstrating the need to specify them.)
2b3.1 Data/Sample for analysis of exclusions (Description of the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included): NA
2b3.2 Analytic Method (Describe type of analysis and rationale for examining exclusions, including exclusion related to patient preference): NA
2b3.3 Results (Provide statistical results for analysis of exclusions, e.g., frequency, variability, sensitivity analyses): NA
If the component measures are combined at the patient level and include outcomes, complete 2e

See Guidance for Definitions of Rating Scale: H=High; M=Moderate; L=Low; I=Insufficient; NA=Not Applicable Created on: 08/07/2012 at 05:39 PM

- **2b4.** Risk Adjustment Strategy. (For outcome measures, adjustment for differences in case mix (severity) across measured entities was appropriately tested with adequate results.)
- 2b4.1 **Data/Sample** (Description of the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included):

NA

2b4.2 **Analytic Method** (Describe methods and rationale for development and testing of risk model or risk stratification including selection of factors/variables):

NA

- 2b4.3 **Testing Results** (<u>Statistical risk model</u>: Provide quantitative assessment of relative contribution of model risk factors; risk model performance metrics including cross-validation discrimination and calibration statistics, calibration curve and risk decile plot, and assessment of adequacy in the context of norms for risk models. <u>Risk stratification</u>: Provide quantitative assessment of relationship of risk factors to the outcome and differences in outcomes among the strata):

 NA
- 2b4.4 If outcome or resource use measure is not risk adjusted, provide rationale and analyses to justify lack of adjustment: NA
- **2b5. Identification of Meaningful Differences in Performance**. (*The performance measure scores were appropriately analyzed and discriminated meaningful differences in quality.*)
- 2b5.1 Data/Sample (Describe the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included):
- Results showing a 66% reduction in central line-associated bloodstream infection rates over an 18-month period in a state-wide effort in Michigan have recently been reported by Pronovost et al.9,10,11 Further evidence from a 30-month Rhode Island ICU Collaborative demonstrates that implementing bundles of effective best practices for CLABSI reduced the CLABSI rate by 74% statewide.12 Similarly, in Hawaii, a statewide ICU Collaborative focusing on comprehensive CLABSI prevention efforts reduced the mean CLABSI rate from 1.5 infections per 1000 catheter days to 0.6 infections per 1000 catheter days 16-18 months post-intervention.13
- 9 Berenholtz SM, Pronovost PJ, Lipset PA, et al. Eliminating catheter-related bloodstream infection in the intensive care unit. Critical Care Medicine. 2004;32:2014-2020.
- 10 Pronovost P, Needham D, Berenholtz S, et al. An intervention to decrease catheter-related bloodstream infections in the ICU. N Engl J Med. 2006 Dec 28;355(26):2725-2732. Erratum in: N Engl J Med. 2007 Jun 21;356(25):2660.
- 11 Pronovost PJ, Goeschel CA, et al. Sustaining reductions in catheter related bloodstream infections in Michigan intensive care units: observational study. BMJ. 2010;340: c309.
- 12 DePalo VA, McNicoll L, et al. The Rhode Island ICU collaborative: a model for reducing central line-associated bloodstream infection and ventilator-associated pneumonia statewide. Qual Saf Health Care. 2010;19(6): 555-561
- 13 Lin DM, Weeks K, et al. Eradicating central line-associated bloodstream infections statewide: The Hawaii experience. Am J Med Qual. 2011.
- 2b5.2 **Analytic Method** (Describe methods and rationale to identify statistically significant and practically/meaningfully differences in performance):

NA

2b5.3 **Results** (Provide measure performance results/scores, e.g., distribution by quartile, mean, median, SD, etc.; identification of statistically significant and meaningfully differences in performance):

NA

- **2b6.** Comparability of Multiple Data Sources/Methods. (If specified for more than one data source, the various approaches result in comparable scores.)
- 2b6.1 **Data/Sample** (Describe the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included):

 NA

2b6.2 Analytic Method (Describe methods and rationale for testing comparability of scores produced by the different data sources specified in the measure): NA
2b6.3 Testing Results (Provide statistical results, e.g., correlation statistics, comparison of rankings; assessment of adequacy in the context of norms for the test conducted): NA
2c. Disparities in Care: H M L I NA (If applicable, the measure specifications allow identification of disparities.)
2c.1 If measure is stratified for disparities, provide stratified results (Scores by stratified categories/cohorts): NA
2c.2 If disparities have been reported/identified (e.g., in 1b), but measure is not specified to detect disparities, please explain: NA
2i. Component Item/Measure Analysis to Justify Inclusion in Composite
2i.1. Data/Sample NA
2i.2. Analytic Method NA
2i.3. Result NA
2j. Component Item/Measure Analysis of Contribution to Variability in Composite Score
2j.1. Data/Sample NA
2j.2. Analytic Method NA
2j.3. Result NA
2k. Analysis to Support Differential Weighting of Component Score
2k.1. Data/Sample NA
2k.2. Analytic Method NA
2k.3. Result NA
2k.4. Describe how the method scoring/aggregation achieves the stated purpose and represent the quality construct NA

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2k.5. Indicate if any alternative scoring/aggregation methods were tested and why not chosen NA
2I. Analysis of Missing Component Scores
2I.1. Data/Sample NA
2I.2. Analytic Method NA
2I.3. Result NA
2.1-2.3 Supplemental Testing Methodology Information:
Steering Committee: Overall, was the criterion, <i>Scientific Acceptability of Measure Properties</i> , met? (<i>Reliability and Validity must be rated moderate or high</i>) Yes No Provide rationale based on specific subcriteria:
If the Committee votes No, STOP
3. USABILITY
Extent to which intended audiences (e.g., consumers, purchasers, providers, policy makers) can understand the results of the measure and are likely to find them useful for decision making. (evaluation criteria)
C.1 Intended Actual/Planned Use (Check all the planned uses for which the measure is intended): Quality Improvement (Internal to the specific organization)
3.1 Current Use (Check all that apply; for any that are checked, provide the specific program information in the following questions): Quality Improvement with Benchmarking (external benchmarking to multiple organizations), Quality Improvement (Internal to the specific organization)
3a. Usefulness for Public Reporting: H M L I (The measure is meaningful, understandable and useful for public reporting.)
3a.1. Use in Public Reporting - disclosure of performance results to the public at large (If used in a public reporting program, provide name of program(s), locations, Web page URL(s)). If not publicly reported in a national or community program, state the reason AND plans to achieve public reporting, potential reporting programs or commitments, and timeline, e.g., within 3 years of endorsement: [For Maintenance – If not publicly reported, describe progress made toward achieving disclosure of performance results to the public at large and expected date for public reporting; provide rationale why continued endorsement should be considered.] The central line bundle is a process/composite measure, not an outcome measure designed for public reporting
3a.2.Provide a rationale for why the measure performance results are meaningful, understandable, and useful for public reporting. If usefulness was demonstrated (e.g., focus group, cognitive testing), describe the data, method, and results: NA
3.2 Use for other Accountability Functions (payment, certification, accreditation). If used in a public accountability program, provide name of program(s), locations, Web page URL(s): NA

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3b. Usefulness for Quality Improvement: H M L I (The measure is meaningful, understandable and useful for quality improvement.)
3b.1. Use in QI . If used in quality improvement program, provide name of program(s), locations, Web page URL(s): [For <u>Maintenance</u> – If not used for QI, indicate the reasons and describe progress toward using performance results for improvement].
IHI Critical Care collaborative and 100,000 and 5 million lives campaigns engaged hospitals in the use of the "central line bundle": hand hygiene; maximal barrier precautions; chlorhexidine skin antisepsis; optimal catheter site selection, w/avoidance of femoral vein; prompt removal of unnecessary lines. www.ihi.org
Keystone ICU study intervention targeted clinicians' use of 5 evidence-based procedures recommended by the CDC: hand hygiene, use of full barrier precautions during CDC insertion, cleaning the skin with chlorhexidine, avoiding the femoral site if possible and removing unnecessary catheters. http://www.mhakeystonecenter.org/icu_overview
3b.2. Provide rationale for why the measure performance results are meaningful, understandable, and useful for quality improvement. If usefulness was demonstrated (e.g., QI initiative), describe the data, method and results: Application of the central line bundle has demonstrated reductions in the rates of central line infections in many hospitals. Results showing a 66% reduction in central line-associated bloodstream infection rates over an 18-month peridod in a state-wide effort in Michigan have been repeorted by Pronovost et al.
Pronovost P, Needham D, Berenholtz S, et al. An intervention to decrease catheter-related bloodstream infections in the ICU. N Engl J Med. 2006 Dec 28;355(26):2725-2732. Erratum in: N Engl J Med. 2007 Jun 21;356(25):2660. Pronovost PJ, Goeschel CA, et al. Sustaining reductions in catheter related bloodstream infections in Michigan intensive care units: observational study. BMJ. 2010;340: c309.
3d. Decomposition of Composite
3d.1 Describe the information that is available from decomposing the composite into its components NA
3e. Achieved Stated Purpose
3e.1 Describe how the scores from testing or use reported in 2f demonstrate that the composite achieves the stated purpose NA
Overall, to what extent was the criterion, <i>Usability</i> , met? H M L I Provide rationale based on specific subcriteria:
4. FEASIBILITY
Extent to which the required data are readily available, retrievable without undue burden, and can be implemented for performance measurement. (evaluation criteria)
4a. Data Generated as a Byproduct of Care Processes: H M L I
4a.1-2 How are the data elements needed to compute measure scores generated? (Check all that apply). Data used in the measure are:
generated by and used by healthcare personnel during the provision of care, e.g., blood pressure, lab value, medical condition, Abstracted from a record by someone other than person obtaining original information (e.g., chart abstraction for quality measure or registry)
4b. Electronic Sources: H M L I
4b.1 Are the data elements needed for the measure as specified available electronically (Elements that are needed to

See Guidance for Definitions of Rating Scale: H=High; M=Moderate; L=Low; I=Insufficient; NA=Not Applicable Created on: 08/07/2012 at 05:39 PM

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4b.2 If ALL data elements are not from electronic sources, specify a credible, near-term path to electronic capture, OR
provide a rationale for using other than electronic sources:
4c. Susceptibility to Inaccuracies, Errors, or Unintended Consequences: H M L I
4c.1 Identify susceptibility to inaccuracies, errors, or unintended consequences of the measurement identified during testing and/or operational use and strategies to prevent, minimize, or detect. If audited, provide results: These measures [compliance with the elements of the bundle] are self reported and not verifiable without extensive and expensive auditing. Currently two states include central line bundle data in state-wide public reporting and do not conduct reliability or validity testing of the data reported.
4d. Data Collection Strategy/Implementation: H M L I
A.2 Please check if either of the following apply (regarding proprietary measures): 4d.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 and frequency of data collection, sampling, patient confidentiality, time and cost of data collection, other feasibility/implementation issues (e.g., fees for use of proprietary measures): Generally, data on the elements of the central line bundle are collected during the process of care, using a "check list" of each of the bundle elements and depending on staff completion. A suggested "sampling plan" - addressing sampling, timing and frequency of data collection, missing data, etc has been tested by hospitals participating in a number of improvement collaboratives: Rotate the days of the week and shifts within a day. On the randomly selected day, all patients with CLs should be examined for evidence of CL bundle compliance. • Only patients with all 5 aspects of CL bundle in place are recorded as being in compliance.
Overall, to what extent was the criterion, <i>Feasibility</i> , met? H M L I C I C Provide rationale based on specific subcriteria:
OVERALL SUITABILITY FOR ENDORSEMENT
Does the measure meet all the NQF criteria for endorsement? Yes No Rationale:
If the Committee votes No, STOP. If the Committee votes Yes, the final recommendation is contingent on comparison to related and competing measures.
5. COMPARISON TO RELATED AND COMPETING MEASURES
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 before a final recommendation is made.
5.1 If there are related measures (either same measure focus or target population) or competing measures (both the same measure focus and same target population), list the NQF # and title of all related and/or competing measures:
5a. Harmonization
5a.1 If this measure has EITHER the same measure focus OR the same target population as NOF-endorsed measure(s) : Are the measure specifications completely harmonized? 5a.2 If the measure specifications are not completely harmonized, identify the differences, rationale, and impact on interpretability and data collection burden:
5b. Competing Measure(s)
5b.1 If this measure has both the same measure focus and the same target population as NQF-endorsed measure(s):

Describe why this measure is superior to competing measures (e.g., a more valid or efficient way to measure quality); OR provide a rationale for the additive value of endorsing an additional measure. (Provide analyses when possible):

CONTACT INFORMATION

- Co.1 Measure Steward (Intellectual Property Owner): Institute for Healthcare Improvement, 20 University Road, 7th Floor, Cambridge, Massachusetts, 02168
- Co.2 Point of Contact: Diane, Jacobsen, MPH, CPHQ, djacobsen@ihi.org, 763-553-0232-
- Co.3 Measure Developer if different from Measure Steward: Institute for Healthcare Improvement, 20 University Road, 7th Floor, Cambridge, Massachusetts, 02168
- Co.4 Point of Contact: Diane, Jacobsen, MPH, CPHQ, djacobsen@ihi.org, 763-553-0232-
- Co.5 Submitter: Diane, Jacobsen, MPH, CPHQ, djacobsen@ihi.org, 763-553-0232-, Institute for Healthcare Improvement
- Co.6 Additional organizations that sponsored/participated in measure development:
- Co.7 Public Contact: Diane, Jacobsen, MPH, CPHQ, djacobsen@ihi.org, 763-553-0232-, Institute for Healthcare Improvement

ADDITIONAL INFORMATION

Workgroup/Expert Panel involved in measure development

- Ad.1 Provide a list of sponsoring organizations and workgroup/panel members' names and organizations. Describe the members' role in measure development.
- Ad.2 If adapted, provide title of original measure, NQF # if endorsed, and measure steward. Briefly describe the reasons for adapting the original measure and any work with the original measure steward:

Measure Developer/Steward Updates and Ongoing Maintenance

- Ad.3 Year the measure was first released:
- Ad.4 Month and Year of most recent revision:
- Ad.5 What is your frequency for review/update of this measure?
- Ad.6 When is the next scheduled review/update for this measure?
- Ad.7 Copyright statement:
- Ad.8 Disclaimers:
- Ad.9 Additional Information/Comments:

Date of Submission (MM/DD/YY): 06/07/2012