NATIONAL QUALITY FORUM

Measure Evaluation 4.1 December 2009

This form contains the measure information submitted by stewards. Blank fields indicate no information was provided. Attachments also may have been submitted and are provided to reviewers. The subcriteria and most of the footnotes from the evaluation criteria are provided in Word comments within the form and will appear if your cursor is over the highlighted area. Hyperlinks to the evaluation criteria and ratings are provided in each section.

TAP/Workgroup (if utilized): Complete all yellow highlighted areas of the form. Evaluate the extent to which each subcriterion is met. Based on your evaluation, summarize the strengths and weaknesses in each section.

<u>Note</u>: If there is no TAP or workgroup, the SC also evaluates the subcriteria (yellow highlighted areas).

Steering Committee: Complete all **pink** highlighted areas of the form. Review the workgroup/TAP assessment of the subcriteria, noting any areas of disagreement; then evaluate the extent to which each major criterion is met; and finally, indicate your recommendation for the endorsement. Provide the rationale for your ratings.

Evaluation ratings of the extent to which the criteria are met

C = Completely (unquestionably demonstrated to meet the criterion)

P = Partially (demonstrated to partially meet the criterion)

M = Minimally (addressed BUT demonstrated to only minimally meet the criterion)

N = Not at all (NOT addressed; OR incorrectly addressed; OR demonstrated to NOT meet the criterion)

NA = Not applicable (only an option for a few subcriteria as indicated)

(for NQF staff use) NQF Review #: PSM-007-10 NQF Project: Patient Safety Measures MEASURE DESCRIPTIVE INFORMATION

 De.1 Measure Title: Risk Adjusted Urinary Tract Infection Outcome Measure After Surgery

 De.2 Brief description of measure: Risk adjusted, case mix adjusted urinary tract infection outcome measure of adults 18+ years after surgical procedure.

 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: Population health, Safety

De.5 IOM Quality Domain: Efficiency, Equity, Safety

De.6 Consumer Care Need: Staying healthy, Living with illness

CONDITIONS FOR CONSIDERATION BY NQF

Four conditions must be met before proposed measures may be considered and evaluated for suitability as voluntary consensus standards:	NQF Staff
 A. The measure is in the public domain or an intellectual property (measure steward agreement) is signed. <i>Public domain only applies to governmental organizations. All non-government organizations must sign a measure steward agreement even if measures are made publicly and freely available.</i> A.1 Do you attest that the measure steward holds intellectual property rights to the measure and the right to use aspects of the measure owned by another entity (e.g., risk model, code set)? Yes A.2 Indicate if Proprietary Measure (<i>as defined in measure steward agreement</i>): A.3 Measure Steward Agreement: Agreement will be signed and submitted prior to or at the time of measure submission A.4 Measure Steward Agreement attached: 	A Y N
B . The measure owner/steward verifies there is an identified responsible entity and process to maintain and update the measure on a schedule that is commensurate with the rate of clinical innovation, but at least	B Y□

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

TAP/Workgroup Reviewer Name:	
Steering Committee Reviewer Name:	
1. IMPORTANCE TO MEASURE AND REPORT	
Extent to which the specific measure focus is important to making significant gains in health care quality (safety, timeliness, effectiveness, efficiency, equity, patient-centeredness) and improving health outcomes for a specific high impact aspect of healthcare where there is variation in or overall poor performance. <i>Measures must be judged to be important to measure and report in order to be evaluated against the remaining criteria.</i> (evaluation criteria) 1a. High Impact	Eval Rating
(for NQF staff use) Specific NPP goal:	
 1a.1 Demonstrated High Impact Aspect of Healthcare: Affects large numbers, Severity of illness, Frequently performed procedure, 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 (CAUTI).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. 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 C P
1a.4 Citations for Evidence of High Impact: 1. Centers for Medicare & Medicaid Services. Medicare Patient	

Safety Monitoring System 2008.

2. Wong E, Hooton T. Guideline for Prevention of Catheter-associated Urinary Tract Infections. http://www.cdc.gov/ncidod/dhqp/gl_catheter_assoc.html. . Accessed December 10, 2008.

3. Klevens RM, Edwards JR, Richards CL, Jr., et al. Estimating health care-associated infections and deaths in U.S. hospitals, 2002. Public Health Rep. Mar-Apr 2007;122(2):160-166.

4. Wald HL, Ma A, Bratzler DW, Kramer AM. Indwelling urinary catheter use in the postoperative period: analysis of the national surgical infection prevention project data. Arch Surg. Jun 2008;143(6):551-557.

5. Saint S. Clinical and economic consequences of nosocomial catheter-related bacteriuria. American Journal of Infection Control. 2000;28(1):68-75.

6. Stone PW, Braccia D, Larson E. Systematic review of economic analyses of health care-associated infections. Am J Infect Control. Nov 2005;33(9):501-509.

7. Anderson DJ, Kirkland KB, Kaye KS, et al. Underresourced hospital infection control and prevention programs: penny wise, pound foolish? Infect Control Hosp Epidemiol. Jul 2007;28(7):767-773.

8. Scott RD. The Direct Medical Costs of Healthcare-Associated Infections in U.S. Hospitals and the Benefits of Prevention. Atlanta, GA: CDC; March 2009.

9. Saint S, Meddings JA, Calfee D, Kowalski CP, Krein SL. Catheter-associated urinary tract infection and the Medicare rule changes. Ann Intern Med. Jun 16 2009;150(12):877-884.

1b. Opportunity for Improvement

1b.1 Benefits (improvements in quality) envisioned by use of this measure: It is anticipated that the performance gap identified can be narrowed or eliminated based on robust performance feedback, consistent with NSQIP experience in the past. See below for description of gap.

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:

10. Saint S, Kaufman SR, Thompson M, Rogers MA, Chenoweth CE. A reminder reduces urinary catheterization in hospitalized patients. Jt Comm J Qual Patient Saf. Aug 2005;31(8):455-462.

11. Saint S, Lipsky BA. Preventing Catheter-Related Bacteriuria: Should We? Can We? How? Arch Intern Med. April 26, 1999 1999;159(8):800-808.

12. Hazelett SE, Tsai M, Gareri M, Allen K. The association between indwelling urinary catheter use in the elderly and urinary tract infection in acute care. BMC Geriatr. 2006;6:15.

13. Munasinghe RL, Yazdani H, Siddique M, Hafeez W. Appropriateness of use of indwelling urinary catheters in patients admitted to the medical service. Infect Control Hosp Epidemiol. Oct 2001;22(10):647-649.

 Gokula RM, Smith MA, Hickner J. Emergency room staff education and use of a urinary catheter indication sheet improves appropriate use of foley catheters. Am J Infect Control. Nov 2007;35(9):589-593.
 Fakih MG, Dueweke C, Meisner S, et al. Effect of Nurse-Led Multidisciplinary Rounds on Reducing the Unnecessary Use of Urinary Catheterization in Hospitalized Patients. Infection Control and Hospital Epidemiology. 2008;29(9):815-819.

16. Gokula RR, Hickner JA, Smith MA. Inappropriate use of urinary catheters in elderly patients at a

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midwestern community teaching hospital. Am J Infect Control. Jun 2004;32(4):196-199. Gould CV, Umscheid CA, Argawal R, Kuntz G, Pegues D, HICPAC. Guideline for Prevention of 17. Catheter-associated Urinary Tract Infections, 2008. Atlanta, GA 2009. Phipps S, Lim YN, McClinton S, Barry C, Rane A, N'Dow J. Short term urinary catheter policies 18. following urogenital surgery in adults. Cochrane Database Syst Rev. 2006(2):CD004374. 19. Tang KK, Wong CK, Lo SF, Ng TK. Is it necessary to catheterise the bladder routinely before gynaecological laparoscopic surgery? Aust N Z J Obstet Gynaecol. Oct 2005;45(5):380-383. Iorio R, Healy WL, Patch DA, Appleby D. The role of bladder catheterization in total knee 20. arthroplasty. Clin Orthop Relat Res. Nov 2000(380):80-84. **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 commorbidities. 1b.5 Citations for data on Disparities: Saint S, Lipsky BA. Preventing Catheter-Related Bacteriuria: Should We? Can We? How? Arch Intern Med. April 26, 1999 1999;159(8):800-808. Saint S, Kaufman SR, Thompson M, Rogers MA, Chenoweth CE. A reminder reduces urinary catheterization in hospitalized patients. Jt Comm J Qual Patient Saf. Aug 2005;31(8):455-462. Hazelett SE, Tsai M, Gareri M, Allen K. The association between indwelling urinary catheter use in the elderly and urinary tract infection in acute care. BMC Geriatr. 2006;6:15. Munasinghe RL, Yazdani H, Siddigue M, Hafeez W. Appropriateness of use of indwelling urinary catheters in patients admitted to the medical service. Infect Control Hosp Epidemiol. Oct 2001;22(10):647-649. Gokula RM, Smith MA, Hickner J. Emergency room staff education and use of a urinary catheter indication sheet improves appropriate use of foley catheters. Am J Infect Control. Nov 2007;35(9):589-593. Fakih MG, Dueweke C, Meisner S, et al. Effect of Nurse-Led Multidisciplinary Rounds on Reducing the Unnecessary Use of Urinary Catheterization in Hospitalized Patients. Infection Control and Hospital Epidemiology. 2008;29(9):815-819. Gokula RR, Hickner JA, Smith MA. Inappropriate use of urinary catheters in elderly patients at a midwestern community teaching hospital. Am J Infect Control. Jun 2004;32(4):196-199. Saint S, Meddings JA, Calfee D, Kowalski CP, Krein SL. Catheter-associated urinary tract infection and the Medicare rule changes. Ann Intern Med. Jun 16 2009;150(12):877-884. Saint S. Lipsky BA. Preventing Catheter-Related Bacteriuria: Should We? Can We? How? Arch Intern Med. April 26, 1999 1999;159(8):800-808. Gould CV, Umscheid CA, Argawal R, Kuntz G, Peques D, HICPAC. Guideline for Prevention of Catheterassociated Urinary Tract Infections, 2008. Atlanta, GA 2009. 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): Outcome Measure. 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, 1c providers can reduce urinary tract infection. However, aside from institutional surveillance data and СΓ 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 M measures, as proposed herein, is an important opportunity to reduce a preventable hospital-acquired N

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: Cohort study, 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): Outcome Measure. 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 	
 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 bag69,70, 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, providing feedback for hospitals to employ to accomplish improvement.	
1c.5 Rating of strength/quality of evidence (<i>also provide narrative description of the rating and by</i>	
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 outcome assessment itself. 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.8 Citations for Evidence (*other than guidelines*): 1. Centers for Medicare & Medicaid Services. Medicare Patient Safety Monitoring System 2008.

2. Wong E, Hooton T. Guideline for Prevention of Catheter-associated Urinary Tract Infections. http://www.cdc.gov/ncidod/dhqp/gl_catheter_assoc.html. . Accessed December 10, 2008.

3. Klevens RM, Edwards JR, Richards CL, Jr., et al. Estimating health care-associated infections and deaths in U.S. hospitals, 2002. Public Health Rep. Mar-Apr 2007;122(2):160-166.

4. Wald HL, Ma A, Bratzler DW, Kramer AM. Indwelling urinary catheter use in the postoperative period: analysis of the national surgical infection prevention project data. Arch Surg. Jun 2008;143(6):551-557.

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6. Stone PW, Braccia D, Larson E. Systematic review of economic analyses of health care-associated infections. Am J Infect Control. Nov 2005;33(9):501-509.

7. Anderson DJ, Kirkland KB, Kaye KS, et al. Underresourced hospital infection control and prevention programs: penny wise, pound foolish? Infect Control Hosp Epidemiol. Jul 2007;28(7):767-773.

8. Scott RD. The Direct Medical Costs of Healthcare-Associated Infections in U.S. Hospitals and the Benefits of Prevention. Atlanta, GA: CDC; March 2009.

9. Saint S, Meddings JA, Calfee D, Kowalski CP, Krein SL. Catheter-associated urinary tract infection and the Medicare rule changes. Ann Intern Med. Jun 16 2009;150(12):877-884.

10. Saint S, Kaufman SR, Thompson M, Rogers MA, Chenoweth CE. A reminder reduces urinary catheterization in hospitalized patients. Jt Comm J Qual Patient Saf. Aug 2005;31(8):455-462.

11. Hazelett SE, Tsai M, Gareri M, Allen K. The association between indwelling urinary catheter use in the elderly and urinary tract infection in acute care. BMC Geriatr. 2006;6:15.

12. Munasinghe RL, Yazdani H, Siddique M, Hafeez W. Appropriateness of use of indwelling urinary catheters in patients admitted to the medical service. Infect Control Hosp Epidemiol. Oct 2001;22(10):647-649.

 Gokula RM, Smith MA, Hickner J. Emergency room staff education and use of a urinary catheter indication sheet improves appropriate use of foley catheters. Am J Infect Control. Nov 2007;35(9):589-593.
 Fakih MG, Dueweke C, Meisner S, et al. Effect of Nurse-Led Multidisciplinary Rounds on Reducing the Unnecessary Use of Urinary Catheterization in Hospitalized Patients. Infection Control and Hospital Epidemiology. 2008;29(9):815-819.

15. Gokula RR, Hickner JA, Smith MA. Inappropriate use of urinary catheters in elderly patients at a midwestern community teaching hospital. Am J Infect Control. Jun 2004;32(4):196-199.

16. Gould CV, Umscheid CA, Argawal R, Kuntz G, Pegues D, HICPAC. Guideline for Prevention of Catheter-associated Urinary Tract Infections, 2008. Atlanta, GA 2009.

17. Phipps S, Lim YN, McClinton S, Barry C, Rane A, N'Dow J. Short term urinary catheter policies following urogenital surgery in adults. Cochrane Database Syst Rev. 2006(2):CD004374.

18. Tang KK, Wong ČK, Lo SF, Ng TK. Is it necessary to catheterise the bladder routinely before gynaecological laparoscopic surgery? Aust N Z J Obstet Gynaecol. Oct 2005;45(5):380-383.

19. Iorio R, Healy WL, Patch DA, Appleby D. The role of bladder catheterization in total knee arthroplasty. Clin Orthop Relat Res. Nov 2000(380):80-84.

20. Akhtar MS, Beere DM, Wright JT, MacRae KD. Is bladder catheterization really necessary before laparoscopy? Br J Obstet Gynaecol. Nov 1985;92(11):1176-1178.

21. SHEA (Society for Healthcare Epidemiology of America). Patient Guides on Healthcare-Associated Infections. http://www.shea-online.org/about/patientguides.cfm. Accessed June, 2009.

22. Saint S. Bladder Bundle. http://www.mhakeystonecenter.org/. Accessed April 2009.

23. Saint S, Kowalski CP, Kaufman SR, et al. Preventing Hospital-Acquired Urinary Tract Infection in the United States: A National Study. Clinical Infectious Diseases. 2008;46(2):243-250.

24. Stephan F, Sax H, Wachsmuth M, Hoffmeyer P, Clergue F, Pittet D. Reduction of urinary tract

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infection and antibiotic use after surgery: a controlled, prospective, before-after intervention study. Clin	
25. Cornia PB, Amory JK, Fraser S, Saint S, Lipsky BA. Computer-based order entry decreases duration	
of indwelling urinary catheterization in hospitalized patients. The American Journal of Medicine. 2003:114(5):404-407	
26. Huang WC, Wann SR, Lin SL, et al. Catheter-Associated Urinary Tract Infections in Intensive Care	
Units Can Be Reduced by Prompting Physicians to Remove Unnecessary Catheters. Infection Control and Hospital Epidemiology, 2004:25(11):974-978	
27. Rosenthal VD, Guzman S, Safdar N. Effect of education and performance feedback on rates of	
catheter-associated urinary tract infection in intensive care units in Argentina. Infect Control Hosp Epidemiol. Jan 2004;25(1):47-50.	
28. Apisarnthanarak A, Thongphubeth K, Sirinvaravong S, et al. Effectiveness of multifaceted	
catheters at a tertiary care center in Thailand. Infect Control Hosp Epidemiol. Jul 2007;28(7):791-798.	
29. Loeb M, Hunt D, O'Halloran K, Carusone SC, Dafoe N, Walter SD. Stop orders to reduce	
Med. Jun 2008;23(6):816-820.	
30. Goetz A, Kedzuf S, Wagener M, Muder RR. Feedback to nursing staff as an intervention to reduce	
404.	
31. Topal J, Conklin S, Camp K, Morris V, Balcezak T, Herbert P. Prevention of Nosocomial Catheter-	
Protocol. American Journal of Medical Quality. May 1, 2005 2005;20(3):121-126.	
69. Gillespie WA, Simpson RA, Jones JE, Nashef L, Teasdale C, Speller DC. Does the addition of	
disinfectant to urine drainage bags prevent infection in catheterised patients? Lancet. May 7 1983:1(8332):1037-1039.	
70. Thompson RL, Haley CE, Searcy MA, et al. Catheter-associated bacteriuria. Failure to reduce attack	
rates using periodic instillations of a disinfectant into urinary drainage systems. JAMA. Feb 10 1984:251(6):747-751	
71. Niel-Weise BS, van den Broek PJ. Antibiotic policies for short-term catheter bladder drainage in	
adults. Cochrane Database Syst Rev. 2005(3):CD005428.	
patients with short-term indwelling urethral catheters: a comparison between a 3-day urinary drainage bag change and no change regimens. Am J Infect Control. Feb 2003;31(1):9-12	
73. Priefer BA, Duthie EH, Jr., Gambert SR. Frequency of urinary catheter change and clinical urinary tract infection. Study in hospital-based, skilled nursing home. Urology, Aug 1982;20(2):141-142	
74. Stelling JD, Hale AM. Protocol for changing condom catheters in males with spinal cord injury. SCI	
Nurs. Jun 1996;13(2):28-34. 75. Reid RI, Webster O, Pead PJ, Maskell R. Comparison of urine bag-changing regimens in elderly	
catheterised patients. Lancet. Oct 2 1982;2(8301):754-756.	
America guidelines for the diagnosis and treatment of asymptomatic bacteriuria in adults. Clin Infect Dis.	
Mar 1 2005;40(5):643-654.	
1c.9 Quote the Specific guideline recommendation (<i>including guideline number and/or page number</i>): There are no ratings for a UTI outcome measure. Associated processes are commented upon above.	
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 (<i>also provide narrative description of the rating and by whom</i>):	
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	
TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for <i>Importance</i> to Measure and Report?	1
Steering Committee: Was the threshold criterion, <i>Importance to Measure and Report</i> , met? Rationale:	1 Y N
2. SCIENTIFIC ACCEPTABILITY OF MEASURE PROPERTIES	
Extent to which the measure, <u>as specified</u> , produces consistent (reliable) and credible (valid) results about the quality of care when implemented. (evaluation criteria)	Eval Rating
2a. MEASURE SPECIFICATIONS	
 S.1 Do you have a web page where current detailed measure specifications can be obtained? S.2 If yes, provide web page URL: 	
2a. Precisely Specified	
2a.1 Numerator Statement (<i>Brief, text description of the numerator - what is being measured about the target population, e.g. target condition, event, or outcome</i>): The outcome of interest is a hospital-specific assessment of risk-adjusted Urinary Tract Infection (UTI: as defined by American College of Surgeons National Surgical Quality Improvement Program (ACS NSQIP)defined below) within 30 days of any listed (CPT) surgical procedure: the list of eligible CPT codes is attached separately.	
2a.2 Numerator Time Window (<i>The time period in which cases are eligible for inclusion in the numerator</i>): Targeted events within 30 days of the index surgical operation are included.	
2a.3 Numerator Details (<i>All information required to collect/calculate the numerator, including all codes, logic, and definitions</i>) : Within 30 days after the index procedure, 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: a. Dipstick test positive for leukocyte esterase and/or nitrate, b. Pyuria (>10 WBCs/mm3 or > 3 WBC/hpf of unspun urine),	2a- specs C P M N

c. Organisms seen on Gram stain of unspun urine,

d. Two urine cultures with repeated isolation of the same uropathogen with >100 colonies/ml urine in non-voided specimen,

e. Urine culture with < 100,000 colonies/ml urine of single uropathogen in patient being treated with appropriate antimicrobial therapy,

f. Physician 's diagnosis,

g. Physician institutes appropriate antimicrobial therapy

Cases are excluded if the patient is identified as having a symptomatic urinary tract infection at the time surgery commences (present preoperatively), or is in a treatment course for such infection at the time surgery commences.

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

Patients undergoing any of the listed (CPT) surgical procedures- list is attached separately. Specifically excluded are certain CPTs involving the urinary tract (excluded: 50220, 50545, 50400, 50205, 51040, 54640, 53852, 55866, 52450, 52234). See attached submitted list of eligible 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, using the supplied CPT code eligbility list, thereby permitting valid application of ACS NSQIP model-based risk adjustment. Participation in NSQIP is not a requirement- see 2a25.

2a.9 Denominator Exclusions (*Brief text description of exclusions from the target population***)**: Major trauma and transplant surgeries are excluded as are surgeries not on the supplied CPT list as eligible for selection. Patients who are ASA 6 (brain-death organ donor) are not eligible surgical cases. A patient who has a second surgical procedure performed within 30 days after an index procedure cannot be accrued into the measure as a new (second) index procedure since the measure is based on 30 day outcomes.

2a.10 Denominator Exclusion Details (All information required to collect exclusions to the denominator, including all codes, logic, and definitions):

Major trauma and solid organ transplant cases have been excluded traditionally from the NSQIP so there is currently no data within the NSQIP on these cases. Historically the reason for this was the existence of highly specialized databases maintained by the various trauma and transplant organizations that were felt to be of higher specific utility for these cases. In addition, these patients and procedures carry very specific and complex risk profiles, yet are not necessarily common across institutions, magnifying risk adjustment and procedure adjustment challenges. Therefore, 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, though any operation performed after the patient has been discharged from the trausplant stay is eligible for selection. Donor procedures on living donors are NOT excluded unless meeting other exclusion criteria.

If surgeries (CPT codes) do not appear on the supplied list (attached) of 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, it is risk-adjusted by the variables defined below.

Note: if an implementation required stratification by race or ethnicity post-hoc, then race/ethnicity variables could be added to the implementation with no other changes necessary under the measure.

Risk adjustment variables (five):

1."CPT Risk" (Log Odds CPT Group: scalar continuous variable, derived as specified under Risk Adjustment Methodology 2a14).

2.Preoperative Functional Status: Independent, Partially Dependent, Totally Dependent. This variable focuses on the patient's abilities to perform activities of daily living (ADLs) in the 30 days prior to surgery. Activities of daily living are defined as 'the activities usually performed in the course of a normal day in a person's life'. ADLs include: bathing, feeding, dressing, toileting, and mobility. Report the corresponding level of self-care for activities of daily living demonstrated by this patient at the time the patient is being considered as a candidate for surgery (which should be no longer than 30 days prior to surgery). Report the level of functional health status as defined by the following criteria.

(1) Independent: The patient does not require assistance from another person for any activities of daily living. This includes a person who is able to function independently with prosthetics, equipment, or devices.

(2) Partially dependent: The patient requires some assistance from another person for activities of daily living. This includes a person who utilizes prosthetics, equipment, or devices but still requires some assistance from another person for ADLs.

(3) Totally dependent: The patient requires total assistance for all activities of daily living.

(4) Unknown: If unable to ascertain the functional status in the specified time period report as unknown. All patients with psychiatric illnesses should be evaluated for their ability to function with or without assistance with ADLs just as the non-psychiatric patient. For instance, if a patient with schizophrenia is able to care for him/herself without the assistance of nursing care, he/she is considered independent.

3.Gender: Female/Male.

4. American Society of Anesthesiology Physical Status Classification ("ASA Class"). [Note: ASA Class 6-EXCLUDED from Eligibility].

Record the American Society of Anesthesiology (ASA) Physical Status Classification of the patient's present physical condition on a scale from 1-6 as it appears on the anesthesia record. Most likely there will be a 2nd assessment of the ASA class prior to anesthesia induction. If this is available, report this most recent assessment. Some hospitals may note the ASA classification as the 'Acuity Code'. The classifications are as follows:

ASA 1 - Normal healthy patient.

ASA 2 - Patient with mild systemic disease.

ASA 3 - Patient with severe systemic disease.

ASA 4 - Patient with severe systemic disease that is a constant threat to life.

ASA 5 - Moribund patient who is not expected to survive without the operation.

ASA 6 - Declared brain-dead patient whose organs are being removed for donor

purposes (ASA 6 cases should be excluded).

None assigned - For cases performed under local anesthesia that meet inclusion criteria but do not have an ASA class assigned, report as "none assigned".

5.Age Group (years): <65yo, 65 - 74, 75 - 84, >= 85.

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 if they involved an excluded urologic procedure as specified in the CPT inclusion/exclusion description (see 2a4), 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.* Missing variables within the ACS NSQIP framework are traditionally handled by imputation, generally invoked mainly for laboratory variables since case inclusion

typically requires complete data (For a discussion of imputation issues within the program approach see J Am Coll Surg 2010;210:125-139).

A Urinary Track Infection (UTI) was defined according to ACS NSQIP definitions (see 2a3). Of the 250,194 patients, 3,980 (1.6%) experienced an UTI event as defined.

To control for procedure-specific effects, CPT code was originally considered a categorical variable but, to maintain methodological consistency with other proposed measures, CPT code was converted to a continuous scalar risk variable: "CPT Risk". This was accomplished by making the categorical CPT code 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 for each CPT code was then used as a continuous predictor in subsequent logistic models which also included all other specified risk predictors. The result is that the scalar "CPT Risk" variable included in the subsequent regressions provides a very high level of control for "procedure" or "procedure mix" within the measure. This alleviates the majority of concern over the measure being dominated by unique, procedure-specific effects.

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 ("CPT Risk"), 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 (CPT Risk, preoperative Functional Status, Gender, ASA Class, and Age Group), the c-statistic was 0.790 and the Hosmer-Lemeshow was 0.006). These five predictor variables are specifically defined under item 2a11- stratification details/variables. 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 five-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=R / [ICC(1 - R)] - R / (1 - R); where N is the required number patients per hospital and R is reliability.

Based on the estimated ICC, patients required per hospital to achieve reliability levels of 0.3, 0.4, 0.5, 0.6, and 0.7 are: 187, 290, 435, 653, and 1015, respectively. A reliability of 0.4 is generally considered minimally acceptable, corresponding to an accrual of 290 cases for the minimum.

For the table detailing risk adjustment factors, odds ratios, and parameters for the hierarchical model, please see attachment ("Parsimonious Model for UTI").

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

*References utilizing CPT groups in risk adjustment:

Hall BL, Hamilton BH, Richards K, et al. (2009) Does Surgical Quality Improve in the American College of

Surgeons National Surgical Quality Improvement Program: An Evaluation of All Participating Hospitals. Ann Surg 250:363-376.

Hall BL, Hsiao EY, Majercik S, et al. (2009) The impact of surgeon specialization on patient mortality: examination of a continuous Herfindahl-Hirschman index. Ann Surg 249:708-716.

Cohen ME, Bilimoria KY, Ko CY, Hall BL. (2009) Development of an American College of Surgeons National Surgery Quality Improvement Program: morbidity and mortality risk calculator for colorectal surgery. J Am Coll Surg 208:1009-1016.

Schilling PL, Dimick JB, Birkmeyer JD. (2008)Prioritizing quality improvement in general surgery. J Am Coll Surg 207:698-704.

2a.15-17 Detailed risk model available Web page URL or attachment: Attachment Parsimonious_Model_and_CPT_List_for_UTI_Measure_080910.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 (UTI) at the hospital; (b) using parameters from the described model, compute predicted event probabilities for each patient in the hospital's data set; (c) the sum of these predicted probabilities defines E for the institution; (d) compute the hospital's O/E ratio and applicable confidence intervals. See also the risk adjustment methodology section and the attached document specifying CPT codes and the parameters of the risk model.

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 (minimum of 290 cases- see Risk-adjustment Methodology section 2a14), 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 cannot be achieved due to low hospital volume, 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, Paper medical record/flow-sheet, Pharmacy data, Electronic clinical data, Electronic Health/Medical Record, Lab data, Management 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.*): Data sources are as above.

The model is based on historical ACS NSQIP data. Data collection is consistent with historical ACS NSQIP approaches. Modeling is based on ACS NSQIP data but measure would not require participation in ACS NSQIP. Implementation by an organization (such as CMS) would involve hospitals transmitting the limited data set specified for the procedures specified to the central implementing organization. Risk adjustment modeling would be performed centrally and institutions would receive results back. Institutions would not have any analytic burden. The implementing organization would also inform institutions of the auditing paradigm for submitted data. NSQIP participation is not required, though institutions participating in NSQIP would already collect all requisite data. The measure has specifically been designed with a very parsimonious, low-burden data requirement so that NSQIP participation would not be required and the burden on hospitals for this measure would be acceptable.

2a.26-28 Data source/data collection instrument reference web page URL or attachment: URL No collection instrument reference is required: data collection is fully described herein. www.acsnsqip.org

2a.29-31 Data dictionary/code table web page URL or attachment: Attachment Parsimonious_Model_and_CPT_List_for_UTI_Measure_080910-634169748621065238.doc

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

Facility/Agency, Population: national, Population: regional/network, Population: states

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

2a.38-41 Clinical Services (*Healthcare services being measured, check all that apply*) Clinicians: Nurses, Clinicians: Physicians (MD/DO)

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. Measure would be based on ongoing data collection.

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. This is an extrememly rigorous approach to estimating reliability of distinction.

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 defined outcome on the significant predictors for UTI. Together with procedure volumes, these ICCs were entered into the following equation to estimate reliability:

R = nICC/(1 + (n - 1)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.

RELIABILITY ESTIMATE	INTERPRETATION
0.00-0.20	Slight
0.21-0.40	Fair
0.41-0.60	Moderate
0.61-0.80	Substantial
0.81-1.00	Excellent

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.

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Μ

N

Reliability RequiredCases %U_S_Hose	MtaRarmnt* %	NSOIPHospMta Rarmnt+	
0.3 187	_94.0	96.2	
0.4290	93.9	94.3	
0.5435	.89.2	92.4	
0.6653	_84.5	82.0	
0.71015	_78.5	59.7	
*Based on volume data from the 2005 Na	ational Inpatient	t Survey and inflated to account for outpatient	
procedures.			
+Based on ACS NSQIP Data file 2008 and over-representation	inflated to acco	ount for procedures that might be excluded for	
2c. Validity testing			
2c.1 Data/sample <i>(description of data/s</i> Specifications and section on Reliability the ACS NSQIP database for 2008.	sample and size, above. Models): See Risk-adjustment Methodology in were constructed using a large sample derived from	
2c.2 Analytic Method <i>(type of validity of See Risk-adjustment Methodology in Spe developmental data set were computed base on 2007 data.</i>	& rationale, met cifications. C-s ; c-statistics we	<i>thod for testing</i>): tatistics and Hosmer-Lemeshow P-values for the re computed for an independent validation data set	
2c.3 Testing Results (statistical results, conducted):	assessment of	adequacy in the context of norms for the test	2c C□ P□
See Risk-adjustment Methodology in Spe demonstrated when the 2008 model was	cifications. Mod applied to 2007	del validity (a similar c-statistic, discrimination) was 7 data.	M N
2d. Exclusions Justified			
2d.1 Summary of Evidence supporting The supplied attached CPT list includes and it would be unreasonable to provide addition, we have explicitly excluded su death organ donors). The ASA 6 exclusi does not require explanation. As this m inclusion of trauma and transplant cases centers, could adversely affect the efficient hospitals might be profound).	exclusion(s): surgeries that w e documentation rgeries related on as regards pr easure is intend s, which tend to acy of risk-adju	yould be appropriate for measurement of quality in on the thousands of inapplicable codes. In to major trauma, transplant, and ASA Class 6 (brain- rediction of postoperative mortality and morbidity led to apply generally to all hospitals doing surgery, be directed towards metropolitan or regional estment (non-overlap of these types of cases across	
2d.2 Citations for Evidence: As exclusions are based on reasoned arg research findings are provided.	ument rather er	mpirical findings neither published evidence nor	
2d.3 Data/sample (description of data/	sample and size,): n/a	
2d.4 Analytic Method <i>(type analysis & r</i> n/a	rationale):		2d C P
2d.5 Testing Results <i>(e.g., frequency, w</i> n/a	variability, sensi	itivity analyses):	
2e. Risk Adjustment for Outcomes/ Re	source Use Mea	isures	2e
2e.1 Data/sample <i>(description of data/s</i> ACS NSQIP Data file. The UTI model use the most recent Data file and data from	sample and size, d 254,194 patie n measure-partic): The data sample is derived from the most recent int records. Future models can be constructed using cipants. If this measure is adopted by sufficient	P M N

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numbers of non-NSQIP hospitals re-modeling can be based on data from the broader sample of hospitals alone. Please see also Risk Adjustment Methodology section.	
2e.2 Analytic Method (<i>type of risk adjustment, analysis, & rationale</i>): 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 <i>(risk model performance metrics)</i> : 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 five-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.	
2e.4 If outcome or resource use measure is not risk adjusted, provide rationale: n/a	
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 (<i>type of analysis & rationale</i>): See also sections on performance gap (1b2) and reliability of distinction (2b3). 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	C P M N
2g. Comparability of Multiple Data Sources/Methods	
2g.1 Data/sample <i>(description of data/sample and size)</i> : 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%	2g C P M N NA

vs. ACS NSQIP complication rate, 28%). Using administrative or claims data may result in significant	
differences in risk-adjusted outcomes than using clinical data.	
Steinberg, S.M., et al., Comparison of risk adjustment methodologies in surgical quality improvement. Surgery, 2008. 144(4): p. 662-7; discussion 662-7.	
2g.2 Analytic Method <i>(type of analysis & rationale)</i> : 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 <i>(scores by stratified categories/cohorts)</i> : 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:	2h C P
There is no stratification of the measure, it is risk-adjusted by the variables described. Note: if an implementation required stratification by race or ethnicity post-hoc, then race/ethnicity variables could be added to the implementation with no other changes necessary under the measure.	M N NA
TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for <i>Scientific</i> Acceptability of Measure Properties?	2
Steering Committee: Overall, to what extent was the criterion, <i>Scientific Acceptability of Measure Properties</i> , met? Rationale:	2 C P M
3. USABILITY	N
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	
Jan Guirent Use. In use	
3a.2 Use in a public reporting initiative (disclosure of performance results to the public at large) (<i>If</i> used in a public reporting initiative, provide name of initiative(s), locations, Web page URL(s). <u>If not</u> <u>publicly reported</u> , state the plans to achieve public reporting within 3 years): Not used in public reporting initiative at this time. Used within existing ACS NSQIP program for most recent	
 3a.2 Use in a public reporting initiative (disclosure of performance results to the public at large) (<i>If used in a public reporting initiative, provide name of initiative(s), locations, Web page URL(s). <u>If not publicly reported</u>, state the plans to achieve public reporting within 3 years): Not used in public reporting initiative at this time. Used within existing ACS NSQIP program for most recent annual reports (confidential reporting to participants).</i> 3a.3 If used in other programs/initiatives (<i>If used in quality improvement or other programs/initiatives, name of initiative(s), locations, Web page URL(s), If not used for OL state the plans to achieve use for OL</i> 	
 3a.2 Use in a public reporting initiative (disclosure of performance results to the public at large) (<i>If</i> used in a public reporting initiative, provide name of initiative(s), locations, Web page URL(s). <u>If not</u> <u>publicly reported</u>, state the plans to achieve public reporting within 3 years): Not used in public reporting initiative at this time. Used within existing ACS NSQIP program for most recent annual reports (confidential reporting to participants). 3a.3 If used in other programs/initiatives (<i>If used in quality improvement or other programs/initiatives, name of initiative(s), locations, Web page URL(s). <u>If not used for QI</u>, state the plans to achieve use for QI within 3 years):</i> Current ACS NSQIP semiannual reporting: roughly 300 participating institutions currently receiving measure performance feedback. 	
 3a.2 Use in a public reporting initiative (disclosure of performance results to the public at large) (<i>If</i> used in a public reporting initiative, provide name of initiative(s), locations, Web page URL(s). <u>If not</u> <u>publicly reported</u>, state the plans to achieve public reporting within 3 years): Not used in public reporting initiative at this time. Used within existing ACS NSQIP program for most recent annual reports (confidential reporting to participants). 3a.3 If used in other programs/initiatives (<i>If used in quality improvement or other programs/initiatives</i>, name of initiative(s), locations, Web page URL(s). <u>If not used for QI</u>, state the plans to achieve use for QI within 3 years): Current ACS NSQIP semiannual reporting: roughly 300 participating institutions currently receiving measure performance feedback. 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 catiefortion of data/sample outcomes of the program and the catiefortion of participation of interpretability of the potential users of this program and the catiefortion of participation of interpretability of the potential users in the program for over 15 years from its inception in the VA. The success of this program and the catiefortion of the participation of the potential interpretability of the participation of the participation of the program and the catiefortion of the participation of the participation of the program and the catiefortion of the participation of the	3a

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.	
Hall BL, Hamilton BH, Richards K, Bilimoria KY, Cohen ME, Ko CY. Does surgical quality improve in the American College of Surgeons National Surgical Quality Improvement Program: an evaluation of all participating hospitals. Ann Surg. Sep 2009;250(3):363-376.	
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/3c. 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 (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 more effectively for quality improvement purposes.	3b C P N N NA
3c. Distinctive or Additive Value 3c.1 Describe the distinctive, improved, or additive value this measure provides to existing NQF- endorsed measures: The measures are not similar- they do not address the same target population, and this measure specification should be a more reliable basis for quality improvement efforts, as described above.	3c C□
5.1 If this measure is similar to measure(s) already endorsed by NOF (i.e., on the same topic and the same target population), Describe why it is a more valid or efficient way to measure quality: Risk adjustment approach, spectrum of included cases, rigorous definition of and experience with variables.	P M N NA
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, <i>Usability</i> , 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? Data generated as byproduct of care processes during care delivery (Data are generated and used by healthcare personnel during the provision of care, e.g., blood pressure, lab value, medical condition), Coding/abstraction performed by someone other than person obtaining original information (E.g., DRG, ICD-9 codes on claims, chart abstraction for quality measure or registry)	4a C P M N
4b. Electronic Sources	
4b.1 Are all the data elements available electronically? (<i>elements that are needed to compute measure scores are in defined, computer-readable fields, e.g., electronic health record, electronic claims</i>) No	
4b.2 If not , specify the near-term path to achieve electronic capture by most providers . A completely electronic medical record would be needed to capture the risk factors that enter into the model- this is an institution specific issue. In addition, web based software (currently available to ACS NSQIP subscribers) can facilitate transfer of information from the EMR to a measure submission database.	4b C P M N
4c. Exclusions	40
 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. Based upon experience with ACS NSQIP data collection, there are very few problems with errors or inaccuracies. Data collectors in the ACS NSQIP receive extensive training and support for accurate data collection. Similar online training would be available for this measure. In addition, data collectors are audited in NSQIP for inter-rater reliability and are held to a 95% or better concordance rate for all variables. Similarly, chart audits have been planned in accordance with CMS stipulations for measure participants who are not ACS NSQIP participants.	4d C P M N
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 2005. 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 upon 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	
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 modeling 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	4e C P M N

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 as described elsewhere in these submission materials.	
4e.3 Evidence for costs: Costs are based upon estimates from historical ACS NSQIP data collection, in which one FTE can reliably collect >1600 cases per year, even though the full NSQIP program requires collection of a much larger number of variables. In contrast, this measure does not require many variables: only one outcome and five risk adjustment variables. Furthermore, sample size is such that reliable results can be achieved after collection of 300-500 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 subcriteria for <i>Feasibility</i> ?	4
Steering Committee: Overall, to what extent was the criterion, Feasibility, met?	4
Rationale:	
	N
RECOMMENDATION	
(for NQF staff use) Check if measure is untested and only eligible for time-limited endorsement.	Time- limited
(for NQF staff use) Check if measure is untested and only eligible for time-limited endorsement.	Time- limited
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I, Bruce Hall, am submitting revisions on behalf of ACS.

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. Testina * Yes, tested, as reported above.

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, as above.

Ad.11 -13 Additional Information web page URL or attachment: Attachment BP Guideline CAUTI.pdf

Date of Submission (MM/DD/YY): 08/10/2010