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Is There Room For Prevention? Examining The Effect Of Outpatient Facility Type On The Risk Of Surgical Site Infection.

By

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2013

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ABSTRACT

Is There Room For Prevention? Examining The Effect Of Outpatient Facility Type On The Risk Of Surgical Site Infection.

By

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Background: Surgical site infections in the inpatient setting have been the focus of much of the previous work on SSI. However, previous risk-adjustment models and analyses have largely ignored the volume of surgical procedures performed in the outpatient setting. This study examined whether the SSI risk for surgical breast procedures is less in ambulatory surgery centers compared to hospital-based outpatient facilities, after adjusting for differences in patient case-mix between facility type and risk of breast SSI.

Methods: Data for this study was obtained from the National Healthcare Safety Network (NHSN), a secure, Internet-based surveillance system managed by the Division of Healthcare Quality and Promotion (DHQP) at the Centers for Disease Control and Prevention (CDC). Unconditional multivariable logistic regression was used to examine the association between facility type and breast SSI.

Results: Out of 86,199 total outpatient breast procedures reported to NHSN between 2010 and 2013, 77,224 were used in the analysis. For patients aged 51 or under, the risk of SSI among ambulatory surgery centers was 0.28 (95% CI: 0.18, 0.44) times the risk of SSI among hospital-based outpatient settings, adjusted for age, ASA class and duration of procedure. For patients older than 51 years, the risk of SSI among ambulatory surgery centers was 0.23 (95% CI: 0.14, 0.39) times the risk of SSI among hospital-based outpatient settings, adjusted for age, ASA class and duration of procedure.

Conclusions: Ambulatory surgery centers have a protective effect on the risk of breast SSI compared to hospital-based outpatient settings, the extent of which differs by age. Though this study may has its limitations, including possible low sensitivity and incomplete control for patient case-mix, these findings strongly suggest that there is bridgeable gap in SSI prevention practices between hospital-based outpatient settings and ASCs. Future studies should examine mechanisms leading to this difference in risk, and target interventions accordingly.

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Chapter I: Literature Review

Healthcare-Associated Infections

Definitions and Burden

Healthcare-associated infections (HAIs) are a major cause of morbidity and mortality in healthcare settings in the United States. The World Health Organization defines an HAI (also called "nosocomial infection") as the following:

> "An infection acquired in hospital by a patient who was admitted for a reason other than that infection, or an infection occurring in a patient in a hospital or other healthcare facility in whom the infection was not present or incubating at the time of admission. This includes infections acquired in the hospital but appearing after discharge, and also occupational infections among staff of the facility" (WHO 2002).

This definition not only applies to hospitals, but all healthcare facilities. There are several major categories of HAI: central line-associated bloodstream infection (CLABSI), catheter-associated urinary tract infection (CAUTI), ventilator-associated pneumonia (VAP), surgical site infections (SSI), and gastrointestinal infections (includes multidrug resistant organism and *Clostridium difficile* infections) (CDC 2015).

The most recent prevalence surveys of HAIs have estimated that approximately 4.0% of inpatients in acute care settings have developed at least one HAI, translating to 721,800 infections in 648,000 patients in 2011 (Magill 2014). Earlier estimates of HAI prevalence have been even higher, citing 1.7 million cases in 2002, with 98,987 of those resulting in mortality directly attributable to the infection (Klevens 2002). It is likely that the true prevalence of HAIs lies in between those two estimates. Out of the total number of HAIs in 2011, approximately 22% were

VAP, 22% were SSI, 18% were gastrointestinal, 13% were CAUTI, 10% were CLABSI, and the rest were other minor types of HAI (Magill 2014).

The presence of HAIs directly reflects and contributes to the quality and cost of healthcare in the United States; therefore, lowering HAI rates is a high priority for governments, hospitals, and healthcare providers around the nation. The annual direct medical cost of treating HAIs has been estimated to range from $28.4 billion to $45 billion (in 2007 dollars), and the average cost to treat a patient with an HAI ranged from $16,000 to $25,000 (Scott 2009). One meta-analysis including studies from 1986-2013 reported an annual HAI cost of $9.8 billion. SSIs contributed to most of the total cost (33.7%), followed by VAP (31.6%), CLABSI (18.9%), *C. difficile* infections (15.4%), and CAUTI (<1%) (Zimlichman 2013). Regardless of the variability in reported cost estimates, it is clear that HAIs exert a substantial financial burden on the US healthcare system.

History, Surveillance, and Prevention

Although hospitals and other healthcare facilities have long been viewed as places where disease transmission is facilitated, HAI surveillance and control efforts did not fully enter the public eye until the 1950s, when outbreaks of penicillin-resistant *Staphylococcus aureus* reached epidemic levels. In the 1960s, individual facilities began instituting infection control programs and employing people dedicated to infection control. The first large-scale movement for HAI control occurred in the 1970s, when collaborative organizations like the Association for Professionals in Infection Control (APIC) and the Society for Healthcare Epidemiology of America (SHEA) became prominent authorities in the field (Dixon 2011). During this time, the landmark Study on the Effectiveness of Nosocomial Infection Control (SENIC) was performed by the Centers for Disease Control and Prevention (CDC) and attempted to assess whether infection control programs were leading to reductions in HAI risk. Out of 338 hospitals enrolled in the study, approximately half had infection control and surveillance programs (Haley 1980).

After controlling for location of the hospital, bed capacity, and teaching status, the study found that hospitals with infection control programs reduced HAI incidence by 32%, while HAI incidence in hospitals without those programs increased by 18% (Haley 1985). The SENIC led to the establishment of many new, evidence-based infection control programs which became mandated by The Joint Commission for hospital accreditation in 1976 (Weinstein 1998). In addition, the CDC established the National Nosocomial Infections Surveillance (NNIS) system in 1970, the first to aggregate data from hospitals around the country and provide feedback to hospitals (NNIS 2004).

Public interest in HAIs saw another spike in 2000 with the Institute of Medicine's *To Err is Human* report, which highlighted the prevalence of preventable medical errors causing morbidity and mortality in patients—the leading causes of which were HAIs (IOM 2000). This marked the resurgence of much work on HAI surveillance and prevention. In the 2000s, the CDC-run NNIS expanded into the National Healthcare Safety Network (NHSN), which collects data on many different types of facilities and a wider variety of patient safety outcomes and prevention measures than its predecessor. Policy measures soon followed as well; in 2008, the Centers for Medicaid and Medicare Services (CMS) began denying reimbursements for care provided for HAIs in order to reduce cost and prevent adverse outcomes (Stone 2010). The passing of the Patient Protection and Affordable Care Act in 2010 introduced the concept of value-based purchasing for hospitals, which rewards hospitals for the quality of care provided rather than the quantity of care. Starting in 2013, CMS withheld a percentage of payments (~2%) depending on how well the hospital performed on certain quality indicators, several of which included HAI, compared to a national benchmark (CMS 2013).

Surveillance for HAIs is essential for prevention efforts. A study of NNIS system use determined that feedback from aggregated surveillance efforts was instrumental in decreasing HAI incidence in the 1990s, likely because healthcare facilities were able to track their performance compared to national benchmarks and make adjustments targeted to specific at-risk

populations (Gaynes 2001). Central to this effect is the concept of risk-adjustment. Currently, HAI data obtained through NHSN are used to identify unmodifiable patient- or hospital-based risk factors for each HAI. These risk factors are then adjusted for in a regression model, so that hospitals serving different populations can easily compare their HAI rates and performance on quality measures with predicted infection counts and rates from the model (CDC 2015). The NHSN reports data from each healthcare facility to CMS, in order for them to determine reimbursement rates and thus increase prevention incentives.

Prevention of HAIs is both necessary and attainable through a variety of different strategies. Recent estimates of the proportion of preventable HAIs ranges from 17-69% of CLABSI and CAUTI, and from 26% to 55% in VAP and SSI (Umscheid 2011). The benefits of prevention from a cost perspective range from $5.7-6.8 billion to $25.0-31.5 billion saved annually (Scott 2009). In 2008, several healthcare quality organizations including SHEA, the Infectious Diseases Society of America (IDSA), the American Hospital Association (AHA), the Joint Commission, and the CDC (among others) collaborated to create the *Compendium of Strategies to Prevent Healthcare-Associated Infections in Acute Care Hospitals*. This compendium served as an outline for nearly all major prevention strategies for each type of HAI, touching on infrastructure improvement, education of patients and healthcare workers, surveillance efforts, and specific targeted practices for high-risk patient populations and procedure types (Yokoe 2008). This and other guidelines, such as those from the Healthcare Infection Control Practices Advisory Committee (HICPAC), have standardized HAI prevention efforts through evidence-based studies, leading to a steady reduction in HAI rates since the early 2000s (CDC HICPAC) (Magill 2014).

Surgical Site Infections

Definitions and Burden

Surgical site infection is one of the most common healthcare-associated infections, comprising approximately 22% of all HAIs (Magill 2014). SSIs fall under one of three categories: superficial incisional (involving only skin or subcutaneous tissue of the incision), deep incisional (involving fascia or muscular layers) or organ/space (CDC 2015).

In addition to being a highly prevalent type of HAI, SSIs also contribute greatly to the mortality and cost burden of HAIs. A 1999 study of 255 pairs of patients with and without SSI matched on age, procedure, NNIS risk index, date of surgery, and surgeon found that those with SSIs have twice the mortality rate of those without SSI and are five times as likely to be readmitted to the hospital. The mean excess hospital stay directly attributable to SSI was 12 days, and the excess costs attributable to SSI were approximately $5,000 per patient (Kirkland 1999). More recent studies have estimated the costs of an SSI to be even higher—a 2007 study cited a range from approximately $11,000 to $35,000 per SSI (Scott 2009), and one meta-analysis of healthcare costs in 2013 determined the cost to be $20,785 per SSI (Zimlichman 2013). Variability in these estimates is likely due to differences in procedure type and the increase in medical costs over the years. In severe cases, SSIs are also highly associated with patient mortality- of all deaths in patients with SSI, 77% have been found to be directly attributable to the SSI (Mangram 1999).

In the inpatient setting, colon surgeries and hysterectomies are the procedures with the highest risk for SSI, and are currently the only SSI procedure types for which reporting is mandated by CMS. Other high risk inpatient procedures include coronary artery bypass grafts, hip prosthesis, and knee prosthesis surgeries. Common risk factors for inpatient SSIs include procedure duration, American Society of Anesthesiologists (ASA) score, patient age, hospital beds, wound class, general anesthesia, endoscope, medical school affiliation, emergency, and

trauma (Mu 2011). In the outpatient setting, however, the highest volume procedures are hernia repair and breast-related surgeries (CDC 2015).

Breast SSIs contribute a substantial portion of SSI in inpatient settings, and also have the one of the highest risk of any procedure type in outpatient settings. In the Netherlands, the rate of SSI following mastectomies in 2006 was 61% as determined by a study in 2006 (Mannien 2006). A case control study performed in 2004 reported SSI rates following breast surgeries to be 25.8% (Vilar-Compte 2004). One study of breast SSI risk in an HOPD reported an overall risk of 5.2%, with procedure-specific risks of 12.4% following mastectomy with immediate implant reconstruction, 6.2% following mastectomy with immediate reconstruction using a transverse rectus abdominis myocutaneous flap, 4.4% following mastectomy only, and 1.1% following breast reduction surgery (Olsen 2008). Another study of SSI following breast cancer-related procedures reported a risk of 18.9% (Vilar-Compte 2009). The cost incurred by each breast SSI attributable to the SSI was estimated by one analysis to be $4,901 per patient (Olsen 2008). Though these estimates of risk vary from 1% to over 30% depending on procedure type, sample population, and definition of SSI, it is clear that breast procedure-related SSIs are a large burden to outpatient healthcare facilities.

Surveillance and Prevention

Both pre-discharge and post-discharge surveillance of surgical site infections are essential for decreasing SSI rates. NHSN conducts surveillance for SSIs through any combination of four main methods: "1) direct examination of patients' wounds during hospitalization, or follow-up visits to either surgery clinics or physicians' offices, 2) review of medical records or surgery clinic patient records, 3) surgeon surveys by mail or telephone, and 4) patient surveys by mail or telephone" (CDC 2015). One study comparing rates of detection between active and passive post-discharge surveillance (PDS) reported almost twice the detection rate in active PDS as compared to passive PDS (Mannien 2006). For retroactive surveillance through medical records,

antimicrobial exposure screening has been shown to be an effective way of improving SSI detection rates, with a sensitivity of 88-91%, compared with a routine surveillance sensitivity of 38-64% (Yokoe 2004). This method identifies patients who have had recorded antimicrobial exposure for a defined number of days after a procedure. Often, this can indicate the presence of an SSI. Other retrospective surveillance efforts have found success using Medicare claims data to identify potential SSIs; claims-based surveillance detected 1.8-4.7 times more SSIs than routine surveillance using CDC criteria (Calderwood 2012). Another study comparing health plan claims surveillance of SSIs to hospital-based traditional methods found that surveillance of health plan data had a sensitivity of 71.8%, compared to a hospital-based sensitivity of 49.7% (Sands 2003). Using a combination of both antimicrobial surveillance and claims-based surveillance resulted in a sensitivity of 77% and a specificity of 94%. (Sands 1999) Although it is clear through several studies that claims-based surveillance is more effective than hospital-based, it is often difficult and time consuming for facilities to put into practice; therefore, an ideal solution would be to use several methods in tandem.

Risk factor analysis from surveillance data bridges the gap between surveillance and prevention efforts. Several studies have examined the risk factors for breast procedure SSIs, both in the inpatient and outpatient settings. A meta-analysis of case-control studies on the risk factors for breast SSI identified 14 significant factors, including increased increased age, hypertension, higher body mass index (BMI), diabetes mellitus, American society of anesthesiologists (ASA) 3 or 4, previous breast biopsy or operation, preoperative chemoradiation, conservation therapy versus other surgical approaches, hematoma, seroma, more intraoperative bleeding, postoperative drain, longer drainage time and second drainage tube placed; however smoking status, immediate reconstruction, axiliary lymph node dissection, preoperative chemotherapy, corticosteroid use and prophylactic antibiotic were not significant (Xue 2012). A study on risk factors of SSI following mastectomy identified procedure duration of 2 hours or longer and smoking status as additional risk factors, along with ASA score, BMI, and diabetes (Davis 2011). For breast biopsies,

significant risk factors include duration of surgery and presence of surgical drains, whereas obesity and preoperative needle localization were not found to be significant (Rey 2005). However, 1998 study had identified obesity and increased age to be risk factors for breast surgeries (Bertin 1998). More procedural factors influencing SSI were described in one study to be suboptimal prophylactic antibiotic dosing, transfusion, mastectomy, and previous chest irradiation. This study also found smoking status to be a significant risk factor for breast surgery (Olsen 2008). Increasing age has been found to be a risk factor for SSI until age 65, after which increasing age independently predicted a decreased risk of SSi (Kaye 2005). Because of the controversial status of smoking status, it is difficult to conclude whether it is an evidence-based risk factor for breast SSI although it is one of the most commonly studied factors. However, the most commonly reported factors significantly associated with SSI include age, ASA score, hypertension, and diabetes.

Prevention efforts target several of the risk factors for SSI in order to isolate high-risk populations and practices in interventions. General strategies include administering antimicrobial prophylaxis, avoiding hair removal at the surgical site, controlling blood glucose immediately after an operation, maintaining normothermia during the perioperative period, optimizing tissue oxygenation during and after surgical procedures involving mechanical ventilation, using alcohol-containing preoperative skin agents, using WHO patient safety checklists, performing surveillance and providing feedback on SSI rates, educating personnel and patients, and promoting hand hygiene of healthcare personnel (Anderson 2014). In breast procedures, targeted prophylaxis antibiotic in high risk populations has shown to reduce the risk of SSI by 81% (Nicolas 2007). Prophylactic antibiotic use is highly supported as an effective prevention strategy for SSI (Webb 2006) (van Kasteren 2005). Adherence to preventive measures is essential for interventions to be effective. A review of the Surgical Care Improvement Program (SCIP), revealed that a focus on process measures rather than outcome measures has been ineffective despite governmental support, financial penalties for non-compliance, and widespread

implementation (Awad 2012). A study on a hand hygiene intervention comparing an alcohol based rub with traditional hand scrubbing showed that although both methods have the same effectiveness in preventing SSI, adherence to the alcohol rub was significantly higher than adherence to traditional scrubbing (Parienti 2002). Preventative strategies for breast SSI specifically are very similar to strategies for all other SSI, although they can be targeted to a more specific population based on specific patient-level risk factors.

Outpatient Facilities

Definitions and Burden

From 1980-1995, a significant trend in surgery was the transition from inpatient settings to outpatient ambulatory surgery settings due to advances in surgical techniques and economic incentives for ambulatory surgery (Kozak 1999). This trend has likely persisted, and more surgeries are performed in ambulatory settings today than ever before. Facilities that conduct outpatient surgery can be categorized in to three classes- ambulatory surgery centers (ASCs), hospital outpatient departments (HOPDs), or inpatient acute care settings where surgery patients are released the same day. An ASC is defined by CMS, for the purposes of CMS reimbursement, to be "a distinct entity that operates exclusively for the purpose of furnishing outpatient surgical services to patients" (CMS 2014). Definitions for HOPDs have not been standardized for CMS or in surveillance systems such as NHSN, so differentiating them from outpatient procedures in inpatient settings is unclear.

In the current literature, the rates of SSI in ambulatory surgery centers is relatively low—however, aggregate numbers of infections can still cause a substantial burden, as those often result in post-surgical visits and morbidity. ASCs have been shown to have a lower SSI rate than inpatient settings; in one study, SSI morbidity and recurrence rates in ambulatory surgery were half the rates in inpatient surgery. A 5-year study of SSIs in ambulatory surgery centers showed a

rate of 2.8 SSI per 100 surgeries (Vilar-Compte 2001). These rates are relatively consistent- another study reported a risk of SSI after outpatient surgery to be 3.5% (Grøgaard 2001). Aside from morbidity alone, postsurgical visits due to SSI acquired during surgery contribute much to the cost burden on healthcare facilities. A study on postsurgical acute care visits for SSIs in ASCs demonstrated a rate of 3.09 SSI-related visits per 1000 procedures at 14 days after surgery and 4.84 per 1000 at 30 days after surgery (Owens 2014). ASCs have also been shown to have a lower SSI rate than inpatient settings- in one study, SSI morbidity and recurrence rates in ambulatory surgery were half the rates in inpatient surgery.

Surveillance and Prevention

Surveillance for SSI in an outpatient surgery setting is more difficult than that in an inpatient setting, largely because patients do not stay in the facility post-operatively and follow-up is not as easily facilitated. Some studies have used administrative claims data for outpatient settings as well; however, the sensitivity of this method is not as high as in inpatient settings. One study reported that only 37% of potential breast SSI identified by outpatient claims data were confirmed to be SSI (Miner 2004). There is little information about surveillance efforts and SSI rates in ambulatory surgery settings, likely due to the difficulties in conducting surveillance.

Risk factor analyses for SSI in outpatient settings are also sparse. One study of hernia repair and varicose veins operations in an ASC using NNIS data found a crude SSI rate of 1.2%, with only once significant risk factor. The use of spinal anesthesia conferred an 11 times higher risk of SSI than patients with any other type of anesthesia (Hirsemann 2005). The Agency for Healthcare Research and Quality published a ranking of risk factors for SSI in ASCs by importance, and the top several were as follows (in order): 1) failure to protect patient effectively, 2) obese patient, 3) staff not well-trained in infection control, 4) failure to administer prophylactic antibiotics, 5) smoker, 6) glove puncture, and 7) failure of the patient to come for post-op visit, among others (Slonim 2012).

Little is known about SSI prevention efforts in outpatient settings. A study of infection control practices in 68 ASCs revealed that 67.6% had at least 1 lapse in infection control, and 17.6% has lapses in 3 or more of the 5 infection control categories; common types included using single dose medication vials for multiple patients, failing to adhere to recommended practices for equipment reprocessing, and handling blood glucose monitoring equipment inappropriately (Schaefer 2010). Standardized prevention practices are greatly needed for outpatient settings; in order for that to happen, outpatient facilities must build greater capacity for surveillance and feedback.

Chapter II: Manuscript

Introduction

Surgical site infection (SSI) is one of the most common healthcare-associated infections (HAIs) and is a major cause of morbidity, hospital readmission and mortality in the US. SSIs comprise of approximately 31% of HAIs among patients in acute care facilities across the nation. Mortality from SSIs is approximately 3%, with 75% of those deaths directly attributable to the SSI. In addition to morbidity and mortality, SSIs are responsible for a significant cost burden on our healthcare system. The cost of preventable SSIs has been estimated by one study to lie between $166 and $345 million annually.

HAIs, including SSIs, are largely preventable. However, effective preventative interventions require analysis of the modifiable and non-modifiable risk factors that contribute to high SSI rates. SSI rates are also widely used as comparison measures of surgical quality among healthcare providers; therefore, risk-adjustment systems are needed to account for the variations in patient case mix with regard to several non-modifiable risk factors of SSI.

SSIs in the inpatient setting have been the focus of much of the previous work on SSI. However, previous risk-adjustment models and analyses have largely ignored the volume of surgical procedures performed in the outpatient setting, from ambulatory surgery centers (ASCs) and hospital-based outpatient facilities. This is likely due to the difficulty of surveillance in these settings, where patient follow up requires active surveillance of patients after leaving the facility. With the increasing number of surgical quality incentives and mandates for reporting SSI, it is becoming necessary to assess the risk factors for SSI in the outpatient setting and develop risk-adjustment systems specific to outpatient facilities.

Breast procedures are among the most common surgeries performed in an outpatient setting, especially ambulatory surgery centers, and contribute to a significant proportion of

outpatient SSIs. The risk of SSI in breast procedures ranges in the literature from approximately 2.3% to 6.7%. Lacking in the literature, however, is an analysis of the differences in risk between outpatient facilities. Crude risks suggest the rate of SSI in ASCs is lower than in hospital-based outpatient facilities; however, these differences can be largely due to the differences in patient variables, and may not be associated inherently with location of procedure. Assessing this risk can set the stage for further surveillance measures and other preventative interventions specifically designed for ambulatory surgery centers. This study examined whether the SSI risk for surgical breast procedures is less in ambulatory surgery centers compared to other outpatient facilities, after adjusting for several patient-based, non-modifiable confounders of the association between facility type and risk of breast SSI.

Methods

Data Source

Data for this study was obtained from the National Healthcare Safety Network (NHSN), a secure, Internet-based surveillance system managed by the Division of Healthcare Quality and Promotion (DHQP) at the Centers for Disease Control and Prevention (CDC). The NHSN collects data about hospital-acquired infections (HAIs), adherence to clinical HAI prevention practices, and adverse events in healthcare, obtained from over 12,000 medical facilities, including acute care hospitals, outpatient facilities, ambulatory surgery centers, and others. Participation in NHSN is voluntary. This study is a secondary analysis of a deidentified dataset from the CDC, and was deemed as exempt by Emory University Institutional Review Board.

Surgical site infection data is reported within the Procedure-Associated Module of the Patient Safety Component within NHSN. Data collection involved active, patient-based, prospective surveillance conducted by infection prevention personnel (Infection Preventionists (IPs), or other designated personnel) at each participating facility. Methods for SSI detection may include direct examination of patients' wounds, review of medical records or surgery clinic patient records, surgeon surveys by mail or telephone, and patient surveys by mail or telephone (although these are often only used in conjunction with another method). Specific methods likely varied between healthcare facilities, but the definition of an SSI was standardized.

Analysis Dataset and Variable Specification

The total population was drawn from NHSN surveillance data from 2010-2013, and included a total of 86, 199 outpatient surgical breast procedures. This range of years was selected because it represented the start of any state-mandated reporting of outpatient breast SSI (2010), until the most recent full year where data was collected (2013). Variable definitions did not

change within that timeframe. The analysis population was a subset of the total population for which observations with one or more missing covariates were excluded, and consisted of 77, 224 procedures.

Surgical site infection is defined in NHSN as the following:

Any infection that occurs within 30 days after any NHSN operative procedure (where day 1 = the procedure date)

AND

patient has at least one of the following:

a. purulent drainage from the superficial incision

b. organisms isolated from an aseptically-obtained culture from the superficial incision or subcutaneous tissue

c. superficial incision that is deliberately opened by a surgeon, attending physician** or other designee and is culture positive or not cultured

AND

patient has at least one of the following signs or symptoms: pain or tenderness; localized swelling; erythema; or heat. A culture negative finding does not meet this criterion

d. diagnosis of a superficial incisional SSI by the surgeon or attending physician or other designee.

Breast surgeries in NHSN are defined to include any procedure involving excision of lesion or tissue of breast including radical, modified, or quadrant resection, lumpectomy, incisional biopsy, or mammoplasty. For a full list of International Classification of Disease (ICD-9) and Current Procedural Terminology (CPT) codes that comprise the NHSN classification of breast surgery, please refer to Table A1. The outcome variable, breast SSI, was defined as any SSI occurring in a breast surgery, in accordance with the definitions above.

The exposure variable (outpatient facility type) was a binary variable, coded as 'Ambulatory Surgery Center' (ASC = 1) and 'non-ASC' (ASC = 0). The majority of facilities classified as 'non-ASC' were general hospital outpatient departments (HOPDs); however, other hospital types were also included (Table A2). Other covariates included in the study were: patient age at procedure, anesthesia use during procedure, American Society of Anesthesiologists (ASA) Classification of Physical Status, duration of procedure in minutes, gender of patient, and wound classification. These variables were selected because they represent patient-level characteristics that have been shown to be biologically plausible confounders of the relationship between location of procedure and risk of SSI.

Patient age (in years) was recorded at the time of the procedure. Patients were excluded if their age was under 15 years or greater than 109 years. For this study, age was categorized as a binary variable at the median value (51 years) to reflect significant differences, after consideration of the linear univariate association of age with risk of breast SSI (Figures A1-4).

Anesthesia use was classified as a binary (yes/no) variable, indicating whether general anesthesia was used during the procedure. General anesthesia use is defined in NHSN as the administration of drugs or gases that enter the general circulation and affect the central nervous system to render the patient pain-free, amnesic, unconscious, and often paralyzed with relaxed muscles.

ASA score was recorded by the anesthesiologist, in accordance with the ASA Classification of Physical Status (ASA 2015). The patient is assigned a score of 1-5, defined as the following:

1. A normally healthy patient
2. A patient with mild systemic disease
3. A patient with severe systemic disease
4. A patient with severe systemic disease that is a constant threat to life
5. A moribund patient who is not expected to survive without the operation.

In this study, ASA class was categorized into 3 levels (1, 2, 3/4/5). This was done because data in the levels 4 and 5 individually was too sparse to conduct statistical analyses and observe significant differences in SSI risk.

Duration of procedure in NHSN was defined as the interval in hours and minutes between the surgery start time and the finish time, as defined by the Association of Anesthesia Clinical Directors. This variable was originally two variables, for hours and for minutes, that was collapsed into one variable that indicated total minutes. Procedures were deemed outliers and excluded if duration was less than or equal to 10 minutes, or greater than or equal to 291 minutes. For the study, duration was categorized as a three level variable (less than or equal to 51 minutes, 52-88 minutes, and greater than 88 minutes) based on quartiles of the distribution in the data. This categorization was determined to reflect significant differences, after consideration of the linear univariate association of procedure duration with risk of breast SSI (Figures A5-8).

Wound classification fell into one of four categories: Clean, Clean Contaminated, Contaminated, or Dirty (for full definitions, please see Table A3). It was then categorized as a binary variable, with one level collapsing clean and clean contaminated, and the other collapsing contaminated and dirty. This was done so that each category would have enough data to detect meaningful and more precise differences in SSI risk.

Statistical Analyses

Descriptive exploratory analysis was first conducted to examine distributions of exposure and covariates in the population. Univariate associations between covariates and the outcome were then examined using likelihood ratio chi-square tests. All statistical tests were performed at the $\alpha=0.05$ level.

Unconditional multivariable logistic regression was used to examine the association between facility type and breast SSI. Observations with missing values in any of the covariates were excluded from the model. The modeling strategy included an interaction assessment,

followed by a confounding assessment. All exposure-covariate interactions were considered, but covariate-covariate interactions were omitted because only the effect of exposure was of interest. An overall (chunk) likelihood ratio test was performed to assess the significance of all interaction terms, followed by a backward elimination strategy to assess the significance of individual interactions (Table A4).

Confounding was assessed using several criteria: biological plausibility (assessed at the variable inclusion stage), association of the variable with exposure and outcome, and whether the risk ratios of the exposure variable changed (by >10%) when a covariate was removed from the logistic regression model (Table A5). The change-in-estimate confounding analysis utilized a best-subsets approach. Variables were dropped from the model if the change in risk ratio was less than 10%.

Collinearity was assessed through examination of condition indices and variance decomposition proportions. Any variable with a condition index greater than 30 was considered a possible source of collinearity. For those variables, collinearity with other covariates was considered present if the variance decomposition proportions were greater than 0.5. A goodness of fit test was conducted using the deviance-based chi-square test. Validation of the model was conducted using a bootstrap method, as described in Table A6. Parameters of interest for validation included the c-index (Area Under the ROC curve, or AUC), and logistic regression coefficients.

The results were expressed as risk ratios with corresponding 95% confidence intervals. Odds ratio estimates obtained from logistic regression were assumed to closely approximate risk ratios because the outcome of interest is a rare outcome. All statistical analyses were conducted using SAS version 9.3 (Cary, NC).

Results

Descriptive characteristics of all variables included in the study are shown in Table 1 for both the total population and the analysis population. Out of 86,199 total procedures, there were 494 SSI (0.57%), and 31,015 procedures from ambulatory surgery centers (36.0%). The analysis population contained 77,224 procedures (89.5% of the total), with 460 SSI (0.60%), and 24,483 procedures from ASCs (31.7%). Distributions of covariates did not change substantially between the total and the analysis population. ASA Class had the highest number of missing values (7,173, 8.3%), whereas all other variables had few missing values (<2.0%). The majority (81.3%) of the observations were collected in 2012 and 2013, with the least (4.0%) collected in 2010.

Univariate analyses between each covariate and the outcome variable are shown in Table 2, with corresponding p-values. All variables were found to be significantly associated with SSI at the 0.05 level. The crude risk of SSI in ambulatory surgery centers was 0.25%, compared with a non-ASC risk of 0.75% (cRR=0.30, $p<0.0001$). Risk ratios also did not vary substantially between the total and analysis populations.

Unconditional logistic regression was performed using all covariates, using the modeling strategy outlined above. Table 3a shows model performance statistics, regression coefficients, and corresponding p-values of the final model, and Table 3b shows risk ratios and 95% confidence intervals. Effect modification was assessed between exposure and all other covariates, but age of patient was found to be the only significant effect modifier ($p= 0.067$). Gender of patient, anesthesia use, and wound classification were determined to contribute minimal or no confounding of the estimate, and were thus excluded from the model (Table A5). Although age was not found to contribute to substantial confounding, it was included in the model because it was found to provide significant effect modification, and inclusion was necessary to keep the model hierarchically well formulated.

For patients aged 51 or under, the risk of SSI among ambulatory surgery centers was 0.28 (95% CI: 0.18, 0.44) times the risk of SSI among non-ASC outpatient settings, adjusted for age, ASA class and duration of procedure. For patients older than 51 years, the risk of SSI among ambulatory surgery centers was 0.23 (95% CI: 0.14, 0.39) times the risk of SSI among non-ASC outpatient settings, adjusted for age, ASA class and duration of procedure.

The model did not significantly deviate from the fully parameterized model, indicating good model fit (p=0.23). The model provided acceptable discrimination between cases and non-cases, with a c-index of 0.720. Table 4 shows the results of the bootstrap validation, for 100 replicates. The model consistently performed acceptably, with a c-index ranging from 0.70 (lower 2.5%) to 0.74 (upper 97.5%). All estimates of regression coefficients remained significant. Although age was not significant in the model, it was found to be significant in the validation.

Discussion

The risks of breast procedure SSI differed greatly in ambulatory surgery centers as compared to non-ASC settings, in both old and young age groups, adjusted for age, ASA score, and duration of procedure. In those 51 or younger, the adjusted SSI risk in ASCs was 0.28 (95% CI: 0.18, 0.44) times the adjusted risk in non-ASCs; for those 51 or older, the adjusted risk was 0.23 (95% CI: 0.14, 0.39) times greater in ASCs than non-ASCs. Overall, ASCs seem to have a much lower risk of SSI following breast procedures than non-ASC outpatient settings, even after adjusting for non-modifiable risk factors. Setting aside the limitations of this study, this naturally leads to the conclusion that the difference in risk between the facility types is associated in part with differences in practice, or modifiable differences.

Though these risk ratios look very similar, the difference of the effect between age groups can be more easily seen when comparing the inverse effects ($1/RR_{<=51}=3.57$, $1/RR_{>51}=4.35$). Based on these results, it seems that older patients benefit more from going to an ASC than younger patients. The reason for this may be that older patients are more sensitive to differences in practice between ASCs and non-ASCs, or that providers at the two facility types treat patients of different ages differently, but this is pure speculation—further research is required in order to elucidate intermediates in the causal mechanism.

The designation of "non-ASC" may be a source of ambiguity when interpreting these findings. Initially, the intention was to compare ASCs to hospital outpatient departments (HOPDs), but since definitions of HOPDs were not standardized in NHSN, it would have been an inappropriate label. The "non-ASC" outpatient designation was assigned when any non-ASC facility reported outpatient breast surgeries to NHSN. However, all of the facilities comprising this designation are acute care hospitals, with 89.4% of them being general hospitals (Table A2). It is reasonable to assume that the non-ASC outpatient procedures were done at the same location

as a corresponding inpatient facility, while ASC procedures were performed at a dedicated outpatient facility.

This study has several limitations. The risk of outpatient breast SSI reported in this study is likely lower than the true risk, due to the difficulty in conducting and validating active, postoperative surveillance of SSI in outpatient settings. Other, smaller surveillance studies such as the American College of Surgeons National Surgical Quality Improvement Program (NSQIP), have measured SSI rates across facility types and procedure categories that have been consistently higher than corresponding NHSN estimates, although overall trends have been similar. However, SSI definitions between the two surveillance systems are different, therefore rendering the two systems somewhat incomparable. Assuming detection rates of SSI events are non-differential with respect to facility type, the magnitude and direction of bias in the risk ratios are estimated to be null.

Another potential limitation is inadequate control for confounding factors. Control for confounding of the association between outpatient facility type and breast SSI was accomplished through instrumental variables to account for the differences in patient case-mix between facility types that would normally cause differences in SSI rates. These instrumental variables are not theoretical confounders in themselves, but are highly associated with unmeasured and immeasurable confounders. Therefore, controlling for these may result in incomplete control of confounding, or residual confounding. In the same vein, duration of procedure is a controversial point of control, as some may argue that it reflects procedural elements of the facility or the skill of the provider rather than patient complexity. In other words, it is not entirely clear whether duration is a confounder or an intermediate in the causal relationship between facility type and SSI. This controversy applies in risk-adjustment models, where skill of the provider is sometimes unwanted as a point of adjustment.

There were several variables that would have been adjusted for had it not been for the limited availability of data. For example, body mass index, hypertension, previous breast surgery,

and diabetes status are factors that greatly influence the risk of breast SSI and also are instrumental variables for patient case-mix; however, reporting those covariates to NHSN was not required during the time of this study. Other variables not captured by NHSN, but included in several risk factor analyses of breast procedures, were preoperative chemoradiation, surgical approaches, intraoperative bleeding, and drainage time. These variables represent modifiable risk factors that may be intermediates of the relationship between facility type and risk of SSI—that is, they may reflect practices that differ between facility types. The objective of this study was to determine if any differences between facility type, other than patient case-mix (which cannot be a target for prevention), result in differences in SSI risk. Therefore, it did not matter that those variables were not captured by NHSN.

Missing data may have also posed a problem for this study. Overall, approximately 10% of the total population was missing in the final analysis. The crude risk of SSI in the missing data was 0.38%, and the crude risk ratio of the association between ASC and SSI in the missing data was 0.85 (95%CI: 0.6508, 1.1051). Distributions of covariates are highly similar in both the total population and the analysis population. However, reasons for the difference need to be explored. In addition, distributions of covariates are highly similar in both the total population and the analysis population.

NHSN is a powerful and far-reaching national surveillance system established by the CDC, and models based on NHSN data are used nationwide as risk-adjustment systems for healthcare facilities to calculate risk-adjusted SSI rates for CMS reimbursement and quality improvement. Using the same risk-adjustment variables in this analysis lends much credibility to the model built in this study, most notably its ability to control for patient case-mix using proven instrumental variables. This is one of the first studies on outpatient data collected by NHSN, and findings indicate that ambulatory surgery centers have significantly and substantially lower rates of SSI, adjusted for patient case-mix. Future studies can fill in the gaps left from this study by examining the intermediate, modifiable variables that may result in the association observed.

These can then be used by hospitals and policymakers as targets for intervention and quality improvement in outpatient surgical care.

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Tables

Table 1. Characteristics of Outpatient Surgical Breast Procedures Reported to NHSN, 2010-2013.

	Total Population (n=86,199)		Analysis Population (n=77,224)
Variable	Total n	n(%) or Mean(SD)	n(%) or Mean(SD)
Surgical Site Infections (SSI)	86,199	494 (0.57%)	460 (0.60%)
Ambulatory Surgery Centers (ASC)	86,199	31,015 (36.0%)	24,483 (31.7%)
Age	85,912	50.5 (15.7)	50.8 (15.7)
Anethesia	86,199	71,175 (82.6%)	65,010 (84.2%)
ASA Class	79,026		
1		19,827 (25.1%)	19,083 (24.7%)
2		45,171 (57.2%)	44,307 (57.4%)
3		13,523 (17.1%)	13,339 (17.3%)
4		497 (0.63%)	487 (0.63%)
5		8 (0.01%)	8 (0.01%)
Duration (minutes)	84,470	67.6 (49.3)	68.3 (54.0)
Gender (Female)	86,199	84,096 (97.6%)	75,469 (97.7%)
Wound Class	86,024		
Clean		82,285 (95.6%)	73,715 (95.5%)
Clean Contaminated		3,059 (3.6%)	2,866 (3.7%)
Contaminated		366 (0.43%)	337 (0.44%)
Dirty		314 (0.37%)	285 (0.37%)
Year of Procedure	85,994		
2010		3,420 (4.0%)	3,314 (4.29%)
2011		12,711 (14.8%)	12,192 (15.8%)
2012		33,113(38.4%)	29, 551(38.3%)
2013		36,955 (42.9%)	32,167 (41.7%)

Abbreviations: NHSN, National Healthcare Safety Network; ASA, American Society of Anesthesiologists

Table 2. Univariate Analysis of Predictors of Surgical Site Infections (SSI) among Outpatient Surgical Breast Procedures Reported to NHSN, 2010-2013.

	Total Population (n=86,199)					Analysis Population (n=77,224)				
Variable	No. of Procedures	No. of SSIs	Risk (%)	Risk Ratio	*P*	No. of Procedures	No. of SSIs	Risk (%)	Risk Ratio	*P*
Facility Type					<.0001					
Non-ASC	55184	416	0.75	1.00		52,741	403	0.76	1.00	<.0001
ASC	31015	78	0.25	0.33		24,483	57	0.23	0.30	
Age					0.0007					
≤51 years	44998	220	0.49	1.00		39,732	206	0.52	1.00	0.0041
>51 years	40914	273	0.67	1.37		37492	254	0.68	1.31	
Anethesia					<.0001					
N	15024	41	0.27	1.00		12214	35	0.29	1.00	<.0001
Y	71175	453	0.64	2.37		65010	425	0.65	2.24	
ASA Class					<.0001					<.0001
1	19827	44	0.22	1.00		19083	42	0.22	1.00	
2	45171	266	0.59	2.68		44307	261	0.59	2.68	
3/4/5	14028	160	1.14	5.18		13834	157	1.13	5.14	
Duration					<.0001					<.0001
≤51 minutes	42119	126	0.30	1.00		37938	112	0.30	1.00	
52-88 minutes	21243	124	0.58	1.94		19579	118	0.60	2.00	
>88 minutes	21108	234	1.11	3.71		19707	230	1.17	3.90	
Gender					0.0195					0.0572
M	2103	5	0.24	1.00		1755	5	0.28	1.00	
F	84096	489	0.58	2.42		75469	455	0.60	2.14	
Wound Category					0.0031					0.0065
C/CC	85344	483	0.57	1.00		76581	450	0.59	1.00	
CO/D	680	11	1.62	2.84		612	10	1.61	2.73	
Year of Procedure					0.0015					0.0020
2010	3420	38	1.11	n/a		3314	37	1.12	n/a	
2011	12711	62	0.49	n/a		12192	60	0.49	n/a	
2012	33113	184	0.56	n/a		29551	168	0.57	n/a	
2013	36955	210	0.57	n/a		32167	195	0.61	n/a	

Table 3a. Multivariable-Adjusted Model Examining the Association between Facility Type and Risk of Outpatient Breast SSI in 77,224 Procedures Reported to NHSN, 2010-2013.

Variable	Estimate	SE	P	Deviance	P	c-Index
Intercept	-6.291	0.18	<.0001	33.1537	0.2300	0.720
ASC	-1.2691	0.22	<.0001			
ASA Classification						
2 vs. 1	0.7688	0.17	<.0001			
3/4/5 vs. 1	1.4211	0.19	<.0001			
Age (>51 vs. <=51)	-0.2048	0.11	0.0542			
Duration						
52-88 min. vs. ≤51 min.	0.6389	0.13	<.0001			
>88 min. vs. ≤51 min.	1.2927	0.12	<.0001			
ASC*Age	0.7847	0.29	0.0067			

Table 3b. Age-Stratified Risk Ratios and 95% CI for the Association between Facility Type and Risk of Outpatient Breast SSI, Adjusted for Age, Duration of Procedure, and ASA Classification.

Stratum	RR	95% CI		P
<= 52 years	0.28	0.18	0.44	<.0001
> 52 years	0.23	0.14	0.39	<.0001

Table 4. Bootstrap Model Validation Estimates and Corresponding 95% Confidence Intervals, Obtained from 100 Replicates of the Dataset.

Variable	Estimate	95% CI		C-index	95% CI	
ASC	-1.269	-1.65	-0.80	0.72	0.70	0.74
ASA Classification						
2 vs. 1	0.769	0.50	1.14			
3/4/5 vs. 1	1.421	1.14	1.83			
Age (>52 vs. <=52)	-0.205	-0.41	-0.05			
Duration						
52-88 min. vs. ≤51 min.	0.639	0.41	0.90			
>88 min. vs. ≤51 min.	1.293	1.07	1.47			
ASC*Age	0.785	0.26	1.34			

Note: Please refer to Appendix A6 for detailed bootstrap resampling method.

Appendix

Table A1. ICD-9 and CPT Codes Comprising the NHSN "BRST" Procedure Category.

ICD-9 Codes	85.12, 85.20-85.23, 85.31-85.36, 85.41-85.48, 85.50, 85.53-85.55, 85.6, 85.70-85.76, 85.79, 85.93-85.96
CPT Codes	19101, 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

Table A2. Distribution of Facility Types Classified as "Non-ASC" among 55,184 Procedures Recorded in NHSN, 2010-2013.

Hospital Type	n(%)
Critical Access Hospital	641 (1.2%)
Children's Hospital	67 (0.12%)
General Hospital, including Acute Trauma and Teaching	49347 (89.4%)
Long Term Acute Care Hospital	2 (0.0%)
Military Hospital	532 (0.96%)
Oncology Hospital	71 (0.13%)
Surgical Hospital	16 (0.03%)
Women's Hospital	3332 (6.0%)
Women's and Children's Hospital	1170 (2.1%)

Table A3. Long-form Definition of the Wound Classification Variable in NHSN.

Wound Class	Definition
Clean	An uninfected operative wound in which no inflammation is encountered and the respiratory, alimentary, genital, or uninfected urinary tracts are not entered. In addition, clean wounds are primarily closed and, if necessary, drained with closed drainage. Operative incisional wounds that follow nonpenetrating (blunt) trauma should be included in this category if they meet the criteria.
Clean Contaminated	Operative wounds in which the respiratory, alimentary, genital, or urinary tracts are entered under controlled conditions and without unusual contamination. Specifically, operations involving the biliary tract, appendix, vagina, and oropharynx are included in this category, provided no evidence of infection or major break in technique is encountered.
Contaminated	Open, fresh, accidental wounds. In addition, operations with major breaks in sterile technique (e.g., open cardiac massage) or gross spillage from the gastrointestinal tract, and incisions in which acute, nonpurulent inflammation is encountered including necrotic tissue without evidence of purulent drainage (e.g., dry gangrene) are included in this category.
Dirty	Includes old traumatic wounds with retained devitalized tissue and those that involve existing clinical infection or perforated viscera. This definition suggests that the organisms causing postoperative infection were present in the operative field before the operation.

Table A4a. Overall (Chunk) Likelihood Ratio Test for Interaction, Including All Exposure*Covariate Interaction Terms.

Overall Test for Interaction	-2 log L	Chi-sqaure	P
Full Model	5294.331	16.955	0.0095
Reduced Model	5311.286		

Table A4b. Backwards Elimination Order for Exposure*Covariate Interaction Terms.

Interaction Terms	Conclusion
All E*C Interactions	Drop ASC*WoundClass
ASC*Gender, ASC*Anesthesia, ASC*Duration, ASC*AGE, ASC*ASA	Drop ASC*Gender
ASC*Anesthesia, ASC*Duration, ASC*AGE, ASC*ASA	Drop ASC*Anesthesia
ASC*Duration, ASC*AGE, ASC*ASA	Drop ASC*Duration
ASC*AGE, ASC*ASA	Drop ASC*ASA
ASC*AGE	**Keep ASC*Age**

Table A5. Age-Stratified Confounding and Precision Assessment Using a Best-Subsets Change-In-Estimate* Strategy.

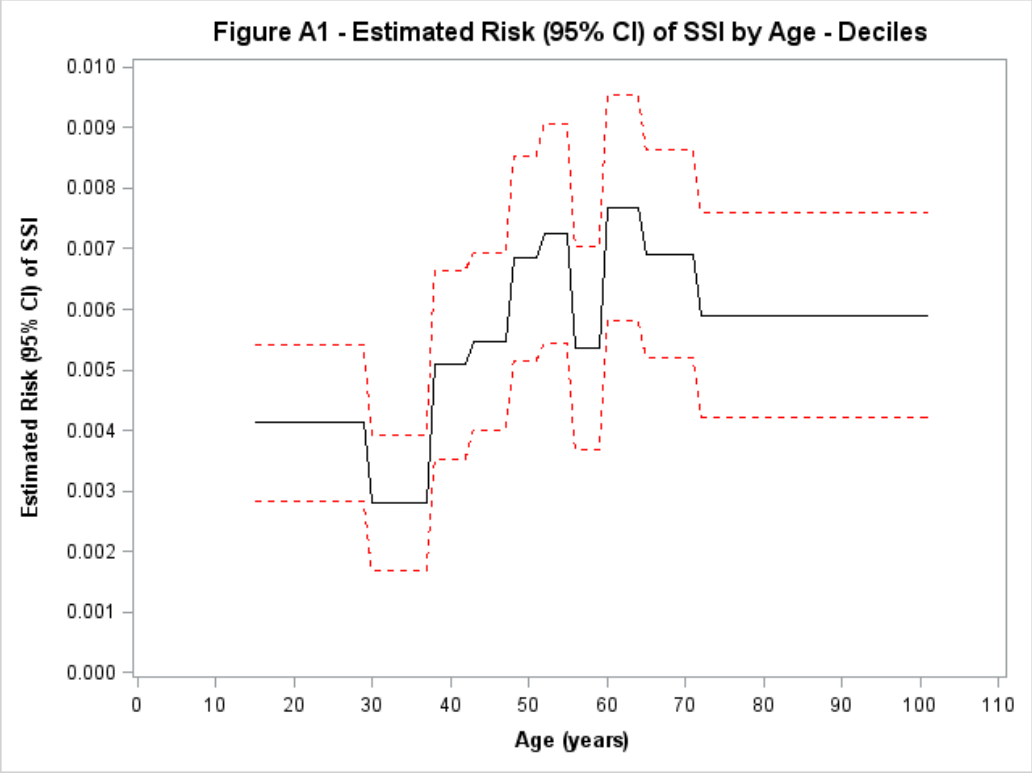
Model	Variables Dropped	**RR <=52 yrs**	% from GS	LL	UL	CI Ratio	**RR >52 yrs**	% from GS	LL	UL	CI Ratio	Drop ?
GS	none	**0.284**		0.183	0.441	2.403	**0.233**		0.138	0.392	2.841	
1	asac	**0.233**	17.846	0.151	0.361	2.386	**0.258**	10.834	0.153	0.434	2.832	
3	durcat	**0.265**	6.829	0.172	0.407	2.358	**0.208**	10.490	0.125	0.348	2.787	
4	anesthesia	**0.283**	0.282	0.183	0.439	2.403	**0.231**	0.516	0.137	0.390	2.841	
5	female	**0.284**	0.035	0.183	0.441	2.404	**0.233**	0.258	0.138	0.393	2.843	Y
6	woundc	**0.282**	0.774	0.182	0.437	2.402	**0.227**	2.451	0.136	0.387	2.841	
7	female, asac	**0.252**	11.193	0.172	0.370	2.145	**0.279**	20.120	0.174	0.450	2.589	
8	female, durcat	**0.265**	6.758	0.173	0.407	2.358	**0.209**	10.060	0.125	0.349	2.785	
9	female, anesthesia	**0.283**	0.246	0.183	0.439	2.403	**0.232**	0.258	0.138	0.391	2.843	Y
10	female, woundc	**0.282**	0.774	0.182	0.437	2.402	**0.230**	1.032	0.137	0.388	2.840	
11	female, anesthesia, asac	**0.252**	11.404	0.172	0.369	2.145	**0.278**	19.304	0.172	0.447	2.590	
12	female, anesthesia, durcat	**0.259**	8.800	0.169	0.398	2.358	**0.203**	12.855	0.121	0.338	2.787	
13	female, anesthesia, woundc	**0.281**	1.056	0.181	0.436	2.402	**0.229**	1.548	0.136	0.386	2.840	Y
14	female, anesthesia, woundc, asac	**0.248**	12.707	0.169	0.363	2.143	**0.273**	17.412	0.170	0.440	2.588	N
15	female, anesthesia, woundc, durcat	**0.258**	9.293	0.168	0.396	2.358	**0.201**	13.715	0.120	0.335	2.787	N

*In this strategy, variables were dropped if their exclusion resulted in the least percent change of the stratum-specific risk ratios from the full (Gold Standard, GS) model, up to 10%. If risk ratios changed greater than 10%, they were determined to be confounders and kept in the model. Precision was assessed through change in the ratio between the upper and lower limits of the 95% confidence interval.

Table A6. Bootstrap Validation Steps.

1	100 independent samples of the same size as the original sample were obtained, each of which was a simple random sample with replacement.
2	Logistic regression was applied to each sample using selected risk factors.
3	The 95% confidence intervals based on 100 independent samples for the estimated effects (of the risk factors) were calculated.
4	If the effects at the 2.5th percentile and the 97.5th percentile were both positive (being risk factors) or negative (being protective factors), the effects were deemed to be significant; if the lower and the upper bound of the effects pointed to different directions (one being positive and the other being negative), the effect was deemed to be nonsignificant.
5	Nonsignificant effect was removed from the models, and the stepwise model selection was run to see whether other new effects could enter the models with this effect absent. The above bootstrapping process was repeated to validate the new models.
6	If several effects were found to be nonsignificant through bootstrapping, we removed the least significant effect in step 5.

Figures A1-8. Linear Risk Models for Categorical Age and Duration.



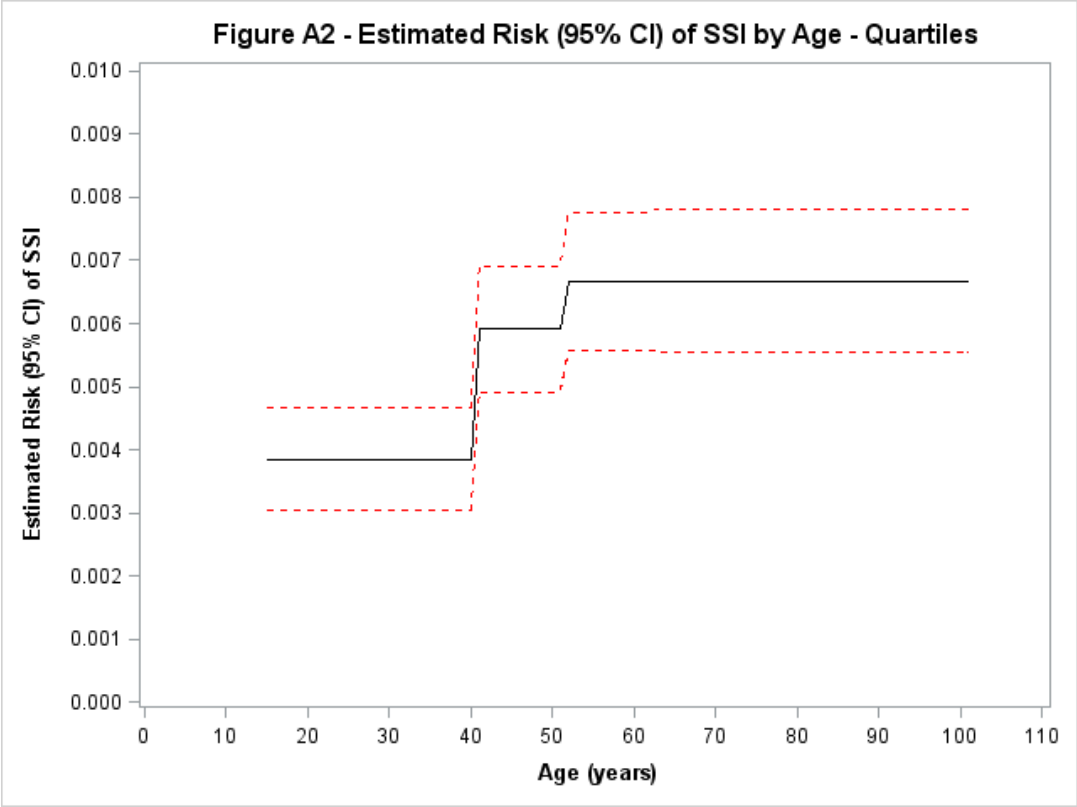


Figure A2 - Estimated Risk (95% CI) of SSI by Age - Quartiles
Estimated Risk (95% CI) of SSI
0.010
0.009
0.008
0.007
0.006
0.005
0.004
0.003
0.002
0.001
0.000
0
10
20
30
40
50
60
70
80
90
100
110
Age (years)

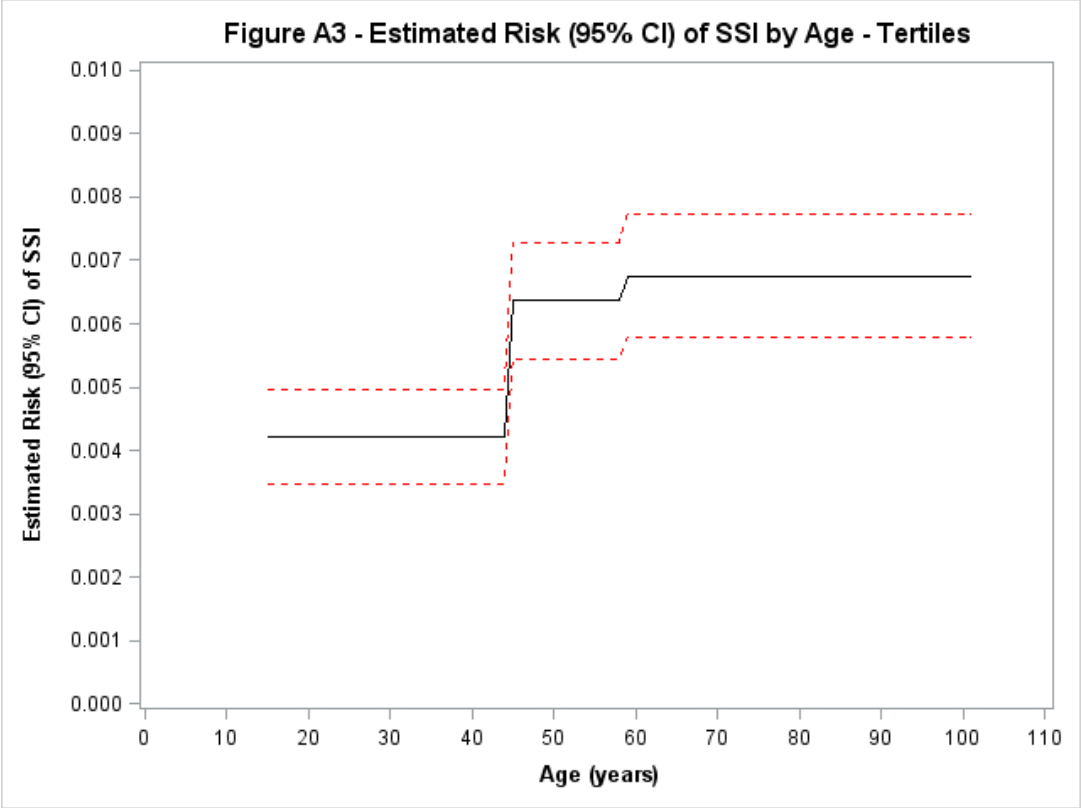


Figure A3 - Estimated Risk (95% CI) of SSI by Age - Tertiles
Estimated Risk (95% CI) of SSI
0.010
0.009
0.008
0.007
0.006
0.005
0.004
0.003
0.002
0.001
0.000
0
10
20
30
40
50
60
70
80
90
100
110
Age (years)

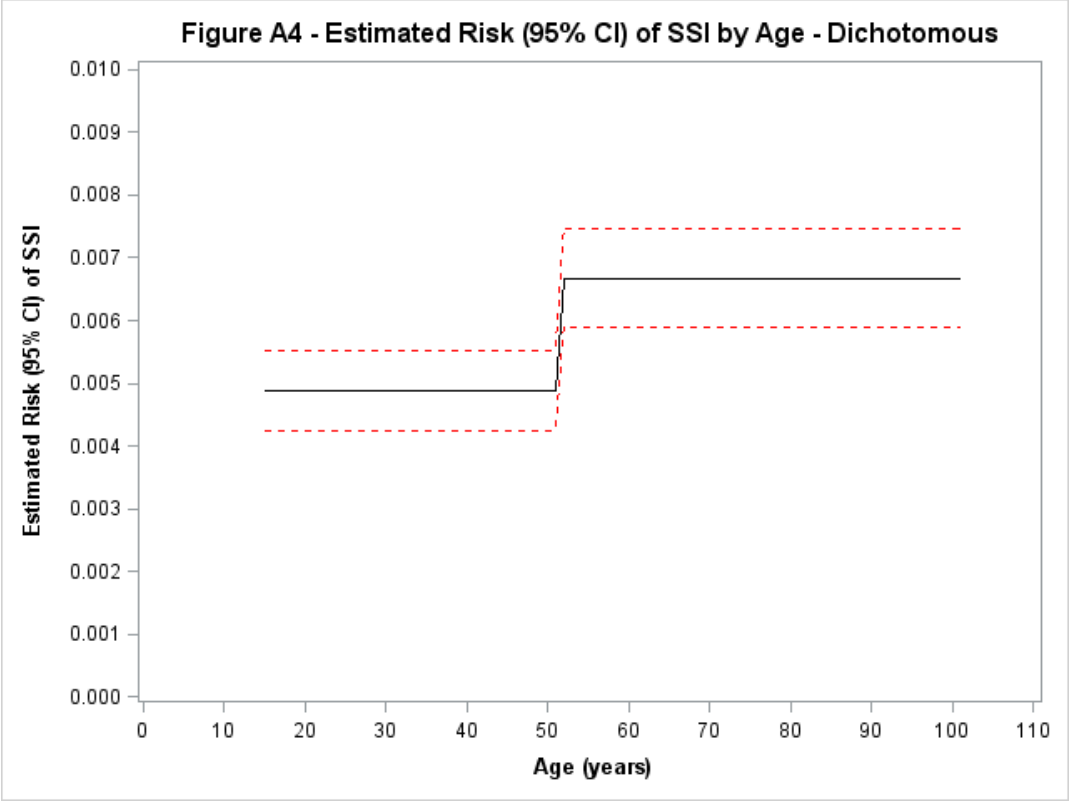


Figure A4 - Estimated Risk (95% CI) of SSI by Age - Dichotomous
Estimated Risk (95% CI) of SSI
0.010
0.009
0.008
0.007
0.006
0.005
0.004
0.003
0.002
0.001
0.000
0
10
20
30
40
50
60
70
80
90
100
110
Age (years)

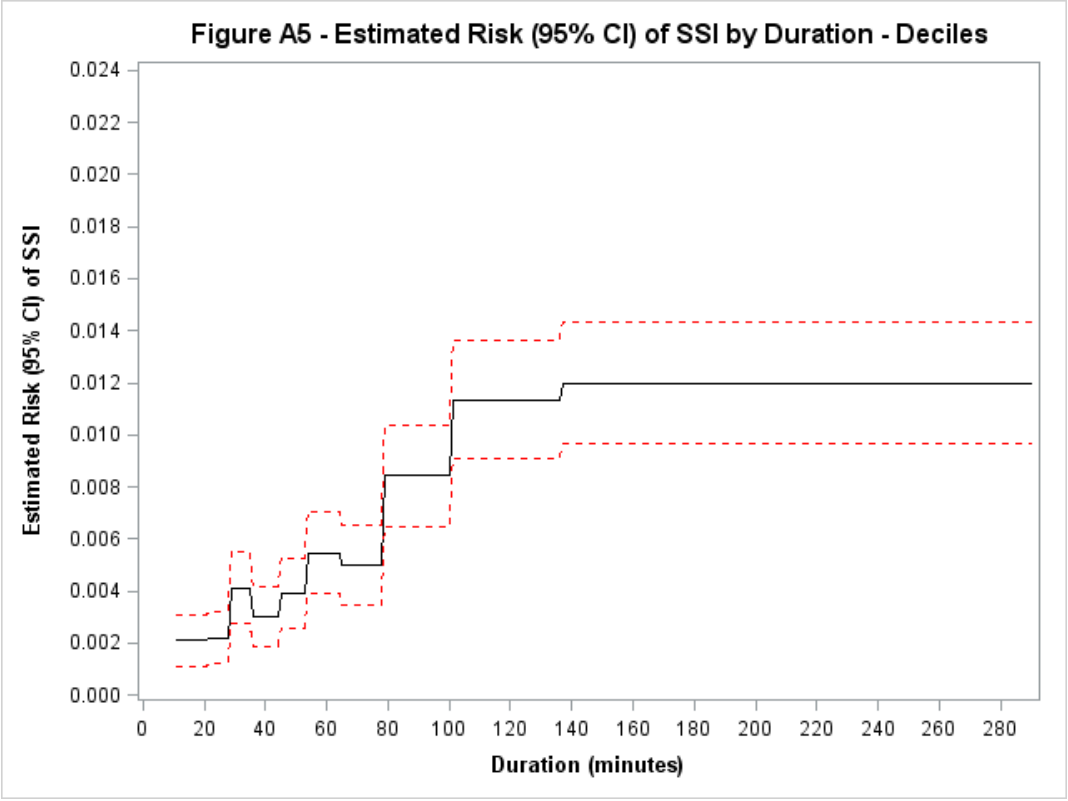


Figure A5 - Estimated Risk (95% CI) of SSI by Duration - Deciles
Estimated Risk (95% CI) of SSI
0.024
0.022
0.020
0.018
0.016
0.014
0.012
0.010
0.008
0.006
0.004
0.002
0.000
0
20
40
60
80
100
120
140
160
180
200
220
240
260
280
Duration (minutes)

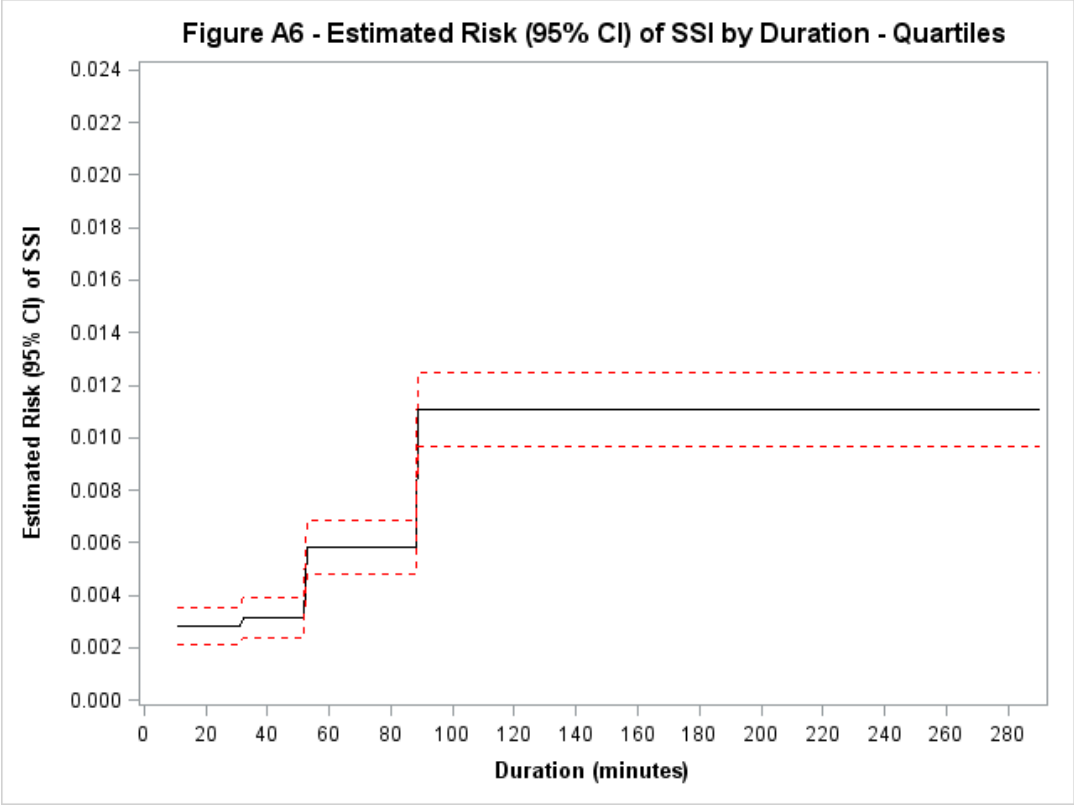


Figure A6 - Estimated Risk (95% CI) of SSI by Duration - Quartiles
Estimated Risk (95% CI) of SSI
0.024
0.022
0.020
0.018
0.016
0.014
0.012
0.010
0.008
0.006
0.004
0.002
0.000
0
20
40
60
80
100
120
140
160
180
200
220
240
260
280
Duration (minutes)

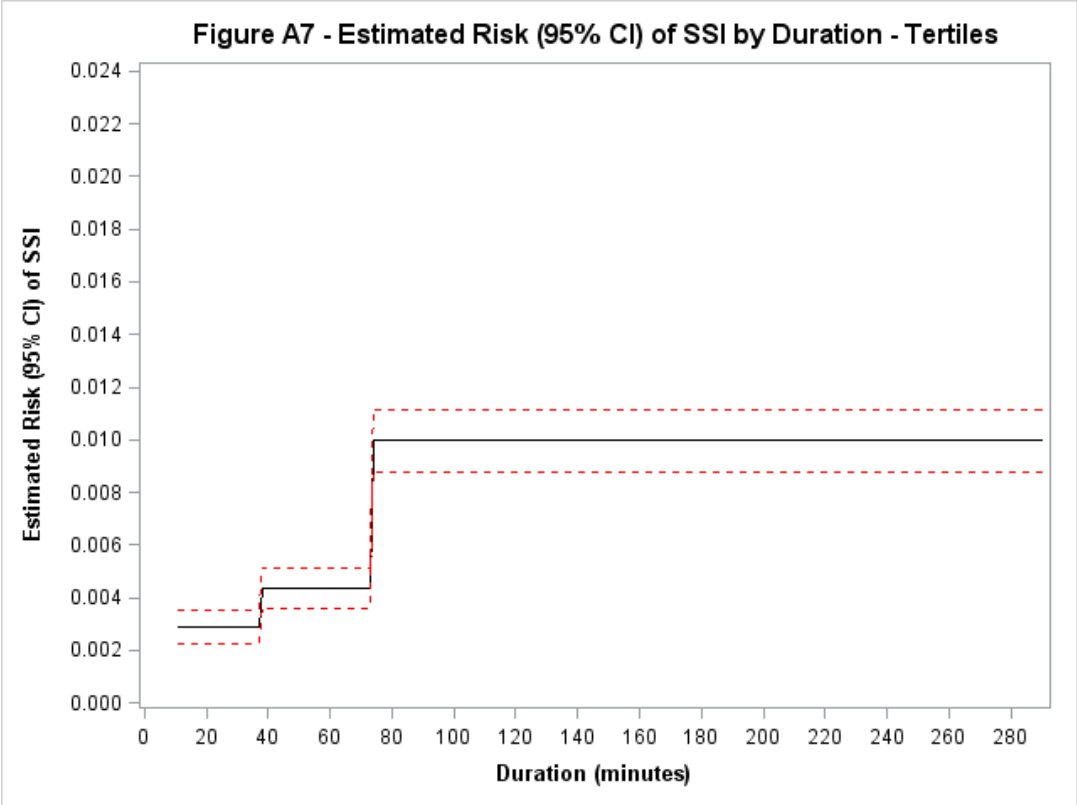


Figure A7 - Estimated Risk (95% CI) of SSI by Duration - Tertiles
Estimated Risk (95% CI) of SSI
0.024
0.022
0.020
0.018
0.016
0.014
0.012
0.010
0.008
0.006
0.004
0.002
0.000
0
20
40
60
80
100
120
140
160
180
200
220
240
260
280
Duration (minutes)

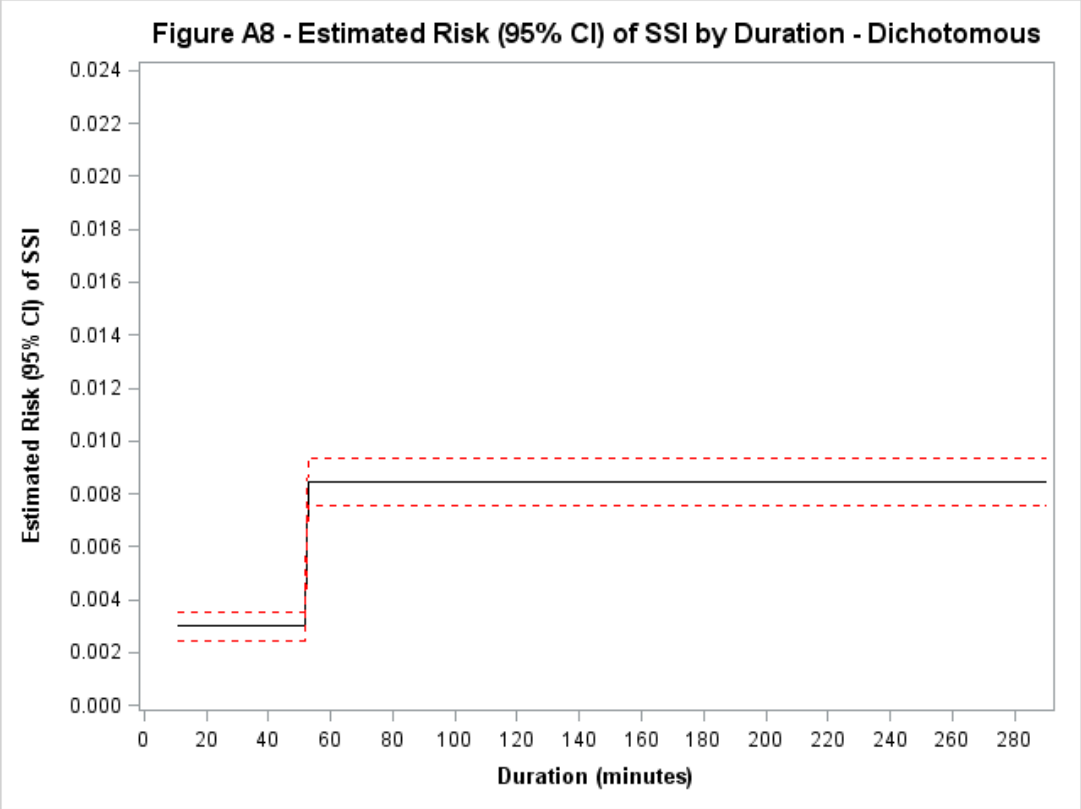


Figure A8 - Estimated Risk (95% CI) of SSI by Duration - Dichotomous
Estimated Risk (95% CI) of SSI
0.024
0.022
0.020
0.018
0.016
0.014
0.012
0.010
0.008
0.006
0.004
0.002
0.000
0
20
40
60
80
100
120
140
160
180
200
220
240
260
280
Duration (minutes)

Chapter III: Summary, Public Health Implications, and Future Directions

Surgical site infections in the inpatient setting have been the focus of much of the previous work on SSI. However, previous risk-adjustment models and analyses have largely ignored the volume of surgical procedures performed in the outpatient setting. This study examined whether the SSI risk for surgical breast procedures is less in ambulatory surgery centers compared to hospital-based outpatient facilities, after adjusting for differences in patient case-mix between facility type and risk of breast SSI. Data for this study was obtained from the National Healthcare Safety Network (NHSN), a secure, Internet-based surveillance system managed by the Division of Healthcare Quality and Promotion (DHQP) at the Centers for Disease Control and Prevention (CDC). Unconditional multivariable logistic regression was used to examine the association between facility type and breast SSI. Out of 86,199 total outpatient breast procedures reported to NHSN between 2010 and 2013, 77,224 were used in the analysis. For patients aged 51 or under, the risk of SSI among ambulatory surgery centers was 0.28 (95% CI: 0.18, 0.44) times the risk of SSI among hospital-based outpatient settings, adjusted for age, ASA class and duration of procedure. For patients older than 51 years, the risk of SSI among ambulatory surgery centers was 0.23 (95% CI: 0.14, 0.39) times the risk of SSI among hospital-based outpatient settings, adjusted for age, ASA class and duration of procedure. Ambulatory surgery centers have a protective effect on the risk of breast SSI compared to hospital-based outpatient settings, the extent of which differs by age.

Limitations and Strengths of the study are addressed in the manuscript.

The implications of this study for public health are simple, yet substantial. Because surveillance of outpatient SSI is a relatively new challenge, this study adds greatly to the growing body of knowledge about the quality of healthcare in outpatient surgical settings. Though this study may have limitations, these findings strongly suggest that there is bridgeable gap in SSI

prevention practices between hospital-based outpatient settings and ASCs. Future studies should examine mechanisms leading to this difference in risk, and target interventions accordingly.