

NATIONAL QUALITY FORUM

Measure Evaluation 4.1 December 2009

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

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

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

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

Evaluation ratings of the extent to which the criteria are met

C = Completely (unquestionably demonstrated to meet the criterion)

P = Partially (demonstrated to partially meet the criterion)

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

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

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

(for NQF staff use) NQF Review #: PSM-006-10 NQF Project: Patient Safety Measures
MEASURE DESCRIPTIVE INFORMATION
De.1 Measure Title: Risk Adjusted Surgical Site Infection Outcome Measure
De.2 Brief description of measure: This is a hospital based, risk adjusted, case mix adjusted surgical site infection measure of adults 18 years of age and over.
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: Effectiveness, Efficiency, Equity, Safety
De.6 Consumer Care Need: Getting better, 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
<p>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></p> <p>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</p> <p>A.2 Indicate if Proprietary Measure (as defined in measure steward agreement):</p> <p>A.3 Measure Steward Agreement: Agreement will be signed and submitted prior to or at the time of measure submission</p> <p>A.4 Measure Steward Agreement attached:</p>	<p>A</p> <p>Y <input type="checkbox"/></p> <p>N <input type="checkbox"/></p>
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	<p>B</p> <p>Y <input type="checkbox"/></p>

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

TAP/Workgroup Reviewer Name:	
Steering Committee Reviewer Name:	
1. IMPORTANCE TO MEASURE AND REPORT	
Extent to which the specific measure focus is important to making significant gains in health care quality (safety, timeliness, effectiveness, efficiency, equity, patient-centeredness) and improving health outcomes for a specific high impact aspect of healthcare where there is variation in or overall poor performance. <i>Measures must be judged to be important to measure and report in order to be evaluated against the remaining criteria.</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: Surgical site infections (SSIs) are the second leading cause of nosocomial infections. Approximately 290,000 SSIs were diagnosed in the United States in 2002, resulting in 8,207 associated deaths. [1] The mortality rate of patients with SSIs is approximately 2-12 times that of patients who do not have a SSI. [2, 3] Surgical site infections result in an additional 7-10 days of hospitalization for each postoperative infection per patient. [4] Furthermore, SSIs represent a significant financial burden to the healthcare system. The attributable direct cost per infection ranges from \$6,000 to \$29,000 depending on the operative procedure and the type of infecting pathogen. [3-5] Estimates indicate that SSIs accounted for \$3.45-10.07 billion in direct costs in 2007. [6] 1a.4 Citations for Evidence of High Impact: 1. Anderson, D.J., et al., Strategies to prevent surgical site infections in acute care hospitals. Infect Control Hosp Epidemiol, 2008. 29 Suppl 1: p. S51-61. 2. Engemann, J.J., et al., Adverse clinical and economic outcomes attributable to methicillin resistance among patients with Staphylococcus aureus surgical site infection. Clin Infect Dis, 2003. 36(5): p. 592-8. 3. Kirkland, K.B., et al., The impact of surgical-site infections in the 1990s: attributable mortality, excess length of hospitalization, and extra costs. Infect Control Hosp Epidemiol, 1999. 20(11): p. 725-30.	1a C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/>

<p>4. Klevens, R.M., et al., Estimating health care-associated infections and deaths in U.S. hospitals, 2002. Public Health Rep, 2007. 122(2): p. 160-6.</p> <p>5. Olsen, M.A., et al., Hospital-associated costs due to surgical site infection after breast surgery. Arch Surg, 2008. 143(1): p. 53-60; discussion 61.</p> <p>6. Scott II, R.D., The Direct Medical Costs of Healthcare-Associated Infections in U.S. Hospitals and the Benefits of Prevention. 2009, Centers for Disease Control and Prevention: Atlanta.</p>	
<p>1b. Opportunity for Improvement</p> <p>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.</p> <p>1b.2 Summary of data demonstrating performance gap (variation or overall poor performance) across providers: SSI rates are highly variable by institution. ACS NSQIP uses clinical, audited, third -party collection, and risk adjusted data. An analysis of ACS NSQIP data shows that O/E ratios for SSI range from 0 to 3.01 for all participating hospitals. The interquartile range for O/E ratios is 0.70-1.24, and the 10th percentile and 90th percentile O/E ratios were 0.45 and 1.52 (more than a three-fold difference), respectively. These statistics demonstrate the significance of the performance gap in SSI outcomes across hospital providers.</p> <p>1b.3 Citations for data on performance gap: The data cited above are unpublished, obtained from an internal analysis of ACS NSQIP data. However, these gaps have been repeatedly demonstrated since the inception of the program in our published semi-annual reports to all participants.</p> <p>1b.4 Summary of Data on disparities by population group: Certain patient-related factors have been associated with an increased risk of SSI, including: advanced age, [7] [8] obesity, [4, 7-9] and gender [10], as well as characteristics associated with certain population groups such as hyperglycemia/diabetes, [4, 7, 8, 11] dyspnea, [8] hypoxia, [11] ASA classification>2, [8, 12]smoking, [4, 7, 8, 13] and alcoholism.</p> <p>1b.5 Citations for data on Disparities:</p> <p>4. Anderson, D.J., et al., Strategies to prevent surgical site infections in acute care hospitals. Infect Control Hosp Epidemiol, 2008. 29 Suppl 1: p. S51-61.</p> <p>5. Olsen, M.A., et al., Hospital-associated costs due to surgical site infection after breast surgery. Arch Surg, 2008. 143(1): p. 53-60; discussion 61.</p> <p>6. Scott II, R.D., The Direct Medical Costs of Healthcare-Associated Infections in U.S. Hospitals and the Benefits of Prevention. 2009, Centers for Disease Control and Prevention: Atlanta.</p> <p>7. Mangram, A.J., et al., Guideline for prevention of surgical site infection, 1999. Hospital Infection Control Practices Advisory Committee. Infect Control Hosp Epidemiol, 1999. 20(4): p. 250-78; quiz 279-80.</p> <p>8. Neumayer, L., et al., Multivariable predictors of postoperative surgical site infection after general and vascular surgery: results from the patient safety in surgery study. J Am Coll Surg, 2007. 204(6): p. 1178-87.</p> <p>9. Anaya, D.A. and E.P. Dellinger, The obese surgical patient: a susceptible host for infection. Surg Infect (Larchmt), 2006. 7(5): p. 473-80.</p> <p>10. Rogers, M.A., et al., Increased risk of infection and mortality in women after cardiac surgery related to allogeneic blood transfusion. J Womens Health (Larchmt), 2007. 16(10): p. 1412-20.</p> <p>11. Cheadle, W.G., Risk factors for surgical site infection. Surg Infect (Larchmt), 2006. 7 Suppl 1: p. S7-11.</p> <p>12. Culver, D.H., et al., Surgical wound infection rates by wound class, operative procedure, and patient risk index. National Nosocomial Infections Surveillance System. Am J Med, 1991. 91(3B): p. 152S-157S.</p> <p>13. Theadom, A. and M. Cropley, Effects of preoperative smoking cessation on the incidence and risk of intraoperative and postoperative complications in adult smokers: a systematic review. Tob Control, 2006. 15(5): p. 352-8.</p>	<p style="text-align: right;">1b C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/></p>
<p>1c. Outcome or Evidence to Support Measure Focus</p>	<p style="text-align: right;">1c</p>

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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. Measurement of SSI as a risk-adjusted outcome is highly relevant to the general surgical population. Despite a wealth of modern infection-control practices (sterilization, antimicrobial prophylaxis, antisepsis and barriers, etc.), SSIs persist in causing a significant number of morbidity and mortality events among hospitalized patients. Since risk of SSI increases with certain patient preoperative factors, a risk-adjusted measure is necessary to ensure that hospitals are receiving an accurate benchmark of their performance based on their patient case-mix. Finally our analyses demonstrate that evidence based NQF endorsed process measures have little to no correlation with clinical risk adjusted outcomes. Evidence that demonstrates the significance and relevance of SSI to the population may be found in RCTs, observational trials, cohort studies, etc. (See below)

1c.2-3. Type of Evidence: Evidence-based guideline, Observational study, Cohort study, Randomized controlled trial, Systematic synthesis of research, Meta-analysis, 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*): Outcomes Measure. A number of existing guidelines and recommendations exist that detail measures that can help prevent SSIs. However, there is little evidence to show that these measures correlate with SSI outcomes. The most highly recommended processes for prevention of SSI are outlined below (SCIP). There are six evidence-based preventive measures for SSI. These processes were selected based on literature detailing the effect of these measures on surgical site infection outcomes.

1. Administer prophylactic antibiotics within one hour prior to surgical incision (vancomycin and fluoroquinolones should be administered 2 hours prior to surgery). (A-I)
2. Select the appropriate antimicrobial prophylaxis based upon published guidelines (A-I)
3. Discontinue use of the prophylactic antibiotic within 24 hours after surgery (48 hours for cardiothoracic procedures in adult patients) (A-I)
4. Remove hair only if it interferes with the operation. If hair removal is necessary, use clippers instead of razors (A-II)
5. Monitor and maintain glucose levels (<200mg/DL) in cardiothoracic surgery patients (including non-diabetic patients) on postoperative days one and two. (A-I)
6. Maintain normothermia perioperatively for patients undergoing colorectal surgery. (B-I)

Occurrence of surgical site infections is likely multi-factorial and there are a number of additional processes that are also highly recommended for implementation based on their potential effect on improving outcomes. The problem being faced currently is the degree to which already-identified SSI processes affect outcomes in the real world setting. Analyses within ACS NSQIP to date show little to no correlation between performance on the SCIP process measures and risk-adjusted outcomes. Thus, an alternative metric for evaluating surgical patient care is to use an SSI outcome-based performance measure, as opposed to measures based on processes.

1c.5 Rating of strength/quality of evidence (*also provide narrative description of the rating and by whom*):

There are no ratings for an SSI outcome measure simply because it is the outcome of interest. The SCIP process measures cited above are generally level I -II evidence. Ratings for SSI related processes are not applicable to this application, however, they are available upon request.

1c.6 Method for rating evidence: Rating method adapted from the Canadian Task Force on Health Examination. These ratings apply to the process measures under "Summary of Evidence"

Category/grade	Definition	Strength of recommendation
A	Good evidence to support a recommendation for use	
B	Moderate evidence to support a recommendation for use	
C	Poor evidence to support a recommendation	

Quality of evidence

- I Evidence from one or more properly randomized, controlled trial
- II Evidence from one or more well-designed clinical trial, without randomization; from cohort or case-control analytic studies (preferably from >1 center); from multiple time series; or from dramatic results from uncontrolled experiments
- III Evidence from opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees

1c.7 Summary of Controversy/Contradictory Evidence: Contradictory evidence exists on the effect of process measures on outcomes. In a highly controlled setting (controlled clinical study) high performance on SCIP measures is related to high performance on outcomes, but in an observational setting, there is little correlation between process and outcomes.

As mentioned above, ACS NSQIP data were used to conduct a cross-sectional study (unpublished data) to determine whether adherence with Surgical Care Improvement Project (SCIP) process measures correlates with risk-adjusted ACS NSQIP outcomes. Thirty-day risk-adjusted outcomes after colorectal surgery, including mortality, serious morbidity, morbidity, surgical site infections, venous thromboembolism (VTE), and cardiac events, at ACS NSQIP hospitals that submitted performance on seven process measures to The Joint Commission between July 1, 2007, and June 30, 2008, were correlated with process measure compliance. Multivariable forward step-wise logistic regression models were constructed to assess 30-day morbidity and mortality adjusted for patient comorbidities, operative risk factors, and process measure compliance. The results of the regression models showed that SCIP process measure compliance was not an important predictor of ACS NSQIP risk-adjusted outcomes.

The above study illustrates that occurrence of SSI is probably multifactorial and it is quite likely that the process measures identified by SCIP for prevention of SSI do not accurately reflect ALL of the processes that account for risk-adjusted SSI outcomes.

Obtaining risk adjusted outcomes will both evaluate and likely improve patient care as well as enable ongoing and future investigations of process effectiveness.

1c.8 Citations for Evidence (*other than guidelines*): 1. Arrowsmith, V.A., et al., Removal of nail polish and finger rings to prevent surgical infection. *Cochrane Database Syst Rev*, 2001(4): p. CD003325.

2. Auerbach, A.D., Chapter 20. Prevention of Surgical Site Infections. *Making Health Care Safer: A Critical Analysis of Patient Safety Practices*.

3. Barie, P.S., Surgical site infections: epidemiology and prevention. *Surg Infect (Larchmt)*, 2002. 3 Suppl 1: p. S9-21.

4. Belda, F.J., et al., Supplemental perioperative oxygen and the risk of surgical wound infection: a randomized controlled trial. *JAMA*, 2005. 294(16): p. 2035-42.

5. Bratzler, D.W. and P.M. Houck, Antimicrobial prophylaxis for surgery: An advisory statement from the National Surgical Infection Prevention Project. *The American Journal of Surgery*, 2005. 189(4): p. 395-404.

6. Bratzler, D.W. and D.R. Hunt, The surgical infection prevention and surgical care improvement projects: national initiatives to improve outcomes for patients having surgery. *Clin Infect Dis*, 2006. 43(3): p. 322-30.

7. Bucher, P., et al., Mechanical bowel preparation for elective colorectal surgery: a meta-analysis. *Arch Surg*, 2004. 139(12): p. 1359-64; discussion 1365.

8. Chow, T.T. and X.Y. Yang, Ventilation performance in operating theatres against airborne infection: review of research activities and practical guidance. *J Hosp Infect*, 2004. 56(2): p. 85-92.

9. Chura, J.C., A. Boyd, and P.A. Argenta, Surgical site infections and supplemental perioperative oxygen in colorectal surgery patients: a systematic review. *Surg Infect (Larchmt)*, 2007. 8(4): p. 455-61.

10. Dellinger, E.P., Preventing surgical-site infections: the importance of timing and glucose control. *Infect Control Hosp Epidemiol*, 2001. 22(10): p. 604-6.

11. Dellinger, E.P., Increasing inspired oxygen to decrease surgical site infection: time to shift the quality improvement research paradigm. *JAMA*, 2005. 294(16): p. 2091-2.

12. Dellinger, E.P., Roles of temperature and oxygenation in prevention of surgical site infection. *Surg Infect (Larchmt)*, 2006. 7(Suppl 3): p. s27-32.

13. Dellinger, E.P., What is the ideal time for administration of antimicrobial prophylaxis for a surgical procedure? *Ann Surg*, 2008. 247(6): p. 927-8.

14. Dellinger, E.P. and D.A. Anaya, Infectious and immunologic consequences of blood transfusion. *Crit*

<p>Care, 2004. 8 Suppl 2: p. S18-23.</p> <p>15. Dharan, S. and D. Pittet, Environmental controls in operating theatres. <i>J Hosp Infect</i>, 2002. 51(2): p. 79-84.</p> <p>16. Digison, M.B., A review of anti-septic agents for pre-operative skin preparation. <i>Plast Surg Nurs</i>, 2007. 27(4): p. 185-9; quiz 190-1.</p> <p>17. Edmiston, C.E., Jr., et al., Comparative of a new and innovative 2% chlorhexidine gluconate-impregnated cloth with 4% chlorhexidine gluconate as topical antiseptic for preparation of the skin prior to surgery. <i>Am J Infect Control</i>, 2007. 35(2): p. 89-96.</p> <p>18. Edwards, P.S., A. Lipp, and A. Holmes, Preoperative skin antiseptics for preventing surgical wound infections after clean surgery. <i>Cochrane Database Syst Rev</i>, 2004(3): p. CD003949.</p> <p>19. Greif, R., et al., Supplemental perioperative oxygen to reduce the incidence of surgical-wound infection. Outcomes Research Group. <i>N Engl J Med</i>, 2000. 342(3): p. 161-7.</p> <p>20. Kluytmans, J.A. and H.F. Wertheim, Nasal carriage of <i>Staphylococcus aureus</i> and prevention of nosocomial infections. <i>Infection</i>, 2005. 33(1): p. 3-8.</p> <p>21. Latham, R., et al., The association of diabetes and glucose control with surgical-site infections among cardiothoracic surgery patients. <i>Infect Control Hosp Epidemiol</i>, 2001. 22(10): p. 607-12.</p> <p>22. Leaper, D., Effects of local and systemic warming on postoperative infections. <i>Surg Infect (Larchmt)</i>, 2006. 7 Suppl 2: p. S101-3.</p> <p>23. Niel-Weise, B.S., J.C. Wille, and P.J. van den Broek, Hair removal policies in clean surgery: systematic review of randomized, controlled trials. <i>Infect Control Hosp Epidemiol</i>, 2005. 26(12): p. 923-8.</p> <p>24. Perl, T.M., et al., Intranasal mupirocin to prevent postoperative <i>Staphylococcus aureus</i> infections. <i>N Engl J Med</i>, 2002. 346(24): p. 1871-7.</p> <p>25. Pryor, K.O., et al., Surgical site infection and the routine use of perioperative hyperoxia in a general surgical population: a randomized controlled trial. <i>JAMA</i>, 2004. 291(1): p. 79-87.</p> <p>26. Tanner, J., K. Moncaster, and D. Woodings, Preoperative hair removal: a systematic review. <i>J Perioper Pract</i>, 2007. 17(3): p. 118-21, 124-32.</p> <p>27. Webster, J. and S. Osborne, Preoperative bathing or showering with skin antiseptics to prevent surgical site infection. <i>Cochrane Database Syst Rev</i>, 2007(2): p. CD004985.</p> <p>1c.9 Quote the Specific guideline recommendation (including guideline number and/or page number): There are no ratings for an SSI outcome measure. Associated processes are commented on above.</p> <p>1c.10 Clinical Practice Guideline Citation: N/A</p> <p>1c.11 National Guideline Clearinghouse or other URL: N/A</p> <p>1c.12 Rating of strength of recommendation (also provide narrative description of the rating and by whom): N/A</p> <p>1c.13 Method for rating strength of recommendation (If different from USPSTF system, also describe rating and how it relates to USPSTF): N/A</p> <p>1c.14 Rationale for using this guideline over others: N/A</p>	
<p>TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for <i>Importance to Measure and Report</i>?</p>	1
<p>Steering Committee: Was the threshold criterion, <i>Importance to Measure and Report</i>, met? Rationale:</p>	1 Y <input type="checkbox"/> N <input type="checkbox"/>
<p>2. SCIENTIFIC ACCEPTABILITY OF MEASURE PROPERTIES</p>	
<p>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)</p>	Eval Rating

2a. MEASURE SPECIFICATIONS	
<p>S.1 Do you have a web page where current detailed measure specifications can be obtained? S.2 If yes, provide web page URL:</p> <p>2a. Precisely Specified</p> <p>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 risk-adjusted Deep Incisional Surgical Site Infection (SSI) or Organ/Space SSI as defined by American College of Surgeons National Surgical Quality Improvement Program (ACS NSQIP), occurring within 30 days of any any of the listed CPT surgical procedures. The list of eligible CPT codes is attached.</p> <p>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 operation are included.</p> <p>2a.3 Numerator Details (<i>All information required to collect/calculate the numerator, including all codes, logic, and definitions</i>): Within 30 days of the index surgical procedure, either Deep incisional or Organ Space SSI or both are identified, as specifically defined by ACS NSQIP (concordant with CDC definitions) and reproduced below: Deep Incisional SSI: Deep Incision SSI is an infection that occurs within 30 days after the operation and the infection appears to be related to the operation and infection involved deep soft tissues (for example, fascial and muscle layers) of the incision and at least one of the following: Purulent drainage from the deep incision but not from the organ/space component of the surgical site; A deep incision spontaneously dehisces or is deliberately opened by a surgeon when the patient has at least one of the following signs or symptoms: fever (> 38 C), localized pain, or tenderness, unless site is culture-negative; An abscess or other evidence of infection involving the deep incision is found on direct examination, during reoperation, or by histopathologic or radiologic examination; Diagnosis of a deep incision SSI by a surgeon or attending physician. Organ/Space SSI: Organ/Space SSI is an infection that occurs within 30 days after the operation and the infection appears to be related to the operation and the infection involves any part of the anatomy (for example, organs or spaces), other than the incision, which was opened or manipulated during an operation and at least one of the following: Purulent drainage from a drain that is placed through a stab wound into the organ/space; Organisms isolated from an aseptically obtained culture of fluid or tissue in the organ/space; An abscess or other evidence of infection involving the organ/space that is found on direct examination, during reoperation, or by histopathologic or radiologic examination; Diagnosis of an organ/space SSI by a surgeon or attending physician.</p> <p>2a.4 Denominator Statement (<i>Brief, text description of the denominator - target population being measured</i>): Patients undergoing any of the specified list of eligible CPT surgical procedure codes. See separate attached list of eligible CPT codes.</p> <p>2a.5 Target population gender: Female, Male 2a.6 Target population age range: Any patient greater than or equal to 18 years of age</p> <p>2a.7 Denominator Time Window (<i>The time period in which cases are eligible for inclusion in the denominator</i>): 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.</p> <p>2a.8 Denominator Details (<i>All information required to collect/calculate the denominator - the target population being measured - including all codes, logic, and definitions</i>): Cases are collected so as to match ACS NSQIP inclusion and exclusion criteria, thereby permitting valid application of ACS NSQIP model-based risk adjustment. Participation in NSQIP is not a requirement- see 2a25.</p> <p>2a.9 Denominator Exclusions (<i>Brief text description of exclusions from the target population</i>): Major</p>	<p>2a- specs</p> <p>C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/></p>

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 transplant 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 (three):

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

2. 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".

3. Wound classification: defined by ACS NSQIP as follows.

Indicate whether the primary surgeon has classified the wound as:

(1) Clean: An uninfected operative wound in which no inflammation is encountered and the respiratory, alimentary, genital, or uninfected urinary tract is not entered. In addition, clean wounds are primarily closed and, if necessary, drained with closed drainage. Operative incisional wounds that follow nonpenetrating (blunt) trauma should be included in this category if they meet the criteria but are not otherwise excluded as major trauma. Examples of "Clean" cases include mastectomy, vascular bypass graft, exploratory laparotomy, hernia repair, thyroidectomy, total hip or knee replacement.

Note: Placement of any drain at the time of surgery does not change the classification of the wound.

(2) Clean/Contaminated: An operative wound in which the respiratory, alimentary, genital, or urinary tracts are entered under controlled conditions and without unusual contamination. Specifically, operations involving the biliary tract, appendix, vagina, and oropharynx are included in this category, provided no evidence of infection or major break in technique is encountered. Examples of "Clean/Contaminated" cases include cholecystectomy, colectomy, colostomy reversals, roux-en-Y, laryngectomy, routine appendectomy, small bowel resection, transurethral resection of the prostate, Whipple pancreaticoduodenectomy.

(3) Contaminated: Open, fresh, accidental wounds. In addition, operations with major breaks in sterile technique or gross spillage from the gastrointestinal tract, and incisions in which acute, nonpurulent inflammation is encountered including necrotic tissue without evidence of purulent drainage (for example dry gangrene) are included in this category. Examples of "Contaminated" cases include appendectomy for inflamed appendicitis, bile spillage during cholecystectomy, or open cardiac massage. Examples of major break in sterile technique include but are not limited to non-sterile equipment or debris found in the operative field.

(4) Dirty/Infected: Old traumatic wounds with retained devitalized tissue and those that involve existing clinical infection or perforated viscera. This definition suggests that the organisms causing postoperative infection were present in the operative field before the operation. Examples of "Dirty/Infected" cases include excision and drainage of abscess, perforated bowel, peritonitis, ruptured appendix.

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 ; 254,200 acceptable records from 211 hospitals (mean/hospital=1,205) were analyzed. Otherwise eligible records were excluded either because of missing values for critical variables or if the primary CPT code could not be categorized into 1 of 136 pre-established "CPT Risk 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).

For this measure, Surgical site infection (SSI) was defined as either a deep SSI or an organ space SSI, according to ACS NSQIP definitions (concordant with CDC); please see specification 2a3. Of the 254,200 patients, 4,532 (1.8%) experienced an SSI 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 the defined SSI outcome 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 12 predictors for inclusion in the model. In order of inclusion these variables were: Log Odds CPT Group ("CPT Risk"), ASA Class, Wound Class, Age Group, Steroid Use, BMI Class, Smoking, Disseminated Cancer, Emergent, Pneumonia, Weight Loss, and Alcohol Use. The c-statistic was 0.810 and the Hosmer-Lemeshow was 0.043. 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 three selected variables (CPT Risk, ASA Class, and Wound Class), the c-statistic was 0.806 and the Hosmer-Lemeshow was 0.002). These three predictor variables are specifically defined under item 2a11- "stratification / variables". The use of these three 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 50 statistical outliers (26 low outliers and 24 high outliers). When the same three 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), 49 outliers were detected (22 low outliers and 27 high outliers). Thus, using a 95% confidence interval, logistic and hierarchical models identified between 11% and 13% of hospitals as high outliers. When the logistic model parameters were applied to an independent validation data set (the 2007 Data file composed of 201,837 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=0.801).

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 0.00156. 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 of 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: 275, 428, 641, 961, and 1495, respectively. A reliability of 0.4 is generally considered minimally acceptable, corresponding to an accrual of 428 cases for the minimum.

For the table detailing CPT codes, risk factors, odds ratios, and parameters for the logistic model, please see attachment ("Parsimonious Model for SSI")

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 be 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_SSI_to_NQF_081010.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 428 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 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_SSI_to_NQF_081010-63417044040339737.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: Chiropractor, 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 extremely 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):*
 See Risk-adjustment Methodology in Specifications.
 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

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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 SSI. 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 0.00156. Using a minimum acceptable reliability for SSI of 0.4, the proportions of hospitals likely to have a “minimally acceptable” reliability estimate are as follows: 89.3% of all U.S. hospitals and 92.4% 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.

Reliability__	RequiredCases__	%U..S.HospMtgRqrmnt*	%NSQIPHospMtg Rqrmnt+
0.3	275	94.0	94.8
0.4	428	89.3	92.4
0.5	641	84.8	82.0
0.6	961	79.7	65.9
0.7	1495	73.1	32.7

*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 and section on Reliability above. 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.

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2d. Exclusions Justified

2d.1 Summary of Evidence supporting exclusion(s):
 The supplied attached CPT code list includes surgeries that would be appropriate for measurement of quality and it would be unreasonable to provide documentation on the thousands of inapplicable codes. In

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<p>addition, we have explicitly excluded surgeries related to major 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).</p> <p>2d.2 Citations for Evidence: As exclusions are based on reasoned argument rather empirical findings neither published evidence nor research findings are provided.</p> <p>2d.3 Data/sample (description of data/sample and size): N/A</p> <p>2d.4 Analytic Method (type analysis & rationale): N/A</p> <p>2d.5 Testing Results (e.g., frequency, variability, sensitivity analyses): N/A</p>	<p>NA <input type="checkbox"/></p>
<p>2e. Risk Adjustment for Outcomes/ Resource Use Measures</p> <p>2e.1 Data/sample (description of data/sample and size): The data sample is derived from the most recent ACS NSQIP Data file. The SSI model used 254,200 patient records. Future models can be constructed using the most recent Data file and data from measure participants. 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 alone. Please see also Risk Adjustment Methodology section.</p> <p>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.</p> <p>2e.3 Testing Results (risk model performance metrics): See Risk-adjustment Methodology in Specifications. A parsimonious predictor set was constructed from the full step-wise set. Step-wise logistic regression (P<0.05 for inclusion), which selected from a total of 26 predictors, identified 12 predictors for inclusion in the model. In order of inclusion these variables were: CPT Risk, ASA Class, Wound Class, Age Group, Steroid Use, BMI Class, Smoking, Disseminated Cancer, Emergent, Pneumonia, Weight Loss, and Alcohol Use. The c-statistic was 0.810 and the Hosmer-Lemeshow was 0.043. 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 three selected variables (CPT Risk, ASA Class, and Wound Class), which is proposed as the risk-adjustment model, the c-statistic was 0.806 and the Hosmer-Lemeshow was 0.002). The use of these three 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 50 statistical outliers (26 low outliers and 24 high outliers). When the same three 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), 49 outliers were detected (22 low outliers and 27 high outliers). Thus, using a 95% confidence interval, logistic and hierarchical models identified between 11% and 13% of hospitals as high outliers.</p> <p>2e.4 If outcome or resource use measure is not risk adjusted, provide rationale: risk adjusted</p>	<p>2e C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/> NA <input type="checkbox"/></p>
<p>2f. Identification of Meaningful Differences in Performance</p>	<p>2f C <input type="checkbox"/></p>

<p>2f.1 Data/sample from Testing or Current Use (<i>description of data/sample and size</i>): See Risk-adjustment Methodology in Specifications.</p> <p>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.</p> <p>2f.3 Provide Measure Scores from Testing or Current Use (<i>description of scores, e.g., distribution by quartile, mean, median, SD, etc.; identification of statistically significant and meaningfully differences in performance</i>): See Risk-adjustment strategy Testing Results</p>	<p>P <input type="checkbox"/></p> <p>M <input type="checkbox"/></p> <p>N <input type="checkbox"/></p>
<p>2g. Comparability of Multiple Data Sources/Methods</p> <p>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% vs. ACS NSQIP complication rate, 28%). Using administrative or claims data may result in significant differences in risk-adjusted outcomes than using clinical data.</p> <p>Steinberg, S.M., et al., Comparison of risk adjustment methodologies in surgical quality improvement. Surgery, 2008. 144(4): p. 662-7; discussion 662-7.</p> <p>2g.2 Analytic Method (<i>type of analysis & rationale</i>): see above</p> <p>2g.3 Testing Results (<i>e.g., correlation statistics, comparison of rankings</i>): see above</p>	<p>2g</p> <p>C <input type="checkbox"/></p> <p>P <input type="checkbox"/></p> <p>M <input type="checkbox"/></p> <p>N <input type="checkbox"/></p> <p>NA <input type="checkbox"/></p>
<p>2h. Disparities in Care</p> <p>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.</p> <p>2h.2 If disparities have been reported/identified, but measure is not specified to detect disparities, provide follow-up plans: 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.</p>	<p>2h</p> <p>C <input type="checkbox"/></p> <p>P <input type="checkbox"/></p> <p>M <input type="checkbox"/></p> <p>N <input type="checkbox"/></p> <p>NA <input type="checkbox"/></p>
<p>TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for <i>Scientific Acceptability of Measure Properties</i>?</p>	<p>2</p>
<p>Steering Committee: Overall, to what extent was the criterion, <i>Scientific Acceptability of Measure Properties</i>, met? Rationale:</p>	<p>2</p> <p>C <input type="checkbox"/></p> <p>P <input type="checkbox"/></p> <p>M <input type="checkbox"/></p> <p>N <input type="checkbox"/></p>
3. USABILITY	
<p>Extent to which intended audiences (e.g., consumers, purchasers, providers, policy makers) can understand</p>	<p>Eval</p>

the results of the measure and are likely to find them useful for decision making. (evaluation criteria)	Rating
<p>3a. Meaningful, Understandable, and Useful Information</p> <p>3a.1 Current Use: In use</p> <p>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. Used within existing ACS NSQIP program for most recent annual reports (confidential reporting to participants).</p> <p>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): Current ACS NSQIP semiannual reporting: roughly 300 participating institutions currently receiving measure performance feedback.</p> <p>Testing of Interpretability (Testing that demonstrates the results are understood by the potential users for public reporting and quality improvement)</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>3a.5 Methods (e.g., focus group, survey, QI project): The data for the above study was ACS NSQIP data collected over 3 years (2005-2007) from 118 hospitals, and was analyzed as longitudinal changes in O/E ratios.</p> <p>3a.6 Results (qualitative and/or quantitative results and conclusions): See above section on 'Testing of interpretability" - Data Sample</p>	<p>3a C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/></p>
<p>3b/3c. Relation to other NQF-endorsed measures</p> <p>3b.1 NQF # and Title of similar or related measures: NQF #0299, Surgical Site Infection (Centers for Disease Control, Centers for Medicare and Medicaid Services).</p>	
<p>(for NQF staff use) Notes on similar/related endorsed or submitted measures:</p>	
<p>3b. Harmonization If this measure is related to measure(s) already endorsed by NQF (e.g., same topic, but different target</p>	<p>3b C <input type="checkbox"/></p>

<p>population/setting/data source <u>or</u> different topic but same target population): 3b.2 Are the measure specifications harmonized? If not, why? The measures were not harmonized due to the different intents for the measures. The CDC SSI measure was developed for surveillance and employs stratification of cases rather than risk adjustment. Thus, raw unadjusted rates are used in each stratified sample. The current ACS NSQIP SSI measure is directed towards accountability and employs an inclusive random sample with risk adjustment. To reiterate, because of the separate aims of the measures (surveillance versus accountability) the measures have not been harmonized. Another issue is that the specifications for the CDC measure include surgical site infections occurring within one year after the procedure if an implant is in place. We are not able to harmonize with this additional numerator due to the difficulty in collecting accurate data on SSIs up to one year after the procedure.</p>	P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/> NA <input type="checkbox"/>
<p>3c. Distinctive or Additive Value 3c.1 Describe the distinctive, improved, or additive value this measure provides to existing NQF-endorsed measures: This proposed measure is related to the endorsed NQF measure, but is different in several aspects. As briefly mentioned above in the prior item, first, the CDC measure appears geared more toward surveillance than quality improvement, since it is based on the reporting of stratified percentages of SSI's per procedure. This reporting method is not as conducive to quality improvement as risk adjusted O/E ratio reporting as proposed here. The CDC measure is stratified according to several risk factors, whereas our proposed measure is risk-adjusted. The experience of the ACS NSQIP is that risk-adjustment is a more robust method for hospitals to accomplish targeted quality improvement, as it facilitates comparisons of each hospital's own performance over time and benchmarking with other hospitals. In addition, the specifications, including follow-up horizon, are rigorously implemented in this proposed measure to optimize implementation, control burden, and provide information targeted to specific quality improvement opportunities.</p> <p>5.1 If this measure is similar to measure(s) already endorsed by NQF (i.e., on the same topic and the same target population), Describe why it is a more valid or efficient way to measure quality: Risk adjustment approach increases validity, rigorous definitions and experience with variables facilitate effective improvement. Please see 3.c.1. also.</p>	3c C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/> NA <input type="checkbox"/>
<p>TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for <i>Usability</i>?</p>	3
<p>Steering Committee: Overall, to what extent was the criterion, <i>Usability</i>, met? Rationale:</p>	3 C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/>
<p>4. FEASIBILITY</p>	
<p>Extent to which the required data are readily available, retrievable without undue burden, and can be implemented for performance measurement. (evaluation criteria)</p>	Eval Rating
<p>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)</p>	4a C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/>
<p>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.</p>	4b C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/>

<p>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.</p>	
<p>4c. Exclusions</p> <p>4c.1 Do the specified exclusions require additional data sources beyond what is required for the numerator and denominator specifications? No</p> <p>4c.2 If yes, provide justification.</p>	<p>4c C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/> NA <input type="checkbox"/></p>
<p>4d. Susceptibility to Inaccuracies, Errors, or Unintended Consequences</p> <p>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.</p>	<p>4d C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/></p>
<p>4e. Data Collection Strategy/Implementation</p> <p>4e.1 Describe what you have learned/modified as a result of testing and/or operational use of the measure regarding data collection, availability of data/missing data, timing/frequency of data collection, patient confidentiality, time/cost of data collection, other feasibility/ implementation issues: 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 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. 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 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.</p> <p>4e.2 Costs to implement the measure (<i>costs of data collection, fees associated with proprietary measures</i>): 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 do not have to be ACS NSQIP hospitals in order to participate in the proposed measure, as described elsewhere in these materials.</p> <p>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 three risk adjustment variables. Furthermore, sample size is such that reliable results can be achieved after collection of 400-500 cases.</p> <p>4e.4 Business case documentation: A business case has not been developed for this measure; however, literature results show that the direct costs for each surgical site infection can range from \$6,000 to</p>	<p>4e C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/></p>

<p>\$29,000 and require an extra 7 days of hospitalization per infected patient. The previously quoted work on improvement in NSQIP indicates that large numbers of events could be avoided for a large hospital (>200 events avoided).</p>	
<p>TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for <i>Feasibility</i>?</p>	<p>4</p>
<p>Steering Committee: Overall, to what extent was the criterion, <i>Feasibility</i>, met? Rationale:</p>	<p>4 C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/></p>
<p style="text-align: center;">RECOMMENDATION</p>	
<p>(for NQF staff use) Check if measure is untested and only eligible for time-limited endorsement.</p>	<p>Time-limited <input type="checkbox"/></p>
<p>Steering Committee: Do you recommend for endorsement? Comments:</p>	<p>Y <input type="checkbox"/> N <input type="checkbox"/> A <input type="checkbox"/></p>
<p style="text-align: center;">CONTACT INFORMATION</p>	
<p>Co.1 Measure Steward (Intellectual Property Owner) Co.1 Organization American College of Surgeons, 633 N. Saint Clair St., Chicago, Illinois, 60611-3211</p> <p>Co.2 Point of Contact Karen, Richards, Adminstrative Director, Division of Research and Optimal Patient Care, krichards@facs.org, 312-202-5282-</p>	
<p>Measure Developer If different from Measure Steward Co.3 Organization American College of Surgeons, 633 N. Saint Clair St., Chicago, Illinois, 60611-3211</p> <p>Co.4 Point of Contact Karen, Richards, Adminstrative Director, Division of Research and Optimal Patient Care, krichards@facs.org, 312-202-5282-</p>	
<p>Co.5 Submitter If different from Measure Steward POC Karen, Richards, Adminstrative Director, Division of Research and Optimal Patient Care, krichards@facs.org, 312-202-5282-, American College of Surgeons</p>	
<p>Co.6 Additional organizations that sponsored/participated in measure development I, Bruce Hall, am submitting revisions on behalf of the ACS.</p>	
<p style="text-align: center;">ADDITIONAL INFORMATION</p>	
<p>Workgroup/Expert Panel involved in measure development Ad.1 Provide a list of sponsoring organizations and workgroup/panel members' names and organizations. Describe the members' role in measure development. American College of Surgeons, Area of Continuous Quality Improvement</p> <p>Clifford Ko Karen Richards Bruce Hall Mark Cohen Mehul Raval Mira Shiloach Angela Ingraham Stanley Frencher</p>	

<p>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.</p>
<p>Ad.2 If adapted, provide name of original measure: n/a Ad.3-5 If adapted, provide original specifications URL or attachment</p>
<p>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?</p>
<p>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 * 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</p>
<p>Ad.11 -13 Additional Information web page URL or attachment: Attachment BP Guideline SSI-633888790679944712.pdf</p>
<p>Date of Submission (MM/DD/YY): 08/10/2010</p>