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-003-10 **NQF Project:** Patient Safety Measures
MEASURE DESCRIPTIVE INFORMATION
De.1 **Measure Title:** National Healthcare Safety Network (NHSN) Catheter-associated Urinary Tract Infection (CAUTI) Outcome Measure
De.2 **Brief description of measure**: De.2. Brief description of measure Standardized Infection Ratio (SIR) of healthcare-associated, catheter-associated urinary tract infections (CAUTI) will be calculated among patients in the following patient care locations: • Intensive Care Units (ICUs) (excluding patients in neonatal ICUs [NICUs: Level II/III and Level III nurseries]) • 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 (excluding Level I and Level II nurseries). 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. *Public domain only applies to governmental organizations. All non-government organizations must sign a measure steward agreement even if measures are made publicly and freely available.*	**A** **Y**☐ **N**☐

A.1 **Do you attest that the measure steward holds intellectual property rights to the measure and the right to use aspects of the measure owned by another entity (e.g., risk model, code set)?** Yes A.2 **Indicate if Proprietary Measure** (*as defined in measure steward agreement*)**:** 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☐ N☐
C. The intended use of the measure includes both public reporting and quality improvement. ►**Purpose:**	**C** Y☐ N☐
D. The requested measure submission information is complete. Generally, measures should be fully developed and tested so that all the evaluation criteria have been addressed and information needed to evaluate the measure is provided. Measures that have not been tested are only potentially eligible for a time-limited endorsement and in that case, measure owners must verify that testing will be completed within 12 months of endorsement. D.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☐ N☐
(for NQF staff use**)** **Have all conditions for consideration been met?** **Staff Notes to Steward** (*if submission returned*)**:**	**Met** Y☐ N☐
Staff Notes to Reviewers (*issues or questions regarding any criteria*)**:**	
Staff Reviewer Name(s):	

TAP/Workgroup Reviewer Name:	
Steering Committee Reviewer Name:	
1. IMPORTANCE TO MEASURE AND REPORT	
Extent to which the specific measure focus is important to making significant gains in health care quality (safety, timeliness, effectiveness, efficiency, equity, patient-centeredness) and improving health outcomes for a specific high impact aspect of healthcare where there is variation in or overall poor performance. *Measures must be judged to be important to measure and report in order to be evaluated against the remaining criteria.* (evaluation criteria) **1a. High Impact**	**Eval Rati ng**
(for NQF staff use) **Specific NPP goal**:	
1a.1 **Demonstrated High Impact Aspect of Healthcare:** Affects large numbers, Frequently performed procedure, Leading cause of morbidity/mortality, Patient/societal consequences of poor quality 1a.2 1a.3 **Summary of Evidence of High Impact:** CAUTI is the most common type of healthcare-associated infection, accounting for more than 30% of acute care hospital infections (Citation-1) 13,000 deaths associated with UTIs each year1 449,334 estimated CAUTIs/yr (Citation 2) $758 medical cost/CAUTI (Citation 2) Total >$340 million attributable to CAUTI in U.S. each year (Citation 2) 1a.4 **Citations for Evidence of High Impact:** 1 Klevens RM, Edwards JR, et al. Estimating healthcare-associated infection and deaths in U.S. hospitals, 2002. Public Health Reports 2007; 122:160-166. 2 Scott, RD. The Direct Medical Costs of Healthcare-Associated Infections in U.S. Hospitals and the Benefits of Prevention. http://www.cdc.gov/ncidod/dhqp/pdf/Scott_CostPaper.pdf accessed April 12, 2010.	**1a** C☐ P☐ M☐ N☐

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).

1b. Opportunity for Improvement

1b.1 Benefits (improvements in quality) envisioned by use of this measure: It is envisioned that the use of this measure will promote CAUTI prevention activities which will lead to improved patient outcomes. Such activities include reducing the number of unnecessary indwelling catheters inserted, removing indwelling catheters at their earliest, clinically-appropriate time; avoiding patient exposures to antibiotics; reducing avoidable medical costs, and patient morbidity and mortality.

1b.2 Summary of data demonstrating performance gap (variation or overall poor performance) across providers:
CAUTI rates vary considerably when stratified by location type and in some instances, by location bed size and type of medical school affiliation of the facility.

1b.3 Citations for data on performance gap:
Edwards JR, Peterson KD, et al. National Healthcare Safety Network (NHSN) report: Data summary for 2006 through 2008, issued December, 2009. American Journal of Infection Control 2009; 37:783-805.

1b.4 Summary of Data on disparities by population group:
According to the cited NHSN Report, CAUTI rates range from low of 0.0 per 1000 catheter days to high of 35.2 per 1000 catheter days between location types and in some instances, location bed-size and type of medical school affiliation of the facility.

1b.5 Citations for data on Disparities:
Edwards JR, Peterson KD, et al. National Healthcare Safety Network (NHSN) report: Data summary for 2006 through 2008, issued December, 2009. American Journal of Infection Control 2009; 37:783-805.

1b
C☐ P☐ M☐ N☐

1c. Outcome or Evidence to Support Measure Focus

1c.1 Relationship to Outcomes (*For non-outcome measures, briefly describe the relationship to desired outcome. For outcomes, describe why it is relevant to the target population*)**:** CAUTI SIRs are relevant to patient populations because prevention recommendations have been published to reduce the incidence of CAUTI. A high SIR indicates an opportunity for improvement.

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

1c.4 Summary of Evidence (*as described in the criteria; for outcomes, summarize any evidence that healthcare services/care processes influence the outcome*)**:**
The Guideline for Prevention of Catheter-associated Urinary Tract Infections, 2009 published by the Healthcare Infection Control Practices and Advisory Committee (HICPAC) retrieved over 1050 published studies from the scientific literature for consideration into the development of the recommendations.

1c.5 Rating of strength/quality of evidence (*also provide narrative description of the rating and by whom***):**
See Attachment under Ad.11 Additional Information

1c.6 Method for rating evidence: See Attachment under Ad.11 Additional Information

1c.7 Summary of Controversy/Contradictory Evidence: None

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

1c.9 Quote the Specific guideline recommendation (*including guideline number and/or page number***):**
see 1c.10

1c.10 Clinical Practice Guideline Citation: The Guideline for Prevention of Catheter-associated Urinary Tract Infections, 2009, HICPAC.
http://www.cdc.gov/hicpac/pdf/CAUTI/CAUTIguideline2009final.pdf Accessed April 13, 2010.

1c
C☐ P☐ M☐ N☐

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.
oPatient experience – evidence that an association exists between the measure ... [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]

1c.11 National Guideline Clearinghouse or other URL:	
1c.12 Rating of strength of recommendation (*also provide narrative description of the rating and by whom***):** See section 1c.6	
1c.13 Method for rating strength of recommendation (*If different from USPSTF system, also describe rating and how it relates to USPSTF)***:**	
1c.14 Rationale for using this guideline over others:	
TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for *Importance to Measure and Report?*	**1**
Steering Committee: Was the threshold criterion, *Importance to Measure and Report***, met?** **Rationale:**	**1** **Y☐** **N☐**
2. SCIENTIFIC ACCEPTABILITY OF MEASURE PROPERTIES	
Extent to which the measure, as specified, produces consistent (reliable) and credible (valid) results about the quality of care when implemented. (evaluation criteria)	**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 (*Brief, text description of the numerator - what is being measured about the target population, e.g. target condition, event, or outcome***):** Total number of observed healthcare-associated CAUTI among inpatients in ICUs (excluding patients in NICUs), SCAs, and other inpatient locations (excluding Level I and Level II nurseries). **2a.2 Numerator Time Window (***The time period in which cases are eligible for inclusion in the numerator***):** 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 CAUTI surveillance is done in a medical ICU during January, all healthcare-associated CAUTI with infection dates in January in Medical ICU 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 CAUTI: CAUTI is a urinary tract infection (UTI) that occurs in a patient who had an indwelling urinary catheter in place within the 48-hour period before the onset of the UTI. NOTE: There is no minimum	**2a-specs** **C☐** **P☐** **M☐** **N☐**

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 NQF's Health Information Technology Expert Panel (HITEP) .

period of time that the catheter must be in place in order for the UTI to be considered catheter-associated.

3.Definition of indwelling catheter: a drainage tube that is inserted into the urinary bladder through the urethra, is left in place, and is connected to a closed collection system; also called a Foley catheter.

4.UTI criteria:
•Symptomatic Urinary Tract Infection (SUTI)
Must meet at least 1 of the following criteria:

Criterion 1a:
Patient had an indwelling urinary catheter in place at the time of specimen collection
AND
at least 1 of the following signs or symptoms with no other recognized cause:
fever (>38°C), suprapubic tenderness, or costovertebral angle pain or tenderness
AND
a positive urine culture of greater than or equal to 100,000 colony-forming units (CFU)/ml with no more than 2 species of microorganisms.

OR

Patient had indwelling urinary catheter removed within the 48 hours prior to specimen collection
AND
at least 1 of the following signs or symptoms with no other recognized cause:
fever (>38°C), urgency, frequency, dysuria, suprapubic tenderness, or costovertebral angle pain or tenderness
AND
a positive urine culture of greater than or equal to 100,000 colony-forming units (CFU)/ml with no more than 2 species of microorganisms.

Criterion 1b:
Patient did not have an indwelling urinary catheter in place at the time of specimen collection nor within 48 hours prior to specimen collection
AND
has at least 1 of the following signs or symptoms with no other recognized cause: fever (>38°C) in a patient that is less than or equal to 65 years of age, urgency, frequency, dysuria, suprapubic tenderness, or costovertebral angle pain or tenderness
AND
a positive urine culture of greater than or equal to 100,000 CFU/ml with no more than 2 species of microorganisms.

Criterion 2a:
Patient had an indwelling urinary catheter in place at the time of specimen collection
AND
at least 1 of the following signs or symptoms with no other recognized cause:
fever (>38°C), suprapubic tenderness, or costovertebral angle pain or tenderness
AND
a positive urinalysis demonstrated by at least 1 of the following findings:

a. positive dipstick for leukocyte esterase and/or nitrite
b. pyuria (urine specimen with greater than or equal to 10 white blood cells [WBC]/mm3 or greater than or equal to 3 WBC/high power field of unspun urine)
c. microorganisms seen on Gram stain of unspun urine

AND
a positive urine culture of greater than or equal to 1,000 and less than 100,000 CFU/ml with no more than 2 species of microorganisms.

OR

Patient had indwelling urinary catheter removed within the 48 hours prior to specimen collection
AND
at least 1 of the following signs or symptoms with no other recognized cause:
fever (>38°C), urgency, frequency, dysuria, suprapubic tenderness, or costovertebral angle pain or tenderness
AND
a positive urinalysis demonstrated by at least 1 of the following findings:

a. positive dipstick for leukocyte esterase and/or nitrite
b. pyuria (urine specimen with greater than or equal to 10 white blood cells [WBC]/mm3 or greater than or equal to 3 WBC/high power field

Criterion 2b:
Patient did not have an indwelling urinary catheter in place at the time of specimen collection nor within 48 hours prior to specimen collection
AND
has at least 1 of the following signs or symptoms with no other recognized cause: fever (>38°C) in a patient that is =65 years of age, urgency, frequency, dysuria, suprapubic tenderness, or costovertebral angle pain or tenderness
AND
a positive urinalysis demonstrated by at least 1 of the following findings:

a. positive dipstick for leukocyte esterase and/or nitrite
b. pyuria (urine specimen with greater than or equal to 10 WBC/mm3 or greater than or equal to 3 WBC/high power field of unspun urine)
c. microorganisms seen on Gram stain of unspun urine

AND
a positive urine culture of greater than or equal to 1,000 and greater than 100,000 CFU/ml with no more than 2 species of microorganisms.

Criterion 3:
Patient less than or equal to 1 year of age with or without an indwelling urinary catheter has at least 1 of the following signs or symptoms with no other recognized cause: fever (>38°C core), hypothermia (<36°C core), apnea, bradycardia, dysuria, lethargy, or vomiting
AND
a positive urine culture of greater than or equal to 100,000 CFU/ml with no more than 2 species of microorganisms.

Criterion 4:
Patient greater than or less than 1 year of age with or without an indwelling urinary catheter has at least 1 of the following signs or symptoms with no other recognized cause: fever (>38°C core), hypothermia (<36°C core), apnea, bradycardia, dysuria, lethargy, or vomiting
AND
a positive urinalysis demonstrated by at least one of the following findings:

a. positive dipstick for leukocyte esterase and/or nitrite
b. pyuria (urine specimen with greater than or equal to 10 WBC/mm3 or greater than or equal to 3 WBC/high power field of unspun urine)
c. microorganisms seen on Gram's stain of unspun urine

AND
a positive urine culture of between greater than or equal to 1,000 and less than 100,000 CFU/ml with no more than two species of microorganisms.

•Asymptomatic Bacteremic Urinary Tract Infection (ABUTI):
Patient with or without an indwelling urinary catheter has no signs or symptoms (i.e. no fever (>38° C) for

patients less than or equal to 65 years of age*; and for any age patient no urgency, frequency, dysuria, suprpubic tenderness, or costovertebral angle pain or tenderness, OR for a patient less than or equal to 1 year of age, no fever (>38° C core), hypothermia (<36° C core), apnea, bradycardia, dysuria, lethargy, or vomiting)
AND
a positive urine culture of greater than or equal to 100,000 CFU/ml with no more than 2 species of uropathogen microorganisms**
AND
a positive blood culture with at least 1 matching uropathogen mircorooganism to the urine culture
*Fever is not diagnostic for UTI in the elderly (greater than 65 years of age) and therefore fever in this age group does not disqualify from meeting the criteria for an ABUTI.
**Uropathogen microorganisms are: Gram-negative bacilli, Staphylococcus spp., yeasts, beta-hemolytic Streptococcus spp. Enterococcus spp., G. vaginalis, Aerococcus urinae, and Corynebacterium (urease positive)
Urinary catheter tips should not be cultured and are not acceptable for the diagnosis of a urinary tract infection.

5.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).

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

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

8.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.

9.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 CAUTIs, which is calculated by multiplying the number of urinary catheter days for each location under surveillance for CAUTI during the period by the CAUTI rate for the same types of locations obtained from the standard population. These expected numbers are summed across locations and used as the denominator of this measure (see also 2a.8).

2a.5 Target population gender: Female, Male
2a.6 Target population age range: Patients of all ages are eligible except patients in Levels I, II, II/III and III nurseries, and in locations where patients do not reside overnight.

2a.7 Denominator Time Window (*The time period in which cases are eligible for inclusion in the denominator***):**
The number of urinary catheter days for the location under surveillance for CAUTI during the period is collected. This number is multiplied by the 2006 through 2008 standard population's CAUTI rate, derived from the NHSN national data, for the same type of location to obtain the number of expected CAUTIs. The expected number of CAUTIs is the sum across all location types during the period. The expected number of CAUTIs will be influenced by the number of catheter days in the facility and the CAUTI 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 urinary catheter days for locations under CAUTI surveillance during the period

2.CAUTI rate per 1000 catheter days for the same location types from the standard population, derived from the NHSN national data, (2006 through 2008; see NHSN Report at http://www.cdc.gov/nhsn/PDFs/dataStat/2009NHSNReport.PDF).

3.Definition of urinary catheter days: Indwelling urinary catheter days are the number of patients with an indwelling urinary catheter device in place at the time when the daily count is made. The counts are done daily, at the same time each day, for each location under surveillance for CAUTI. The daily counts are summed and the total for the month is used as a denominator.

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 [major, graduate, limited, not affiliated:
•Major: A hospital that is an important part of the teaching program of a medical school and the majority of medical students rotate through multiple clinical services.
•Graduate: Hospital is used by the medical school for graduate trainings only (residency and/or fellowships).
•Limited: Hospital is used in the medical school's teaching program to only a limited extent.

2a.9 Denominator Exclusions (*Brief text description of exclusions from the target population***):** Non-indwelling catheters by NHSN definitions:
1.Suprapubic catheters
2.Condom catheters
3."In and out" catheterizations

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.
2a. 8 Facility Specific Data)

2a.12-13 Risk Adjustment Type: SIR is an indirect standardization method for summarizing HAI experience across any number of stratified groups of data (in this case, CAUTI incidence rates stratified by patient care location and in some instances, location bed size and type of medical school affiliation). Expected numbers of CAUTI (and CAUTI rates) in a medical ICU are not the same as in a surgical ICU, for example.

2a.14 Risk Adjustment Methodology/Variables (*List risk adjustment variables and describe conceptual models, statistical models, or other aspects of model or method***):**
CAUTI rates per 1000 urinary catheter days provide adjustment for the influence of length of stay and catheter utilization stratified by patient care location. 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.

Comment [k9]: 11 Risk factors that influence outcomes should not be specified as exclusions.
12 Patient preference is not a clinical exception to eligibility and can be influenced by provider interventions.

2a.18-19 Type of Score: 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 CAUTI in each location type
2.Total these numbers for an observed number of CAUTIs
3.Obtain the expected number of CAUTIs 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 catheter days observed by the expected CAUTI rate for that location.
4.Sum the number of expected CAUTIs from all locations.
5.Divide the total number of observed CAUTI ("2" above) by the "expected" number of CAUTI ("3" above).
6. Result = SIR
See example attached under Ad.11. Additional information
(The NHSN analysis tool will perform the calculations once the patient infection data and denominator information are entered into the system.)

2a.22 Describe the method for discriminating performance *(e.g., significance testing)***:**
Performance evaluation can be conducted through at least 2 processes. First an SIR can be compared to the nominal value of 1.0 through significance testing, i.e., P value and confidence intervals. Second, successive SIRs obtained for a given reporting entity can be compared to each other to assess changes over time.

2a.23 Sampling (Survey) Methodology *If measure is based on a sample (or survey), provide instructions for obtaining the sample, conducting the survey and guidance on minimum sample size (response rate)*:
Not based on sample or survey

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 Urinary Tract Infection form; NHSN Denominators for Intensive Care Unit (ICU)/Other Locations (not NICU or SCA) form; NHSN Denominators for Specialty Care Areas form.

2a.26-28 Data source/data collection instrument reference web page URL or attachment: URL
http://www.cdc.gov/nhsn/forms/57.114_UTI_BLANK.pdf;
http://www.cdc.gov/nhsn/forms/57.118_DenominatorICU_BLANK.pdf;http://www.cdc.gov/nhsn/forms/57.117_DenominatorSCA_BLANK.pdf

2a.29-31 Data dictionary/code table web page URL or attachment: Attachment Data Dictionary.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 CAUTI rates used in the SIR calculations are from 15 different types of ICUs, 5 different types of SCAs, and 18 types of other inpatient locations. The numerators of these location-specific rates range from approximately 1 to 2100 CAUTI for the ICU locations, from 1 to 695 for the SCA locations, and from 0-4200 in other inpatient locations while the denominators range from approximately 2,000 to 676,000 urinary catheter days in the ICU locations, 870 to

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

124,500 in the SCA locations, and 300 to 717,000 in other inpatient locations. 11 of the 15 ICU locations have >200,000 urinary catheter days, but only 2 of the SCA or other inpatient locations do. We conclude for most of the locations, the standard population's rates are robust enough to use for determining the expected number of CAUTI. (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 CAUTI reporting is greatest in ICUs there are a number of facilities reporting CAUTI data in SCA and other inpatient locations and the number is growing. In 2010, over 570 acute care facilties reported at least one month's CAUTI data in a non-ICU/SCA location and 60 of those locations were new for NHSN CAUTI reporting in 2010. 49 long-term acute care facilities reported at least one month of CAUTI data in 2010 and 7 of those locations were new for NHSN CAUTI reporting in that year.
National Healthcare Safety Network (NHSN) report: Data summary for 2006 through 2008, issued December 2009, Am J of Infect Control 2009; 37: 783-805.)

2b.2 Analytic Method *(type of reliability & rationale, method for testing)*:
An SIR is identical in concept to a standardized mortality ratio (SMR) and can summarizies 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 CAUTI experiences within facilities because it:
•provides a single measure that is simple to interpret for assessing CAUTI 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.

2c. Validity testing

2c.1 Data/sample *(description of data/sample and size)*: The CAUTI 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, CAUTI 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. 38 previously reported CAUTI cases were reviewed as well as 57 positive urine cultures that were not reported as CAUTI. Overall, 85.7% specificity and 79.1% sensitivity was found between facility and auditor CAUTI determinations, with a positive predictive value of 63.1% and negative predictive value of 93%. 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.

2c.2 Analytic Method *(type of validity & rationale, method for testing)*:
To address concerns regarding validity, HHS has provided funding, utilizing Recovery Act of 2009 funds, to CDC to support 10 state Emerging Infections Programs in validating NHSN-related measures and to support reporting on HHS metrics through NHSN.

2c.3 Testing Results *(statistical results, assessment of adequacy in the context of norms for the test*

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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.

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.

conducted):

2d. Exclusions Justified

2d.1 **Summary of Evidence supporting exclusion(s):**
Nursery locations are excluded since indwelling urinary catheters are rarely used in patients in these locations.

Subject matter experts inform us that these devices are not commonly used, because these incontinent patients are diapered and there is the increased possibility of stool contamination of the catheter tubing with resulting introduction into the bladder.

2d.2 **Citations for Evidence:**

2d.3 **Data/sample** *(description of data/sample and size)*:

2d.4 **Analytic Method** *(type analysis & rationale)*:

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

2d
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2e. Risk Adjustment for Outcomes/ Resource Use Measures

2e.1 **Data/sample** *(description of data/sample and size)*: The standard population's CAUTI rates used in the SIR calculations are from 15 different types of ICUs, 5 different types of SCAs, and 18 types of other inpatient locations. The numerators of these location-specific rates range from approximately 1 to 2100 CAUTI for the ICU locations, from 1 to 695 for the SCA locations, and from 0-4200 in other inpatient locations while the denominators range from approximately 2,000 to 676,000 urinary catheter days in the ICU locations, 870 to 124,500 in the SCA locations, and 300 to 717,000 in other inpatient locations. 11 of the 15 ICU locations have >200,000 urinary catheter days, but only 2 of the SCA or other inpatient locations do. We conclude for most of the locations, the standard population's rates are robust enough to use for determining the expected number of CAUTI. (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 CAUTI reporting is greatest in ICUs there are a number of facilities reporting CAUTI data in SCA and other inpatient locations and the number is growing. In 2010, over 570 acute care facilties reported at least one month's CAUTI data in a non-ICU/SCA location and 60 of those locations were new for NHSN CAUTI reporting in 2010. 49 long-term acute care facilities reported at least one month of CAUTI data in 2010 and 7 of those locations were new for NHSN CAUTI reporting in that year.
National Healthcare Safety Network (NHSN) report: Data summary for 2006 through 2008, issued December 2009, Am J of Infect Control 2009; 37: 783-805.)

2e.2 **Analytic Method** *(type of risk adjustment, analysis, & rationale)*:
The SIR is the ratio of the observed number of CAUTI to the expected number of CAUTI. CAUTI rates per 1000 urinary catheter days, which are used to calculate the expected number of CAUTI for the denominator of the SIR, are indirectly standardized rates accounting for the influence of length of stay and length of urinary catheterization, and are stratified by patient care location, which adjusts for differences in patient morbidity and disease-specific variables which may influence CAUTI risk. If the number of CAUTIs 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 CAUTIs 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 CAUTIs 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 CAUTIs for that location type). See also 2a.4 and 2a.20.

2e.3 **Testing Results** *(risk model performance metrics)*:

2e
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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 patient preference and the effect on the measure is transparent (e.g., numerator category computed separately, denominator exclusion category computed separately).

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.

2e.4 If outcome or resource use measure is not risk adjusted, provide rationale:	
2f. Identification of Meaningful Differences in Performance **2f.1 Data/sample from Testing or Current Use** *(description of data/sample and size)*: SIRs have been used as metrics for identifying differences in performance by state. **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 CAUTI SIR of 2.0 represents twice as many CAUTIs as expected for the patient population). Additionally, the confidence interval provides further information regarding the likelihood that the SIR occurs within a specified range. See NHSN State Report for an example. **2f.3 Provide Measure Scores from Testing or Current Use** *(description of scores, e.g., distribution by quartile, mean, median, SD, etc.; identification of statistically significant and meaningfully differences in performance)*: 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).	**2f** C☐ P☐ M☐ N☐
2g. Comparability of Multiple Data Sources/Methods **2g.1 Data/sample** *(description of data/sample and size)*: **2g.2 Analytic Method** *(type of analysis & rationale)*: **2g.3 Testing Results** *(e.g., correlation statistics, comparison of rankings)*:	**2g** C☐ P☐ M☐ N☐ NA☐
2h. Disparities in Care **2h.1 If measure is stratified, provide stratified results** *(scores by stratified categories/cohorts)*: **2h.2 If disparities have been reported/identified, but measure is not specified to detect disparities, provide follow-up plans:**	**2h** C☐ P☐ M☐ N☐ NA☐
TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for *Scientific Acceptability of Measure Properties?*	**2**
Steering Committee: Overall, to what extent was the criterion, *Scientific Acceptability of Measure Properties*, **met?** **Rationale:**	*2* C☐ P☐ M☐ N☐
3. USABILITY	
Extent to which intended audiences (e.g., consumers, purchasers, providers, policy makers) can understand the results of the measure and are likely to find them useful for decision making. (evaluation criteria)	**Eval 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). If not publicly reported, state the plans to achieve public reporting within 3 years*):	**3a** C☐ P☐ M☐ N☐

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.

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.

The SMR is a widely accepted measurement tool within the public health community and the SIR is but a variation on this method. The SIR has been available and used by NHSN member facilities for surgical site infection rate surveillance since 2005 and in NNIS facilities before that.
A Centers for Disease Control and Prevention report on HAIs with SIRs for individual U.S. states 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 ICU locations but also data from other inpatient locations and long-term acute-care units (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 CAUTI surveillance, two states currently require some reporting of CAUTIs from locations outside the ICU. Pennsylvania reporting requirements have included CAUTI data from all other inpatient locations and from SCAs since 2008, and Alabama began requiring adult medical, surgical and medical-surgical non-ICU locations to report CAUTI surveillance data in January of 2011. While there has been limited use of CAUTI surveillance in SCA, 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). If not used for QI, 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.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
If this measure is related to measure(s) already endorsed by NQF (e.g., same topic, but different target population/setting/data source or different topic but same target population):
3b.2 **Are the measure specifications harmonized? If not, why?**

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NA ☐

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

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

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N☐
NA ☐

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

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).

The cited existing measures are the CAUTI rate measures. The currently proposed measure, CAUTI 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.	
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☐** **P☐** **M☐** **N☐**
4. FEASIBILITY	
Extent to which the required data are readily available, retrievable without undue burden, and can be implemented for performance measurement. (evaluation criteria)	**Eval Rating**
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 CAUTI and catheter days must be collected by trained hospital staff from information available in clinical data sources. The standard population's CAUTI rates are available from the NHSN Report. The NHSN analysis tool will automatically calculate SIRs.	**4a** **C☐** **P☐** **M☐** **N☐**
4b. Electronic Sources **4b.1 Are all the data elements available electronically?** (*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☐** **P☐** **M☐** **N☐**
4c. Exclusions **4c.1 Do the specified exclusions require additional data sources beyond what is required for the numerator and denominator specifications?** No **4c.2 If yes, provide justification.**	**4c** **C☐** **P☐** **M☐** **N☐** **NA☐**
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 CAUTI. It is possible that reviewers may miss symptoms or fail to identify that patients meet criteria thereby underreporting CAUTI events. Data collectors might also intentionally underreport CAUTIs. 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 CAUTI when in fact they do not meet CAUTI 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 CAUTI 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/hospital-acquired_infection.pdf, p20).	**4d** **C☐** **P☐** **M☐** **N☐**
4e. Data Collection Strategy/Implementation	**4e**

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.

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).

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: CAUTI 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 UTI were streamlined in 2009 and the asymptomatic bacteriuria specific site of UTI dropped as it was felt to represent colonization rather than infection. **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 CAUTI to be 30 minutes, and 2.5 hours per selected location per month for collecting and reporting urinary catheter days. As an example of the cost to implement the measure, if a hospital identifies and reports 5 CAUTI from 2 medical ICUs per month for a year, it would be 90 hours of effort. If the salary of the data collectors averaged $36 per hour, that level of effort would cost $3240 per year for the hospital. **4e.3 Evidence for costs:** See OMB submission number 0920-0666, expires 03-31-2011 (labor cost adjusted for inflation). **4e.4 Business case documentation:**	**C☐ P☐ M☐ N☐**
TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for *Feasibility*?	**4**
Steering Committee: Overall, to what extent was the criterion, *Feasibility*, **met?** **Rationale:**	**4** **C☐ P☐ M☐ N☐**
RECOMMENDATION	
(for NQF staff use) **Check if measure is untested and only eligible for time-limited endorsement.**	**Time-limited ☐**
Steering Committee: Do you recommend for endorsement? **Comments:**	**Y☐ N☐ A☐**

CONTACT INFORMATION
Co.1 Measure Steward (Intellectual Property Owner) **Co.1 Organization** Centers for Disease Control and Prevention , 1600 Clifton Rd, NE, Mailstop A-24, Atlanta, Georgia, 30333 **Co.2 Point of Contact** Daniel, Pollock, M.D., DPA1@cdc.gov, 404-639-4237-
Measure Developer If different from Measure Steward **Co.3 Organization** Centers for Disease Control and Prevention, 1600 Clifton Rd, NE, Mailstop A-24, Atlanta, Georgia, 30333 **Co.4 Point of Contact** Daniel, Pollock, M.D., DPA1@cdc.gov, 404-639-4237-
Co.5 Submitter If different from Measure Steward POC Daniel, Pollck, M.D., DPA1@cdc.gov, 404-639-4237-, Centers for Disease Control and Prevention
Co.6 Additional organizations that sponsored/participated in measure development

ADDITIONAL INFORMATION
Workgroup/Expert Panel involved in measure development Ad.1 **Provide a list of sponsoring organizations and workgroup/panel members' names and organizations. Describe the members' role in measure development.**
Ad.2 **If adapted, provide name of original measure:** NQF 0138 Catheter-associated Urinary Tract Infection Ad.3-5 **If adapted, provide original specifications URL or attachment** http://www.cdc.gov/nhsn/pdfs/pscManual/7pscCAUTIcurrent.pdf
Measure Developer/Steward Updates and Ongoing Maintenance Ad.6 **Year the measure was first released:** 2004 Ad.7 **Month and Year of most recent revision:** 01, 2009 Ad.8 **What is your frequency for review/update of this measure?** annually and when needed Ad.9 **When is the next scheduled review/update for this measure?** 04, 2011
Ad.10 **Copyright statement:**
Ad.11 **Disclaimers:**
Ad.12 -14 **Additional Information web page URL or attachment:** Attachment Additional Information NQF Measure.docx
Date of Submission (*MM/DD/YY*)**:** 04/23/2010

Page 3: [1] Comment [k4] **Karen Pace** **10/5/2009 8:59:00 AM**

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.

Page 3: [2] Comment [k5] **Karen Pace** **10/5/2009 8:59:00 AM**

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.

Page 3: [3] Comment [k6] **Karen Pace** **10/5/2009 8:59:00 AM**

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.

NQF Measure: National Health Safety Network (NHSN) Catheter –associated Urinary Tract Infection (CAUTI) Outcome Measure

2a.29 Data Dictionary or Code Table

URLs:

http://www.cdc.gov/nhsn/pdfs/pscManual/7pscCAUTIcurrent.pdf

http://www.cdc.gov/nhsn/PDFs/pscManual/15LocationsDescriptions_current.pdf

http://www.cdc.gov/nhsn/PDFs/pscManual/14_Tables_of_Instructions.pdf

http://www.cdc.gov/nhsn/PDFs/pscManual/16pscKeyTerms_current.pdf

http://www.cdc.gov/nhsn/PDFs/dataStat/2009NHSNReport.PDF

NQF Measure: National Health Safety Network (NHSN) Catheter –associated Urinary Tract Infection (CAUTI) Outcome Measure

Additional Information Not Able to Enter In Other Fields

2a. 21 Calculation Algorithm

The SIR is calculated as follows:

1. *Identify the number of CAUTI in each location type*
2. *Total these numbers for an observed number of CAUTIs*
3. *Obtain the number of expected number of CAUTIs in the same location types for a standard population using the NHSN data report (* http://www.cdc.gov/nhsn/PDFs/dataStat/2009NHSNReport.PDF)
4. *Identify the number of expected CAUTIs for the facility based on its location types and numbers of catheter days:*
    a. *For each location type, multiply the number of catheter days experienced, by the expected CAUTI rate for that location*
    b. *Sum the number of expected CAUTIs from all locations*
5. *Divide the total number of observed CAUTI events ("2" above) by the "expected" number of CAUTI rates ("4.c." above).*
6. *Result = SIR*

See example below:

Risk Group Stratifier	*Observed CAUTI Rates*			*NHSN CAUTI Rates for 2006-2008 (Standard Population)*		
Location Type	*#CAUTI*	*# Catheter days*	*CAUTI rate*	*# CAUTI*	*# Catheter days*	*CAUTI rate*
Medical ICU	*3*	*480*	*6.25*	*1531*	*324,082*	*4.7*
Surgical ICU	*5*	*500*	*10.0*	*2033*	*474,506*	*4.3*
SIR = observed = $\frac{3+5}{480 \times \frac{4.7}{1000} + 500 \times \frac{4.3}{1000}} = \frac{8}{2.26 + 2.15} = \frac{8}{4.41}$ = 1.8 95% CI= 0.84, 3.44						

1c.5 Rating of Strength/Quality of Evidence:

HICPAC rated the quality of the evidence for each of the recommendations made in the 2009 prevention guidelines. The recommendations were classified as follows:

HICPAC Recommendations	Weighting Benefits and Harms for Critical Outcomes	Quality of Evidence
Strong (I)	Interventions with net benefits or net harms	• IA- High to Moderate • IB- Low or Very Low (Accepted Practice)

		• IC- High to Very Low (Regulatory)
Weak (II)	Interventions with tradeoffs between benefits and harms	High to Very Low
No recommendation/unresolved issue		Low to Very Low

1c.6. Method for Rating Evidence

As taken from the HICPAC Guideline for Prevention of Catheter-associated Urinary Tract Infections, 2009

Data Extraction and Synthesis

Data on the study author, year, design, objective, population, setting, sample size, power, follow-up, and definitions and results of clinically relevant outcomes were extracted into evidence tables (Appendix 2). Three evidence tables were developed, each of which represented one of our key questions. Studies were extracted into the most relevant evidence table. Then, studies were organized by the common themes that emerged within each evidence table. Data were extracted by one author (R.K.A.) and cross-checked by another (C.V.G.). Disagreements were resolved by the remaining authors. Data and analyses were extracted as originally presented in the included studies. Meta-analyses were performed only where their use was deemed critical to a recommendation, and only in circumstances where multiple studies with sufficiently homogenous populations, interventions, and outcomes could be analyzed. Systematic reviews were included in our review. To avoid duplication of data, we excluded primary studies if they were also included in a systematic review captured by our search. The only exception to this was if the primary study also addressed a relevant question that was outside the scope of the included systematic review. Before exclusion, data from the primary studies that we originally captured were abstracted into the evidence tables and reviewed. We also excluded systematic reviews that analyzed primary studies that were fully captured in a more recent systematic review. The only exception to this was if the older systematic review also addressed a relevant question that was outside the scope of the newer systematic review. To ensure that all relevant studies were captured in the search, the bibliography was vetted by a panel of clinical experts.

Grading of Evidence

First, the quality of each study was assessed using scales adapted from existing methodology checklists, and scores were recorded in the evidence tables. Appendix 3 includes the sets of questions we used to assess the quality of each of the major study designs. Next, the quality of the evidence base was assessed using methods adapted from the GRADE Working Group.[32] Briefly, GRADE tables were developed for each of the interventions or questions addressed within the evidence tables. Included in the GRADE tables were the intervention of interest, any outcomes listed in the evidence tables that were judged to be clinically important, the quantity and type of evidence for each outcome, the relevant findings, and the GRADE of evidence for each outcome, as well as an overall GRADE of the evidence base for the given intervention or question. The initial GRADE of evidence for each outcome was deemed high if the evidence base included a randomized controlled trial (RCT) or a systematic review of RCTs, low if the evidence base included only observational studies, or very low if the evidence base consisted only of uncontrolled studies. The initial GRADE could then be modified by eight criteria.[34] Criteria which could decrease the GRADE of an evidence base included quality, consistency, directness, precision, and publication bias. Criteria that could increase the GRADE included a large magnitude of effect, a dose-response gradient, or inclusion of unmeasured confounders that would increase the magnitude of effect (Table 3). GRADE definitions are as follows:

1. High - further research is very unlikely to change confidence in the estimate of effect
2. Moderate - further research is likely to affect confidence in the estimate of effect and may change the estimate
3. Low - further research is very likely to affect confidence in the estimate of effect and is likely to change the estimate
4. Very low - any estimate of effect is very uncertain

After determining the GRADE of the evidence base for each outcome of a given intervention or question, we calculated the overall GRADE of the evidence base for that intervention or question. The overall GRADE was based on the lowest GRADE for the outcomes deemed critical to making a recommendation.

Table 3. Rating the Quality of Evidence Using the GRADE Approach

Type of Evidence	Initial Grade	Criteria to Decrease Grade	Criteria to Increase Grade	Overall Quality Grade

RCT	High	Quality Serious (-1 grade) or very serious (-2 grades) limitation to study quality Consistency Important inconsistency (-1 grade) Directness Some (-1 grade) or major (-2 grades) uncertainty about directness Precision Imprecise or sparse data (-1 grade) Publication bias High risk of bias (-1 grade)	Strong association Strong (+1 grade) or very strong evidence of association (+2 grades) Dose-response Evidence of a dose-response gradient (+1 grade) Unmeasured Confounders Inclusion of unmeasured confounders increases the magnitude of effect (+1 grade)	High
				Moderate
Observational study	Low			Low
Any other evidence (e.g., expert opinion)	Very low			Very low