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-002-10 **NQF Project:** Patient Safety Measures
MEASURE DESCRIPTIVE INFORMATION
De.1 **Measure Title:** National Healthcare Safety Network (NHSN) Surgical Site Infection (SSI) Outcome Measure
De.2 **Brief description of measure***:* Standardized Infection Ratio (SIR) of deep incisional and organ/space Surgical Site Infections (SSI) at the primary incision site among patients undergoing selected inpatient operative procedure categories.
1.1-2 **Type of Measure:** Outcome De.3 **If included in a composite or paired with another measure, please identify composite or paired measure**
De.4 **National Priority Partners Priority Area:** Safety De.5 **IOM Quality Domain**: Safety De.6 **Consumer Care Need:**

CONDITIONS FOR CONSIDERATION BY NQF	
Four conditions must be met before proposed measures may be considered and evaluated for suitability as voluntary consensus standards:	**NQF Staff**
A. The measure is in the public domain or an intellectual property (measure steward agreement) is signed. *Public domain only applies to governmental organizations. All non-government organizations must sign a measure steward agreement even if measures are made publicly and freely available.* A.1 **Do you attest that the measure steward holds intellectual property rights to the measure and the right to use aspects of the measure owned by another entity (e.g., risk model, code set)?** Yes A.2 **Indicate if Proprietary Measure** (*as defined in measure steward agreement*)**:** A.3 **Measure Steward Agreement:** Government entity and in the public domain - no agreement necessary A.4 **Measure Steward Agreement attached:**	**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 both public reporting and 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.1**Testing:** Yes, fully developed and tested D.2 **Have NQF-endorsed measures been reviewed to identify if there are similar or related measures?** Yes	**D** **Y**☐ **N**☐
(for NQF staff use**)** **Have all conditions for consideration been met?** **Staff Notes to Steward** (*if submission returned*)**:**	**Met** **Y**☐ **N**☐
Staff Notes to Reviewers (*issues or questions regarding any criteria*)**:**	
Staff Reviewer Name(s):	

TAP/Workgroup Reviewer Name:	
Steering Committee Reviewer Name:	
1. IMPORTANCE TO MEASURE AND REPORT	
Extent to which the specific measure focus is important to making significant gains in health care quality (safety, timeliness, effectiveness, efficiency, equity, patient-centeredness) and improving health outcomes for a specific high impact aspect of healthcare where there is variation in or overall poor performance. *Measures must be judged to be important to measure and report in order to be evaluated against the remaining criteria.* (evaluation criteria) **1a. High Impact**	Eval Rating
(for NQF staff use) Specific NPP goal:	
1a.1 Demonstrated High Impact Aspect of Healthcare: Affects large numbers, Leading cause of morbidity/mortality, Frequently performed procedure, Severity of illness, Patient/societal consequences of poor quality **1a.2** **1a.3 Summary of Evidence of High Impact:** Estimated to account for 20% of all HAIs1 290,485 estimated SSIs/yr2 Estimated 8,205 deaths associated with SSIs each year1 Estimated 11% of all deaths occurring in intensive care units are associated with SSIs1 $34,670 medical cost/SSI2 Total >$10 billion attributable to SSI in U.S. each year2 **1a.4 Citations for Evidence of High Impact:** 1Klevens RM, Edwards JR, et al. Estimating healthcare-associated infection and deaths in U.S. hospitals, 2002. Public Health Reports 2007; 122:160-166. 2 Scott, RD. The Direct Medical Costs of Healthcare-Associated Infections in U.S. Hospitals and the Benefits of Prevention. http://www.cdc.gov/ncidod/dhqp/pdf/Scott_CostPaper.pdf accessed April 12, 2010.	**1a** **C**☐ **P**☐ **M**☐ **N**☐
1b. Opportunity for Improvement	**1b** **C**☐

1b.1 Benefits (improvements in quality) envisioned by use of this measure: It is envisioned the use of this measure will promote SSI prevention activities which will lead to improved patient outcomes including reduction of avoidable medical costs, and patient morbidity and mortality. Prevention activities include but are not limited to, appropriate ordering, administration and discontinuation of preoperative prophylactic antibiotics, proper surgical site preparation, optimal glucose control in certain surgical patients, maintenance of patient normothermia during surgery and SSI surveillance with feedback of surgeon-specific SSI data to surgeons.

1b.2 Summary of data demonstrating performance gap (variation or overall poor performance) across providers:
When SIRs are compared over time, assessment of performance can be made.

1b.3 Citations for data on performance gap:

1b.4 Summary of Data on disparities by population group:

1b.5 Citations for data on Disparities:

P☐ M☐ N☐

1c. Outcome or Evidence to Support Measure Focus

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

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

1c.4 Summary of Evidence (*as described in the criteria; for outcomes, summarize any evidence that healthcare services/care processes influence the outcome*)**:**
Two guidelines address the prevention of SSI:
1) Strategies to Prevent Surgical Site Infections in Acute Care Hospitals, 2008 (Society for Healthcare Epidemiology of America) and
2) The Guideline for Prevention of Surgical Site Infection, 1999 published by the Healthcare Infection Control Practices and Advisory Committee (HICPAC).
Both of these publications cite multiple studies (over 500 in the HICPAC guideline), scientific evidence, and recommendations of other prevention organizations which show that actions taken before, and at the time of, surgery can decrease the rate of SSI. The publications provide recommendations for healthcare practitioners and infection preventionists that can be implemented in efforts to reduce the incidence of SSIs.

1c.5 Rating of strength/quality of evidence (*also provide narrative description of the rating and by whom***):**
The Guideline for Prevention of Surgical Site Infection, 1999, provides recommendations concerning reduction of surgical site infection risk. Each recommendation was categorized on the basis of existing scientific data, theoretical rationale, and applicability. See Additional Information, Ad.11.

1c.6 Method for rating evidence: See Ic.5.

1c.7 Summary of Controversy/Contradictory Evidence:

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

1c.9 Quote the Specific guideline recommendation (*including guideline number and/or page number***):**
" Additionally, the NNIS risk index does not adequately discriminate the SSI risk for all types of

1c
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operations.27,410 It seems likely that a combination of risk factors specific to patients undergoing an operation will be more predictive. A few studies have been performed to develop procedure specific risk indices218,411-414 and research in this area continues within CDC's NNIS system." The Guideline for Prevention of Surgical Site Infection, 1999, HICPAC, pp 264-265. **1c.10 Clinical Practice Guideline Citation:** 1) Strategies to Prevent Surgical Site Infections in Acute Care Hospitals, 2008 (Society for Healthcare Epidemiology of America) http://www.journals.uchicago.edu/doi/full/10.1086/591064 Accessed April 26, 2010. 2) The Guideline for Prevention of Surgical Site Infection, 1999, HICPAC. http://www.cdc.gov/ncidod/dhqp/pdf/guidelines/SSI.pdf Accessed April 26, 2010. **1c.11 National Guideline Clearinghouse or other URL:** **1c.12 Rating of strength of recommendation (***also provide narrative description of the rating and by whom***):** See above. **1c.13 Method for rating strength of recommendation** (*If different from* USPSTF system*, also describe rating and how it relates to USPSTF)***:** **1c.14 Rationale for using this guideline over others:** These utilized guidelines are published by two internationally recognized organizations, Centers for Disease Control and Prevention and Society for Healthcare Epidemiology of America.	
TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for *Importance to Measure and Report?*	**1**
Steering Committee: Was the threshold criterion, *Importance to Measure and Report***, met?** **Rationale:**	**1** **Y☐** **N☐**
2. SCIENTIFIC ACCEPTABILITY OF MEASURE PROPERTIES	
Extent to which the measure, as specified, produces consistent (reliable) and credible (valid) results about the quality of care when implemented. (evaluation criteria)	Eval Rating
2a. MEASURE SPECIFICATIONS	
S.1 Do you have a web page where current detailed measure specifications can be obtained? **S.2 If yes, provide web page URL:** **2a. Precisely Specified**	
2a.1 Numerator Statement (*Brief, text description of the numerator - what is being measured about the target population, e.g. target condition, event, or outcome***):** Total number of observed deep incisional primary (DIP) and organ/space SSIs detected during admission or readmission among patients who have undergone the following inpatient NHSN operative procedure categories: 1. Abdominal Aortic Aneurysm Repair (AAA) 2. Coronary Artery Bypass Graft with both chest and donor site incisions (CBGB); only SSI from the chest (primary site) are included 3. Coronary Artery Bypass Graft with chest incision only (CBGC) 4. Colon surgery (COLO)	**2a-specs** **C☐** **P☐** **M☐** **N☐**

5. Hip Arthroplasty (HPRO)
6. Abdominal Hysterectomy (HYST)
7. Knee Arthroplasty (KPRO)
8. Peripheral Vascular Bypass surgery (PVBY)
9. Rectal surgery (REC)
10. Vaginal Hysterectomy (VHYS)

2a.2 Numerator Time Window (*The time period in which cases are eligible for inclusion in the numerator***):**
Cases are included if the date of the procedure to which the SSI is attributed is a month in which that procedure was selected for surveillance (i.e., if SSI surveillance for COLO procedures is performed for January, all SSIs as described in the numerator statement, 2a.1, that occurred in COLOs performed in January are included; Note: SSI may occur in different month than the month of the procedure). With low numbers of expected infections, it will be necessary to have a data sample of sufficient size to generate meaningful SIRs, thus the time window will be a period greater than monthly.

2a.3 Numerator Details (*All information required to collect/calculate the numerator, including all codes, logic, and definitions***):**
1) Definition of NHSN Operative Procedure: A procedure:
a) is performed on a patient who is an NHSN inpatient or an NHSN outpatient
b) takes place during an operation (defined as a single trip to the operating room (OR) where a surgeon makes at least one incision through the skin or mucous membrane, including laparoscopic approach, and closes the incision before the patient leaves the OR; and
c) is included in Table 1 NHSN Operative Procedure Category Mappings to ICD9-CM Codes included as attachment under Additional Information. http://www.cdc.gov/nhsn/PDFs/ICD-9-cmCODEScurrent.pdf
2) Definition of NHSN Inpatient: A patient whose date of admission to the healthcare facility and the date of discharge are different calendar days.
3) Definition of NHSN Operating Room (OR): A patient care area that meets the American Institute of Architects (AIA) criteria for an operating room7. This may include an operating room, C-Section room, interventional radiology room, or a cardiac catheterization lab.
4) Definition of Implant: A nonhuman-derived object, material, or tissue that is permanently placed in a patient during an operative procedure and is not routinely manipulated for diagnostic or therapeutic purposes. Examples include: porcine or synthetic heart valves, mechanical heart, metal rods, mesh, sternal wires, screws, cements, and other devices.
5) Definition of SSI:
a) A deep incisional SSI must meet one of the following criteria:
i) Infection occurs within 30 days after the operative procedure if no implant is left in place or within one year if implant is in place and the infection appears to be related to the operative procedure AND
ii) involves deep soft tissues (e.g., fascial and muscle layers) of the incision AND
iii) patient has at least one of the following:
a. purulent drainage from the deep incision but not from the organ/space component of the surgical site
b. a deep incision spontaneously dehisces or is deliberately opened by a surgeon and is culture-positive or not cultured and the patient has at least one of the following signs or symptoms: fever (>38°C), or localized pain or tenderness. A culture-negative finding does not meet this criterion.
c. an abscess or other evidence of infection involving the deep incision is found on direct examination, during reoperation, or by histopathologic or radiologic examination
d. diagnosis of a deep incisional SSI by a surgeon or attending physician.
b) An organ/space SSI must meet one of the following criteria:
i) Infection occurs within 30 days after the operative procedure if no implant is left in place or within one year if implant is in place and the infection appears to be related to the operative procedure AND
ii) infection involves any part of the body, excluding the skin incision, fascia, or muscle layers, that is opened or manipulated during the operative procedure AND
iii) patient has at least one of the following:
a. purulent drainage from a drain that is placed through a stab wound into the organ/space
b. organisms isolated from an aseptically obtained culture of fluid or tissue in the organ/space
c. 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

d. diagnosis of an organ/space SSI by a surgeon or attending physician.

NOTE: Deep Incisional Primary (DIP) – a deep incisional SSI that is identified in a primary incision in a patient that has had an operation with one or more incisions (e.g., chest incision for CBGB but not donor site incision for CBGB)

REPORTING INSTRUCTIONS:
- Classify infection that involves both superficial and deep incision sites as deep incisional SSI.
- Occasionally an organ/space infection drains through the incision. Such infection generally does not involve reoperation and is considered a complication of the incision. Therefore, classify it as a deep incisional SSI.
- Report mediastinitis following cardiac surgery that is accompanied by osteomyelitis as SSI-MED rather than SSI-BONE.
- If meningitis (MEN) and a brain abscess (IC) are present together after operation, report as SSI-IC.
- Report CSF shunt infection as SSI-MEN if it occurs = 1 year of placement; if later or after manipulation/access, it is considered CNS-MEN and is not reportable under this manual.
- Report spinal abscess with meningitis as SSI-MEN following spinal surgery
- Episiotomy is not considered an operative procedure in NHSN.

NOTE: Specific sites of an organ/space SSI are found included as attachment under Additional Information. See Ad.11

NOTE: If a patient has several NHSN operative procedures prior to an infection, report the operative procedure code of the operation that was performed most closely in time prior to the infection date, unless there is evidence that the infection is associated with a different operation.

NOTE: If more than one NHSN operative procedure was done through a single incision, attempt to determine the procedure that is thought to be associated with the infection. If it is not clear (as is often the case when the infection is a superficial incisional SSI), or if the infection site being reported is not an SSI, use the NHSN Principal Operative Procedure Selection Lists to select which operative procedure to report. (Table of NHSN Principal Operative Procedure Selection Lists included as attachment under Additional Information. See Ad.11)

6) Surgical Site Infection Form (CDC 57.120) must be completed. This form is included as attachment under Additional Information. http://www.cdc.gov/nhsn/forms/57.120_SSI_BLANK.pdf

7) Date of event: In the case of an infection event, the date when the first signs or symptoms of infection (clinical evidence) appeared, or the date the specimen used to meet the infection criterion was collected, whichever came first.

8) Facility-specific data :

a) Bed size

b) Medical school affiliation: Yes or No

2a.4 Denominator Statement (*Brief, text description of the denominator - target population being measured***):**
Using multivariable procedure-specific logistic regression models, the expected number of SSIs is obtained. These expected numbers are summed across strata (e.g., procedure categories, surgeons, etc) and used as the denominator of this measure (see also 2a.8).

2a.5 Target population gender: Female, Male
2a.6 Target population age range: Patients of all ages are eligible

2a.7 Denominator Time Window (*The time period in which cases are eligible for inclusion in the denominator***):**
The probability of SSI for each procedure category is calculated using the corresponding procedure-specific logistic regression model (see 2a. 15). The probabilities are summed for the period to yield the expected number of SSIs (denominator). The expected number of SSIs will be influenced by the number of operative procedures in the facility and the distribution of the factors relevant to each procedure's logistic model. A data sample of sufficient size will be necessary to generate meaningful SIRs therefore the time window may vary.

2a.8 Denominator Details (*All information required to collect/calculate the denominator - the target*

population being measured - including all codes, logic, and definitions):
Data required to calculate the denominator:
1) Inpatient operative procedure data for each operative procedure for which SSI surveillance was performed during the period (determined by ICD-9-CM procedure code applied to table of NHSN Operative Procedure Category Mappings to ICD-9-CM included as attachment under Additional Information. http://www.cdc.gov/nhsn/PDFs/ICD-9-cmCODEScurrent.pdf
2) Parameter estimates for operative procedure-specific logistic regression models are needed to calculate the expected number of SSIs. See 2a.15 attachment.
3) Completion of NHSN Denominator for Procedure Form (CDC 57.121) included as attachment under Additional Information. http://www.cdc.gov/nhsn/forms/57.121_DenomProc_BLANK.pdf
4) Dependent on the operative procedure, the following candidate variables may need to be identified:
a) Duration of procedure: The interval in hours and minutes between the skin incision and skin closure.
b) Wound class: An Assessment of the degree of contamination of a surgical wound at the time of the operation. The wound class system used in NHSN is an adaptation of the American College of Surgeons wound classification schema. Wounds are divided into four classes:
i) Clean: An uninfected operative wound in which no inflammation is encountered and the respiratory, alimentary, genital, or uninfected urinary tracts are 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.
ii) Clean-Contaminated: Operative wounds 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.
iii) Contaminated: Open, fresh, accidental wounds. In addition, operations with major breaks in sterile technique (e.g., open cardiac massage) or gross spillage from the gastrointestinal tract, and incisions in which acute, nonpurulent inflammation is encountered are included in this category.
iv) Dirty or Infected: Includes 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.
c) Patient Age: This will be calculated by the system when date of birth and date of procedure are entered.
d) Patient Gender: Female, Male or Other
e) American Society of Anesthesia Classification of Physical Status (ASA): Assigned preoperatively at the time of surgery as assessment of patient's physical condition:
i) Normally healthy patient
ii) Patient with mild systemic disease
iii) Patient with severe systemic disease that is not incapacitating
iv) Patient with an incapacitating systemic disease that is a constant threat to life
v) Moribund patient who is not expected to survive for 24 hours with or without the operation
f) Emergency status- non-elective, unscheduled operative procedure.
g) Endoscope use- Yes or No: Entire operative procedure was performed using an endoscope/laparoscope.
h) Primary vs. revision and total vs. partial statuses-
i) HPRO- Identify which one of the following applies: Total Primary; Partial Primary; Total Revision; or Partial Revision
ii) KPRO- Identify which one of the following applies: Total Primary; or Total or Partial Revision
i) Facility-specific data :
i) Bed size
ii) Medical school affiliation: Yes or No

2a.9 Denominator Exclusions (*Brief text description of exclusions from the target population***):** None

2a.10 Denominator Exclusion Details (*All information required to collect exclusions to the denominator, including all codes, logic, and definitions***):**
None

2a.11 Stratification Details/Variables (*All information required to stratify the measure including the stratification variables, all codes, logic, and definitions***):**
None

2a.12-13 Risk Adjustment Type: SIR is an indirect standardization method for summarizing HAI experience across any number of stratified groups of data.

2a.14 Risk Adjustment Methodology/Variables (*List risk adjustment variables and describe conceptual models, statistical models, or other aspects of model or method***):**

The models were developed through step-wise logistic regression from a set of potential predictors shown in section 2a.8.

2a.15-17 Detailed risk model available Web page URL or attachment: Attachment NHSN SSI Models for SCIP procedures for NQF.xlsx

2a.18-19 Type of Score: Ratio
2a.20 Interpretation of Score:
2a.21 Calculation Algorithm (*Describe the calculation of the measure as a flowchart or series of steps***):**
The SIR is calculated as follows:
1. Identify the number of observed SSIs for each operative procedure category selected for surveillance
2. Sum these numbers for the observed SSI total.
3. For every patient undergoing the operative procedure in the period, calculate the probability of SSI using the patient data and parameter estimates of the factors in the applicable model.
4. Sum the probabilities to obtain the total expected number of SSI.
5. Divide the total number of observed SSIs by the total number of expected SSIs for the resulting SIR.

(The NHSN analysis tool will perform the calculations once all necessary data has been entered.)

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

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

2a.24 Data Source (*Check the source(s) for which the measure is specified and tested)*
Electronic clinical data, Electronic Health/Medical Record, Lab data, Paper medical record/flow-sheet, Special or unique data

2a.25 Data source/data collection instrument (*Identify the specific data source/data collection instrument, e.g. name of database, clinical registry, collection instrument, etc.***):**
1) NHSN SSI Event form (CDC 57.120)
2) NHSN Denominator for Procedure form (CDC 57.121)

2a.26-28 Data source/data collection instrument reference web page URL or attachment: URL http://www.cdc.gov/nhsn/forms/57.120_SSI_BLANK.pdf, http://www.cdc.gov/nhsn/forms/57.121_DenomProc_BLANK.pdf

2a.29-31 Data dictionary/code table web page URL or attachment: Attachment 2a29 Data Dictionary-634082211083812400.docx

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

tested)
Facility/Agency, Population: national, Population: states

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

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

TESTING/ANALYSIS

2b. Reliability testing

2b.1 Data/sample *(description of data/sample and size)***:** The logistic regression models used in the SIR calculations were based on data from 805 facilities. We conclude for most of the procedure categories, the data are robust enough to use for determining the expected number of SSIs. For a few of the categories with relatively smaller numbers of reported procedures, additional data may be needed to improve the models.

The SIR doesn't itself predict risk, but the underlying multivariable models do.

2b.2 Analytic Method *(type of reliability & rationale, method for testing)***:**
A SIR is identical in concept to a standardized mortality ratio (SMR) and can summarizies HAI experience across any number of stratified groups of data using indirect standardization. The SMR is a widely accepted method of measurement within the public health community. An SIR is felt to be a good measurement for SSI experiences within facilities because it:
- provides a single measure that is simple to interpret for assessing SSI incidence problems and prevention efficacy,
- gives a better estimate of the infection experience when there are small numerators or denominators in some or all strata.

2b.3 Testing Results *(reliability statistics, assessment of adequacy in the context of norms for the test conducted)***:**

2b
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P☐
M☐
N☐

2c. Validity testing

2c.1 Data/sample *(description of data/sample and size)***:** The SSI data used in this measure have been endorsed by NQF in a previous measure set (see 3b.1) and as described in 2b.2, the SMR, upon which the SIR is based, is a widely accepted method for summarizing mortality experience. Therefore, we conclude the SIR measure has inherent face validity. However, we are undertaking validity studies beginning in July 2010 (see 2c.2).

3 states have independently completed and reported validity testing in their state HAI report. Those reports can be found at the following URLs:
- New York – 2007 annual report described methods and results for "CLABSI surveillance audit" (http://www.nyhealth.gov/statistics/facilities/hospital/hospital_acquired_infections/2008/docs/hospital-acquired_infection-full_report.pdf). Validation methods have increased in complexity, but have not been published again in great detail since the 2007 report; though the validation was briefly referred to in the 2008 and 2009 reports. They hope to publish in greater detail in their next report.
- South Carolina – http://www.scdhec.gov/health/disease/hai/docs/2010%20HIDA%20Annual%20Report.pdf (Annual report makes reference to validation study but does not describe methodology or findings in-depth.)
- Pennsylvania - www.portal.state.pa.us/portal/server.pt/.../padoh_2009_hai_report_pdf (Annual Report identifies current methods of monthly internal consistency checks that are completed, as well as annual on-site facility audits that are scheduled to begin the summer of 2010.

Validity testing has begun in July, 2010 in one state and in 2 states in August, 2010 and is expected to begin in 7 other states in August, 2010. Using ARRA funding, another state has also started validation testing in

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May, 2010 and 2 others are presently working on protocols to do so. 2c.2 **Analytic Method** *(type of validity & rationale, method for testing)*: To address concerns regarding validity, HHS has provided funding, utilizing Recovery Act of 2009 funds, to CDC to support 10 state Emerging Infections Programs in validating NHSN-related measures and to support reporting on HHS metrics through NHSN. 2c.3 **Testing Results** *(statistical results, assessment of adequacy in the context of norms for the test conducted)*:	
2d. Exclusions Justified 2d.1 **Summary of Evidence supporting exclusion(s):** No exclusions. 2d.2 **Citations for Evidence:** 2d.3 **Data/sample** *(description of data/sample and size)*: 2d.4 **Analytic Method** *(type analysis & rationale)*: 2d.5 **Testing Results** *(e.g., frequency, variability, sensitivity analyses)*:	**2d** C☐ P☐ M☐ N☐ NA☐
2e. Risk Adjustment for Outcomes/ Resource Use Measures 2e.1 **Data/sample** *(description of data/sample and size)*: See 2b.1. 2e.2 **Analytic Method** *(type of risk adjustment, analysis, & rationale)*: Expected numbers of SSI are calculated from operative procedure-specific logistic regression models that account for differences in SSI risk. See 2a.15 attachment. 2e.3 **Testing Results** *(risk model performance metrics)*: 2e.4 **If outcome or resource use measure is not risk adjusted, provide rationale:**	**2e** C☐ P☐ M☐ N☐ NA☐
2f. Identification of Meaningful Differences in Performance 2f.1 **Data/sample from Testing or Current Use** *(description of data/sample and size)*: SIRs have been used as metrics for identifying differences in performance by state. http://www.cdc.gov/nhsn/index.html. 2f.2 **Methods to identify statistically significant and practically/meaningfully differences in performance** *(type of analysis & rationale)*: The SIR by nature identifies variation from an expected rate of occurrence of an event and a sense of the magnitude of that variation (e.g., a facility SSI SIR of 2.0 represents twice as many SSIs as expected for the patient population). Additionally, the confidence interval provides further information regarding the likelihood that the SIR occurs within a specified range. See NHSN State Report for an example. http://www.cdc.gov/nhsn/index.html. 2f.3 **Provide Measure Scores from Testing or Current Use** *(description of scores, e.g., distribution by quartile, mean, median, SD, etc.; identification of statistically significant and meaningfully differences in performance)*: The SIR and 95% confidence interval will be calculated and graphically represented to show relationship to the nominal value of 1.0 (i.e., where observed equals expected).	**2f** C☐ P☐ M☐ N☐
2g. Comparability of Multiple Data Sources/Methods	**2g**

2g.1 **Data/sample** *(description of data/sample and size)*: 2g.2 **Analytic Method** *(type of analysis & rationale)*: 2g.3 **Testing Results** *(e.g., correlation statistics, comparison of rankings)*:	**C☐ P☐ M☐ N☐ NA☐**
2h. Disparities in Care 2h.**1 If measure is stratified, provide stratified results** *(scores by stratified categories/cohorts)*: 2h.2 **If disparities have been reported/identified, but measure is not specified to detect disparities, provide follow-up plans:**	**2h** **C☐ P☐ M☐ N☐ NA☐**
TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for *Scientific Acceptability of Measure Properties?*	**2**
Steering Committee: Overall, to what extent was the criterion, *Scientific Acceptability of Measure Properties*, **met?** **Rationale:**	*2* **C☐ P☐ M☐ N☐**
3. USABILITY	
Extent to which intended audiences (e.g., consumers, purchasers, providers, policy makers) can understand the results of the measure and are likely to find them useful for decision making. (evaluation criteria)	Eval Rating
3a. Meaningful, Understandable, and Useful Information 3a.1 **Current Use:** In use 3a.2 **Use in a public reporting initiative (disclosure of performance results to the public at large)** (*If used in a public reporting initiative, provide name of initiative(s), locations, Web page URL(s). If not publicly reported, state the plans to achieve public reporting within 3 years*): 3a.1. The SMR is a widely accepted measurement tool within the public health community and the SIR is but a variation on this method. The SIR has been available and used by NHSN member facilities for surgical site infection rate surveillance since 2005 and in NNIS facilities before that. 3a.2. A Centers for Disease Control and Prevention report on HAIs with SIRs for individual U.S. states is scheduled for publication in May, 2010 on the NHSN website at http://www.cdc.gov/nhsn/index.html. A precedent has been set for using SIRs for public reporting of HAIs by several states. Such states include Pennsylvania (report may be found at http://www.portal.health.state.pa.us/portal/server.pt/community/department_of_health_home/1745), Tennessee (report may be found at http://health.state.tn.us/Downloads/TN_HAI_Report_2008_Jan_Dec_final.pdf), and South Carolina (http://www.scdhec.gov/health/disease/hai/reports.htm). 3a.3 **If used in other programs/initiatives (***If used in quality improvement or other programs/initiatives, name of initiative(s), locations, Web page URL(s). If not used for QI, state the plans to achieve use for QI within 3 years***):** See 3a.2. **Testing of Interpretability** (*Testing that demonstrates the results are understood by the potential users for public reporting and quality improvement*) 3a.4 **Data/sample** *(description of data/sample and size)*:	**3a** **C☐ P☐ M☐ N☐**

3a.5 Methods *(e.g., focus group, survey, QI project)*: **3a.6 Results** *(qualitative and/or quantitative results and conclusions)*:	
3b/3c. Relation to other NQF-endorsed measures **3b.1 NQF # and Title of similar or related measures:** NQF #0299 Surgical Site Infection Rate	
(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?**	**3b** C☐ P☐ M☐ N☐ NA☐
3c. Distinctive or Additive Value **3c.1 Describe the distinctive, improved, or additive value this measure provides to existing NQF-endorsed measures:** **5.1 If this measure is similar to measure(s) already endorsed by NQF (i.e., on the same topic and the same target population), Describe why it is a more valid or efficient way to measure quality:** Similar measures have been submitted as proposed measures to NQF for catheter-associated urinary tract infection (CAUTI) SIR and central line-associated bloodstream infection (CLABSI) SIR outcome measures. The currently proposed measure, SSI SIR, uses data from the same NHSN system for development of the logistic regression models used for calculating the expected number of SSIs. As already described, SIRs are useful risk-adjusted summary metrics that complement the existing NQF-endorsed measures.	**3c** C☐ 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, *Usability*, **met?** **Rationale:**	**3** C☐ P☐ M☐ N☐
4. FEASIBILITY	
Extent to which the required data are readily available, retrievable without undue burden, and can be implemented for performance measurement. (evaluation criteria)	Eval Rating
4a. Data Generated as a Byproduct of Care Processes **4a.1-2 How are the data elements that are needed to compute measure scores generated?** Other SSI data must be collected by trained hospital staff from information available in clinical data sources. The NHSN analysis tool will automatically calculate SIRs.	**4a** C☐ P☐ M☐ N☐
4b. Electronic Sources **4b.1 Are all the data elements available electronically?** (*elements that are needed to compute measure scores are in defined, computer-readable fields, e.g., electronic health record, electronic claims*) No	**4b** C☐ P☐ M☐ N☐

4b.2 **If not, specify the near-term path to achieve electronic capture by most providers.** Some of the data may be available electronically, but not all.	
4c. Exclusions 4c.1 **Do the specified exclusions require additional data sources beyond what is required for the numerator and denominator specifications?** No 4c.2 **If yes, provide justification.**	**4c** C☐ P☐ M☐ N☐ NA☐
4d. Susceptibility to Inaccuracies, Errors, or Unintended Consequences 4d.1 **Identify susceptibility to inaccuracies, errors, or unintended consequences of the measure and describe how these potential problems could be audited. If audited, provide results.** Patient medical records and other sources of patient data must be reviewed to determine if the patient meets the necessary criteria for a SSI. It is possible that reviewers may miss symptoms or fail to identify that patients meet criteria thereby underreporting SSI events. Data collectors might also intentionally underreport SSIs. Both of these actions would result in an SIR that is calculated to be lower than actual. Alternatively, patients may be identified as having a SSI when in fact they do not meet SSI criteria and thereby calculate an SIR that is higher than actual. Numbers of operative procedures may be collected inaccurately thereby impacting the SIR. In addition, it is possible SIRs may be miscalculated. The NHSN reporting tool includes business logic to minimize misclassification of SSI. In addition, site visits can be conducted to audit data validity and this has been done for other infection types by some of the states using NHSN as their mandatory reporting tool (for example, see New York's audit process summary: http://www.health.state.ny.us/statistics/facilities/hospital/hospital_acquired_infections/2008/docs/hospital-acquired_infection.pdf, p20).	**4d** C☐ P☐ M☐ N☐
4e. Data Collection Strategy/Implementation 4e.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:** SSI rates and SIR using the methodologies described above have been in use by hospitals participating in CDC surveillance systems since 1986, and the rate measure has been endorsed by NQF in a previous measure set since 2007. Risk models for specific operative procedure categories have been developed using aggregate data from over 805 facilities in order to better reflect factors influencing the development of SSI in different patient populations. SIR has proven to be a useful metric for summarizing HAI experience especially when sample sizes within strata are small and when a summary statistic is desired. 4e.2 **Costs to implement the measure** (*costs of data collection, fees associated with proprietary measures*)**:** Time for identifying and reporting an SSI is estimated to be 30 minutes. Eight minutes per operative procedure record for collecting and reporting denominator information manually is estimated. Example of the cost to implement the measure: if a hospital identifies and reports 2 SSIs per month and performs 70 of the selected procedures per month for a year, it would take approximately 124 hours of effort. If the salary of the data collectors averaged $36 per hour, the level of effort would cost $4464 per year for the hospital. 4e.3 **Evidence for costs:** See OMB submission number 0920-0666, expires 09-30-2012 (labor cost adjusted for inflation). 4e.4 **Business case documentation:**	**4e** C☐ P☐ M☐ N☐
TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for *Feasibility*?	**4**
Steering Committee: Overall, to what extent was the criterion, *Feasibility*, **met?** **Rationale:**	**4** C☐

	P☐ M☐ N☐
RECOMMENDATION	
(for NQF staff use) **Check if measure is untested and only eligible for time-limited endorsement.**	**Time-limited** ☐
Steering Committee: Do you recommend for endorsement? **Comments:**	**Y☐ N☐ A☐**

CONTACT INFORMATION

Co.1 Measure Steward (Intellectual Property Owner)
Co.1 Organization
* Centers for Disease Control and Prevention, 1600 Clifton Rd, Atlanta, Georgia, 30329

Co.2 Point of Contact
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Measure Developer If different from Measure Steward
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Co.5 Submitter If different from Measure Steward POC
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Co.6 Additional organizations that sponsored/participated in measure development

ADDITIONAL INFORMATION

Workgroup/Expert Panel involved in measure development
Ad.1 Provide a list of sponsoring organizations and workgroup/panel members' names and organizations. Describe the members' role in measure development.

Ad.2 If adapted, provide name of original measure: NQF #0299 Surgical Site Infection Rate
Ad.3-5 If adapted, provide original specifications URL or attachment
http://wwwdev.cdc.gov/nhsn/PDFs/pscManual/9pscSSIcurrent.pdf

Measure Developer/Steward Updates and Ongoing Maintenance
Ad.6 Year the measure was first released: 2008
Ad.7 Month and Year of most recent revision: 11, 2007
Ad.8 What is your frequency for review/update of this measure? annuallly and when needed
Ad.9 When is the next scheduled review/update for this measure? 04, 2011

Ad.10 Copyright statement/disclaimers:

Ad.11 -13 Additional Information web page URL or attachment: Attachment Ad11- SSI-NQF additional info.docx

Date of Submission (*MM/DD/YY*)**:** 08/12/2010