NATIONAL QUALITY FORUM
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MEASURE WORKSHEET

This document summarizes the evaluation of the measure as it progresses through National Quality Forum's (NQF) Consensus Development Process (CDP). The information submitted by the measure developers/stewards is included after the *Brief Measure Information*, *Preliminary Analysis*, and *Pre-meeting Public and Member Comments* sections.

To navigate the links in the worksheet: Ctrl + click link to go to the link; ALT + LEFT ARROW to return

Brief Measure Information

NQF #: 3025

Measure Title: Ambulatory Breast Procedure Surgical Site Infection (SSI) Outcome Measure

Measure Steward: Centers for Disease Control and Prevention

Brief Description of Measure: This measure is for the risk-adjusted Standardized Infection Ratio (SIR) for all Surgical Site Infections (SSI) following breast procedures (BRST) conducted at ambulatory surgery centers (ASCs) among adult patients (ages 18 - 108 years) and reported to the Centers for Disease Control and Prevention (CDC) National Healthcare Safety Network (NHSN). The measure compares the reported number of surgical site infections observed at an ASC with a predicted value based on nationally aggregated data. The measure was developed collaboratively by the CDC, the Ambulatory Surgery Center Quality Collaboration (ASC QC), and the Colorado Department of Public Health and Environment. CDC is the measure steward.

Developer Rationale: The measure provides summary results that ASCs can use as quantitative aids in their efforts to evaluate and reduce breast surgery surgical site infection rates. The SIRs can be used by ASCs to benchmark SSI rates, identify opportunities for improvement, and gauge the impact of prevention efforts. At the outset, the SIRs provide a set of signals that often warrant further analysis, such as an examination of lapses in infection control practices that may contribute to high incidence of SSI. Some of the analytic follow up can be completed with data reported to CDC's National Healthcare Safety Network (NHSN) Patient Safety Component Procedure-Associated (PA) Module, using analytic features built into the NHSN application. However, additional analyses to determine the cause of infections as targets for prevention in individual instances are likely to require access to data that is beyond the scope of data collection and analysis using the NHSN module.

Breast procedures were specifically chosen for this measure due to the observed burden of breast procedure-associated SSI. Out of 67,150 ASC procedures reported to NHSN from 2010-2013, 30,787 (45.9%) were breast procedures. Out of the 142 SSIs reported from ASCs during the same time period, 78 (54.9%) were related to breast procedures, indicating an SSI risk of 0.25%. This was the highest volume and SSI risk out of all outpatient ASC procedures reported in the timeframe.

Numerator Statement: Surgical site infections (SSIs) during the 30-day (superficial SSI) and 90-day (deep and organ/space SSI) postoperative periods following breast procedures in Ambulatory Surgery Centers.

Denominator Statement: Breast procedures, as specified by the operative procedure codes that comprise the breast procedure category of the NHSN Outpatient Procedure Component Protocol, are performed at ambulatory surgery centers.

Denominator Exclusions: Hospital inpatients and hospital outpatient department patients, patients under age 18 or age 109 or over, and brain-dead patients whose organs are being removed for donor purposes.

Measure Type: Outcome

Data Source: Electronic Health Records

Electronic Health Data

Other (specify)

Data collection for SSIs following outpatient operative procedures is via NHSN Outpatient Procedure Component.

Level of Analysis: Facility

IF Endorsement Maintenance – Original Endorsement Date: 1/26/2017 **Most Recent Endorsement Date:** 1/26/2017

Preliminary Analysis: Maintenance of Endorsement

To maintain NQF endorsement, endorsed measures are evaluated periodically to ensure that the measure still meets the NQF endorsement criteria ("maintenance"). The emphasis for maintaining endorsement is focused on how effective the measure is for promoting improvements in quality. Endorsed measures should have some experience from the field to inform the evaluation. The emphasis for maintaining endorsement is noted for each criterion.

Criteria 1: Importance to Measure and Report

1a. Evidence

Maintenance measures – less emphasis on evidence unless there is new information or a change in evidence since the prior evaluation

1a. Evidence. The evidence requirements for a ***health outcome*** measure include providing empirical data that demonstrate a relationship between the outcome and at least one healthcare structure, process, intervention, or service; if these data are not available, data demonstrating wide variation in performance can be used, assuming the data are from a robust number of providers and the results are not subject to systematic bias. For measures derived from a patient report, the evidence also should demonstrate that the target population values the measured outcome, process, or structure and finds it meaningful.

The developer provides the following description for this measure:

- This is a maintenance measure at the facility level that determines the risk-adjusted standardized infection ratio (SIR) for all Surgical Site Infections (SSI) following breast procedures (BRST) conducted at ambulatory surgery centers (ASCs) among adult patients (ages 18 - 108 years) and reported to the Centers for Disease Control and Prevention (CDC) National Healthcare Safety Network (NHSN).
- The developer provides a logic model that depicts a reduction in breast surgical site infections as a direct outcome of combined best practices within successful ambulatory surgery centers and leading from reductions in opportunities for microbial infection with said facilities.

Summary of prior review in 2016

- The previous Standing Committee noted:
    - That the overall body of evidence on the incidence, outcomes, and prevention of SSIs in the ASC patient population is sparse but the available data suggest risks for SSIs following some breast procedures in some settings may be as high as 30%.
    - ASCs have been shown to have a lower SSI rate than inpatient settings. Though estimates of risk for breast procedures specifically vary from 1% to over 30% (and rate varies from 3 SSI to 28 SSI per 1000 procedures) depending on breast procedure type, sample population, and definition of SSI, it is clear that breast procedure-related SSIs are a large burden to outpatient healthcare facilities and provide much room for benefit. There is little data on the number or proportion of preventable SSI specifically following breast procedures conducted in ASCs.
    - The developer cites a Centers for Disease Control and Prevention guideline focused on steps that can be taken to prevent SSI based on a targeted systematic review of the available evidence on SSI prevention from 1998 through April 2014.

Changes to evidence from the last review

☐ The developer attests that there have been no changes in the evidence since the measure was last evaluated.

☒ The developer provided updated citations for the evidence for this measure, however, the underlying evidence is the same.

Question for the Standing Committee:

- *Is there at least one thing that the provider can do to achieve a change in the measure results?*
- *The developer attests the underlying evidence for the measure has not changed since the last NQF endorsement review. Does the Committee agree the evidence basis for the measure has not changed and there is no need for repeat discussion and vote on Evidence?*

Guidance From the Evidence Algorithm

Health outcome measure (Box 1) -> Empirical data demonstrates relationship between health outcome and at least one healthcare action (Box 2) -> Pass

Preliminary rating for evidence: ☒ Pass ☐ No Pass

1b. Gap in Care/Opportunity for Improvement and Disparities

Maintenance measures – increased emphasis on gap and variation

1b. Performance Gap. The performance gap requirements include demonstrating quality problems and opportunity for improvement.

- The developer highlights that an exploratory analysis of NHSN data showed that out of 67,150 ASC procedures reported to NHSN from 2010-2013, 30,787 (45.9%) were breast procedures. Out of the 142 SSIs reported from ASCs during the same time period, 78 (54.9%) were related to breast procedures, indicating a risk of SSI of 0.25%.
- The developer does not provide data since the previous endorsement.

Disparities

- Disparities data around number of surgical breast procedures to number of SSI was provided across age and gender from 2010- 2013:
    - Age: 52-62 years were at the highest risk (41 percent), followed by greater than 62 years old (38 percent), 41-51 years old (21 percent and less than 40 years old (4 percent).

    - Gender: Females were 26% more likely than males to report SSI following breast procedures
- The developer states that while disparities data for SSI in ASCs is sparse, several studies are referenced which argue that SSIs lead to an excess cost burden as well as excess hospital stay for patients, which may cause disparities in care for SSI.

Questions for the Standing Committee:

- *Is there a gap in care that warrants a national performance measure?*
- *Does the Standing Committee have any concerns that there is no current performance data?*

Preliminary rating for opportunity for improvement: ☐ **High** ☐ **Moderate** ☐ **Low** ☒ **Insufficient**

Criteria 2: Scientific Acceptability of Measure Properties

Complex measure evaluated by the Scientific Methods Panel (SMP)? ☐ **Yes** ☒ **No**

2a. Reliability: Specifications and Testing

For maintenance measures—no change in emphasis—specifications should be evaluated the same as with new measures.

2a1. Specifications require the measure, as specified, to produce consistent (i.e., reliable) and credible (i.e., valid) results about the quality of care when implemented.

For maintenance measures – less emphasis if no new testing data are provided.

2a2. Reliability testing demonstrates whether the measure data elements are repeatable and producing the same results a high proportion of the time when assessed in the same population during the same time period, and/or whether the measure score is precise enough to distinguish differences in performance across providers.

Specifications:

- The developer states that no changes have been made to the specifications since the last review.
- Measure specifications are clear and precise.

Reliability Testing:

- Did the developer conduct new reliability testing? ☒ Yes ☐ No
- Reliability testing conducted at the Accountable-Entity Level:
    - The developer conducted a signal-to-noise analysis using data from January 1 to December 31, 2021 from 16 facilities from seven different US states.
    - The developer found that 94% (15 out of 16) of facilities have reliability scores above 0.7 mean reliability and one facility had a reliability score below 0.7 of 0.687.

Questions for the Standing Committee regarding reliability:

- *Do you have any concerns that the measure cannot be consistently implemented (i.e., are the measure specifications adequate)?*

Guidance From the Reliability Algorithm

Specifications are precise and unambiguous (Box 1) -> Empirical reliability testing conducted using the measure as specified (Box 2) -> Testing conducted at the appropriate level of analysis (Box 4) -> Signal-to-noise testing conducted (Box 5) -> MODERATE

Preliminary rating for reliability: ☐ **High** ☒ **Moderate** ☐ **Low** ☐ **Insufficient**

2b. Validity: Validity Testing; Exclusions; Risk Adjustment; Meaningful Differences; Comparability; Missing Data

For maintenance measures – less emphasis if no new testing data are provided

2b1. Measure Intent: The measure specifications are consistent with the measure's intent and capture the most inclusive target population.

2b2. Validity testing should demonstrate the measure data elements are correct and/or the measure score correctly reflects the quality of care provided, adequately identifying differences in quality.

2b2-2b6. Potential threats to validity should be assessed/addressed.

Validity Testing

- Did the developer conduct new validity testing? ☐ Yes ☒ No
- Validity testing was conducted at the Accountable-Entity Level:
    - The developer conducted face validity testing for the measure's initial endorsement in 2015.
    - The Ambulatory Surgery Center Quality Collaboration (ASC QC) administered a questionnaire that included questions related to the four measure attributes to 11 professionals currently working in ASC.
    - The questionnaire rated the respondent's level of agreement with statements related to each measure attribute based on a 5-point Likert Scale with a rating of 5 expressing agreement and 1 expressing disagreement. It also allowed respondents to elaborate on their ratings in open-ended questions.
        - The developer reported that there was a high level of agreement among the ASC professionals in response to the question of whether the measure appears to measure what it is intended to (nine of 11 agreed). Nine of 11 respondents also thought the measure would allow for consistent interpretation across centers.
        - One respondent expressed that there is difficulty inherent in dividing breast surgery SSI into categories of superficial and deep incisional due to the nature of the procedure.
        - Eight of 11 respondents agreed that the measure score accurately reflects the quality of a center's performance.
        - Seven of 11 respondents agree that the measure score can be used to distinguish between good and poor performance.
        - Seven out of eleven respondents thought that factors other than the quality of a center's performance, such as risk factors and the quality of a surgeon, can influence the SSI.
        - Seven out of eleven respondents also noted that scores may be affected by factors outside a facility's control, such as patient comorbidities, poor hygiene, and non-compliance with post-op instructions.

- The developer states that no additional testing was performed for the current submission, and that they were unable to perform empirical validity testing of the measure score due to the limited data available. They state that statistical testing would not be powered to detect significance and strength of an association with other quality measures.

Exclusions

- The measure uses exclusions. Exclusion criteria were applied prior to risk adjusting the SIR denominator.
- The developer states that in 2021, only 82 (0.05%) of the 16,298 BRST procedures reported to NHSN's Outpatient Procedure Component were excluded from the SIR calculation due to not meeting all the inclusion criteria.
  - The reasons for exclusion from the SIR were: reporting a procedure duration of less than 5 minutes (35.3%), reporting a procedure duration that exceeded the interquartile range of more than five times (32.9%), and having a BMI that did not fall within 12-60 (25.6%).
  - Although 82 procedures were excluded, no records were excluded due to a missing value of required fields.
- The developer states that exclusions are based on data outliers and data quality issues.

Risk Adjustment

- The measure is risk-adjusted using a statistical risk model with three risk factors: anesthesia, age and BMI categories.
- A bootstrap sampling method was used to validate the models.
- The C-statistic was 0.7114, and Hosmer-Lemeshow calibration statistic was p=0.726.
- The developer states that social risk factors were not analyzed and were not available.

Meaningful Differences

- The developer states the SIR can discriminate between and test if there is a difference between facilities. A meaningful difference in the SIR was defined as an SIR and a confidence interval that was statistically different from 1. Out of 119 total facilities reporting in 2015, SIRs were able to be calculated for 12 of them. Out of 95 total facilities reporting in 2021, 16 facilities met minimum precision criterion of predicted values greater or equal than 1 and thus SIRs were able to be calculated. Of these, 15 facilities (93.75 percent) were not significantly different from 1. LINK to tables in submission.
- The developer states that the SIR enables detection of statistically significant and clinically meaningful differences in SSI that warrant further analysis and possible action. Although exposure volume is low, leading to few statistically significant SIRs in this population, the value of the calculated SIRs can reflect practical measures of performance.

Missing Data and Carve Outs

- The developer indicates that all facilities participating in NHSN and reporting ambulatory breast SSI events follow the same protocol for reporting events. The NHSN application provides "Alerts" to participating healthcare facilities in the event of missing data. In addition, CDC analysts conduct regular data quality checks and perform outreach to facilities regarding any missing or implausible

data. Facilities that are not reporting data elements that are required by NHSN would not be eligible to receive an SIR; therefore, the overall frequency of missing data is zero.

Comparability

- The measure only uses one set of specifications for this measure.

Questions for the Standing Committee regarding validity:

- *The developer attests that additional validity testing was not conducted because there is insufficient data available to test the measure score with accuracy. Does the Standing Committee have any concerns with the lack of empirical validity testing provided?*
- *Do you have any concerns regarding how the developer handled any potential threats to the validity of the measure (e.g., exclusions, risk adjustment approach, etc.)?*

Guidance From the Reliability Algorithm

Threats to validity were assessed (Box 1) -> Empirical validity testing not conducted and rationale provided (Box 2) -> Face validity was systematically assessed by experts (Box 3) -> Moderate

Preliminary rating for validity: ☐ **High** ☒ **Moderate** ☐ **Low** ☐ **Insufficient**

Criterion 3. Feasibility

Maintenance measures – no change in emphasis – implementation issues may be more prominent

3. Feasibility is the extent to which the specifications, including measure logic, require data that are readily available or could be captured without undue burden and can be implemented for performance measurement.

- The developer reported that data for this measure is generated through medical record chart abstractions at each ASC.
- The developer noted that some data elements are not amenable to electronic capture such as physician/nurses notes.
- As ambulatory surgery centers incorporate more options for electronic medical records, NHSN will begin to adapt the criteria to align with electronic data capture.

Questions for the Standing Committee:

- *Are the required data elements routinely generated and used during care delivery?*
- *Are the required data elements available in electronic form (e.g., EHR or other electronic sources)?*
- *Is the data collection strategy ready to be put into operational use?*

Preliminary rating for feasibility: ☐ **High** ☒ **Moderate** ☐ **Low** ☐ **Insufficient**

Criterion 4: Use and Usability

Maintenance measures – increased emphasis – much greater focus on measure use and usefulness, including both impact/improvement and unintended consequences

4a. Use (4a1. Accountability and Transparency; 4a2. Feedback on measure)

4a. Use evaluates the extent to which audiences (e.g., consumers, purchasers, providers, and policymakers) use or could use performance results for both accountability and performance improvement activities.

4a.1. Accountability and Transparency. Performance results are used in at least one accountability application within three years after initial endorsement and are publicly reported within six years after initial endorsement (or the data on performance results are available). If they are not in use at the time of initial endorsement, then a credible plan for implementation within the specified time frames is provided.

Current uses of the measure

Publicly reported?	☒ Yes	☐ No			
Current use in an accountability program?	☒ Yes	☐ No	☐ UNCLEAR		
Planned use in an accountability program?	☐ Yes	☐ No	☒ NA		

Accountability program details

- The measure is used for public reporting, public health/disease surveillance, quality improvement with benchmarking, and internal quality improvement within NHSN, with 284 ASCs reporting.
- National Healthcare Safety Network (NHSN), Centers for Disease Control and Prevention
- Colorado Department of Public Health and Environment Patient Safety Program

4a.2. Feedback on the measure provided by those being measured or others. Three criteria demonstrate feedback: (1) Those being measured have been given performance results or data, as well as assistance with interpreting the measure results and data; (2) Those being measured and other users have been given an opportunity to provide feedback on the measure performance or implementation; and (3) This feedback has been considered when changes are incorporated into the measure.

Feedback on the measure provided by those being measured or others

- The developer reports that typical feedback from other users, specifically State health departments indicate that due to low volume of data reported, public reporting of measures was not performed.
    - The developer also reports that feedback received from state health departments is not publicly reported.
- The developer states that feedback from users is being compiled and will be taken into consideration for any future revisions to the measure.

***Questions for the Standing Committee**:*

- *How have (or can) the performance results be used to further the goal of high quality, efficient healthcare?*
- *How has the measure been vetted in real-world settings by those being measured or others?*

Preliminary rating for Use: ☒ **Pass** ☐ **No Pass**

4b. Usability (4b1. Improvement; 4b2. Benefits of measure)

4b. Usability evaluates the extent to which audiences (e.g., consumers, purchasers, providers, and policymakers) use or could use performance results for both accountability and performance improvement activities.

4b.1 Improvement. Progress toward achieving the goal of high quality, efficient healthcare for individuals or populations is demonstrated.

Improvement results

- The developer states that due to the low use of the measure, data was not analyzed for trends.

4b2. Benefits versus harms. The benefits of the performance measure in facilitating progress toward achieving high quality, efficient healthcare for individuals or populations outweigh evidence of unintended negative consequences to individuals or populations (if such evidence exists).

Unexpected findings (positive or negative) during implementation

- The developer reports that NHSN 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.
    - The developer also reports that data collectors might also unintentionally underreport SSIs.

Potential harms

- No potential harm was reported by the developers.

***Questions for the Standing Committee**:*

- *How can the performance results be used to further the goal of high quality, efficient healthcare?*
- *Do the benefits of the measure outweigh any potential unintended consequences?*

Preliminary rating for Usability and Use: ☐ **High** ☐ **Moderate** ☐ **Low** ☒ **Insufficient**

RATIONALE: The developer does not provide any trends around performance results due to the low use of the measure.

Criterion 5: Related and Competing Measures

Related Measures

- NQF #3357: Facility-Level 7-Day Hospital Visits after General Surgery Procedures Performed at Ambulatory Surgical Centers
- NQF #2687: Hospital Visits after Hospital Outpatient Surgery
- NQF #0527: Prophylactic Antibiotic Received Within One Hour Prior to Surgical Incision
- NQF #0528: Prophylactic Antibiotic Selection for Surgical Patients
- NQF #0529: Prophylactic Antibiotics Discontinued Within 24 Hours After Surgery End Time
- NQF #0269: Timing of Prophylactic Antibiotics - Administering Physician

Harmonization

- The developer reports that while all above measures focus on the same target population (ASC patients), this measure is the only one specifically evaluating occurrence of breast surgical site infections.

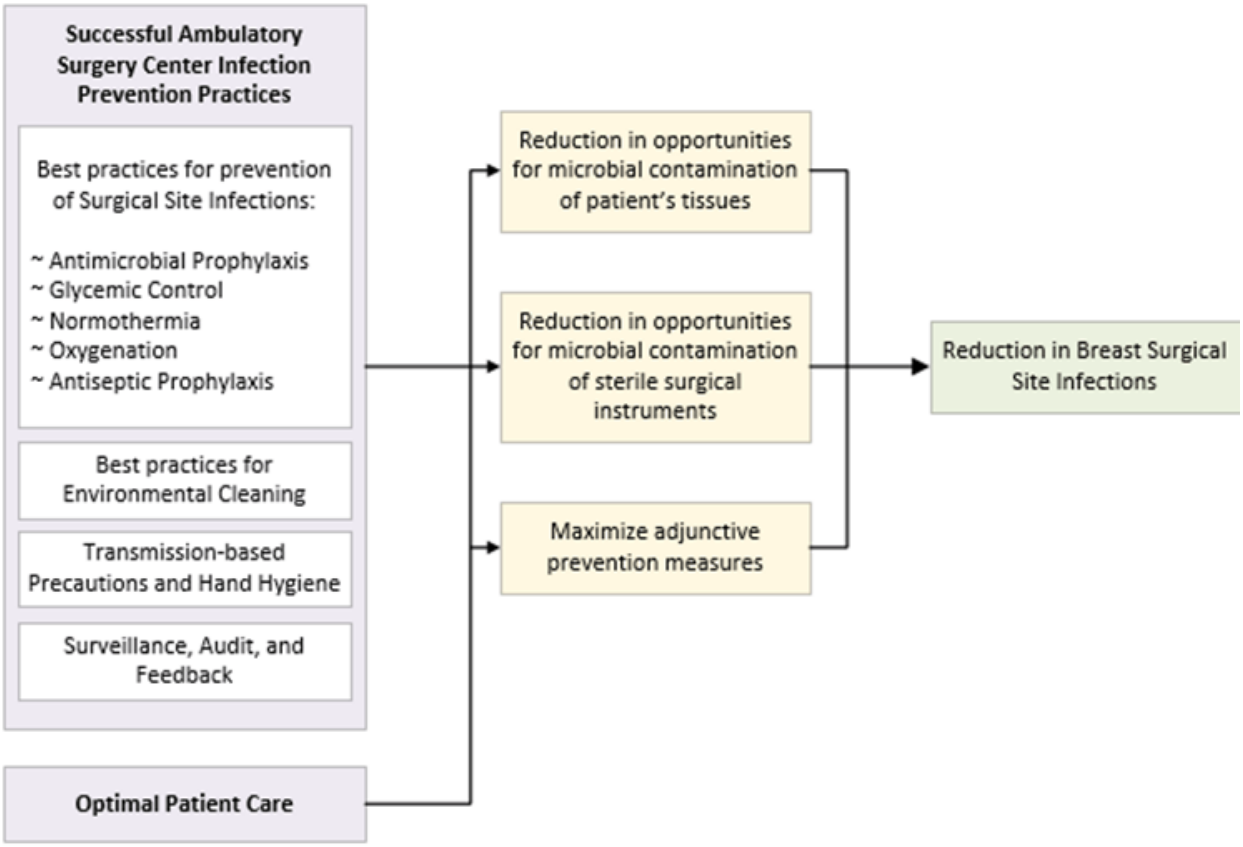
Criteria 1: Importance to Measure and Report

1a. Evidence

1a.01. Provide a logic model.

Briefly describe the steps between the healthcare structures and processes (e.g., interventions, or services) and the patient's health outcome(s). The relationships in the diagram should be easily understood by general, non-technical audiences. Indicate the structure, process or outcome being measured.

[Response Begins]



With the ability to track and trend facility-specific breast SSI data both internally and nationwide, facilities can determine which prevention practices (as outlined above) may be put into place to reduce the occurrence of breast SSI events.

[Response Ends]

1a.02. Provide evidence that the target population values the measured outcome, process, or structure and finds it meaningful.

Describe how and from whom input was obtained.

[Response Begins]

Numerous individual studies and systematic reviews provide strong evidence that measurement and feedback of surgical site infections leads to lower SSI rates in the long term. Although standardized metrics have been developed to measure SSI rates for inpatient surgeries in the hospital setting (Mu 2009), these have not yet been widely used for outpatient surgeries in ASCs, which comprise a fast-growing proportion of all surgeries performed in the US (Kozak 1999). The measure serves as a quantitative guide for ASCs, enabling them to benchmark SSI rates in their facilities against nationally aggregated data and set targets for improvement. This measure is currently required by the states of Colorado and New Jersey providing ASCs with benchmarking data. Colorado publishes a Healthcare-associated infection Annual Report with specific data collected for each facility in the state. In the state of New Jersey, data is shared internally with all enrolled facilities. As we work to expand the use of the measure, we expect to see an increased focus on SSI rate reduction in the Ambulatory Surgery Center setting.

Updated Evidence:

1. Cerezo O, Oñate-Ocaña LF, Arrieta-Joffe P, González-Lara F, García-Pasquel MJ, Bargalló-Rocha E, Vilar-Compte D. Validation of the Mexican-Spanish version of the EORTC QLQ-C30 and BR23 questionnaires to assess health-related quality of life in Mexican women with breast cancer. Eur J Cancer Care (Engl). 2012 Sep;21(5):684-91. doi: 10.1111/j.1365-2354.2012.01336.x. Epub 2012 Feb 14. PMID: 22329843.
2. Olsen MA, Nickel KB, Fox IK. Surveillance and Prevention of Surgical Site Infections in Breast Oncologic Surgery with Immediate Reconstruction. Curr Treat Options Infect Dis. 2017 Jun;9(2):155-172. doi: 10.1007/s40506-017-0117-9. Epub 2017 May 11. PMID: 28959143; PMCID: PMC5612330.
3. Pivot D, Hoch G, Astruc K, Lepelletier D, Lefebvre A, Lucet JC, Beaussier M, Philippe HJ, Vons C, Triboulet JP, Grandbastien B, Aho Glélé LS. A systematic review of surgical site infections following day surgery: a frequentist and a Bayesian meta-analysis of prevalence. J Hosp Infect. 2019 Feb;101(2):196-209. doi: 10.1016/j.jhin.2018.07.035. Epub 2018 Jul 30. PMID: 30071265.

Previous Citations:

1. Anderson, Deverick J, Kelly Podgorny, Sandra I. Berríos-Torres, et al. Strategies to Prevent Surgical Site Infections in Acute Care Hospitals: 2014 Update. Infection Control & Hospital Epidemiology. 2014; 35: 605-627.
2. Mangram AJ, Horan TC, Pearson ML, Silver LC, Jarvis WR. Guideline for prevention of surgical site infection, 1999. Hospital Infection Control Practices Advisory Committee. Infect Control Hosp Epidemiol. 1999;?20: 250-278. http://www.cdc.gov/hicpac/pdf/guidelines/SSI_1999.pdf.
3. Gaynes R, Richards C, Edwards JR, et al. Feeding back surveillance data to prevent hospital-acquired infections. Emerg Infect Dis. 2001; 7: 295–298.
4. Vilar-Compte, D., Rosales, S., Hernandez-Mello, N., Maafs, E., & Volkow, P. Surveillance, control, and prevention of surgical site infections in breast cancer surgery: a 5-year experience. American journal of infection control. 2009; 37(8): 674-679.
5. Mu, Y., et al. Improving risk-adjusted measures of surgical site infection for the national healthcare safety network. Infect Control Hosp Epidemiol. 2011; 32(10): 970-86.
6. Kozak LJ, McCarthy E, Pokras R. Changing patterns of surgical care in the United States, 1980-1995. Health Care Finance Rev. 1999; 21(1): 31-49.

[Response Ends]

1a.03. Provide empirical data demonstrating the relationship between the outcome (or PRO) and at least one healthcare structure, process, intervention, or service.

[Response Begins]

Centers for Disease Control and Prevention offer a guideline focused on prevention of Surgical Site Infections (SSI).

"This guideline's recommendations were developed based on a targeted systematic review of the best available evidence on SSI prevention conducted in MEDLINE, EMBASE, CINAHL, and the Cochrane Library from 1998 through April 2014."

Each intervention is graded and a recommendation for best practice is provided. The following are the recommendations for reduction in SSI:

"Before surgery, patients should shower or bathe (full body) with soap (antimicrobial or nonantimicrobial) or an antiseptic agent on at least the night before the operative day. Antimicrobial prophylaxis should be administered only when indicated based on published clinical practice guidelines and timed such that a bactericidal concentration of the agents is established in the serum and tissues when the incision is made. In cesarean section procedures, antimicrobial prophylaxis should be administered before skin incision. Skin preparation in the operating room should be performed using an alcohol-based agent unless contraindicated. For clean and clean-contaminated procedures, additional prophylactic antimicrobial agent doses should not be administered after the surgical incision is closed in the operating room, even in the presence of a drain. Topical antimicrobial agents should not be applied to the surgical incision. During surgery, glycemic control should be implemented using blood glucose target levels less than 200 mg/dL, and normothermia should be maintained in all patients. Increased fraction of inspired oxygen should be administered during surgery and after extubation in the immediate postoperative period for patients with normal pulmonary function undergoing general anesthesia with endotracheal intubation. Transfusion of blood products should not be withheld from surgical patients as a means to prevent SSI."[1] Other interventions such as, hand hygiene and environmental surface cleaning are also practices that contribute to reducing the burden of SSI.[2]

An additional reference cites processes for surveillance, audits as well as feedback to surgeons and surgical staff as factors that aid in reducing SSI.[2] An important part of surveillance in the outpatient surgery setting includes processes for post-discharge surveillance. A prospective observational study of surgical patients demonstrated patient self-reporting of SSI as a sensitive method of detection of SSI.[3]

References

1. Berríos-Torres SI, Umscheid CA, Bratzler DW, et al. Centers for Disease Control and Prevention Guideline for the Prevention of Surgical Site Infection, 2017. *JAMA Surg.* 2017;152(8):784–791. doi:10.1001/jamasurg.2017.0904
2. Anderson DJ, Podgorny K, Berríos-Torres SI, Bratzler DW, Dellinger EP, Greene L, Nyquist AC, Saiman L, Yokoe DS, Maragakis LL, Kaye KS. Strategies to prevent surgical site infections in acute care hospitals: 2014 update. Infect Control Hosp Epidemiol. 2014 Jun;35(6):605-27. doi: 10.1086/676022. PMID: 24799638; PMCID: PMC4267723.
3. Pham JC, Ashton MJ, Kimata C, Lin DM, Nakamoto BK. Surgical site infection: comparing surgeon versus patient self-report. J Surg Res. 2016 May 1;202(1):95-102. doi: 10.1016/j.jss.2015.12.039. Epub 2015 Dec 30. PMID: 27083953; PMCID: PMC5642958.

[Response Ends]

1b. Gap in Care/Opportunity for Improvement and Disparities

1b.01. Briefly explain the rationale for this measure.

Explain how the measure will improve the quality of care, and list the benefits or improvements in quality envisioned by use of this measure.

[Response Begins]

The measure provides summary results that ASCs can use as quantitative aids in their efforts to evaluate and reduce breast surgery surgical site infection rates. The SIRs can be used by ASCs to benchmark SSI rates, identify opportunities for improvement, and gauge the impact of prevention efforts. At the outset, the SIRs provide a set of signals that often warrant further analysis, such as an examination of lapses in infection control practices that may contribute to high incidence of SSI. Some of the analytic follow up can be completed with data reported to CDC's National Healthcare Safety

Network (NHSN) Patient Safety Component Procedure-Associated (PA) Module, using analytic features built into the NHSN application. However, additional analyses to determine the cause of infections as targets for prevention in individual instances are likely to require access to data that is beyond the scope of data collection and analysis using the NHSN module.

Breast procedures were specifically chosen for this measure due to the observed burden of breast procedure-associated SSI. Out of 67,150 ASC procedures reported to NHSN from 2010-2013, 30,787 (45.9%) were breast procedures. Out of the 142 SSIs reported from ASCs during the same time period, 78 (54.9%) were related to breast procedures, indicating an SSI risk of 0.25%. This was the highest volume and SSI risk out of all outpatient ASC procedures reported in the timeframe.

[Response Ends]

1b.02. Provide performance scores on the measure as specified (current and over time) at the specified level of analysis.

Include mean, std dev, min, max, interquartile range, and scores by decile. Describe the data source including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities include. This information also will be used to address the sub-criterion on improvement (4b) under Usability and Use.

[Response Begins]

An exploratory analysis of NHSN data showed that out of 67,150 ASC procedures reported to NHSN from 2010-2013, 30,787 (45.9%) were breast procedures. Out of the 142 SSIs reported from ASCs during the same time period, 78 (54.9%) were related to breast procedures, indicating a risk of SSI of 0.25%. This was the highest volume and SSI risk among all outpatient ASC procedures reported in the timeframe.

[Response Ends]

1b.03. If no or limited performance data on the measure as specified is reported above, then provide a summary of data from the literature that indicates opportunity for improvement or overall less than optimal performance on the specific focus of measurement. Include citations.

[Response Begins]

Numerous individual studies and systematic reviews provide strong evidence that measurement and feedback of surgical site infections leads to lower SSI rates in the long term. (Anderson 2014, Mangram 1999, Gaynes 2001, Vilar-Compte 2009). Although standardized metrics have been developed to measure SSI rates for inpatient surgeries in the hospital setting (Mu 2009), these have not yet been developed for outpatient surgeries in ASCs, which comprise a fast-growing proportion of all surgeries performed in the US (Kozak 1999). The measure will serve as a quantitative guide for ASCs, enabling them to benchmark SSI rates in their facilities against nationally aggregated data and set targets for improvement.

Citations:

1. Anderson, Deverick J, Kelly Podgorny, Sandra I. Berríos-Torres, et al. Strategies to Prevent Surgical Site Infections in Acute Care Hospitals: 2014 Update. Infection Control & Hospital Epidemiology. 2014; 35: 605-627.
2. Mangram AJ, Horan TC, Pearson ML, Silver LC, Jarvis WR. Guideline for prevention of surgical site infection, 1999. Hospital Infection Control Practices Advisory Committee. Infect Control Hosp Epidemiol. 1999;?20: 250-278. http://www.cdc.gov/hicpac/pdf/guidelines/SSI_1999.pdf.
3. Gaynes R, Richards C, Edwards JR, et al. Feeding back surveillance data to prevent hospital-acquired infections. Emerg Infect Dis. 2001; 7: 295–298.

4. Vilar-Compte, D., Rosales, S., Hernandez-Mello, N., Maafs, E., & Volkow, P. Surveillance, control, and prevention of surgical site infections in breast cancer surgery: a 5-year experience. American journal of infection control. 2009; 37(8): 674-679.
5. Mu, Y., et al. Improving risk-adjusted measures of surgical site infection for the national healthcare safety network. Infect Control Hosp Epidemiol. 2011; 32(10): 970-86.
6. Kozak LJ, McCarthy E, Pokras R. Changing patterns of surgical care in the United States, 1980-1995. Health Care Financ Rev. 1999; 21(1): 31-49.

[Response Ends]

1b.04. Provide disparities data from the measure as specified (current and over time) by population group, e.g., by race/ethnicity, gender, age, insurance status, socioeconomic status, and/or disability.

Describe the data source including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included. Include mean, std dev, min, max, interquartile range, and scores by decile. For measures that show high levels of performance, i.e., "topped out", disparities data may demonstrate an opportunity for improvement/gap in care for certain sub-populations. This information also will be used to address the sub-criterion on improvement (4b) under Usability and Use.

[Response Begins]

Age and Gender Disparities in Surgical Site Infections (SSIs) among Outpatient Surgical Breast Procedures, Reported to NHSN, 2010- 2013

Variable	No. Procedures	No. SSIs	Risk (%)	P (Likelihood Ratio)
Age	*	*	*	< 0.0001
< 40 years	8071	3	0.04	*
41-51 years	7546	16	0.21	*
52-62 years	7875	32	0.41	*
> 62 years	7175	27	0.38	*
Gender	*	*	*	0.0414
Female	30001	78	0.26	*
Male	810	0	0	*

* Cell intentionally left empty

[Response Ends]

1b.05. If no or limited data on disparities from the measure as specified is reported above, then provide a summary of data from the literature that addresses disparities in care on the specific focus of measurement. Include citations. Not necessary if performance data provided in above.

[Response Begins]

Data on disparities in surgical site infections in ASCs, as well as in hospitals, are sparse. No studies or reviews were found specifically on disparities surrounding SSI in any healthcare facility. However, it has been extensively documented that

surgical site infections lead to an excess cost burden as well as excess hospital stay for patients (Zimlichman 2013, Olsen 2008, Kirkland 1999). These additional costs may cause disparities in care for SSI, which are reflective of disparities in access to health care in general (Brown 2000, Lasser 2008).

Citations:

1. Zimlichman E, Henderson D, Tamir O, et al. Health Care–Associated Infections: A Meta-analysis of Costs and Financial Impact on the US Health Care System. JAMA Intern Med. 2013;173(22):2039-2046.
2. Olsen MA, et al. Hospital-Associated Costs Due to Surgical Site Infection After Breast Surgery. Arch Surg. 2008; 143(1): 53-60.
3. Kirkland KB, Briggs JP, Trivette SL, Wilkinson WE, Sexton DJ. The impact of surgical-site infections in the 1990s: attributable mortality, excess length of hospitalization, and extra costs. Infect Control Hosp Epidemiol. 1999;?20:725-730.
4. Brown, E. R., Ojeda, V. D., Wyn, R., & Levan, R. (2000). Racial and ethnic disparities in access to health insurance and health care. UCLA Center for Health Policy Research.
5. Lasser, Karen E., David U. Himmelstein, and Steffie Woolhandler. "Access to care, health status, and health disparities in the United States and Canada: results of a cross-national population-based survey." Health Policy: Crisis and Reform in the US Health Care Delivery System (2008): 379.

[Response Ends]

Criteria 2: Scientific Acceptability of Measure Properties

2a. Reliability

sp.01. Provide the measure title.

Measure titles should be concise yet convey who and what is being measured (see What Good Looks Like).

[Response Begins]

Ambulatory Breast Procedure Surgical Site Infection (SSI) Outcome Measure

[Response Ends]

sp.02. Provide a brief description of the measure.

Including type of score, measure focus, target population, timeframe, (e.g., Percentage of adult patients aged 18-75 years receiving one or more HbA1c tests per year).

[Response Begins]

This measure is for the risk-adjusted Standardized Infection Ratio (SIR) for all Surgical Site Infections (SSI) following breast procedures (BRST) conducted at ambulatory surgery centers (ASCs) among adult patients (ages 18 - 108 years) and reported to the Centers for Disease Control and Prevention (CDC) National Healthcare Safety Network (NHSN). The measure compares the reported number of surgical site infections observed at an ASC with a predicted value based on nationally aggregated data. The measure was developed collaboratively by the CDC, the Ambulatory Surgery Center Quality Collaboration (ASCQC), and the Colorado Department of Public Health and Environment. CDC is the measure steward.

[Response Ends]

sp.04. Check all the clinical condition/topic areas that apply to your measure, below.

Please refrain from selecting the following answer option(s). We are in the process of phasing out these answer options and request that you instead select one of the other answer options as they apply to your measure.

Please do not select:

- *Surgery: General*

[Response Begins]

Infectious Diseases (ID)

Surgery

[Response Ends]

sp.05. Check all the non-condition specific measure domain areas that apply to your measure, below.

[Response Begins]

Primary Prevention

Safety: Healthcare Associated Infections

[Response Ends]

sp.06. Select one or more target population categories.

Select only those target populations which can be stratified in the reporting of the measure's result.

Please refrain from selecting the following answer option(s). We are in the process of phasing out these answer options and request that you instead select one of the other answer options as they apply to your measure.

Please do not select:

- *Populations at Risk: Populations at Risk*

[Response Begins]

Adults (Age >= 18)

[Response Ends]

sp.07. Select the levels of analysis that apply to your measure.

Check ONLY the levels of analysis for which the measure is SPECIFIED and TESTED.

Please refrain from selecting the following answer option(s). We are in the process of phasing out these answer options and request that you instead select one of the other answer options as they apply to your measure.

Please do not select:

- *Clinician: Clinician*
- *Population: Population*

[Response Begins]

Facility

[Response Ends]

sp.08. Indicate the care settings that apply to your measure.

Check ONLY the settings for which the measure is SPECIFIED and TESTED.

[Response Begins]

Ambulatory Care

Outpatient Services

[Response Ends]

sp.09. Provide a URL link to a web page specific for this measure that contains current detailed specifications including code lists, risk model details, and supplemental materials.

Do not enter a URL linking to a home page or to general information. If no URL is available, indicate "none available".

[Response Begins]

https://www.cdc.gov/nhsn/opc/ssi/index.html

[Response Ends]

sp.12. Attach the data dictionary, code table, or value sets (and risk model codes and coefficients when applicable). Excel formats (.xlsx or .csv) are preferred.

Attach an excel or csv file; if this poses an issue, contact staff. Provide descriptors for any codes. Use one file with multiple worksheets, if needed.

[Response Begins]

Available in attached Excel or csv file

[Response Ends]

Attachment: NHSN Data Dictionary 9.5_OP_20210304.xlsx

For the question below: state the outcome being measured. Calculation of the risk-adjusted outcome should be described in sp.22.

sp.13. State the numerator.

Brief, narrative description of the measure focus or what is being measured about the target population, i.e., cases from the target population with the target process, condition, event, or outcome).

DO NOT include the rationale for the measure.

[Response Begins]

Surgical site infections (SSIs) during the 30-day (superficial SSI) and 90-day (deep and organ/space SSI) postoperative periods following breast procedures in Ambulatory Surgery Centers.

[Response Ends]

For the question below: describe how the observed outcome is identified/counted. Calculation of the risk-adjusted outcome should be described in sp.22.

sp.14. Provide details needed to calculate the numerator.

All information required to identify and calculate the cases from the target population with the target process, condition, event, or outcome such as definitions, time period for data collection, specific data collection items/responses, code/value sets.

Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format at sp.11.

[Response Begins]

sOPC SSI Surveillance (cdc.gov)

SSIs are defined in the NHSN Outpatient Procedure Component Protocol:

https://www.cdc.gov/nhsn/xls/opc/opc-cpt-pcm-nhsn.xlsx

SSI event chapter CTP Agreement (cdc.gov)

Please refer to Table 2. *Surveillance Periods for SSIs Following Selected NHSN Operative Procedure Categories.*

Surgical site infection: An infection, following a breast procedure (BRST), of either the skin, subcutaneous tissue and breast parenchyma at the incision site (superficial incisional SSI), deep soft tissues of the incision site (deep incisional SSI), or any part of the breast deeper than the fascial/muscle layers (subpectoral) that is opened or manipulated during the operative procedure (organ/space SSI).

There are three categories: Outpatient Procedure Component, Breast, Superficial Incisional Surgical Site Infection (OPC BRST - Superficial incisional SSI), Outpatient Procedure Component, Breast, Deep Incisional SSI (OPC BRST - Deep incisional SSI), and Outpatient Procedure Component, Breast, Organ Space SSI (OPC BRST - Organ/Space SSI)

Surgical site infection: An infection, following a breast procedure, of either the skin, subcutaneous tissue and breast parenchyma at the incision site (superficial incisional SSI), deep soft tissues of the incision site (deep incisional SSI), or any part of the body deeper than the fascial/muscle layers that is opened or manipulated during the operative procedure (organ/space SSI).

OPC BRST - Superficial incisional SSI

Must meet the following criteria:

Date of event for infection occurs within 30 days after a BRST; where day 1 = the procedure date AND involves either the skin, subcutaneous tissue (for example, fatty tissue) or breast parenchyma (for example, milk ducts and glands that produce milk) at the incision AND patient has at least one of the following:

a. purulent drainage from the superficial incision.
b. organisms identified from an aseptically-obtained specimen from the superficial incision or subcutaneous tissue by a culture or non-culture based microbiologic testing method which is performed for purposes of clinical diagnosis or treatment (for example, not Active Surveillance Culture/Testing [ASC/AST]).
c. superficial incision that is deliberately opened by a surgeon, physician or physician designee and culture or non-culture based testing of the superficial incision or subcutaneous tissue is not performed. and patient has at least one of the following signs or symptoms: localized pain or tenderness; localized swelling; redness (erythema); or heat. A culture or nonculture based test that has a negative finding does not meet this criterion.
d. diagnosis of a superficial incisional SSI by a physician or physician designee.

Comments for OPC BRST – Superficial Incisional SSI The two specific types of superficial incisional SSIs are: 1. Superficial incisional primary (SIP) – a superficial incisional SSI that is identified in a primary incision in a patient that has had an operation with one or more incisions (for example, the breast incision for BRST procedure). 2. Superficial incisional secondary (SIS) – a superficial incisional SSI that is identified in the secondary incision in a patient that has had an

operation with more than one incision (for example, transverse rectus abdominis myocutaneous [TRAM] flap incision site for BRST).

OPC BRST - Deep incisional SSI Must meet the following criteria:

Date of event for infection occurs within 90 days after a BRST; where day 1 = the procedure date AND involves deep soft tissues of the incision (for example, fascial and muscle layers) AND patient has at least one of the following:

a. purulent drainage from the deep incision.
b. a deep incision that spontaneously dehisces, or is deliberately opened or aspirated by a surgeon, physician or physician designee. and organism is identified from the deep soft tissues of the incision by a culture or non-culture based microbiologic testing method which is performed for purposes of clinical diagnosis or treatment (for example, not Active Surveillance Culture/Testing [ASC/AST]) or culture or non-culture based microbiologic testing method is not performed. A culture or nonculture based test that has a negative finding does not meet this criterion. and patient has at least one of the following signs or symptoms: fever (>38°C); localized pain or tenderness.
c. an abscess or other evidence of infection involving the deep incision that is detected on gross anatomical or histopathologic exam.
d. diagnosis of a superficial incisional SSI by a physician or physician designee.

Comments for OPC BRST – Superficial Incisional SSI The two specific types of superficial incisional SSIs are: 1. Superficial incisional primary (SIP) – a superficial incisional SSI that is identified in a primary incision in a patient that has had an operation with one or more incisions (for example, the breast incision for BRST procedure). 2. Superficial incisional secondary (SIS) – a superficial incisional SSI that is identified in the secondary incision in a patient that has had an operation with more than one incision (for example, transverse rectus abdominis myocutaneous [TRAM] flap incision site for BRST).

OPC BRST - Deep incisional SSI Must meet the following criteria:

Date of event for infection occurs within 90 days after a BRST; where day 1 = the procedure date AND involves deep soft tissues of the incision (for example, fascial and muscle layers) AND patient has at least one of the following:

a. purulent drainage from the deep incision.
b. a deep incision that spontaneously dehisces, or is deliberately opened or aspirated by a surgeon, physician or physician designee. and organism is identified from the deep soft tissues of the incision by a culture or non-culture based microbiologic testing method which is performed for purposes of clinical diagnosis or treatment (for example, not Active Surveillance Culture/Testing [ASC/AST]) or culture or non-culture based microbiologic testing method is not performed. A culture or nonculture based test that has a negative finding does not meet this criterion. and patient has at least one of the following signs or symptoms: fever (>38°C); localized pain or tenderness.
c. an abscess or other evidence of infection involving the deep incision that is detected on gross anatomical or histopathologic exam.

Comments for OPC BRST – Deep Incisional SSI The two specific types of deep incisional SSIs are: 1. 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 (for example, the breast incision for BRST procedure). 2. Deep incisional secondary (DIS) – a deep incisional SSI that is identified in the secondary incision in a patient that has had an operation with more than one incision (for example, transverse rectus abdominis myocutaneous [TRAM] flap incision site for BRST).

OPC BRST - Organ/Space SSI Must meet the following criteria:

Date of event for infection occurs within 90 days a BRST; where day 1 = the procedure date AND infection involves any part of the body deeper than the fascial/muscle layers (subpectoral), that is opened or manipulated during the operative procedure. AND patient has at least one of the following:

a. purulent drainage from a drain that is placed into the organ/space (for example, closed suction drainage system, open drain, T-tube drain, and CT guided drainage).

b. organisms identified from affected breast tissue or fluid obtained by invasive procedure by a culture or non-culture based microbiologic testing method which is performed for purposes of clinical diagnosis or treatment (for example, not Active Surveillance Culture/Testing [ASC/AST]).

c. breast abscess or other evidence of infection on gross anatomic or histopathologic exam or imaging test consistent with breast infection.

NOTES:

- Breast surgeries may involve a secondary operative incision, specifically, procedures that include a transverse rectus abdominis myocutaneous [TRAM] flap. The flap site is the secondary operative incision. Secondary sites have a 30-day surveillance period. If the secondary site meets criteria for an SSI, it is reported as either a superficial incisional SSI at the secondary site or deep incisional infection at the incisional site.• Accessing a breast expander after a breast surgery is considered an invasive procedure and any subsequent infection is not deemed an SSI attributable to the breast surgery.
- Meeting additional infection criteria found in the Patient Safety Component Chapter 17, CDC/NHSN Surveillance Definitions for Specific Types of Infections is NOT a part of the OPC BRST - Organ/Space SSIs reporting criteria.
- ** The term attending physician for the purposes of application of the NHSN SSI criteria may be interpreted to mean the surgeon(s), infectious disease, other physician on the case, emergency physician or physician's designee (nurse practitioner or physician's assistant).

Table 2. Surveillance Periods for SSIs Following Selected NHSN Operative Procedure Categories. Day 1 = the date of the procedure.

30-day Surveil-lance	**30-day Surveillance**	**30-day Surveillance**	**30-day Surveillance**
Category	**Operative Procedure**	**Category**	**Operative Procedure**
AMP	Limb amputation	NECK	Neck surgery
APPY	Appendix surgery	NEPH	Kidney surgery
AVSD	Shunt for dialysis	OVRY	Ovarian surgery
BILI	Bile duct, liver or pancreatic surgery	PRST	Prostate surgery
CEA	Carotid endarterectomy	REC	Rectal surgery
CHOL	Gallbladder surgery	SB	Small bowel surgery
COLO	Colon surgery	SPLE	Spleen surgery
GAST	Gastric surgery	THOR	Thoracic surgery
HYST	Abdominal hysterectomy	THYR	Thyroid and/or parathyroid surgery
LAM	Laminectomy	VHYS	Vaginal hysterectomy
*	*	XLAP	Exploratory Laparotomy
90-day Surveil-lance	**90-day Surveillance**	**90-day Surveillance**	**90-day Surveillance**
Category	**Operative Procedure**	*	*
BRST	Breast surgery	*	*
FUSN	Spinal fusion	*	*
FX	Open reduction of fracture	*	*

30-day Surveil-lance	30-day Surveillance	30-day Surveillance	30-day Surveillance
HER	Herniorrhaphy	*	*
HPRO	Hip prosthesis	*	*
KPRO	Knee prosthesis	*	*
PACE	Pacemaker surgery	*	*
PVBY	Peripheral vascular bypass surgery	*	*
VSHN	Ventricular shunt	*	*

* Cell intentionally left empty

NOTES: Superficial incisional SSIs are only followed for a 30-day period for all procedure types.

Secondary incisional SSIs are only followed for a 30-day period regardless of the surveillance period for the primary site.

[Response Ends]

For the question below: state the target population for the outcome. Calculation of the risk-adjusted outcome should be described in sp.22.

sp.15. State the denominator.

Brief, narrative description of the target population being measured.

[Response Begins]

Breast procedures, as specified by the operative procedure codes that comprise the breast procedure category of the NHSN Outpatient Procedure Component Protocol, are performed at ambulatory surgery centers.

[Response Ends]

For the question below: describe how the target population is identified. Calculation of the risk-adjusted outcome should be described in sp.22.

sp.16. Provide details needed to calculate the denominator.

All information required to identify and calculate the target population/denominator such as definitions, time period for data collection, specific data collection items/responses, code/value sets.

Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format at sp.11.

[Response Begins]

CPT codes for NHSN Breast Procedure category:

11970, 19101, 19105, 19110, 19112, 19120, 19125, 19126, 19300, 19301, 19302, 19303, 19304, 19305, 19306, 19307, 19316, 19318, 19324, 19325, 19328, 19330, 19340, 19342, 19350, 19355, 19357, 19361, 19364, 19366, 19367, 19368, 19369, 19370, 19371, 19380

See attached spreadsheet for descriptions of each code.: https://www.cdc.gov/nhsn/xls/opc/opc-cpt-pcm-nhsn.xlsx

See attached spreadsheet for descriptions of each code.: https://www.cdc.gov/nhsn/xls/opc/opc-cpt-pcm-nhsn.xlsx

Note: Bilateral breast procedures performed during the same trip to operating room are counted as two separate procedures

Ambulatory surgical center (ASC): any distinct entity that operates exclusively for the purpose of providing surgical services to patients not requiring hospitalization and in which the expected duration of services would not exceed 24 hours following an admission.

Any ASC as defined by the Code of Federal Regulations 42 CFR § 416.2 and has a "C" as the 3rd digit of its CMS Certification Number (CCN) is eligible to join NHSN OPC. These ASCs will use this protocol for surveillance of surgical patients receiving an eligible NHSN outpatient procedure.

Parameter estimates for breast procedure logistic regression model are needed to calculate the expected number of SSIs (included in the attached document).

Patient-specific data: Age, American Society of Anesthesiologists Physical Status Classification (ASA Class).

[Response Ends]

sp.17. Describe the denominator exclusions.

Brief narrative description of exclusions from the target population.

[Response Begins]

Hospital inpatients and hospital outpatient department patients, patients under age 18 or age 109 or over, and brain-dead patients whose organs are being removed for donor purposes

[Response Ends]

sp.18. Provide details needed to calculate the denominator exclusions.

All information required to identify and calculate exclusions from the denominator such as definitions, time period for data collection, specific data collection items/responses, code/value sets – Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format at sp.11.

[Response Begins]

Exclusion Criteria:

1. Inpatient breast procedures*

2. Breast procedures performed on patients under age 18 or age 109 or over.

3. Breast procedures with ASA Class VI (6).

*Breast procedures performed in hospital outpatient departments (HOPDs) are not included in the measure scope.

[Response Ends]

sp.19. Provide all information required to stratify the measure results, if necessary.

Include the stratification variables, definitions, specific data collection items/responses, code/value sets, and the risk-model covariates and coefficients for the clinically-adjusted version of the measure when appropriate. Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format in the Data Dictionary field.

[Response Begins]

Age at time of procedure (2 groups: 18 to 44 years; 45 years or older)

Anesthesia (Yes or No)

Body Mass Index (BMI; 2 groups: less than 30; 30 or more)

[Response Ends]

sp.20. Is this measure adjusted for socioeconomic status (SES)?

[Response Begins]

No

[Response Ends]

sp.21. Select the risk adjustment type.

Select type. Provide specifications for risk stratification and/or risk models in the Scientific Acceptability section.

[Response Begins]

Statistical risk model

[Response Ends]

sp.22. Select the most relevant type of score.

Attachment: If available, please provide a sample report.

[Response Begins]

Ratio

[Response Ends]

sp.23. Select the appropriate interpretation of the measure score.

Classifies interpretation of score according to whether better quality or resource use is associated with a higher score, a lower score, a score falling within a defined interval, or a passing score

[Response Begins]

Better quality = Lower score

[Response Ends]

sp.24. Diagram or describe the calculation of the measure score as an ordered sequence of steps.

Identify the target population; exclusions; cases meeting the target process, condition, event, or outcome; time period of data, aggregating data; risk adjustment; etc.

[Response Begins]

Each SIR is calculated as follows:

1. Identify the number of infections reported during the measurement period for an observed number of infections.

2. Obtain the predicted number of infections by applying the risk adjustment model to all eligible breast procedures during the measurement period.
4. Divide the observed number of infections by the predicted number of infections.
5. Result = SIR for the given period.
6. Note: SIRs are not calculated when the number of predicted infections is less than 1.0.

[Response Ends]

sp.27. If measure testing is based on a sample, provide instructions for obtaining the sample and guidance on minimum sample size.

Examples of samples used for testing:

- *Testing may be conducted on a sample of the accountable entities (e.g., hospital, physician). The analytic unit specified for the particular measure (e.g., physician, hospital, home health agency) determines the sampling strategy for scientific acceptability testing.*
- *The sample should represent the variety of entities whose performance will be measured. The 2010 Measure Testing Task Force recognized that the samples used for reliability and validity testing often have limited generalizability because measured entities volunteer to participate. Ideally, however, all types of entities whose performance will be measured should be included in reliability and validity testing.*
- *The sample should include adequate numbers of units of measurement and adequate numbers of patients to answer the specific reliability or validity question with the chosen statistical method.*
- *When possible, units of measurement and patients within units should be randomly selected.*

[Response Begins]

Does not apply

[Response Ends]

sp.30. Select only the data sources for which the measure is specified.

[Response Begins]

Electronic Health Data

Electronic Health Records

Other (specify)

[Other (specify) Please Explain]

Data collection for SSIs following outpatient operative procedures is via NHSN Outpatient Procedure Component.

Paper Medical Records

[Response Ends]

sp.31. Identify the specific data source or data collection instrument.

For example, provide the name of the database, clinical registry, collection instrument, etc., and describe how data are collected.

[Response Begins]

NHSN webpage with specific information provided as part of the NHSN Outpatient Procedure Component

[Response Ends]

sp.32. Provide the data collection instrument.

[Response Begins]

Available at measure-specific web page URL identified in sp.09

[Response Ends]

2ma.01. Indicate whether additional empirical reliability testing at the accountable entity level has been conducted. If yes, please provide results in the following section, Scientific Acceptability: Reliability - Testing. Include information on all testing conducted (prior testing as well as any new testing).

Please separate added or updated information from the most recent measure evaluation within each question response in the Scientific Acceptability sections. For example:

Current Submission:

Updated testing information here.

Previous Submission:

Testing from the previous submission here.

[Response Begins]

No

[Response Ends]

2ma.02. Indicate whether additional empirical validity testing at the accountable entity level has been conducted. If yes, please provide results in the following section, Scientific Acceptability: Validity - Testing. Include information on all testing conducted (prior testing as well as any new testing).

Please separate added or updated information from the most recent measure evaluation within each question response in the Scientific Acceptability sections. For example:

Current Submission:

Updated testing information here.

Previous Submission:

Testing from the previous submission here.

[Response Begins]

No

[Response Ends]

2ma.03. For outcome, patient-reported outcome, resource use, cost, and some process measures, risk adjustment/stratification may be conducted. Did you perform a risk adjustment or stratification analysis?

[Response Begins]

No

[Response Ends]

2ma.04. For maintenance measures in which risk adjustment/stratification has been performed, indicate whether additional risk adjustment testing has been conducted since the most recent maintenance evaluation. This may include updates to the risk adjustment analysis with additional clinical, demographic, and social risk factors.

Please update the Scientific Acceptability: Validity - Other Threats to Validity section.

Note: This section must be updated even if social risk factors are not included in the risk adjustment strategy.

[Response Begins]

No additional risk adjustment analysis included

[Response Ends]

Measure testing must demonstrate adequate reliability and validity in order to be recommended for endorsement. Testing may be conducted for data elements and/or the computed measure score. Testing information and results should be entered in the appropriate fields in the Scientific Acceptability sections of the Measure Submission Form.

- Measures must be tested for all the data sources and levels of analyses that are specified. If there is more than one set of data specifications or more than one level of analysis, contact NQF staff about how to present all the testing information in one form.
- All required sections must be completed.
- For composites with outcome and resource use measures, Questions 2b.23-2b.37 (Risk Adjustment) also must be completed.
- If specified for multiple data sources/sets of specifications (e.g., claims and EHRs), Questions 2b.11-2b.13 also must be completed.
- An appendix for supplemental materials may be submitted (see Question 1 in the Additional section), but there is no guarantee it will be reviewed.
- Contact NQF staff with any questions. Check for resources at the Submitting Standards webpage.
- For information on the most updated guidance on how to address social risk factors variables and testing in this form refer to the release notes for the 2021 Measure Evaluation Criteria and Guidance.

Note: The information provided in this form is intended to aid the Standing Committee and other stakeholders in understanding to what degree the testing results for this measure meet NQF's evaluation criteria for testing.

2a. Reliability testing demonstrates the measure data elements are repeatable, producing the same results a high proportion of the time when assessed in the same population in the same time period and/or that the measure score is precise. For instrument-based measures (including PRO-PMs) and composite performance measures, reliability should be demonstrated for the computed performance score.

2b1. Validity testing demonstrates that the measure data elements are correct and/or the measure score correctly reflects the quality of care provided, adequately identifying differences in quality. For instrument based measures (including PRO-PMs) and composite performance measures, validity should be demonstrated for the computed performance score.

2b2. Exclusions are supported by the clinical evidence and are of sufficient frequency to warrant inclusion in the specifications of the measure;

AND

If patient preference (e.g., informed decision-making) is a basis for exclusion, there must be evidence that the exclusion impacts performance on the measure; in such cases, the measure must be specified so that the information about patient preference and the effect on the measure is transparent (e.g., numerator category computed separately, denominator exclusion category computed separately).

2b3. For outcome measures and other measures when indicated (e.g., resource use):

- an evidence-based risk-adjustment strategy (e.g., risk models, risk stratification) is specified; is based on patient factors (including clinical and social risk factors) that influence the measured outcome and are present at start of care; 14,15 and has demonstrated adequate discrimination and calibration
- rationale/data support no risk adjustment/ stratification.

2b4. Data analysis of computed measure scores demonstrates that methods for scoring and analysis of the specified measure allow for identification of statistically significant and practically/clinically meaningful 16 differences in performance;

OR

there is evidence of overall less-than-optimal performance.

2b5. If multiple data sources/methods are specified, there is demonstration they produce comparable results.

2b6. Analyses identify the extent and distribution of missing data (or nonresponse) and demonstrate that performance results are not biased due to systematic missing data (or differences between responders and non-responders) and how the specified handling of missing data minimizes bias.

2c. For composite performance measures, empirical analyses support the composite construction approach and demonstrate that:

2c1. the component measures fit the quality construct and add value to the overall composite while achieving the related objective of parsimony to the extent possible; and

2c2. the aggregation and weighting rules are consistent with the quality construct and rationale while achieving the related objective of simplicity to the extent possible.

(if not conducted or results not adequate, justification must be submitted and accepted)

Definitions

Reliability testing applies to both the data elements and computed measure score. Examples of reliability testing for data elements include, but are not limited to: inter-rater/abstractor or intra-rater/abstractor studies; internal consistency for multi-item scales; test-retest for survey items. Reliability testing of the measure score addresses precision of measurement (e.g., signal-to-noise).

Validity testing applies to both the data elements and computed measure score. Validity testing of data elements typically analyzes agreement with another authoritative source of the same information. Examples of validity testing of the measure score include, but are not limited to: testing hypotheses that the measures scores indicate quality of care, e.g., measure scores are different for groups known to have differences in quality assessed by another valid quality measure or method; correlation of measure scores with another valid indicator of quality for the specific topic; or relationship to conceptually related measures (e.g., scores on process measures to scores on outcome measures). Face validity of the measure score as a quality indicator may be adequate if accomplished through a systematic and transparent process, by identified experts, and explicitly addresses whether performance scores resulting from the measure as specified can be used to distinguish good from poor quality. The degree of consensus and any areas of disagreement must be provided/discussed.

Examples of evidence that an exclusion distorts measure results include, but are not limited to: frequency of occurrence, variability of exclusions across providers, and sensitivity analyses with and without the exclusion.

Patient preference is not a clinical exception to eligibility and can be influenced by provider interventions.

Risk factors that influence outcomes should not be specified as exclusions.

With large enough sample sizes, small differences that are statistically significant may or may not be practically or clinically meaningful. The substantive question may be, for example, whether a statistically significant difference of one percentage point in the percentage of patients who received smoking cessation counseling (e.g., 74 percent v. 75 percent) is clinically meaningful; or whether a statistically significant difference of $25 in cost for an episode of care (e.g.,

$5,000 v.$5,025) is practically meaningful. Measures with overall less-than-optimal performance may not demonstrate much variability across providers.

Please separate added or updated information from the most recent measure evaluation within each question response in the Scientific Acceptability sections. For example:

Current Submission:

Updated testing information here.

Previous (Year) Submission:

Testing from the previous submission here.

2a.01. Select only the data sources for which the measure is tested.

[Response Begins]

Electronic Health Data

Electronic Health Records

Other (specify)

[Other (specify) Please Explain]

Data collection for SSIs following outpatient operative procedures is via NHSN Outpatient Procedure Component.

Paper Medical Records

[Response Ends]

2a.02. If an existing dataset was used, identify the specific dataset.

The dataset used for testing must be consistent with the measure specifications for target population and healthcare entities being measured; e.g., Medicare Part A claims, Medicaid claims, other commercial insurance, nursing home MDS, home health OASIS, clinical registry).

[Response Begins]

The data source is the NHSN surveillance system

[Response Ends]

2a.03. Provide the dates of the data used in testing.

Use the following format: "MM-DD-YYYY - MM-DD-YYYY"

[Response Begins]

01-01-2021 – 12-31-2021

[Response Ends]

2a.04. Select the levels of analysis for which the measure is tested.

Testing must be provided for all the levels specified and intended for measure implementation, e.g., individual clinician, hospital, health plan.

Please refrain from selecting the following answer option(s). We are in the process of phasing out these answer options and request that you instead select one of the other answer options as they apply to your measure.

Please do not select:

- *Clinician: Clinician*
- *Population: Population*

[Response Begins]

Facility

[Response Ends]

2a.05. List the measured entities included in the testing and analysis (by level of analysis and data source).

Identify the number and descriptive characteristics of measured entities included in the analysis (e.g., size, location, type); if a sample was used, describe how entities were selected for inclusion in the sample.

[Response Begins]

Testing Dataset

Descriptive Characteristics of Ambulatory Surgery Centers reporting Outpatient Surgical Breast Procedures to NHSN that met Minimum Precision Criteria to Calculate SIR, 2021 (n=16).	*
Variable	n(%)
State	*
Colorado	7 (43.8%)
New Jersey	4 (25.0%)
Massachusetts	1 (6.3%)
North Carolina	1 (6.3%)
Tennessee	1 (6.3%)
Virginia	1 (6.3%)
Washington	1 (6.3%)
Procedure Volume	9,049

* Cell intentionally left empty

[Response Ends]

2a.06. Identify the number and descriptive characteristics of patients included in the analysis (e.g., age, sex, race, diagnosis), separated by level of analysis and data source; if a sample was used, describe how patients were selected for inclusion in the sample.

If there is a minimum case count used for testing, that minimum must be reflected in the specifications.

[Response Begins]

Reliability testing dataset patient characteristics:

Table 4. Descriptive Characteristics of Predictors of Surgical Site Infections among Outpatient Surgical Breast Procedures Performed in Ambulatory Surgery Centers Reported to NHSN that met Minimum Precision Criteria to Calculate SIR, 2021 (n=9,049).	*
Variable	n(%) or Mean (SD)
Surgical Site Infections	41
Age of Patient	*
>=45	5849 (64.6%)
18 - 44	3200 (35.4%)
General Anesthesia Used	8463 (93.5%)
BMI	*
>=30	2803 (31.0%)
<30	6246 (69.0%)
Female Gender	8848 (97.8%)
Duration of Procedure	63.8 (44.5)
ASA Classification	*
1	1517 (16.8%)
2	6296 (69.6%)
3/4/5	1236 (13.7%)
Wound Classification	*
Clean/Clean Contaminated	9033 (99.8%)
Contaminated/Dirty	16 (0.2%)

* Cell intentionally left empty

[Response Ends]

2a.07. If there are differences in the data or sample used for different aspects of testing (e.g., reliability, validity, exclusions, risk adjustment), identify how the data or sample are different for each aspect of testing.

[Response Begins]

A universal exclusion criterion was applied prior to risk adjusting the SIR denominator (procedures). Procedures meeting any of the following potential data quality issues were excluded:

1. Procedures linked to SSI events that are present at time of surgery
2. Procedures with procedure date before date of birth
3. Procedure duration under 5 minutes
4. Procedures with patient age greater than 109
5. Procedures with missing surgical closure technique
6. Procedures with patient's gender reported as "other"
7. Procedures missing wound class value
8. Procedures in adult patients with BMI greater than 60 or BMI less than 12
9. Procedures exceeding the interquartile range (The IQR5 is calculated as five times the interquartile range (Q1-Q3) above the 75th percentile.)

[Response Ends]

2a.08. List the social risk factors that were available and analyzed.

For example, patient-reported data (e.g., income, education, language), proxy variables when social risk data are not collected from each patient (e.g. census tract), or patient community characteristics (e.g. percent vacant housing, crime rate) which do not have to be a proxy for patient-level data.

[Response Begins]

Social risk factors were not available or analyzed

[Response Ends]

Note: If accuracy/correctness (validity) of data elements was empirically tested, separate reliability testing of data elements is not required – in 2a.09 check patient or encounter-level data; in 2a.010 enter "see validity testing section of data elements"; and enter "N/A" for 2a.11 and 2a.12.

2a.09. Select the level of reliability testing conducted.

Choose one or both levels.

[Response Begins]

Accountable Entity Level (e.g., signal-to-noise analysis)

[Response Ends]

2a.10. For each level of reliability testing checked above, describe the method of reliability testing and what it tests.

Describe the steps—do not just name a method; what type of error does it test; what statistical analysis was used.

[Response Begins]

Reliability for the Standardized Infection Ratio (SIR) was calculated using a signal to noise approach. The SIR is defined as SIR=O/P, where O represents the sum of the SSI events in the facility and P represents the sum of the predicted number of events calculated from the risk-adjustment model. Reliability is calculated as $\sigma_b^2/(\sigma_b^2 + \sigma_w^2)$ where σ_b^2 denotes between facility variance and σ_w^2 denotes within facility variance (see Adams J.L. "The Reliability of Provider Profiling: A Tutorial"; RAND Corporation, TR-653-NCQA, 2009). The between facility variance was obtained from a hierarchical linear model applied to the facility-level SIRs. The within facility variance of the SIR for each facility was calculated as Var(O/P) where O was assumed to follow a Poisson distribution and P is constant. The result is $Var(O/P) = Var(O)/P^2 = P/P^2 = 1/P$. This approach uses a single year (2021) of facility-level pooled SIRs consistent with the intended use that is being evaluated.

[Response Ends]

2a.11. For each level of reliability testing checked above, what were the statistical results from reliability testing?

For example, provide the percent agreement and kappa for the critical data elements, or distribution of reliability statistics from a signal-to-noise analysis. For score-level reliability testing, when using a signal-to-noise analysis, more than just one overall statistic should be reported (i.e., to demonstrate variation in reliability across providers). If a particular method yields only one statistic, this should be explained. In addition, reporting of results stratified by sample size is preferred (pg. 18, NQF Measure Evaluation Criteria).

[Response Begins]

Table 5. Reliability Testing Annual, pooled facility-level OPC Breast SSI SIRs, 2021

*	Reliability Annual, pooled facility-level OPC Breast SSI SIRs, 2021	*	*	*	*	*	*
N. of facilities	**Mean**	**p10**	**p25**	**p50**	**p75**	**p90**	**>=0.7**
16	0.791	0.732	0.747	0.782	0.843	0.863	15/16 (94%)

* Cell intentionally left empty

[Response Ends]

2a.12. Interpret the results, in terms of how they demonstrate reliability.

(In other words, what do the results mean and what are the norms for the test conducted?)

[Response Begins]

Reliability scores vary across facilities from zero to one, with a score of zero indicating that all variation is attributable to noise (variation across patients within facilities) and a score of one indicating that all variation is caused by real differences in performance across facilities.

There is no strict cut-off to define minimum reliability. However, values above 0.7 are generally considered acceptably reliable. The reliability analysis for Ambulatory Breast Procedure Surgical Site Infection measure, shows 94% of facilities have reliability above 0.7 and thus we conclude the measure is reliable. The one facility that had reliability<0.7 had reliability=0.687.

[Response Ends]

2b. Validity

2b.01. Select the level of validity testing that was conducted.

[Response Begins]

Systematic assessment of face validity of performance measure score as an indicator of quality or resource use (i.e., is an accurate reflection of performance on quality or resource use and can distinguish good from poor performance)

[Response Ends]

2b.02. For each level of testing checked above, describe the method of validity testing and what it tests.

Describe the steps—do not just name a method; what was tested, e.g., accuracy of data elements compared to authoritative source, relationship to another measure as expected; what statistical analysis was used.

[Response Begins]

Validity Testing was performed for the previous submission.

Methods from previous submission:

The Centers for Disease Control and Prevention (CDC), working with the Ambulatory Surgery Center Quality Collaboration (ASC QC), developed a measure to assess the incidence of surgical site infections (SSI) following breast procedures. The validity, feasibility, interpretability, and actionability of the measure were assessed through a formal consensus process. Specifically, ASC QC administered a questionnaire, which included questions related to the four measure attributes, to 11 professionals currently working in ambulatory surgery centers (ASC). Seven respondents were registered nurses, working in regional operations, administration, clinical management, information technology, or quality improvement. The remaining four respondents were medical doctors; two general surgeons and two plastic surgeons. The questionnaire rated the respondent's level of agreement with statements related to each measure attribute based on a 5-point Likert Scale with a rating of 5 expressing agreement and 1 expressing disagreement. It also allowed respondents to elaborate on their ratings in open-ended questions. All respondents provided complete numeric ratings of the measure characteristics, and several respondents provided comments on open-ended questions. Questionnaire responses were analyzed to assess the panel's consensus with respect to the validity, feasibility, interpretability, and actionability of the measure.

[Response Ends]

2b.03. Provide the statistical results from validity testing.

Examples may include correlations or t-test results.

[Response Begins]

Results from previous submission. No additional testing performed for current submission.

Validity Testing

There was high level of agreement among the respondents regarding the validity of the measure. Out of 11 respondents, 9 (81.8%) agreed that the measure appears to measure what it is intended to, giving a 5/5 rating response. The other two respondents rated their level of agreement with this statement with a 4/5 rating. Regarding the statement on whether the measure allows for consistent interpretation across centers, 9 out of 11 (81.8%) respondents agreed with a 5/5 rating, and 1 provided a 4/5 rating. The remaining respondent gave a 3/5 rating and expressed the difficulty inherent in dividing breast surgery SSI into categories of superficial and deep incisional due to the nature of the procedure.

The questionnaire also inquired about the extent to which the measure's score accurately reflects the quality of a center's performance. The majority of respondents (8 out of 11) agreed with the statement with a rating of 4/5 or 5/5; 2 neither agreed nor disagreed (3/5); and 1 disagreed (1/5). Several respondents elaborated that factors other than the quality of a center's performance, such as patient comorbidities, risk factors, and the quality of a surgeon can influence SSI. Regarding the statement that the measure's score can be used to distinguish between good and poor performance, 7 respondents (63.6%) agreed, giving a minimum rating of 4/5, 3 (27.3%) gave a rating of 3/5, and 1 disagreed with the statement (1/5). Several respondents again noted that SSI cannot be solely attributed to the quality of a center, and factors outside a facility's control, such as patient comorbidities, poor hygiene, and non-compliance with post-op instructions, may affect the measure's score.

The statements related to validity are listed below. Each statement was measured on a 5-point Likert Scale with a rating of 5 expressing agreement and a rating of 1 expressing disagreement.

- The measure appears to measure what it is intended to. (Median: 5.0/5.0; Mean: 4.8/5.0)
- The measure is defined in a way that will allow for consistent interpretation of the inclusion and exclusion criteria from center to center. (Median: 5.0/5.0; Mean: 4.7/5.0)
- The measure score is an accurate reflection of the quality of center performance. (Median: 4.0/5.0; Mean: 3.6/5.0)
- The measure score can be used to distinguish good from poor performance. (Median: 4.0/5.0; Mean: 3.6/5.0)

Feasibility Testing

In addition to validity, the questionnaire inquired about the feasibility of the measure with respect to effort and cost. The majority of respondents expressed agreement that data for the measure could be obtained with reasonable effort (81.8% with a minimum rating of 4/5) and reasonable cost (90.9% with a minimum rating of 4/5). In their open-ended responses, respondents noted the need for more patient engagement and increased labor costs to obtain the required data. One respondent indicated that 90 days is a difficult measure in ASCs.

The statements related to feasibility are listed below. Each statement was measured on a 5-point Likert Scale with a rating of 5 expressing agreement and a rating of 1 expressing disagreement.

- The data required for the measure are likely to be obtained with reasonable effort. (Median: 4.0/5.0; Mean: 4.2/5.0)
- The data required for the measure are likely to be obtained with reasonable cost. (Median: 4.0/5.0; Mean: 4.4/5.0)

Interpretability and Actionability Testing

All respondents agreed that providers can understand the results of the measure, giving a minimum rating of 4/5 to the relevant statement. The questionnaire responses also indicated that the measure is actionable. The majority of respondents (10 out of 11) agreed that a provider can take action based on measure results, with 8 respondents giving a 5/5 rating and 2 giving a 4/5 rating. One respondent gave a 2/5 rating. Regarding the existence of a direct linkage between the measure and improving the outcome/processes of care, 10 out of 11 respondents agreed with at least a 4/5 rating while 1 respondent gave a 2/5 rating. In response to the associated open-ended question, one of the respondents indicated some apprehension in the implementation of measures related to SSI due to the role of patient compliance in the prevention of SSI.

The statements related to interpretability and actionability are listed below. Each statement was measured on a 5-point Likert Scale with a rating of 5 expressing agreement and a rating of 1 expressing disagreement.

- A provider can understand the results of the measure. (Median: 5.0/5.0; Mean: 4.8/5.0)
- If necessary, a provider can use the results of the measure to take action. (Median: 5.0/5.0; Mean: 4.6/5.0)
- This measure has a direct link to improving the outcome and/or related processes of care. (Median: 5.0/5.0; Mean: 4.4/5.0)

[Response Ends]

2b.04. Provide your interpretation of the results in terms of demonstrating validity. (i.e., what do the results mean and what are the norms for the test conducted?)

[Response Begins]

We are unable to perform empirical validity testing of the measure score due to the limited data available. Statistical testing would not be powered to detect significance and strength of an association with other quality measures. Due to the limited data available, the survey results serve as a validity testing for this measure. There was a high level of agreement amongst the ASC professionals regarding the validity of the measure. The literature cites common signs and symptoms of SSI post breast surgery as swelling, redness, abnormal/purulent drainage, fever, positive culture findings, and/or breast pain[1,2]. These findings support the responses of the ASC professionals as it relates to the survey question of if indeed "the measure appears to measure what it is intended to". The signs and symptoms cited in the literature align with the data elements included in the breast measure. In addition to validity, the majority of respondents expressed agreement that data for the measure could be obtained with reasonable effort and reasonable cost. All respondents agreed that providers can understand the results of the measure.

1. Connell J, Carlton J, Grundy A, Taylor Buck E, Keetharuth AD, Ricketts T, Barkham M, Robotham D, Rose D, Brazier J. The importance of content and face validity in instrument development: lessons learnt from service users when developing the Recovering Quality of Life measure (ReQoL). Qual Life Res. 2018 Jul;27(7):1893-1902. doi: 10.1007/s11136-018-1847-y. Epub 2018 Apr 19. PMID: 29675691; PMCID: PMC5997715.

2. Basta, Marten N. MD; Liu, Paul Y. MD, FACS; Kwan, Daniel MD; Breuing, Karl H. MD, FACS; Sullivan, Rachel MD; Jehle, Charles C. MD; Bass, Jonathan L. MD; Zienowicz, Richard J. MD, FACS; Schmidt, Scott MD. Improved Diagnostic Accuracy of Periprosthetic Breast Infection: Novel Application of the Alpha Defensin-1 Biomarker. Plastic and Reconstructive Surgery - Global Open: November 2019 - Volume 7 - Issue 11 - p e2542 doi: 10.1097/GOX.0000000000002542

[Response Ends]

2b.05. Describe the method for determining if statistically significant and clinically/practically meaningful differences in performance measure scores among the measured entities can be identified.

Describe the steps—do not just name a method; what statistical analysis was used? Do not just repeat the information provided in Importance to Measure and Report: Gap in Care/Disparities.

[Response Begins]

The models calculated the predicted number of surgical site infections. The Standardized Infection Ratio (SIR) and confidence interval were calculated as: reported number of surgical site infections/predicted number of surgical site infections. The SIR is not calculated when the predicted value is less than 1.0. Using the mid-p exact test, the calculated SIR and its confidence interval were compared to an SIR of 1.

[Response Ends]

2b.06. Describe the statistical results from testing the ability to identify statistically significant and/or clinically/practically meaningful differences in performance measure scores across measured entities.

Examples may include number and percentage of entities with scores that were statistically significantly different from mean or some benchmark, different from expected; how was meaningful difference defined.

[Response Begins]

The SIR can discriminate between and test if there is a difference between facilities. A meaningful difference in the SIR was defined as an SIR and a confidence interval that was statistically different from 1. Out of 119 total facilities reporting in 2015, SIRs were able to be calculated for 12 of them. Below is a table showing the percentage of SIRs that were significantly different from 1.

Distribution of SIRs Calculated for ASCs Reporting in 2015 at the time of baseline determination	*	*
SIR	No. of Facilities	Percent
Not Significantly different from 1	1	8.33
Significantly lower than 1	7	58.33
Significantly higher than 1	4	33.33

* Cell intentionally left empty

Out of 95 total facilities reporting in 2021, 16 facilities met minimum precision criterion of predicted values greater or equal than 1 and thus SIRs were able to be calculated. Below is a table showing the percentage of SIRs that were significantly different from 1.

Distribution of SIRs Calculated for ASCs Reporting in 2021	*	*
SIR	No. of Facilities	Percent
Not Significantly different from 1	15	93.75
Significantly lower than 1	0	0
Significantly higher than 1	1	6.25

* Cell intentionally left empty

[Response Ends]

2b.07. Provide your interpretation of the results in terms of demonstrating the ability to identify statistically significant and/or clinically/practically meaningful differences in performance across measured entities.

In other words, what do the results mean in terms of statistical and meaningful differences?

[Response Begins]

The SIR enables detection of statistically significant and clinically meaningful differences in SSI that warrant further analysis and possible action. Although exposure volume is low, leading to few statistically significant SIRs in this population, the value of the calculated SIRs can reflect practical measures of performance.

[Response Ends]

2b.08. Describe the method of testing conducted to identify the extent and distribution of missing data (or non-response) and demonstrate that performance results are not biased due to systematic missing data (or differences between responders and non-responders). Include how the specified handling of missing data minimizes bias.

Describe the steps—do not just name a method; what statistical analysis was used.

[Response Begins]

All facilities participating in NHSN and reporting ambulatory breast SSI events follow the same protocol for reporting events. The NHSN application provides "Alerts" to participating healthcare facilities in the event of missing data. In addition, CDC analysts conduct regular data quality checks and perform outreach to facilities regarding any missing or implausible data. Facilities that are not reporting data elements that are required by NHSN would not be eligible to receive an SIR.

[Response Ends]

2b.09. Provide the overall frequency of missing data, the distribution of missing data across providers, and the results from testing related to missing data.

For example, provide results of sensitivity analysis of the effect of various rules for missing data/non-response. If no empirical sensitivity analysis was conducted, identify the approaches for handling missing data that were considered and benefits and drawbacks of each).

[Response Begins]

The overall frequency of missing variables is 0 (zero). The criteria of the OPC protocol are supported within the application by business rules which prevent records from being saved before all required fields are completed. The business rules prevent missing variables in completed records. Only completed records are included in data analysis and contribute to SIR calculation. The table below demonstrates zero missing data for surgical closure technique and wound class variables.

BRST Procedures Excluded from final Measure Calculation

Reasons for Exclusion:

Year	Total Exclusions	Included Procedures	% Excluded	Procedure before DOB	Procedure Duration <5 minutes	Patient Age > 109	Missing Surgical Closure Technique	Gender reported as 'other'	Missing Wound Class Value	BMI not within 12-60	Procedures exceeding interquartile range
2021	82	16298	0.05%	0	29	1	0	4	0	21	27

The overall frequency of missing infection events and denominators (procedure records) is 0 (zero). Additional business rules require infection events to be entered and if no events are identified for the reporting period, this triggers an alert which the facility is required to address by entering events or by selecting "Report No Events". This satisfies the missing events alert and results in no missing data. Likewise, business rules require all denominators (procedure records) to be entered and if no procedures are entered for the reporting period, this triggers an alert which the facility is required to address by entering all procedure records or by selecting "No Procedures Performed".

The above-described function of the business rules ensures with a high degree of certainty that there is no missing data.

[Response Ends]

2b.10. Provide your interpretation of the results, in terms of demonstrating that performance results are not biased due to systematic missing data (or differences between responders and non-responders), and how the specified handling of missing data minimizes bias.

In other words, what do the results mean in terms of supporting the selected approach for missing data and what are the norms for the test conducted; if no empirical analysis was conducted, justify the selected approach for missing data.

[Response Begins]

Due to enforced business rules inside of the NHSN application, the majority of healthcare facilities are completing 100% of all required data entry, and thus minimal "missing" data exist.

[Response Ends]

Note: This item is directed to measures that are risk-adjusted (with or without social risk factors) OR to measures with more than one set of specifications/instructions (e.g., one set of specifications for how to identify and compute the measure from medical record abstraction and a different set of specifications for claims or eCQMs). It does not apply to measures that use more than one source of data in one set of specifications/instructions (e.g., claims data to identify the denominator and medical record abstraction for the numerator). Comparability is not required when comparing performance scores with and without social risk factors in the risk adjustment model. However, if comparability is not demonstrated for measures with more than one set of specifications/instructions, the different specifications (e.g., for medical records vs. claims) should be submitted as separate measures.

2b.11. Indicate whether there is more than one set of specifications for this measure.

[Response Begins]

No, there is only one set of specifications for this measure

[Response Ends]

2b.12. Describe the method of testing conducted to compare performance scores for the same entities across the different data sources/specifications.

Describe the steps—do not just name a method. Indicate what statistical analysis was used.

[Response Begins]

[Response Ends]

2b.13. Provide the statistical results from testing comparability of performance scores for the same entities when using different data sources/specifications.

Examples may include correlation, and/or rank order.

[Response Begins]

[Response Ends]

2b.14. Provide your interpretation of the results in terms of the differences in performance measure scores for the same entities across the different data sources/specifications.

In other words, what do the results mean and what are the norms for the test conducted.

[Response Begins]

[Response Ends]

2b.15. Indicate whether the measure uses exclusions.

[Response Begins]

Yes, the measure uses exclusions.

[Response Ends]

2b.16. Describe the method of testing exclusions and what was tested.

Describe the steps—do not just name a method; what was tested, e.g., whether exclusions affect overall performance scores; what statistical analysis was used?

[Response Begins]

Universal exclusion criteria were applied prior to risk adjusting the SIR denominator (procedures). Procedures meeting any of the following potential data quality issues were excluded:

- Procedures linked to SSI events that are present at time of surgery
- Procedures with procedure date before date of birth
- Procedure duration under 5 minutes

- Procedures with patient age greater than 109
- Procedures with missing surgical closure technique
- Procedures with patient's gender reported as "other"
- Procedures missing wound class value
- Procedures in adult patients with BMI greater than 60 or BMI less than 12
- Procedures exceeding the interquartile range (The IQR5 is calculated as five times the interquartile range (Q1 - Q3) above the 75th percentile.)

[Response Ends]

2b.17. Provide the statistical results from testing exclusions.

Include overall number and percentage of individuals excluded, frequency distribution of exclusions across measured entities, and impact on performance measure scores.

[Response Begins]

In 2021, only 82 (0.05%) of the 16,298 BRST procedures reported to NHSN's Outpatient Procedure Component were excluded from the SIR calculation due to not meeting all the inclusion criteria. The reasons for exclusion from the SIR were: reporting a procedure duration of less than 5 minutes (35.3%), reporting a procedure duration that exceeded the interquartile range of more than five times (32.9%), and having a BMI that did not fall within 12-60 (25.6%). Although 82 procedures were excluded, no records were excluded due to a missing value of required fields.

BRST Procedures Excluded from final Measure Calculation

Reasons for Exclusion:

Year	Total Exclusions	Included Procedures	% Excluded	Procedure before DOB	Procedure Duration <5 minutes	Patient Age > 109	Missing Surgical Closure Technique	Gender reported as 'other'	Missing Wound Class Value	BMI not within 12-60	Procedures exceeding interquartile range
2021	82	16298	0.05%	0	29	1	0	4	0	21	27

[Response Ends]

2b.18. Provide your interpretation of the results, in terms of demonstrating that exclusions are needed to prevent unfair distortion of performance results.

In other words, the value outweighs the burden of increased data collection and analysis. Note: If patient preference is an exclusion, the measure must be specified so that the effect on the performance score is transparent, e.g., scores with and without exclusion.

[Response Begins]

Exclusions are based on data outliers and data quality issues

[Response Ends]

2b.19. Check all methods used to address risk factors.

[Response Begins]

Statistical risk model with risk factors (specify number of risk factors)

[Statistical risk model with risk factors (specify number of risk factors) Please Explain]

3 risk factors

[Response Ends]

2b.20. If using statistical risk models, provide detailed risk model specifications, including the risk model method, risk factors, risk factor data sources, coefficients, equations, codes with descriptors, and definitions.

[Response Begins]

Table 6. Statistical risk model Summary

Analysis of Maximum Likelihood Estimates	*	*	*	*	*	*
Parameter	*****	**DF**	**Estimate**	**Standard Error**	**Wald Chi-Square**	**Pr > ChiSq**
Intercept	*	1	-8.5239	0.8109	110.4923	<.0001
Anesthesia	Y	1	1.5877	0.7267	4.7735	0.0289
Age at Procedure	45+	1	1.1318	0.4218	7.1993	0.0073
BMI	30+	1	1.0286	0.3186	10.4213	0.0012

* Cell intentionally left empty

[Response Ends]

2b.21. If an outcome or resource use measure is not risk-adjusted or stratified, provide rationale and analyses to demonstrate that controlling for differences in patient characteristics (i.e., case mix) is not needed to achieve fair comparisons across measured entities.

[Response Begins]

[Response Ends]

2b.22. Select all applicable resources and methods used to develop the conceptual model of how social risk impacts this outcome.

[Response Begins]

Published literature

Internal data analysis

[Response Ends]

2b.23. Describe the conceptual and statistical methods and criteria used to test and select patient-level risk factors (e.g., clinical factors, social risk factors) used in the statistical risk model or for stratification by risk.

Please be sure to address the following: potential factors identified in the literature and/or expert panel; regression analysis; statistical significance of p<0.10 or other statistical tests; correlation of x or higher. Patient factors should be present at the start of care, if applicable. Also discuss any "ordering" of risk factor inclusion; note whether social risk factors are added after all clinical factors. Discuss any considerations regarding data sources (e.g., availability, specificity).

[Response Begins]

1. Potential adjustment factors were limited by the scope of variables collected by NHSN. Those considered, based on factors identified in literature, were: age of patient, anesthesia use, ASA classification, duration of procedure, gender of patient, and surgical wound classification (see Table 4).
2. Univariate analyses were conducted between each of these factors and the outcome to determine if the association was significant. Statistically significant univariate associations led to inclusion in the modeling process (all were significant).
3. Modeling process involved a backwards elimination of predictors from the saturated model. In each iteration, the least significant predictor was removed from the model until all remaining factors were significant. Other subsets of predictors were ant factor, but was excluded because of clinical concerns about eligibility as a confounding factor.
4. The final model adjusted for anesthesia, age and BMI categories

[Response Ends]

2b.24. Detail the statistical results of the analyses used to test and select risk factors for inclusion in or exclusion from the risk model/stratification.

[Response Begins]

Final risk adjustment model:

Final Model to Predict Surgical Site Infections (n=41) among Outpatient Surgical Breast Procedures Performed in Ambulatory Surgery Centers (n=116) Reported to NHSN, 2015.

Procedure	Parameter	*	Estimate
BREAST	Intercept	*	-8.5239
*	anesthesia	Y	1.5877
*	Age at Procedure	>=45	1.1318
*	BMI	>=30	1.0286

* Cell intentionally left empty

[Response Ends]

2b.25. Describe the analyses and interpretation resulting in the decision to select or not select social risk factors.

Examples may include prevalence of the factor across measured entities, availability of the data source, empirical association with the outcome, contribution of unique variation in the outcome, or assessment of between-unit effects and within-unit effects. Also describe the impact of adjusting for risk (or making no adjustment) on providers at high or low extremes of risk.

[Response Begins]

1. Potential adjustment factors were limited by the scope of variables collected by NHSN. Those considered, based on factors identified in literature, were: age of patient, anesthesia use, ASA classification, duration of procedure, gender of patient, and surgical wound classification (see Table 4).

2. Univariate analyses were conducted between each of these factors and the outcome to determine if the association was significant. Statistically significant univariate associations led to inclusion in the modeling process (all were significant).
3. Modeling process involved a backwards elimination of predictors from the saturated model. In each iteration, the least significant predictor was removed from the model until all remaining factors were significant. Other subsets of predictors were ant factor, but was excluded because of clinical concerns about eligibility as a confounding factor.
4. The final model adjusted for anesthesia, age and BMI categories

[Response Ends]

2b.26. Describe the method of testing/analysis used to develop and validate the adequacy of the statistical model or stratification approach (describe the steps—do not just name a method; what statistical analysis was used). Provide the statistical results from testing the approach to control for differences in patient characteristics (i.e., case mix) below. If stratified ONLY, enter "N/A" for questions about the statistical risk model discrimination and calibration statistics.

Validation testing should be conducted in a data set that is separate from the one used to develop the model.

[Response Begins]

Bootstrap sampling method was used to validate the models.

Model validation steps:

1. For each multiple logistic regression model, calculate the c-index as $C_{original}$.
2. Generate 100 bootstrap samples from the original dataset with the same number of records as the original sample size using sampling with replacement.
3. For each one of the new samples m=1, …,100, using the predictors of the logistic regression model from step 1 to fit the data with backward elimination approach and calculate the discrimination C_{boot}(m)-. Note that the model we select from each of the m bootstrap samples could be different from the original model.
4. For each bootstrap sample, the original dataset is used for validation. For this step, the regression coefficients are fixed to their values from step 3 to determine the joint degree of over fitting from both selection and estimation. We obtain $C_{original}$(m) from this step.
5. For each one of the bootstrap samples, first we will calculate the optimism in the fit: $O(m)= C_{boot}(m)- C_{original}(m)$. Then we obtain O by taking the average of O(m) from M bootstrap samples.
6. The optimism corrected performance of the original model is: $C_{adj}=C_{original}-O$-. This value is a nearly unbiased estimate of the expected value of the optimism that would be obtained from external validation.

Table 8. Model Validation testing

*	EST	2.50%	97.50%	ODDS	2.50%	97.50%	B	FLAG
Intercept	-8.524	-16.481	-0.568	0	0	0.567	96	1
anesthesia=Y	1.588	-6.288	9.464	4.895	0.002	12893.74	96	0
Age at Procedure=45+	1.132	0.198	2.066	3.101	1.219	7.892	96	1
BMI=>30	1.029	0.328	1.729	2.797	1.389	5.633	96	1

* Cell intentionally left empty

Table 9. C_index from Model Validation

*	index.orig	training	test	optimism	index.corrected	B
C_index	0.7114	0.7186	0.7144	0.0042	0.7072	100

* Cell intentionally left empty

[Response Ends]

2b.27. Provide risk model discrimination statistics.

For example, provide c-statistics or R-squared values.

[Response Begins]

c-index = 0.7114

[Response Ends]

2b.28. Provide the statistical risk model calibration statistics (e.g., Hosmer-Lemeshow statistic).

[Response Begins]

Hosmer-Lemeshow p= 0.726

[Response Ends]

2b.29. Provide the risk decile plots or calibration curves used in calibrating the statistical risk model.

The preferred file format is .png, but most image formats are acceptable.

[Response Begins]

See 2b.28 for HL statistic

Hosmer-Lemeshow p= 0.726

[Response Ends]

2b.30. Provide the results of the risk stratification analysis.

[Response Begins]

Analysis by risk stratification not performed.

[Response Ends]

2b.31. Provide your interpretation of the results, in terms of demonstrating adequacy of controlling for differences in patient characteristics (i.e., case mix).

In other words, what do the results mean and what are the norms for the test conducted?

[Response Begins]

The model can control for differences in patient case-mix adequately. Further measure maintenance may be required in the future to update the model with more volume of data from higher number of reporting facilities.

Hosmer-Lemeshow p= 0.726 indicates that the risk adjust model fits the data well.

The C index is interpreted as the probability that a randomly selected breast surgery patient who had breast SSI will have a higher predicted probability of having breast SSI than a randomly selected breast surgery patient who did not have a breast SSI. It ranges from zero to one. A value of 0.5 indicates that the model is no better on classifying SSI events than random chance. The closer the C index is to one, the better the model is at correctly classifying SSI events. C-index=0.7114 from risk adjust model shows acceptable discrimination on classifying SSI events.

[Response Ends]

2b.32. Describe any additional testing conducted to justify the risk adjustment approach used in specifying the measure.

Not required but would provide additional support of adequacy of the risk model, e.g., testing of risk model in another data set; sensitivity analysis for missing data; other methods that were assessed.

[Response Begins]

No additional test conducted

[Response Ends]

Criterion 3. Feasibility

3.01. Check all methods below that are used to generate the data elements needed to compute the measure score.

[Response Begins]

Abstracted from a record by someone other than person obtaining original information (e.g., chart abstraction for quality measure or registry)

[Response Ends]

3.02. Detail to what extent the specified data elements are available electronically in defined fields.

In other words, indicate whether data elements that are needed to compute the performance measure score are in defined, computer-readable fields.

[Response Begins]

Some data elements are in defined fields in electronic sources

[Response Ends]

3.03. If ALL the data elements needed to compute the performance measure score are not from electronic sources, specify a credible, near-term path to electronic capture, OR provide a rationale for using data elements not from electronic sources.

[Response Begins]

Some data elements are not currently amenable electronic capture, such as physician/nurses notes. NHSN is moving towards complete electronic capture of data as documentation changes occur in ambulatory surgery centers (i.e., as facilities move to full electronic health record capture).

[Response Ends]

3.04. Describe any efforts to develop an eCQM.

[Response Begins]

No efforts are currently underway to develop an eCQM for this measure.

[Response Ends]

3.06. Describe difficulties (as a result of testing and/or operational use of the measure) regarding data collection, availability of data, missing data, timing and frequency of data collection, sampling, patient confidentiality, time and cost of data collection, other feasibility/implementation issues.

[Response Begins]

Use of NHSN surveillance protocol, definitions, and data collection methods for SSI have proven feasible across multiple healthcare settings, including ambulatory surgery centers. During the formal consensus process outlined in Q2b.02, feasibility was assessed, and respondents agreed that data for the measure could be obtained with reasonable effort and cost. Although specific data collection methods may vary between facilities, standardized data collection procedures (specified by the NHSN protocol and definitions) are provided which decrease the need for facilities to develop these resources and tools. Additionally, technical guidance provided by CDC will aid and facilitate accurate data collection and reporting. Lastly, the use of NHSN for reporting this measure is secure and the risk of breaches in patient confidentiality is low.

[Response Ends]

Consider implications for both individuals providing data (patients, service recipients, respondents) and those whose performance is being measured.

3.07. Detail any fees, licensing, or other requirements to use any aspect of the measure as specified (e.g., value/code set, risk model, programming code, algorithm),

Attach the fee schedule here, if applicable.

[Response Begins]

No fees or licensing requirements. To use this SIR measure, ASCs must be enrolled in NHSN. Detailed instructions on how to enroll can be found here: http://www.cdc.gov/nhsn/ambulatory-surgery/enroll.html.

[Response Ends]

Criterion 4: Use and Usability

4a. Use

4a.01. Check all current uses. For each current use checked, please provide:

- **Name of program and sponsor**
- **URL**
- **Purpose**
- **Geographic area and number and percentage of accountable entities and patients included**
- **Level of measurement and setting**

[Response Begins]

Public Reporting

[Public Reporting Please Explain]

Name of Program and Sponsor - National Healthcare Safety Network (NHSN), Centers for Disease Control and Prevention.

URL: https://www.cdc.gov/nhsn/index.html

Purpose - NHSN is a national system used by CDC and its partners in clinical care and public health for surveillance of healthcare-associated infections, healthcare worker safety, blood safety, antimicrobial use and resistance, and adherence to prevention practices. The system is designed to provide actionable data for healthcare facilities and systems, public health agencies at the state and federal levels, and prevention collaborations. NHSN is the data source for multiple NQF-endorsed measures for which CDC reports measure results on behalf of healthcare facilities to the Centers for Medicare and Medicaid Services (CMS) quality measurement reporting programs.

Geographic area and number and percentage of accountable entities and patients included - NHSN provides national coverage and from 2015 to present, there are 284 ASCs reporting to NHSN.

Public Health/Disease Surveillance

[Public Health/Disease Surveillance Please Explain]

Name of Program and Sponsor - National Healthcare Safety Network (NHSN), Centers for Disease Control and Prevention.

URL: https://www.cdc.gov/nhsn/index.html

Purpose - NHSN is a national system used by CDC and its partners in clinical care and public health for surveillance of healthcare-associated infections, healthcare worker safety, blood safety, antimicrobial use and resistance, and adherence to prevention practices. The system is designed to provide actionable data for healthcare facilities and systems, public health agencies at the state and federal levels, and prevention collaborations. NHSN is the data source for multiple NQF-endorsed measures for which CDC reports measure results on behalf of healthcare facilities to the Centers for Medicare and Medicaid Services (CMS) quality measurement reporting programs.

Geographic area and number and percentage of accountable entities and patients included - NHSN provides national coverage and from 2015 to present, there are 284 ASCs reporting to NHSN.

Quality Improvement with Benchmarking (external benchmarking to multiple organizations)

[Quality Improvement with Benchmarking (external benchmarking to multiple organizations) Please Explain]

Name of program and sponsor - Colorado Department of Public Health and Environment Patient Safety Program

URL: https://cdphe.colorado.gov/

Purpose - Healthcare-associated infections (HAI) are among the top ten leading causes of death in the United States. Colorado recognizes the seriousness of this public health problem and passed the HAI reporting legislation in 2006. House bill 1045 requires hospitals, hospital units, ambulatory surgery centers and dialysis centers to report healthcare-associated infections using the National Healthcare Safety Network (NHSN). This legislation created the Patient Safety Program at the Colorado Department of Public Health and Environment (CDPHE).

Geographic are and number and percentage of accountable entities and patients included - Ambulatory surgery centers (ASCs) began reporting their measures to NHSN on October 1, 2008. Of the 123 licensed ASCs in the state, 33 provide procedures tracked in NHSN (27%); 33/33 (100%) are currently reporting in NHSN. Since the inception of this measure in 2018, 61 ASC facilities in Colorado are reporting to NHSN.

Quality Improvement (Internal to the specific organization)

[Quality Improvement (Internal to the specific organization) Please Explain]

Name of program and sponsor - Colorado Department of Public Health and Environment Patient Safety Program

URL: https://cdphe.colorado.gov/

Purpose - Healthcare-associated infections (HAI) are among the top ten leading causes of death in the United States. Colorado recognizes the seriousness of this public health problem and passed the HAI reporting legislation in 2006. House bill 1045 requires hospitals, hospital units, ambulatory surgery centers and dialysis centers to report healthcare-associated infections using the National Healthcare Safety Network (NHSN). This legislation created the Patient Safety Program at the Colorado Department of Public Health and Environment (CDPHE).

Geographic are and number and percentage of accountable entities and patients included - Ambulatory surgery centers (ASCs) began reporting their measures to NHSN on October 1, 2008. Of the 123 licensed ASCs in the state, 33 provide procedures tracked in NHSN (27%); 33/33 (100%) are currently reporting in NHSN. Since the inception of this measure in 2018, 61 ASC facilities in Colorado are reporting to NHSN.

[Response Ends]

4a.02. Check all planned uses.

[Response Begins]

Payment Program

[Response Ends]

4a.03. If not currently publicly reported OR used in at least one other accountability application (e.g., payment program, certification, licensing), explain why the measure is not in use.

For example, do policies or actions of the developer/steward or accountable entities restrict access to performance results or block implementation?

[Response Begins]

The measure is a part of the Outpatient Procedure Component. It is open for use by any Centers for Medicare and Medicaid Services (CMS) approved-ASC and was developed to surveil for surgical site infections (SSIs) occurring in breast surgeries performed in these facilities. Public reporting of SSIs is currently required by several states, including Colorado and New Jersey, as part of their state-specific reporting for ASCs. Colorado publishes an annual report of breast SSI for each ASC and these data are reported publicly. New Jersey does not publicly report its data for breast SSI, however, these data are shared internally among enrolled facilities.

[Response Ends]

4a.04. If not currently publicly reported OR used in at least one other accountability application, provide a credible plan for implementation within the expected timeframes: used in any accountability application within 3 years, and publicly reported within 6 years of initial endorsement.

A credible plan includes the specific program, purpose, intended audience, and timeline for implementing the measure within the specified timeframes. A plan for accountability applications addresses mechanisms for data aggregation and reporting.

[Response Begins]

The CDC's National Healthcare Safety Network (NHSN) will continue to work with ASC leaders to further evaluate the measure's usefulness for SSI prevention, to refine the measure as needed to improve its value for assessing variation in

SSI rates intra- and inter-organizationally, and to serve as the data aggregating system. The NHSN Outpatient Procedure Component will provide the technical infrastructure for data collection, analysis, and measure results reporting to participating ASCs, including national benchmarks presented using the SIRs as the summary measures. This additional field experience with measure data, coupled with systematic studies, will serve to define what additional data and methods, if any, are needed to recommend use of this measure for accountability purposes on the federal level and ongoing state-specific reporting.

[Response Ends]

4a.05. Describe how performance results, data, and assistance with interpretation have been provided to those being measured or other users during development or implementation.

Detail how many and which types of measured entities and/or others were included. If only a sample of measured entities were included, describe the full population and how the sample was selected.

[Response Begins]

Sampling based on facilities reporting into the NHSN application from the 2015 national aggregate data. Facility types that are Ambulatory Surgery Centers were included. Each procedure category had one SSI Event (outcome) and minimum of 1000 procedures. This parameter was used to break down the data into categories and subcategories. A facility that reported at least one month of in plan data was included. In-plan implies that the data included all risk factors involved in the risk adjustment.

Annual trainings and NSHN reference guides are provided to help interpret measures metrics and are provided to users for assistance with interpretation of performance results and data. Web-based trainings are provided for all users and cover a wide variety of topics to assist users including how to download, review and interpret their data. While this measure was in use, CDC presented an hour-long training on how to complete and interpret the Standardized Infection Ratio used for all SSI models available, one of which included the BRST measure. Information about the BRST measure has also been included in the NHSN Guide to the SIR resource. This resource guide provides all variables that are included in the model, what model was used, risk factor contributions to the model, and exclusion criteria that are applied to the measure. Information about the BRST measure can be found starting on page 45 here, https://www.cdc.gov/nhsn/pdfs/ps-analysis-resources/nhsn-sir-guide.pdf

Should users require additional one on one assistance, all users can email the NHSN help desk and be put in contact with the appropriate subject matter expert (SME).

[Response Ends]

4a.06. Describe the process for providing measure results, including when/how often results were provided, what data were provided, what educational/explanatory efforts were made, etc.

[Response Begins]

Facilities have immediate access to their data once the data is entered into the NHSN application. The SIR measure can be generated based on their reporting needs. This includes generating SIR by month, quarter, half-year, full year, and cumulative options. NHSN provides educational resources on the website , including guides on how to generate, interpret and apply the SIRs.

[Response Ends]

4a.07. Summarize the feedback on measure performance and implementation from the measured entities and others. Describe how feedback was obtained.

[Response Begins]

Feedback received from State health departments are analyzed for internal data quality checks and outreach to the ir facilities. The data is not publicly shared

[Response Ends]

4a.08. Summarize the feedback obtained from those being measured.

[Response Begins]

We have not received feedback on the denominator, numerator, calculation, or risk adjustment of the measure from user

[Response Ends]

4a.09. Summarize the feedback obtained from other users.

[Response Begins]

Feedback from other users, specifically State health departments indicate that due to low volume of data reported, public reporting of measures was not performed. Users have not provided feedback on the measure numerator, denominator, or risk adjustment.

[Response Ends]

4a.10. Describe how the feedback described has been considered when developing or revising the measure specifications or implementation, including whether the measure was modified and why or why not.

[Response Begins]

The feedback from users is being compiled and will be taken into consideration for any future revisions to the measure such as rebaselining.

[Response Ends]

4b. Usability

4b.01. You may refer to data provided in Importance to Measure and Report: Gap in Care/Disparities, but do not repeat here. Discuss any progress on improvement (trends in performance results, number and percentage of people receiving high-quality healthcare; Geographic area and number and percentage of accountable entities and patients included). If no improvement was demonstrated, provide an explanation. If not in use for performance improvement at the time of initial endorsement, provide a credible rationale that describes how the performance results could be used to further the goal of high-quality, efficient healthcare for individuals or populations.

[Response Begins]

This measure was not in use for performance improvement at the time of initial endorsement. To further the goal of high-quality, efficient healthcare for individuals or population, the measure can be used to perform national reporting and national benchmarking. Due to the low use of the measure, data was not analyzed for trends.

[Response Ends]

4b.02. Explain any unexpected findings (positive or negative) during implementation of this measure, including unintended impacts on patients.

[Response Begins]

NHSN 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. Majority of facilities that reported data for this measure were concentrated within a small group of states.

[Response Ends]

4b.03. Explain any unexpected benefits realized from implementation of this measure.

[Response Begins]

There were no unexpected benefits realized form the implementation of this measure.

[Response Ends]

Criterion 5: Related and Competing Measures

5.01. Search and select all NQF-endorsed related measures (conceptually, either same measure focus or target population).

(Can search and select measures.)

[Response Begins]

3357: Facility-Level 7-Day Hospital Visits after General Surgery Procedures Performed at Ambulatory Surgical Centers

2687: Hospital Visits after Hospital Outpatient Surgery

0527: Prophylactic Antibiotic Received Within One Hour Prior to Surgical Incision

0528: Prophylactic Antibiotic Selection for Surgical Patients

0529: Prophylactic Antibiotics Discontinued Within 24 Hours After Surgery End Time

0269: Timing of Prophylactic Antibiotics - Administering Physician

[Response Ends]

5.02. Search and select all NQF-endorsed competing measures (conceptually, the measures have both the same measure focus or target population).

(Can search and select measures.)

[Response Begins]

[Response Ends]

5.03. If there are related or competing measures to this measure, but they are not NQF-endorsed, please indicate the measure title and steward.

[Response Begins]

N/A

[Response Ends]

5.04. If this measure conceptually addresses EITHER the same measure focus OR the same target population as NQF-endorsed measure(s), indicate whether the measure specifications are harmonized to the extent possible.

[Response Begins]

No

[Response Ends]

5.05. If the measure specifications are not completely harmonized, identify the differences, rationale, and impact on interpretability and data collection burden.

[Response Begins]

While all above measures focus on the same target population (ASC patients), this measure is the only one specifically evaluating occurrence of breast surgical site infections.

[Response Ends]

5.06. Describe why this measure is superior to competing measures (e.g., a more valid or efficient way to measure quality). Alternatively, justify endorsing an additional measure.

Provide analyses when possible.

[Response Begins]

N/A

[Response Ends]