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 sub-criteria and most of the footnotes from the evaluation criteria are provided in Word comments and will appear if your cursor is over the highlighted area (or in the margin if your Word program is set to show revisions in balloons). 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 sub-criterion 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 sub-criteria (yellow highlighted areas).

**Steering Committee**: Complete all pink highlighted areas of the form. Review the workgroup/TAP assessment of the sub-criterion, 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 sub-criteria as indicated)

<table>
<thead>
<tr>
<th>(for NQF staff use) NQF Review #: PSM-007-10</th>
<th>NQF Project: Patient Outcomes Measures: Phases I and II</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>MEASURE DESCRIPTIVE INFORMATION</strong></td>
<td></td>
</tr>
<tr>
<td>De.1 Measure Title: Risk Adjusted Urinary Tract Infection Outcome Measure</td>
<td></td>
</tr>
<tr>
<td>De.2 Brief description of measure: Risk adjusted, case mix adjusted urinary tract infection outcome measure of adults 18+ years.</td>
<td></td>
</tr>
<tr>
<td>1.1-2 Type of Measure: outcome</td>
<td></td>
</tr>
<tr>
<td>De.3 If included in a composite or paired with another measure, please identify composite or paired measure</td>
<td></td>
</tr>
<tr>
<td>De.4 National Priority Partners Priority Area: population health, safety</td>
<td></td>
</tr>
<tr>
<td>De.5 IOM Quality Domain: efficiency, equity, safety</td>
<td></td>
</tr>
<tr>
<td>De.6 Consumer Care Need: Getting Better</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CONDITIONS FOR CONSIDERATION BY NQF</th>
</tr>
</thead>
<tbody>
<tr>
<td>Four conditions must be met before proposed measures may be considered and evaluated for suitability as voluntary consensus standards:</td>
</tr>
<tr>
<td>NQF Staff</td>
</tr>
<tr>
<td>A. The measure is in the public domain or an intellectual property (measure steward agreement) is signed.</td>
</tr>
<tr>
<td>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.</td>
</tr>
<tr>
<td>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)? <strong>Yes</strong></td>
</tr>
<tr>
<td>A.2 Indicate if Proprietary Measure (as defined in measure steward agreement): proprietary complex measure with fees</td>
</tr>
<tr>
<td>A.3 Measure Steward Agreement: agreement signed and submitted</td>
</tr>
<tr>
<td>A.4 Measure Steward Agreement attached: <strong>Y</strong></td>
</tr>
</tbody>
</table>

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

C. The intended use of the measure includes both public reporting and quality improvement.
►Purpose: public reporting, quality improvement 0,0,0,

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: No, testing will be completed within 12 months
D.2 Have NQF-endorsed measures been reviewed to identify if there are similar or related measures? Yes

(for NQF staff use) Have all conditions for consideration been met?
Staff Notes to Steward (if submission returned):

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

TAP/Workgroup Reviewer Name:
Steering Committee Reviewer Name:

1. IMPORTANCE TO MEASURE AND REPORT

Extant 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

(for NQF staff use) Specific NPP goal:

1a.1 Demonstrated High Impact Aspect of Healthcare: affects large numbers, severity of illness, frequently performed procedure, a leading cause of morbidity/mortality, patient/societal consequences of poor quality, high resource use
1a.2

1a.3 Summary of Evidence of High Impact: Urinary tract infection is the most common hospital-acquired infection. Over 5% of Medicare patients in 2005 were diagnosed with postoperative urinary infections.1 Urinary tract infections represent 32-40% of all nosocomial infections, which occur in up to 1.7 million patients annually. 2, 3 As many as 80% of urinary infections are attributable to urinary catheterization.1 In a recent study of over 36,000 patients undergoing major surgery, 86% of these patients had perioperative urinary catheters.4 Of note, patients who had indwelling catheters for longer than 2 days postoperatively were twice as likely to develop a CAUTI. One UTI episode results in direct and indirect costs of $676 and $2,386, respectively.5 Patients who experience UTIs require an additional 1-3.8 hospital days.6-8 It is estimated that UTIs account for $340-450 million in additional health care costs every year.6-8 In response, the Centers for Medicare and Medicaid Services no longer provides reimbursement to providers of covered beneficiaries for the treatment of inappropriate UTIs.9 In addition, a new measure scheduled for inclusion in the Surgical Care Improvement Project (SCIP Inf-9) will require providers to submit data on the proportion of the sample of surgical patients captured for whom a urinary catheter (if used) was removed on postoperative day 1 or 2.9
### 1a.4 Citations for Evidence of High Impact:


### 1b. Opportunity for Improvement

#### 1b.1 Benefits (improvements in quality) envisioned by use of this measure:

#### 1b.2 Summary of data demonstrating performance gap (variation or overall poor performance) across providers:

Despite the proven benefit of certain policies and procedures aimed at reducing urinary tract infections such as bladder scanners, fewer than 33% hospitals are using bladder scanners and less than 10% conduct daily, automated reminders that prompt doctors to review the need for a catheter. Asking over 700 hospitals about its infection control methods, researchers found no consistently applied strategies to combat urinary tract infections.

UTI rates are highly variable by institution. An analysis of ACS NSQIP data calculated the risk-adjusted observed to expected (O/E) ratios for UTI using the methodology for the measure proposed herein. The results show that O/E ratios for UTI range from 0 to 3.16 for all participating hospitals. Therefore, the worst-performing hospital had 3 times the expected number of UTIs after adjusting for the patient case mix. The interquartile range for O/E ratios is 0.37-1.70, and the 10th percentile and 90th percentile O/E ratios were 0.65 and 1.27, respectively. These statistics demonstrate the significance of the performance gap in UTI outcomes across hospital providers.

#### 1b.3 Citations for data on performance gap:


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


1b.4 Summary of Data on disparities by population group:
Certain patient-related factors have been associated with an increased risk of UTI, including: advanced age, and gender, as well as characteristics associated with certain population groups such as hyperglycemia/diabetes, and other comorbidities.

1b.5 Citations for data on Disparities:


1c. Outcome or Evidence to Support Measure Focus

1c.1 Relationship to Outcomes (For non-outcome measures, briefly describe the relationship to desired outcome. For outcomes, describe why it is relevant to the target population): Increasing evidence is emerging that contradicts our assumptions regarding the inevitability of urinary tract infections. By targeting at-risk behaviors such as prolonged duration or unneeded urinary catheterization, providers can reduce urinary tract infection. However, aside from institutional surveillance data and studies using administrative claims, we lack the necessary metrics to make risk adjusted comparable determinations about the rates of urinary tract infections across providers. Therefore, developing measures, as is being proposed herein, is an important opportunity to reduce a preventable hospital-acquired condition. Evidence that demonstrates the significance and relevance of UTI to the population may be found in RCTs,
observational trials, cohort studies, etc. (See below).

1c.2-3. Type of Evidence: evidence based guideline, expert opinion

1c.4 Summary of Evidence (as described in the criteria; for outcomes, summarize any evidence that healthcare services/care processes influence the outcome):
Fundamentally, identification and removal of unnecessary bladder catheters has been shown to reduce rates of urinary tract infection and should be a priority. Certain measures during the insertion and maintenance of a urinary catheter can help prevent against associated infection. Many focus broadly on standardizing application of indications for urinary catheters, maintenance of catheters and timing of removal of catheters. Some of these include specific recommendations such as: use of alternate bladder drainage methods when appropriate, educating staff regarding proper insertion and maintenance of urinary catheters, using standard precautions prior to manipulation, and maintaining closed drainage systems. Education of patients and caretakers via “fact sheets” or nurse-directed education, competency based training, or skills labs may help reinforce appropriate provider adherence and self-protective behaviors consistent with many of the recommendation cited above (e.g. keeping the urinary drainage bag secure, unobstructed, and lower than the bladder). 21

Several of the basic and special approaches outlined above can be implemented unit- or institution-wide as a “bladder bundle” that uses the mnemonic ABCDE: 22, 23?

? Adherence to generally recommended infection control principles (e.g. hand hygiene, aseptic insertion, proper maintenance).
? Bladder ultrasound may avoid indwelling catheterization
? Condom and intermittent catheterization in appropriate patients
? Do not use the indwelling catheter unless you must
? Early removal of the catheter using reminders or stop-orders

Unit- and institution-wide protocols to identify and remove unnecessary bladder catheters should be implemented, including:
? Procedure-specific guidelines for postoperative catheter removal 24
? Institutional policies requiring daily reassessment of need for continued catheterization
? Daily, physician reminders (in chart, electronic, or nurse-generated) to alert providers that an indwelling catheter is still in place and that its continued use should be reassessed 10, 25-28
? Automatic stop orders requiring renewal of the indwelling bladder catheter 29
? Daily wards rounds by nurses/physicians to review patients with bladder catheters and determine continuing necessity 14, 30, 31

Providers can also establish policies directed at not implementing processes of questionable or harmful effect including: adding antibiotics to drainage bag 69,70 , using systemic antibiotic prophylaxis 71, changing catheters or drainage bags routinely 72-75 or screening for or treat asymptomatic bacteriuria in catheterized patients 9, 11, 76.

Thus, like virtually all complications, there are a number of associated potential processes that may be performed to minimize and prevent occurrences.

The final path of these processes is the outcome, which in this case is UTI. The currently proposed measure seeks to evaluate the risk adjusted and case mix adjusted UTI outcome rates per hospital.

1c.5 Rating of strength/quality of evidence (also provide narrative description of the rating and by whom):
There are no ratings for an UTI outcome measure simply because it is the outcome of interest. The SCIP process measures cited above are generally Level I -II evidence. Ratings for UTI related processes are not applicable to this application, however, they are available upon request.

1c.6 Method for rating evidence: Not applicable for outcomes. For the associated processes, a systematic review of the literature was conducted by (1) performing a literature search using Medline/PubMed, Cochrane database as well as (2) reviewing established guidelines/recommendations. These guidelines were culled for their supporting evidence. We then rated evidence from established guidelines and new
evidence (not attributed to established guidelines).

1c.7 Summary of Controversy/Contradictory Evidence: Similar to SSI, UTIs are likely multifactorial with a wide-range if evidence supporting the various processes of care related to minimizing UTIs. Whether a process to outcome link can be demonstrated in real world observational settings (i.e. effectiveness) remains to be seen. Obtaining risk adjusted outcomes will both evaluate and likely improve patient care as well as enable on-going and future investigations of process effectiveness.


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

There are no ratings for an SSI outcome measure simply because it is the outcome of interest.

1c.10 **Clinical Practice Guideline Citation:** n/a

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

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

n/a

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

n/a
1c.14 Rationale for using this guideline over others: n/a

<table>
<thead>
<tr>
<th>TAP/Workgroup: What are the strengths and weaknesses in relation to the sub-criteria for Importance to Measure and Report?</th>
<th>1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Steering Committee: Was the threshold criterion, Importance to Measure and Report, met?</td>
<td>Y</td>
</tr>
</tbody>
</table>

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)

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):
The outcome of interest is a hospital-specific risk-adjusted Urinary Tract Infection (UTI) as defined by American College of Surgeons National Surgical Quality Improvement Program (ACS NSQIP) within 30 days of any ACS NSQIP listed (CPT) surgical procedure.

2a.2 Numerator Time Window (The time period in which cases are eligible for inclusion in the numerator):
Targeted events within 30 days of the operation are included.

2a.3 Numerator Details (All information required to collect/calculate the numerator, including all codes, logic, and definitions):
Postoperative symptomatic urinary tract infection must meet ONE of the following TWO criteria:

Criterion One:
One of the following five:
a. fever (>38 degrees C),
b. urgency,
c. frequency,
d. dysuria,
e. suprapubic tenderness
AND a urine culture of > 100,000 colonies/ml urine with no more than two species of organisms.

OR

Criterion Two:
Two of the following five:
a. fever (>38 degrees C),
b. urgency,
c. frequency,
d. dysuria,
e. suprapubic tenderness
AND ANY ONE or MORE of the following seven:
f. Dipstick test positive for leukocyte esterase and/or nitrate,
g. Pyuria (>10 WBCs/mm3 or > 3 WBC/hpf of unspun urine),
h. Organisms seen on Gram stain of unspun urine,
i. Two urine cultures with repeated isolation of the same uropathogen with >100 colonies/ml urine in non-voided specimen,
j. Urine culture with < 100,000 colonies/ml urine of single uropathogen in patient being treated with appropriate antimicrobial therapy,
k. Physician's diagnosis,
l. Physician institutes appropriate antimicrobial therapy

2a.4 Denominator Statement (Brief, text description of the denominator - target population being measured):
Patients undergoing any ACS NSQIP listed (CPT) surgical procedure except certain CPTs involving the urinary tract (50220, 50545, 50400, 50205, 51040, 54640, 53852, 55866, 52450, 52234. (see separate list of ACS NSQIP CPT codes)

2a.5 Target population gender: Female, Male
2a.6 Target population age range: Any patient greater than or equal to 18 years of age

2a.7 Denominator Time Window (The time period in which cases are eligible for inclusion in the denominator):
Data are derived from a systematic sample collected over a one year period constructed to as to meet sample size requirements specified for the measure.

2a.8 Denominator Details (All information required to collect/calculate the denominator - the target population being measured - including all codes, logic, and definitions):
Cases are collected so as to match ACS NSQIP inclusion and exclusion criteria, thereby permitting valid application of ACS NSQIP model-based risk adjustment.

2a.9 Denominator Exclusions (Brief text description of exclusions from the target population): Trauma and transplant surgeries are excluded as are surgeries not on the ACS NSQIP CPT list as eligible for selection. Patients who are ASA 6 (brain-death organ donor) are not eligible surgical cases.

2a.10 Denominator Exclusion Details (All information required to collect exclusions to the denominator, including all codes, logic, and definitions):
A patient who is admitted to the hospital with acute trauma and has surgery for that trauma is excluded though any operation performed after the patient has been discharged from the trauma stay can be included. A patient who is admitted to the hospital for a transplant and has a transplant procedure and any additional surgical procedures during the transplant hospitalization will be excluded, tough any operation performed after the patient has been discharged from the transplant stay is eligible for selection. If surgeries do not appear in the list of ACS NSQIP CPT codes, they are not eligible for selection. A patient classified as ASA Class 6 is not eligible for inclusion.

2a.11 Stratification Details/Variables (All information required to stratify the measure including the stratification variables, all codes, logic, and definitions):
There is no stratification of the measure.

2a.12-13 Risk Adjustment Type: case-mix adjustment

2a.14 Risk Adjustment Methodology/Variables (List risk adjustment variables and describe conceptual models, statistical models, or other aspects of model or method):
From 271,368 patient records in the 2008 ACS NSQIP Data File; 250,194 acceptable records from 211 hospitals (mean/hospital=1,186) were analyzed. Records were excluded because they involved a urologic procedure, there were missing values for critical variables, or because the primary CPT code could not be categorized into 1 of the 136 pre-established CPT “Groups”. These categorizations have been defined and implemented for risk adjustment in previously published research.*

A Urinary Track Infection (UTI) was defined according to ACS NSQIP definitions. Of the 250,194 patients, 3,980 (1.6%) experienced an UTI event as defined. CPT Group was originally considered a categorical variable but, because of frequent empty cells, which precluded logistic model convergence (quasi-complete separation), CPT Group was converted to continuous risk variable. This was accomplished by making the categorical Group variable a single predictor for UTI and invoking the Firth penalized likelihood method in the logistic modeling software (SAS PROC LOGISTIC). The patient-based predicted log odds from this model was then used as a continuous predictor in subsequent logistic models which also included the standard
Step-wise logistic regression (P<0.05 for inclusion), which selected from a total of 26 NSQIP predictors, identified 13 predictors for inclusion in the model. In order of inclusion these variables were: Log Odds CPT Group, preoperative Functional Status, Gender, ASA Class, Age Group, Steroid Use, Previous Neurological Event/Disease, Weight Loss, Disseminated Cancer, Diabetes, Previous Vascular Event/Disease, History of COPD, and BMI Class. The c-statistic was 0.793 and the Hosmer-Lemeshow was 0.007. Because of the very large sample sizes studied here, a statistically significant Hosmer-Lemeshow statistic is not considered informative with respect to calibration.

Using only the first five selected variables (Log Odds CPT Group, preoperative Functional Status, Gender, ASA Class, and Age Group), the c-statistic was 0.790 and the Hosmer-Lemeshow was 0.006). The use of these five predictors for modeling was further evaluated. Using a 95% confidence interval for the ratio of observed to expected events (O/E), this three-variable logistic model identified 59 statistical outliers (32 low outliers and 27 high outliers). When the same five variables were used in a random intercept, fixed slope, hierarchical model (SAS PROC GLIMMIX) using only the fixed portion of the prediction equation (NOBLUP option), 61 outliers were detected (26 low outliers and 35 high outliers). Thus, using a 95% confidence interval, logistic and hierarchical models identified between 13% and 17% of hospitals as high outliers. When the logistic model parameters were applied to an independent validation data set (the 2007 PUF Data file composed of 200,483 patients) after coding CPT Groups with log odds derived from the original 1-variable model on 2008 data, the c-statistic was essentially unchanged (c-statistic=0.793).

A GEE (generalized estimating equations) approach (SAS PROC GENMOD) with compound symmetry was used to estimate the intraclass correlation (ICC) which is reported in GENMOD as the exchangeable working correlation. The ICC was 0.00230. The relationship between sample size, the ICC, and reliability is defined as:

\[ N = \frac{R}{[ICC(1 - R)]} - \frac{R}{(1 - R)}, \]

where \( N \) is the required number patients per hospital and \( R \) is reliability.

Based on the estimated ICC, patients per hospital to achieve reliability levels of 0.3, 0.4, 0.5, 0.6, and 0.7 are 187, 290, 435, 653, and 1,015, respectively.

For the table detailing risk factors, odds ratios, and parameters for the logistic model, please see attachment (Parsimonious Model for UTI-63388774739734230.doc)

For initial year(s) of measure use, ACS NSQIP data-derived model parameters will be used to construct risk-adjusted O/E ratios for participating hospitals. Once data from measure-participating hospitals is substantial, models will derived from that data.

*References utilizing CPT groups


For initial year(s) of measure use, ACS NSQIP data-derived model parameters will be used to construct risk-adjusted O/E ratios for participating hospitals. Once data from measure-participating hospitals is substantial, models will derived from that data.

*References utilizing CPT groups


2a.15-17 Detailed risk model available Web page URL or attachment: Attachment Parsimonious Model for UTI-63388774739734230.doc
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):**
For data collected during the one year time interval at each hospital: (a) \( O \) = the number of observed adverse events at the hospital; (b) using parameters from the applicable model derived logistic equation, compute predicted event probabilities for each patient in the hospital’s data set; (c) the sum of these predicted probabilities defines \( E \); (d) compute the hospital’s O/E ratio and applicable confidence intervals.

2a.22 **Describe the method for discriminating performance (e.g., significance testing):**
The default methodology for discrimination performance will be based on the computed 95% CI for the O/E ratio. If the interval is above, and does not overlap 1.0, the hospital is identified as having performance significantly worse than expected. If the interval is below, and does not overlap 1.0, the hospital is identified as having performance significantly better than expected. Depending on programmatic objectives, the implementing organization could also opt for outlier status being defined by percentile rank, for example, in upper or lower distributional deciles of O/E ratios.

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):
For each data collection year, hospitals would need to estimate their number of qualifying surgeries. Based on that denominator and the required sample size to achieve reliability of 0.4 (see Risk-adjustment Methodology section), hospitals would take a systematic sample (e.g., every 3rd qualifying case), to achieve the minimum sample size. In the event that the required sample size can not be achieved, hospitals would collect data on all eligible patients.

2a.24 **Data Source (Check the source(s) for which the measure is specified and tested)**
Documentation of original self-assessment, Management data, pharmacy 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.):**
ACS NSQIP Data file

2a.26-28 **Data source/data collection instrument reference web page URL or attachment:** URL
https://acsnsqip.org/puf/PufRequestHomepage.aspx

2a.29-31 **Data dictionary/code table web page URL or attachment:** URL

2a.32-35 **Level of Measurement/Analysis (Check the level(s) for which the measure is specified and tested)**
Facility/Agency

2a.36-37 **Care Settings (Check the setting(s) for which the measure is specified and tested)**
Hospital

2a.38-41 **Clinical Services (Healthcare services being measured, check all that apply)**
Clinicians: Physicians (MD/DO), Clinicians: Pharmacist, Clinicians: Nurses, Clinicians: PA/NP/Advanced Practice Nurse, Clinicians: Respiratory Therapy, Clinicians: Dietician/Nutritional professional

**TESTING/ANALYSIS**

2b. **Reliability testing**

2b.1 **Data/sample (description of data/sample and size):** See Risk-adjustment Methodology in Specifications. Models were constructed using a large sample derived from the ACS NSQIP database for 2008.

2b.2 **Analytic Method (type of reliability & rationale, method for testing):**
See Risk-adjustment Methodology in Specifications. Reliability was determined using ICCs estimated by SAS PROC GENMOD.

Rating: C= Completely; P= Partially; M= Minimally; N= Not at all; NA= Not applicable
2b.3 **Testing Results** *(reliability statistics, assessment of adequacy in the context of norms for the test conducted):*

The relative variation between hospitals defined by the intra-class correlation coefficient (ICC) for hospitals can be estimated for continuous outcomes using linear mixed models, but the within-hospital variation needed to calculate ICCs is not routinely estimated for dichotomous outcomes. Hence, the usual measure of ICC based on a latent variable formulation using the standard logistic distribution was estimated. The between-hospital variation component of the ICC was estimated from SAS PROC GENMOD regressing the composite outcome on the significant predictors for UTI. Together with procedure volumes, these ICCs were entered into the following equation to estimate reliability:

\[ R = \frac{n \text{ICC}}{1 + (n - 1) \text{ICC}}, \]

where \( R \) is the reliability, \( n \) is the case load per hospital and ICC is the intra-class correlation.

There are no definitive criteria for what level of reliability is acceptable, but it is proposed to be similar to inter-rater reliability standards used for assessing survey instruments.

<table>
<thead>
<tr>
<th>RELIABILITY ESTIMATE</th>
<th>INTERPRETATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.00-0.20</td>
<td>Slight</td>
</tr>
<tr>
<td>0.21-0.40</td>
<td>Fair</td>
</tr>
<tr>
<td>0.41-0.60</td>
<td>Moderate</td>
</tr>
<tr>
<td>0.61-0.80</td>
<td>Substantial</td>
</tr>
<tr>
<td>0.81-1.00</td>
<td>Excellent</td>
</tr>
</tbody>
</table>

The ICC was estimated at 0.00230. Using a minimum acceptable reliability for UTI of 0.4, the proportions of hospitals likely to have a “minimally acceptable” reliability estimate are as follows. 93.9% of all U.S. hospitals and 94.3% of ACS NSQIP hospitals meet the 0.4 reliability requirement.

Table 1. Estimates of Procedure Volume Required to Achieve Specified Measure Reliability, and Proportions of U.S. Hospitals and ACS NSQIP Hospitals Meeting the Volume Requirements.

<table>
<thead>
<tr>
<th>Reliability</th>
<th>Required Cases</th>
<th>% U.S. Hosp Mtg Rqmnt*</th>
<th>% NSQIP Hosp Mtg Rqmnt+</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.3</td>
<td>187</td>
<td>94.0</td>
<td>96.2</td>
</tr>
<tr>
<td>0.4</td>
<td>290</td>
<td>93.9</td>
<td>94.3</td>
</tr>
<tr>
<td>0.5</td>
<td>435</td>
<td>89.2</td>
<td>92.4</td>
</tr>
<tr>
<td>0.6</td>
<td>653</td>
<td>84.5</td>
<td>82.0</td>
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<tr>
<td>0.7</td>
<td>1015</td>
<td>78.5</td>
<td>59.7</td>
</tr>
</tbody>
</table>

*Based on volume data from the 2005 National Inpatient Survey and inflated to account for outpatient procedures.

+Based on ACS NSQIP Data file 2008 and inflated to account for procedures that might be excluded for over-representation.

2c. **Validity testing**

2c.1 **Data/sample** *(description of data/sample and size):* See Risk-adjustment Methodology in Specifications. Models were constructed using a large sample derived from the ACS NSQIP database for 2008.

2c.2 **Analytic Method** *(type of validity & rationale, method for testing):* See Risk-adjustment Methodology in Specifications. C-statistics and Hosmer-Lemeshow P-values for the developmental data set were computed; c-statistics were computed for an independent validation data set base on 2007 data.

2c.3 **Testing Results** *(statistical results, assessment of adequacy in the context of norms for the test conducted):*
See Risk-adjustment Methodology in Specifications. Model validity (a similar c-statistic, discrimination) was demonstrated when the 2008 model was applied to 2007 data.

2d. Exclusions Justified

2d.1 Summary of Evidence supporting exclusion(s):
The ACS NSQIP CPT list includes all surgeries that would be appropriate for measurement of quality and it would be unreasonable to provide documentation on the thousands of inapplicable codes. In addition, we have explicitly excluded surgeries related to trauma, transplant, and ASA Class 6 (brain-death organ donors). The ASA 6 exclusion as regards prediction of postoperative mortality and morbidity does not require explanation. As this measure is intended to apply generally to all hospitals doing surgery, inclusion of trauma and transplant cases, which tend to be directed towards metropolitan or regional centers, could adversely affect the efficacy of risk-adjustment (non-overlap of these types of cases across hospitals might be profound).

2d.2 Citations for Evidence:
As exclusions are based on reasoned argument rather empirical findings neither published evidence nor research findings are provided.

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

2d.4 Analytic Method (type analysis & rationale): n/a

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

2e. Risk Adjustment for Outcomes/Resource Use Measures

2e.1 Data/sample (description of data/sample and size): The data sample is derived from the most recent ACS NSQIP Data file. The UTI model used 254,194 patient records. Future models can be constructed using the most recent Data file. If this measure is adopted by sufficient numbers of non-NSQIP hospitals re-modeling can be based on data from the broader sample of hospitals.

2e.2 Analytic Method (type of risk adjustment, analysis, & rationale): Preliminary risk-adjustment models were constructed for these developmental purposes using step-wise logistic regression. Compared to hierarchical models this methodology poses fewer convergence problems, has step-wise variable-selection methodology, and we have found that it provides nearly identical risk-adjustment as random intercept hierarchical models. Odds ratios and parameters reported here are derived from hierarchical model methodology applied to the predictor set established using step-wise logistic regression methods.

2e.3 Testing Results (risk model performance metrics):
Step-wise logistic regression (P<0.05 for inclusion), which selected from a total of 26 predictors, identified 13 predictors for inclusion in the model. In order of inclusion these variables were: Log Odds CPT Group, preoperative Functional Status, Gender, ASA Class, Age Group, Steroid Use, Previous Neurological Event/Disease, Weight Loss, Disseminated Cancer, Diabetes, Previous Vascular Event/Disease, History of COPD, and BMI Class. The c-statistic was 0.793 and the Hosmer-Lemeshow was 0.007. Because of the very large sample sizes studied here, a statistically significant Hosmer-Lemeshow statistic is not considered informative with respect to calibration. Using only the first five selected variables (Log Odds CPT Group, preoperative Functional Status, Gender, ASA Class, and Age Group), which is being advocated as the risk-adjustment model, the c-statistic was 0.790 and the Hosmer-Lemeshow was 0.006. The use of these five predictors for modeling was further evaluated. Using a 95% confidence interval for the ratio of observed to expected events (O/E), this three-variable logistic model identified 59 statistical outliers (32 low outliers and 27 high outliers). When the same five variables were used in a random intercept, fixed slope, hierarchical model (SAS PROC GLIMMIX) using only the fixed portion of the prediction equation (NOBLUP option), 61 outliers were detected (26 low outliers and 35 high outliers). Thus, using a 95% confidence interval, logistic and hierarchical models identified between 13% and 17% of hospitals as high outliers.
<table>
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<th>2e.4 If outcome or resource use measure is not risk adjusted, provide rationale:</th>
<th>n/a</th>
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</table>

### 2f. Identification of Meaningful Differences in Performance

#### 2f.1 Data/sample from Testing or Current Use *(description of data/sample and size):* See Risk Adjustment Strategy Data Sample Section.

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

The default methodology for discrimination performance will be based on the computed 95% CI for the O/E ratio. If the interval is above, and does not overlap, 1.0, the hospital is identified as having performance significantly worse than expected. If the interval is below, and does not overlap, 1.0, the hospital is identified as having performance significantly better than expected. Depending on programmatic objectives, the implementing organization could also opt for outlier status being defined by percentile rank, for example, in upper or lower distributional percentiles of O/E ratios.

#### 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):*

See Risk-adjustment strategy Testing Results.

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

#### 2g.1 Data/sample *(description of data/sample and size):*

The only sources of data are those indicated above. This measure will require mostly clinical data (electronic or paper records), with administrative data added only as necessary. The advantage of clinical data versus administrative or claims data in identifying risk-adjusted outcomes is exemplified in the study by Steinberg et al (2008). The study compared comorbidities collected and postsurgical complications from the ACS NSQIP database and the University HealthSystem Consortium (UHC). Comorbidities per patient were identified twice as often in the UHC system, while there was a discordance of 26% in identifying complications (UHC complication rate, 2% vs. ACS NSQIP complication rate, 28%). Using administrative or claims data may result in significant differences in risk-adjusted outcomes than using clinical data.


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

See above.

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

See above.

### 2h. Disparities in Care

#### 2h.1 If measure is stratified, provide stratified results *(scores by stratified categories/cohorts):* Measure is not stratified; measure is case mix adjusted.

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

n/a

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

#### 2

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

Rationale:
### 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):*

Not used in public reporting initiative at this time.

#### 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):*

ACS NSQIP

**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):*

Although this specific measure has not been formally tested for interpretability, the ACS NSQIP has been using similar O/E ratios to measure outcomes in the program for over 15 years from its inception in the VA. The success of this program and the satisfaction of participants provide evidence of interpretability of this outcome measure. Hospitals are able to compare their observed complications with their number of expected complications in a ratio that provides a very straightforward measure of performance, while simultaneously being complex enough to adjust for each hospital’s case mix. Hospitals are also able to benchmark their performance against other participating hospitals, so that better and worse performers are easily identified.

This risk-adjusted and benchmarked measure provides enormous motivation for hospitals to see their outcomes improve. A recent analysis (Hall et al., 2009) has shown that 66% of ACS NSQIP hospitals improved their risk-adjusted mortality and 82% of hospitals improved their risk-adjusted complication rates. The effect on avoided complications is also significant, as the analysis demonstrates that between 250 and 500 complications per hospital were avoided in 2007.

The data for the above study was ACS NSQIP data collected over 3 years (2005-2007) from 118 hospitals. This measure will be reported annually.


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

An analysis of longitudinal changes in O/E ratios

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

See above section on “Testing of interpretability”

### 3b. Relation to other NQF-endorsed measures

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

#0138, Urinary catheter-associated urinary tract infection for intensive care unit (ICU) patients

(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?

These measure specifications are not harmonized. The endorsed measure calculates the numerator as the
number of indwelling catheter-associated UTIs, and the denominator as the number of indwelling urinary catheter days for ICU patients. The measure is stratified by the type of ICU. Our proposed measure is on the same topic, but is defined very differently. The numerator is the number of UTIs presenting within 30 days after the operative procedure (does not have to be associated with a catheter), while the denominator is different in that the target population is any patient undergoing a procedure qualifying for inclusion in ACS NSQIP (not only ICU patients). In addition, the proposed measure calculates the hospital’s risk-adjusted UTI outcome based on case-mix, and can be used for quality improvement purposes.

3c. Distinctive or Additive Value
3c.1 Describe the distinctive, improved, or additive value this measure provides to existing NQF-endorsed measures:
The measures are not similar - they do not address the same target population.

5.1 Competing Measures 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:

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

Steering Committee: Overall, to what extent was the criterion, Usability, met?

Rationale:

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

4a.1-2 How are the data elements that are needed to compute measure scores generated? data generated as byproduct of care processes during delivery, coding/abstraction performed by someone other than person obtaining original information,

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.
A completely electronic medical record will be needed to capture the risk factors that enter into the model. In addition, a software module (currently available to ACS NSQIP subscribers) will be required to transfer information from the EMR to a measure submission database.

4c. Exclusions

4c.1 Do the specified exclusions require additional data sources beyond what is required for the numerator and denominator specifications?

4c.2 If yes, provide justification.

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.
Based upon experience with ACS NSQIP data collection, there are very few problems with errors or
Data collectors in the ACS NSQIP receive extensive training and support for accurate data collection. In addition, data collectors are audited for inter-rater reliability and are held to a 95% or better concordance rate for all variables. Additionally, chart audits have been planned in accordance with CMS stipulations for measure participants who are not ACS NSQIP participants.

### 4e. Data Collection Strategy/Implementation

**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:**

ACS NSQIP has been open to subscription by private sector hospitals since 2004. Ten years prior to this time the program was implemented in the U.S. Department of Veterans Affairs. Thus we have long term experience with in the data collection and operational use of the O/E ratio for quality improvement and benchmarking on which this measure is based. Historically, the use of trained data collectors within ACS NSQIP and a comprehensive support system has resulted in high reliability of data and very few problems with missing data. Participants in the program are required to hire a dedicated FTE for data collection to ensure reliable assessment of clinical data.

Data definitions are continually evaluated and inter-rater reliability audits are regularly performed. ACS NSQIP has placed a very high value on accuracy of data collection while maintaining a sample size large enough for statistical model and keeping within regulations for patient confidentiality. The methodology of our program has been highly successful with increasing numbers of participants every year, and measureable improvements in surgical outcomes over time based on the O/E ratios for mortality and various post surgical complications. Due to the much smaller number of variables needed for participation in this measure than in the full program, we expect that hospitals that are not ACS NSQIP participants will also be able to achieve highly reliable results.

**4e.2 Costs to implement the measure (costs of data collection, fees associated with proprietary measures):**

Using a conservative estimate, approximately .125 to .333 of a FTE will be needed to collect the data for the measure. There are no fees associated with this measure. Hospitals that do not participate in the ACS NSQIP will be able to participate in this measure.

**4e.3 Evidence for costs:**

Costs are based upon an estimate from ACS NSQIP data collection, in which one FTE can collect 1600 cases per year, but is required to collect a large number of variables, as well as 30-day follow up which can consume many hours. In contrast, this measure does not require many variables, and sample size is such that reliable results can be achieved after collection of 200-500 cases.

**4e.4 Business case documentation:** Business case has not been developed for this measure; however, literature results show that the each UTI results in costs of up to $2,386 and require an additional 1 - 3.8 hospital days per patient.

### TAP/Workgroup: What are the strengths and weaknesses in relation to the sub-criteria for Feasibility?

**Steering Committee: Overall, to what extent was the criterion, Feasibility, met?**

**Rationale:**

**RECOMMENDATION**

(for NQF staff use) Check if measure is untested and only eligible for time-limited endorsement.

**Steering Committee: Do you recommend for endorsement?**

**Comments:**

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

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<thead>
<tr>
<th>Co.1</th>
<th>Measure Steward (Intellectual Property Owner)</th>
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<td></td>
<td>Karen Richards, Administrative Director, Division of Research and Optimal Patient Care</td>
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### Measure Developer If different from Measure Steward

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<th>Co.3</th>
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<tr>
<th>Co.6</th>
<th>Additional organizations that sponsored/participated in measure development</th>
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### 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.

- Clifford Ko
- Karen Richards
- Bruce Hall
- Mark Cohen
- Mehul Raval
- Mira Shiloach
- Angela Ingraham
- Stanley Frencher

This group used ACS NSQIP data to develop the statistical risk-adjusted model on which this measure is based. The workgroup also reviewed and summarized the literature that supports the importance of using this measure to as a tool to improve surgical quality.

Ad.2 If adapted, provide name of original measure: n/a

Ad.3-5 If adapted, provide original specifications URL or attachment

**Measure Developer/Steward Updates and Ongoing Maintenance**

Ad.6 Year the measure was first released:

Ad.7 Month and Year of most recent revision:

Ad.8 What is your frequency for review/update of this measure?

Ad.9 When is the next scheduled review/update for this measure?

Ad.10 Copyright statement/disclaimers: UPDATED CONDITIONS SECTION:

Type of measure * Outcome

Four conditions must be met before a proposed measure may be considered and evaluated for suitability as voluntary consensus standards:

A. The measure steward is a governmental organization or a 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.

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
Please check if either of the following apply
Proprietary measure
Measure Steward Agreement *
Agreement will be signed and submitted prior to or at the time of measure submission
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 will be provided in the contact section (in the Additional tab)
C. The intended use of the measure includes both public reporting and quality improvement.
Purpose *
Public reporting
Internal quality improvement
Additional purposes
None
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 24 months of endorsement.
Testing *
No, testing will be completed within 24 months

Have NQF-endorsed® measures been reviewed to identify if there are similar or related measures? *
If there are similar or related measures, be sure to address those items in the Usability tab.
Yes

Additional Information web page URL or attachment:  Attachment  BP Guideline CAUTI.pdf

Date of Submission (MM/DD/YY):  09/18/2009