

Guide for the Prevention of Mediastinitis Surgical Site Infections Following Cardiac Surgery



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Guide Overview

Purpose

The purpose of this guideline is to assist the infection preventionist with implementation of evidence-based strategies to minimize the risk of postoperative mediastinitis following cardiac surgery procedures in the inpatient hospital setting.

Key Concepts

An effective surgical site infection prevention program includes an understanding of the surgical population and the associated risk factors, effective methods for case finding, expertise in the analysis of the data, effective communication of the outcomes, and facilitating the identified opportunities for improvement in order to positively impact future outcomes.

Traditionally, preventionists advocate for improved patient outcomes by presenting evidence-based practice strategies to patients and healthcare providers. This requires close scrutiny of products, literature reviews and research to determine the most appropriate programs for their practice environments.

However, in today's healthcare environment, preventionists must also prepare a carefully crafted business case that illustrates the financial impact of healthcare-associated infections (HAIs). Providing this information to administrators is essential to secure sufficient resources to operate infection prevention programs. Therefore, in addition to prevention strategies, two different methodologies for creating the successful business case—attributable costs and cost-benefit analysis—are presented to assist preventionists with this important process.

Background

According to the American Heart Association, approximately 700,000 open heart procedures are performed every year in the United States and of these, more than 67% are coronary artery bypass grafting procedures (CABG).¹ Mediastinitis is a devastating infectious complication, involving the mediastinal space of the chest, which can occur after an open heart surgical procedure. The National Nosocomial Infections Surveillance (NNIS) System Report from 2004 published mediastinitis surgical site infection (SSI) rates for patients who underwent CABG procedures. Rates ranged from 0.12% to 2.33%, depending on the patient risk index category.

There were 393,839 patients who underwent CABG procedures from January 1992 to June 2004 in the database, representing approximately 300 participating hospitals. The number of patients who developed mediastinitis totaled 3,460 during this same time period.²

The literature reports mediastinitis rates following cardiac surgery of between 0.5% and 5.0%,³ with a mortality rate as high as 40%.⁴ Percentages and rates have a tendency to distance administrators and healthcare providers from the scope of the problem in terms of the actual numbers of patients affected by these outcomes. Therefore, if the rates are applied to actual numbers of patients based on the reported literature, then somewhere between 2,345 and 23,450 patients develop a mediastinitis SSI complication following CABG procedures every year. Patients who are diagnosed with mediastinitis require an average of

30 additional hospital days and at least one additional surgical procedure, and are at risk for other HAIs, such as ventilator-associated pneumonia and central line-related bacteremias.⁵

Financial Outcomes

The average attributable cost of a CABG procedure is approximately \$11,002 (in year 2000 U.S. dollars).⁶ However, if the patient develops a mediastinal SSI, the cost may increase to as much as three times greater⁷ with significant out-of-pocket expenses for the uninsured, under-insured, or a patient who has a large deductible associated with his or her insurance plan. If the patient is unable to return to work in a timely manner, or perhaps never work again, there could be lifelong financial, psychosocial, and health consequences.

Currently, 33 states have enacted legislation or are considering legislation to mandate public reporting of infection rates.⁸ This new culture of transparency will adversely impact hospitals with high SSI rates, resulting in a loss of reputation as well as associated revenues when consumers and payers choose to take their business elsewhere.

Likewise, extended length of stay (LOS) due to the complications of SSI exceeds the reimbursement cost from payers, creating financial losses and preventing hospitals from admitting new patients to generate additional revenue.⁹ The actual costs for providing care in terms of supplies, extended hospital stays, additional surgical procedures, and healthcare provider expertise also contribute to reduced revenue.

Consumer Activism

Following the 1999 Institute of Medicine (IOM) report, *To Err is Human: Building a Safer Health System*,¹⁰ consumers challenged the healthcare industry to provide safer patient care. It is no longer acceptable to view an SSI as a possible risk and unfortunate outcome of a surgical procedure, especially since research has verified that when effective infection prevention programs are implemented, SSIs can be significantly reduced.

Consumers are demanding that hospitals become more transparent, requesting healthcare provider-specific SSI information that will enable them to make informed decisions as to where they receive their care. The policy brief *Public Disclosure Will Encourage Hospitals to Improve Infection Practices*, written by the Consumers Union in 2007, cites the success of the public reporting of mortality rates for CABG procedures.¹¹ Although nationwide CABG mortality rates declined by 13% after public reporting was adopted, the state of New York reported an even greater reduction of 28%. This significant reduction in rates compared to the national rates was attributed to the early adoption of comparing and publishing CABG mortality rates within the state, and the quality improvements that were implemented based on the data.

Pay for Performance

As a result of the Deficit Reduction Act (DRA) of 2005, reimbursements from the Centers for Medicare & Medicaid Services (CMS) are changing. The Inpatient Prospective Payment System (IPPS) was developed under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.

In fiscal year (FY) 2005, the DRA authorized CMS to require IPPS hospitals by FY 2007 to report on 10 quality measures. IPPS hospitals that did not submit data received a 2.0% reduction in their Annual Payment Update for Medicare in FY 2007.

Although participation was originally voluntary, CMS may now reduce these payments, based on failure to participate or failure to meet the requirements of the quality measures.¹² In FY 2007, Congress directed the CMS to reduce reimbursements even further, and increase the number of quality measures each participating hospital must report.¹³

CMS is incrementally changing its payment structure from a fee-for-service model to a value-based purchasing model, which is based on measures of quality and efficiencies of care. The payment structures are designed to incentivize hospitals to adopt evidence-based practices that improve outcomes for the Medicare population.

CMS has selected ten “Hospital-Acquired Conditions” for FY 2009, including mediastinitis, for which reimbursement will be reduced.¹⁴ From a financial perspective, hospitals cannot afford to offer patients open heart procedures that result in mediastinal SSI complications.

It is expected that private insurers will eventually create similar payment structures. Based on other indirect costs, such as a reduction in patient satisfaction and physician referrals, and the potential increase in litigation, mediastinitis could create financial losses for hospitals, in addition to suboptimal patient outcomes. Therefore, preventionists must ensure that effective programs are in place in hospitals that perform open heart procedures, to reduce the risks associated with mediastinitis.

Mediastinitis

Mediastinitis is characterized by an infection that begins as a small, focused area of infection in the mediastinal cavity just below the sternum. The ensuing inflammation and tissue necrosis infects the surrounding soft tissues beneath the sternum and mediastinal space, which may or may not include osteomyelitis of the sternum itself.¹⁵ Seventy percent of patients with mediastinitis require at least one additional surgical procedure for incision and drainage of the infected area.¹⁶ The standard of care is to perform a muscle flap to establish sufficient blood supply to the sternum to promote healing.

Contributing factors to SSIs in general, and mediastinitis in particular, include the exogenous and endogenous sources that contaminate the surgical wound during the procedure. Exogenous sources include unsterile/contaminated fluids, hair and skin cell shedding from the surgical team, and poor hand hygiene practices. Endogenous sources include the patient's own skin flora and the presence of an existing infection at a remote site.¹⁷

Risk Factors for Mediastinitis

Patients with chronic conditions such as renal failure, hypertension, chronic obstructive pulmonary disease (COPD), peripheral vascular disease (PVD), osteoporosis, and diabetes are at higher risk for experiencing post-op mediastinitis. Other risk factors include obesity (defined as a body mass index, or BMI, greater than or equal to 30), diabetes, smoking (the risk of mediastinitis is more than three times greater for a smoker than a non-smoker), hospitalization prior to the surgical procedure, age, male gender, previous CABG procedures, an emergency procedure, and large breast size.¹⁸ Of all of these risk factors, the ones that are most consistently reported in the literature as independent variables for mediastinitis are obesity, diabetes, and hospitalization prior to the procedure.

Obesity is a growing concern, as the incidence of obesity has increased significantly over the last several decades. According to the National Health and Nutrition Examination Surveys (NHANES, 2008), the prevalence of obesity in the United States has increased from 15.0% (NHANES, 1976-1980 survey) to 32.9%.¹⁹

Obese patients are more likely to have impaired pulmonary function, immobility, hyperglycemia and poor nutritional status. The surgical procedure may be more difficult due to the patient's size and potential for tissue trauma due to difficult visualization of the operative field. Therefore, overall surgical time may be prolonged. Postoperatively, adipose tissue may cause undue pressure on suture lines, causing dehiscence.²⁰

Large breast size is considered a risk factor for mediastinitis due to the undue traction placed on the sternotomy site and the increased vascular demands to the breasts, which may compete with the sternum for an adequate blood supply to promote healing.²¹

Like obesity, the prevalence of diabetes is also on the rise. The Centers for Disease Control and Prevention (CDC) reports that in 2007, more than 23 million Americans were diagnosed with diabetes, while more than 5.7 million people remained undiagnosed, and 57 million people were considered pre-diabetic.²² In addition, the stress response induced by surgical procedures increases blood glucose levels. Therefore, non-diabetics may also experience hyperglycemia during this critical perioperative period.²³ Diabetic patients are at higher

risk for all HAIs including SSIs when compared to the general population. They experience higher mortality rates and longer hospitalizations. Controlling hyperglycemia in diabetics and non-diabetics during the patient's hospitalization has been associated with lower mediastinitis and mortality rates as well as a decrease in costs and length of stay.²³

The third major risk factor for mediastinitis is hospitalization prior to the procedure. The longer a patient is hospitalized preoperatively, the higher the risk for acquiring an SSI.²⁴ However, standard practice among hospitals today requires that patients be admitted on the day of surgery, therefore reducing this risk factor for the majority of patients.

Program Interventions

Program interventions fall into three distinct categories: non-modifiable patient characteristics, the monitoring of compliance with current standards of care, and the implementation of new programs and products based on new research and/or the opportunities for improvement that are unique to each hospital setting.

Non-modifiable Patient Characteristics

Patients who present with chronic diseases such as COPD and diabetes mellitus cannot have these risk factors reduced or eliminated prior to their surgical procedures. Likewise, patient age, male gender, history of previous CABG procedure, and urgent/emergent surgeries also place patients at higher risk for mediastinitis, but cannot be modified pre-operatively.

Although some may argue that the risk factors of obesity and smoking are modifiable behaviors, clearly the time to address these issues is well before the patient presents to the hospital requiring CABG surgery. Therefore, patient care plans must be designed to mitigate these risk factors preoperatively as well as throughout the course of the patient's hospitalization and post-discharge care.

The Monitoring of Compliance with Standards of Care

Standards of care are considered essential for the prevention of mediastinitis and must be monitored for compliance on an ongoing basis to observe for trends and to identify opportunities for improvement. The standards require that work processes be developed in accordance with evidence-based literature and designed in such a way that the standard is met for every patient, every time.

Preventionists need to evaluate current infection prevention practices in their institutions in order to determine to what extent these best practice standards are being followed. If compliance with best practice standards is suboptimal, the preventionist should facilitate the process of bringing together a multidisciplinary team to address improving work processes at every level of the patient care continuum. The Surgical Care Improvement Project (SCIP) is an important example of these standards of care. Participation in this project can facilitate compliance with these important quality measures.

SCIP Standards

The SCIP project was developed as a partnership between the CMS and the CDC in 2004. Their mission is to “reduce preventable surgical morbidity and mortality by 25% by 2010.”²⁵ SCIP process and outcome measures include six standards that pertain to the cardiac surgical population. These six standards are:

SCIP INF 1: Prophylactic antibiotic received within one hour prior to surgical incision (two hours if Vancomycin or a quinolone is used).

SCIP INF 2: Prophylactic antibiotic selection for surgical patients.

SCIP INF 3: Prophylactic antibiotics discontinued within 24 hours after surgery end time (48 hours for cardiac patients).

SCIP INF 4: Cardiac surgery patients have controlled 6 a.m. postoperative serum glucose.

SCIP INF 5: Postoperative wound infection diagnosed during index hospitalization (this outcome measure is currently under development).

SCIP INF 6: Surgery patients undergo appropriate hair removal.

In addition to the SCIP standards, other well-recognized ways to prevent SSIs, and mediastinitis in particular, include hand hygiene, surgical skin antisepsis, aseptic technique, surgical technique, and post-op dressings.²⁶ Pre-operative showering with chlorhexidine gluconate (CHG) and nasal decolonization with Mupirocin are also becoming standard practice, although evidence for these practices is still unclear. All cardiac surgery programs should ensure that all 10 of the following interventions for basic mediastinal SSI prevention are implemented.

Preventionists play an important role in monitoring these program elements through the measurement of process and outcome data. The mediastinitis SSI rates calculated utilizing the National Healthcare Safety Network (NHSN) methodology (formerly known as NNIS) is an example of an outcome measure that will guide the surgical team in process improvement efforts based on the analysis of internal and national comparative rates, causative organisms, and patient populations. Compliance with the SCIP standards is an example of process measurements that can determine if work processes must be further refined to meet the required standards of care for every patient, every time.

Mediastinitis Prevention Recommendations

I. Hand Hygiene

Hand hygiene is an important component of any infection prevention program. It is well-documented in the literature that compliance with hand hygiene prevents the transmission of organisms and subsequent infections.²⁷ The Joint Commission adopted hand hygiene as a National Patient Safety Goal beginning in 2004 and its importance as a prevention initiative cannot be overstated.²⁸ In addition to hand hygiene products being readily available to healthcare workers (HCW) on the patient care units, sufficient products must also be available throughout the surgical suite. Literature lists two reports that directly link inadequate hand hygiene to an increase in mediastinitis.

The first describes an outbreak of *Nocardia farcinica*, a gram-positive opportunistic pathogen that is found in environments such as soil and decaying vegetation. A hospital outbreak of sternotomy infections caused by *N. farcinica* prompted an investigation that revealed two statistically significant risk factors for mediastinitis surgical site infections in this patient population: the presence of diabetes and exposure to a specific anesthesiologist. The *Nocardia* organism was epidemiologically linked to the colonized flora on the anesthesiologist's hands and fomites at his home. Strict hand washing and the increased use of barriers by the anesthesiologist during patient care terminated the outbreak.²⁹

The second report involved a hospital system that reported an increased rate of mediastinitis in one of two hospitals that were served by the same surgeons.³⁰ The infection rate at Hospital A was significantly higher than in Hospital B. The resulting investigation concluded that poor hand hygiene practices by the Intensive Care Unit (ICU) nurses at Hospital A was the greatest contributing factor. When strict hand hygiene practices were implemented and enforced in the ICU, mediastinitis surgical site infections were significantly reduced at Hospital A.

2. Antibiotic Prophylaxis

Three of the six SCIP indicators relate to antibiotic prophylaxis. The appropriate choice of antibiotic, dosing, timing, and duration have been well-demonstrated in the literature to prevent SSIs. Guidelines are available to assist practitioners with ordering the antibiotics that will be most efficacious based on the surgical procedure and the potential pathogens that may be encountered.³¹

The recommended prophylaxis for cardiac procedures is Cefazolin or Cefuroxime. If patients report significant allergies to penicillin or β -lactams, Vancomycin or Clindamycin are appropriate alternatives, although the latter is associated with *Clostridium difficile* Infection (CDI). Dosing requires an adjustment for patients with a BMI greater than or equal to 30 and therefore, dosing should be adjusted accordingly. Many institutions have standardized the dosing of Cefazolin to two grams for all patients who receive Cefazolin, to simplify the process and ensure proper dosing for all patients.

The timing requires that cephalosporins be delivered within 60 minutes of the incision time, however, delivery within 30 minutes is ideal. Vancomycin and Clindamycin infusions should begin 60 to 120 minutes before the incision. Procedures more than three to four hours in length require additional intra-operative doses of antibiotics with half-lives of three to four hours (e.g. Cefazolin, Cefuroxime) in order to maintain appropriate

tissue levels. Some cardiac programs choose to administer an additional dose after the pump run or after every 1,000 cc of blood loss. Although this has merit due to the hemodilution of the pump or the anticipated loss of antibiotic levels due to blood loss, there is no literature supporting these practices.

Postoperatively, administration should be discontinued within 48 hours, whereas the prolonged use of prophylaxis increases the risk of CDI and emergence of multidrug-resistant organisms. In order to participate in the SCIP measures, all three data points related to cardiac surgery antibiotic prophylaxis must be collected and reported. Compliance of greater than 90% is required, although continual improvement from baseline is taken into consideration. These process outcomes measure how well the work processes have been standardized to deliver the same care to every patient, every time.

3. Blood Glucose Control

Hyperglycemia is a significant risk factor for SSI. Tight glucose control in cardiac surgery patients with diabetes is known to reduce mediastinitis, mortality, length of stay and costs.³² Latham, et al. (2001) reported that patients undergoing cardiothoracic surgical procedures were three times more likely to develop an SSI if their blood glucose levels during or within 48 hours of their procedure were greater than 300mg/dL.³³ Carr et al. (2005) demonstrated that tight glucose control in non-diabetic patients undergoing cardiac surgical procedures also benefited from glucose control protocols.³⁴ The standard of care requires controlling post-op blood glucose below 200mg/dL. Based on the SCIP performance improvement measure, open heart surgery programs will be required to implement protocols designed to meet this measure by 6 a.m. on post-op day one and post-op day two.³⁵

4. Pre-operative Hair Removal

The literature has clearly demonstrated that hair removal should not be performed with razors, due to the resulting skin abrasions that colonize with microbes from the patient's own skin flora during the shaving process.³⁶ The patient should be instructed not to shave the surgical site. If hair removal is necessary, it should be performed with clippers and as close to the time of surgery as possible. The hair removal procedure should not, however, be performed in the operating room suite, whereas there is an increased risk of contaminating the sterile field through the carriage of skin and hair cells onto the sterile field via air currents during this process.³⁷ The use of clippers and the location where the hair removal takes place should be considered part of the open heart surgery program monitoring process.

5. Surgical Skin Antisepsis

Meticulous skin antisepsis is important to reduce the microbial count on the skin as low as possible to prevent endogenous sources of wound contamination. Although pre-op showering programs are designed to reduce microbial counts, opportunity, compliance, and efficiency of showering may not always be possible. Therefore, washing the patient's skin with an antimicrobial soap, rinsing, and drying well prior to the application of skin antisepsis should be performed. In doing so, a clean surface will allow the skin antisepsis of choice maximal efficacy.

The attributes of an appropriate surgical skin antiseptic require:

- The ability to significantly reduce microorganisms
- Broad spectrum activity
- A rapid and persistent effect
- Ease of use

Antiseptics most commonly used include iodine, alcohol, iodine/alcohol, CHG/alcohol and iodine/povacrylex/alcohol combinations.³⁸ Unfortunately, there is little outcome-based literature available to determine which antiseptic is the most efficacious in reducing SSIs. Ultimately, the choice should be made in collaboration with the end user, operating room nurses and surgeons, and driven by the most current research, the institution's own outcome data and the above criteria for surgical skin antisepsis. In addition to the product choice, the application of the product is just as important and therefore, the use of aseptic technique according to manufacturers' instructions is also an important aspect of surgical skin antisepsis.

6. Aseptic Technique

The strict adherence to aseptic technique by the entire surgical team is important to monitor for compliance, because breaches greatly contribute to intra-operative wound contamination and subsequent surgical site infections. Proper surgical hand antisepsis, meticulous patient skin antisepsis, the establishment and maintenance of the sterile surgical field, proper operating room attire and sterilization practices, including flash sterilization, are all processes that must be observed for behavior trends that may lead to opportunities for improvement.³⁹

Outbreaks of SSI caused by *Group A Streptococcus* and *Staphylococcus aureus* have been associated with colonized and infected HCWs. The organisms were likely transmitted by friction and movement through air currents created by traffic in the operating room (OR).⁴⁰ Periodic overview of surgical teams utilizing observation tools designed to measure compliance with aseptic technique will assist in quantifying observed behaviors (see Appendix A). Providing measurable feedback to the surgical team is a valuable method for improving compliance with behaviors that lead to the reduction of surgical site infections.

7. Surgical Technique

The 1999 Healthcare Infection Control Practices Advisory Committee (HICPAC) Guidelines outlined the essential surgical practices that are important to prevent SSIs.⁴¹ These practices, when applied to mediastinitis prevention, include: judicious use of bone wax and electrocautery units used to reduce bleeding from the sternal edges, appropriate use of drains to eliminate dead spaces, and gentle handling of tissue to prevent trauma. Furthermore, evidence suggests that meticulous hemostasis and treatment of intra-operative coagulopathies will prevent post-operative re-explorations for bleeding and tamponade.⁴²

Blood supply to the sternum is compromised with the use of internal mammary arteries (IMAs) which can impair wound healing and may also be a significant contributor to mediastinal SSI.⁴³ Lepelletier and colleagues defend the use of IMAs due to the greater patency rate when compared to the use of saphenous vein grafts. Standard of care is the use of the left IMA whenever possible during bypass grafting procedures. The risk of using bilateral IMAs versus a single IMA must be weighed against the risk of infection, such as obesity and diabetes, for each individual patient.

The use of implants, including sternal wires which are considered implants, increases the risk of SSI. Therefore, judicious use of sternal wires is important to mitigate the risk related to the presence of these implants. Preventionists must review each mediastinal surgical site infection with the surgical team while performing SSI case analysis to determine root causes and opportunities for improvement.

8. Post-op Dressings

Postoperative surgical dressings are an important part of SSI prevention. Optimal dressing characteristics include: permeability to allow for gas exchange, impermeability to prevent microorganism and exogenous sources of contamination, and the ability to provide an insulating effect to maintain a temperature of approximately 37 degrees Celsius. These are considered ideal conditions to promote a moist, healing environment.⁴⁴ The type of dressings utilized, when and how they are applied intra-operatively, and post-operative wound care should all be reviewed for opportunities for improvement.

9. Pre-operative Showering

Mangram et al. discussed pre-operative showering with chlorhexidine gluconate (CHG) as a Category 1B recommendation in the 1999 HICPAC *Guideline for the Prevention of Surgical Site Infection*. Category 1B is defined as: “Strongly recommended for implementation and supported by some experimental, clinical, or epidemiological studies and strong theoretical rationale.” The Association of periOperative Registered Nurses (AORN) 2008 *Perioperative Standards and Recommended Practices* guideline for skin antisepsis also supports this recommendation.⁴⁵

However, Webster and Osborne published research from the Cochrane Collaboration that refutes this recommendation. In a review of six trials and more than 10,000 patients, they concluded that the use of antiseptic showering did not show any benefits in reducing SSIs over other types of bathing products.⁴⁶ If CHG is the product of choice, the patient should use the product on at least two consecutive occasions to benefit from the additive action of the CHG, which is what makes CHG a superior choice over other antibacterial soaps. However, caution must be used to prevent exposure to mucous membranes such as the eyes, inner canal of the ear, and perineum.

Skin cleanliness reduces the microbial bioburden that can contribute to mediastinitis SSI. Patient education related to overall cleanliness is an important SSI prevention strategy. Patients undergoing elective CABG surgical procedures should be instructed to shower the night before and the day of surgery with antibacterial soap and to use clean towels, linens and clothing as part of their preoperative teaching (see Appendix B).

10. Nasal Decolonization

The literature reports that *Staphylococcus aureus* causes approximately 25% to 35% of all healthcare-associated infections. Therefore, patient carriers are at higher risk. Risk factors for nasal carriage included obesity, male gender, and a history of a previous cerebral vascular accident.⁴⁷ Because 25% to 30% of all patients are colonized at any given time, carriers are two to nine times more likely to have an SSI.^{48,49} One hospital reported that in a cohort of 3,443 CABG patients, *S. aureus* was isolated from 49% of the SSIs and was significantly associated with deep sternal wound infections.⁵⁰

Nasal decolonization with Mupirocin ointment significantly reduces HAIs in patients who are nasal carriers. This is significant in that 20% of all surgical patients acquire some type of HAI during their postoperative course.⁵¹ However, a significant reduction in SSIs was not noted by Perl, et al. in this study.

Research published by Martorell, et.al. describes the implementation of a CHG showering program combined with nasal decolonization with Mupirocin for their cardiac surgery population, which significantly reduced their SSI rates from less than 8% to less than 2% during the study period.

Likewise, a meta-analysis by Kallen, et al. concluded that the use of intranasal Mupirocin preoperatively appeared to decrease SSIs in clean surgery patient populations.⁵² Nasal decolonization with Mupirocin is recommended for the prevention of mediastinitis due to the risk of *S. aureus* as the causative organism and the ease of program implementation. However, the literature is unclear regarding the dosage and length of use, ranging from two to three times daily for a period of three to five days.

Cardiac Surgery Surveillance Methodology

There are many factors to consider when designing a cardiac surgery surveillance program. The first steps include defining the population at risk and determining the resources available. For example, will all cardiac surgery procedures be monitored, or just coronary bypass grafting with both chest and donor site incision (CBGB) procedures? Many institutions choose to follow only CBGB procedures, rather than all cardiac surgeries, to save time and resources. If opportunities for improvement are identified in the CBGB population, then any process improvements related to this population will be easily carried over into the cardiac surgery (CARD) and coronary artery bypass graft, chest only (CBGC) populations due to the similarity of all cardiac surgical procedures. Once the population is defined, the denominator data—the number of defined procedures performed during the same predetermined time period—must be obtained.⁵³

Case Finding Methodology

Case finding methodology should be established for the defined population. This will be dependent on what data and resources are available within the organization and may include:

1. Wound culture reports
2. Operating room incision and drainage procedure reports
3. Admission lists that include diagnosis
4. Pharmacy antibiotic utilization lists
5. Coding department data, such as ICD codes related to surgical infections
6. Medical record review
7. Data obtained from healthcare providers such as surgeons and nurses
8. Post-discharge surveillance data

Some validation of these processes should be conducted to ensure that as many cases as possible are being captured. If certain methods are more fruitful than others, low-yield methods should be discontinued in order to increase efficiency and minimize expenditure of time and resources.⁵⁴

Data Collection

The specific data points required to determine whether an infection has occurred are best obtained using NHSN methodology, regardless of whether or not the facility participates in NHSN reporting.⁵⁵ This methodology is a thorough and standardized approach to infection surveillance and is widely accepted as the gold standard for surveillance. All open heart procedures are followed for one year, as sternal wires are considered implants. Leg incisions are only followed for 30 days.

Strict interpretation and application of surveillance definitions should be utilized to determine each infection. In addition, each potential case should be reviewed with another party, preferably an infectious disease physician or hospital epidemiologist. This serves two purposes; the data will be well-scrutinized by another clinician, and a consensus will be reached for the numerator data. The clinician will also serve as an advocate and support for the infection prevention department when the data are generated, presented to, and reviewed by surgeons and committees.

To maximize efficiency and accuracy, data should be collected using standardized data collection forms. These forms should be designed to collect the data needed to define the HAIs being monitored. Whenever possible, data should be obtained, managed, and analyzed using electronic databases and information technology. To help further stratify the data to direct process improvements efforts, additional data points may be needed. However, this should not be collected on a routine basis because time and energy can be wasted on data that is not used for routine surveillance activities. Data such as antibiotic prophylaxis compliance, hair removal methods, and instrument flashing may prove to be important in determining opportunities for improvement. Appendix C is an example of a data collection tool designed specifically for cardiac SSI surveillance.

Outcome Reports

The numerator (the number of SSIs) and the denominator (the total number of specific operative procedures), should be obtained and rates should be calculated to determine potential trends and opportunities for improvement. The calculation for the SSI rate (percent) is:

The number of SSIs following a specific operative procedure, divided by the total number of specific operative procedures, multiplied by 100.⁵⁶

Example: 3 CBGB SSIs/80 CBGB procedures = $.0375 \times 100 = 3.75\%$

These calculations are performed separately for different types of operative procedures and NHSN risk indexes. Regardless of your facility's participation in the NHSN program, it is important to report the data, stratified by risk index. The risk index methodology utilized by NHSN is easy to calculate manually, if necessary. Whenever rates are displayed, the numerator and denominator should be present to allow the reader an understanding of how rates were obtained, the sample size of the population, and the raw number of infections noted during the reported time period.

Whenever possible, these rates should be compared to national data such as the most current NHSN data, and should be reported quarterly to provide greater statistical significance, with a minimum of 30 cases per reporting period. Data calculated monthly do not contain numbers large enough (such as < 30 cases) to represent meaningful trends and therefore may be misleading. In addition, process improvements should not be evaluated based on one monthly/quarterly data point unless a significant special cause event such as an outbreak was noted during this time period.

Ideally, a cumulative rate should also be calculated and provided at regular intervals to demonstrate the strongest statistical meaning over time. This is accomplished by adding all of the numerators and denominators over the past two to three years and then calculating the rate. When the numbers become too large, the oldest year's worth of data can be subtracted from the equation to maintain a consistent number of years, thereby making data more manageable.

For comparing two sets of data, p values are commonly used. The p value can be used for comparing an organization's SSI rates either internally or externally with a benchmark, such as NHSN SSI data, to determine if differences noted are significant. A p value of less than 0.05 is generally considered to be significant. Although infection rates may appear high, when a p value is calculated, the difference between two rates may not be considered statistically significant. Ultimately, it is the institution's internal trends that are of the greatest importance. If an organization's SSI rate is not statistically different when compared to NHSN, but

is a sustained upward trend over time from baseline, this should be cause for concern. In addition, caution should be utilized when reporting p values, as some readers may dismiss the data if it is not determined to be significant. Even though the data may not be statistically significant, each SSI is very significant to the patient. Therefore, raw numbers of infections should always be reported and emphasized during the reporting process.

Surgeon-specific rates are also useful in providing information to practitioners. Overall feedback via committee is important, but surgeon-specific rates assist surgeons with determining if their own specific surgical practice (and that of their surgical team) is influencing the SSI rates. Also, surgeon-specific rates are well-received when surgeons are part of the decision-making process as to what procedures will be monitored, how rates will be reported, and when they can be assured that individual rates will remain strictly confidential throughout the reporting process, and are not used to place blame. It is also important to include p values and be cognizant of the fact that low numbers may influence SSI rates.⁵⁸ An example outcome report is identified in Table 6.1.

Table 6.1. Example Outcome Report.

Risk index	1st Q	2nd Q	3rd Q	4th Q	2007 total	Cumulative total (2004-2007)	NHSN 50th percentile
1	1.0 (2/200)	0.0 (0/166)	1.78 (3/168)	1.10 (2/181)	0.98 (7/715) < NHSN 10th (1.56)	1.5 (38/2521) < NHSN 25th (2.17)	3.17
2	4.76 (1/21)	11.76 (2/17)	5.26 (1/19)	10.0 (2/20)	7.8 (6/77) > NHSN 75th (7.64)	5.42 (13/240) > NHSN 50th	5.16
Total # of patients	3	2	4	4	13	51	

The data should be calculated and displayed in many different formats in order to allow the reader to analyze the information appropriately. There are numerous ways to accomplish this. In addition to the overall rate, basic reports should include stratifications of each procedure, comparisons of risk indexes, chest rates, leg rates, infection type (skin, soft tissue, or mediastinitis), and causative organisms. Figures 6.1 through 6.6 provide examples of graphical display of outcome data.

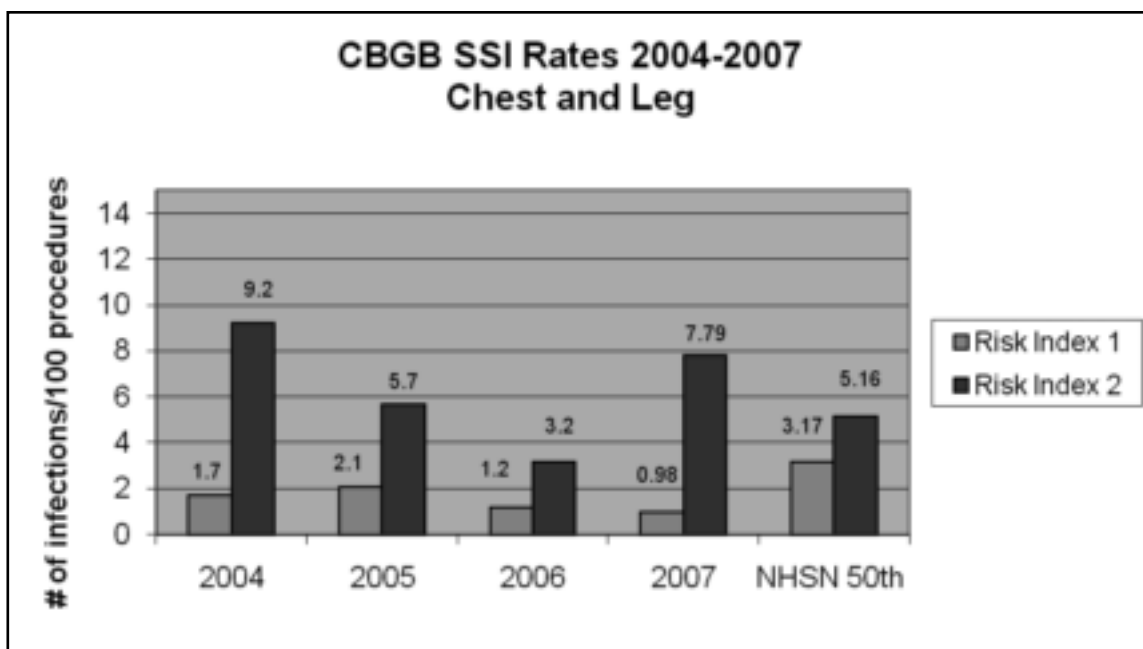


Figure 6.1. CBGB SSI Rates for Chest and Leg.

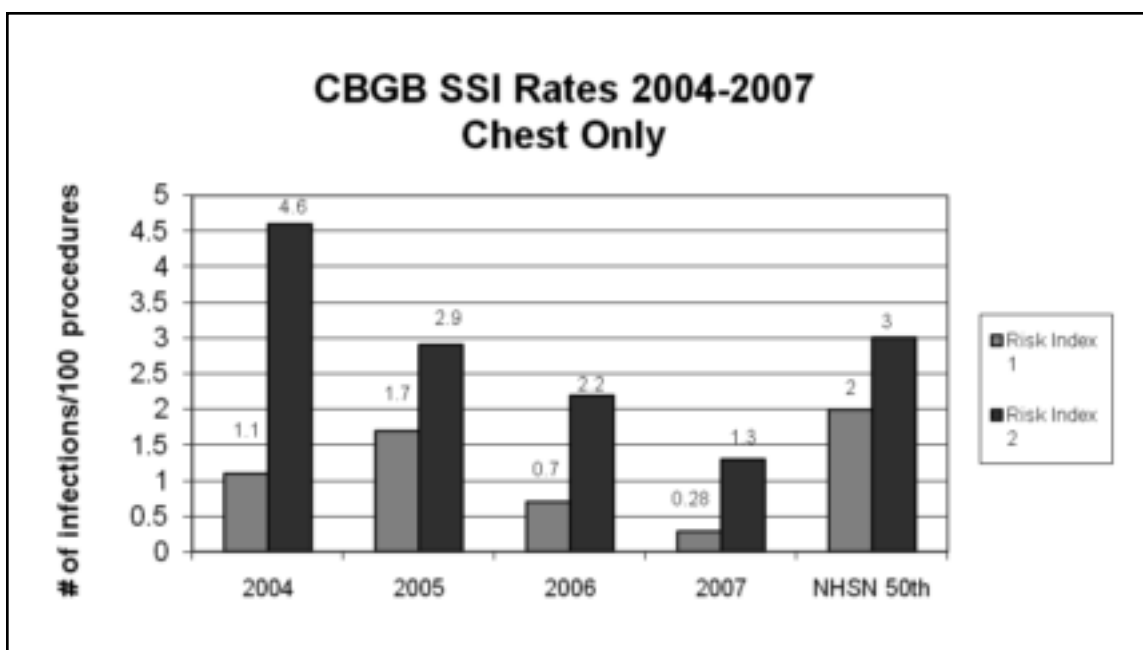


Figure 6.2. CBGB SSI Rates for Chest Only.

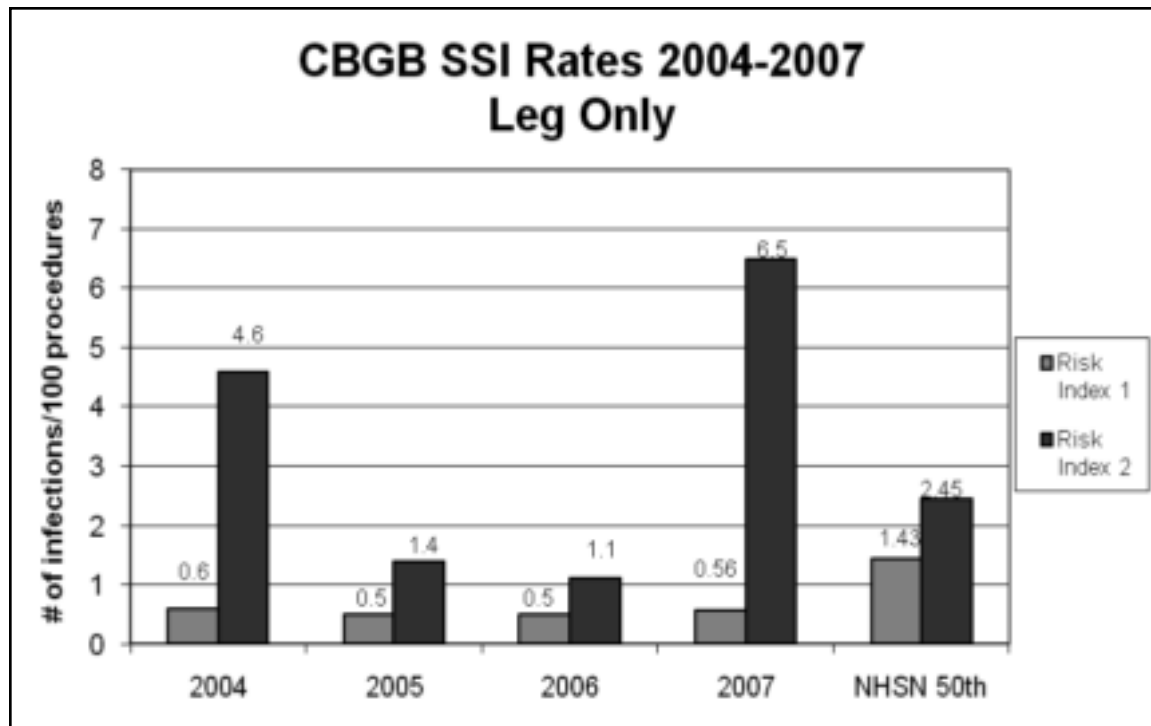
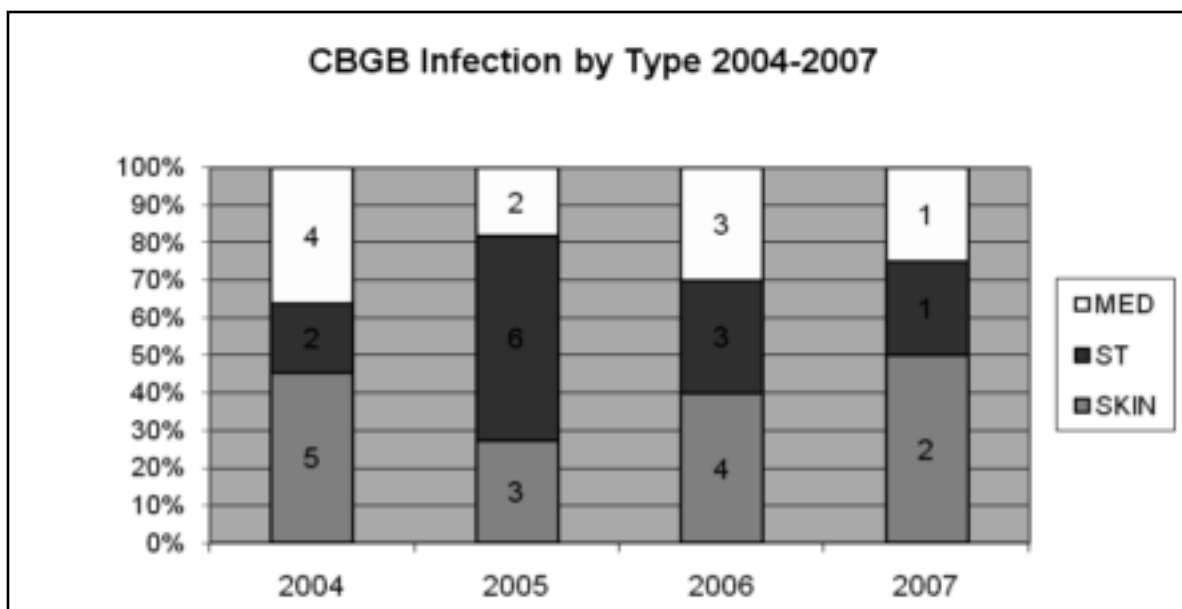


Figure 6.3. CBGB SSI Rates for Leg Only.



Note: MED = mediastinitis; ST = soft tissue; SKIN = superficial infections

Figure 6.4. CBGB Infections By Type.

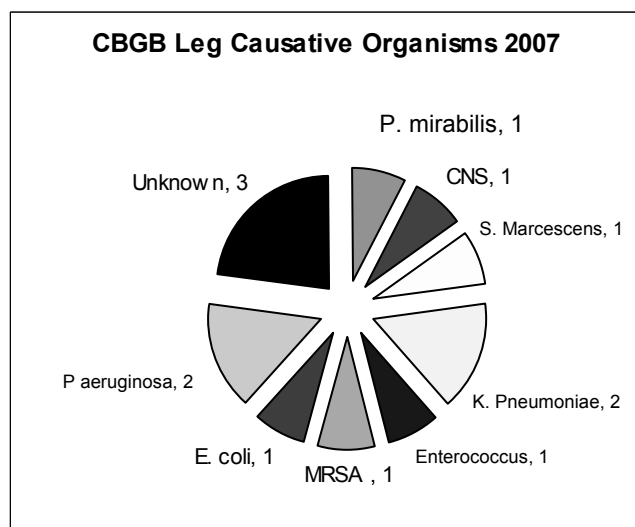


Figure 6.5. CBGB Causative Organisms – Leg.

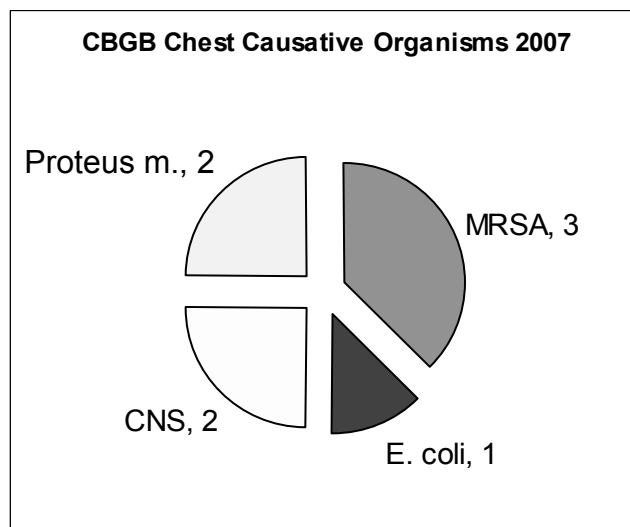


Figure 6.6. CBGB Causative Organisms – Chest.

The analysis of causative organisms is important in order to identify any trends toward gram-positive or gram-negative organisms. For example, gram-positive organisms *Staphylococcus aureus* or *coagulase negative Staphylococcus* (CNS) may point towards the endogenous sources of skin antisepsis or exogenous sources, such as compliance with dress codes and hair containment of the surgical team. Gram-negative organisms like *Pseudomonas aeruginosa* may point towards environmental sources, such as contaminated water or equipment.

Process Improvement Opportunities

Process improvements should be driven by the data outcomes. Stratification is important to enable the appropriate analysis of the data, recognize trends, and focus efforts on meaningful improvement activities. A line list of the infected patients that includes important data points should be utilized to observe trends and highlight opportunities. Non-modifiable risk factors are useful when appropriate to serve as descriptors for providers so that they become familiar with the population they serve. The risk factor for obesity, for example, can then be correlated to compliance with the proper dosing of antibiotic prophylaxis for this population. Appendix D is an example of a cardiac SSI line list.

Basic process improvement opportunities for cardiac surgery populations include pre-op showering and nasal decolonization programs, antibiotic prophylaxis, hair removal, glucose control, surgical skin antisepsis, instrument flashing, aseptic technique, surgical technique, and post-op dressings.

- 1. Pre-op Showering and Nasal Decolonization:** If a pre-op program consisting of showering and nasal decolonization is not in place, one should be implemented to reduce SSI rates, particularly in the presence of *Staphylococcus aureus* as the predominant causative organisms. If these programs are in place, compliance with pre-op showering and nasal decolonization should be monitored and results should be reviewed for performance improvement opportunities. These programs may be cost-neutral when patients can purchase these pre-op products on an outpatient basis.
- 2. Antibiotic Prophylaxis:** Each SSI case should be reviewed for compliance with antibiotic choice, timing, and dosing-compliance standards. Deficiencies in any of these areas should be noted in the analysis and the processes evaluated for improvement opportunities.
- 3. Hair Removal:** The hair removal methodology should be reviewed with the OR staff. The timing of the hair removal, removal with the use of clippers versus razors, and where the removal is performed (i.e., in a pre-op location versus the OR) are important processes that must be reviewed and changed when necessary to meet current standards. Preoperative teaching should instruct the patient not to shave the surgical site(s), including the legs if they are to be used for vein harvesting.
- 4. Glucose Control:** Compliance with the SCIP standards for glucose control should be monitored and appropriate action taken as needed.
- 5. Surgical Skin Antisepsis:** The type of skin antisepsis products utilized by the surgical team and the prepping technique should be observed to assess opportunities for improvement. Not all prep solutions are appropriate for all surgical procedures. The proper application method is an important step in reducing the microbial count to prevent endogenous sources of wound contamination.
- 6. Flash Sterilization:** Instruments flashed during a surgical procedure must be avoided whenever possible, whereas the risk of contamination to the sterile field upon the delivery of the instrument to the field is high. Therefore, the use of flashed instruments, including the type of procedure and reasons for flashing, should be monitored. Containers used for flashing should be closed to prevent contamination, regardless of the proximity of the autoclave to the OR. All flashing that occurs should be documented in the operative record according to hospital policy. Making a notation of this during data collection can help establish

a trend. Correlating overall department flashing rates with infection rates and then reporting these rates within the organization's quality improvement process may prove to be a valuable opportunity for improvement.⁵⁹

7. **Aseptic Technique:** Observing aseptic technique while cases are in progress will provide an excellent opportunity for the trained preventionist to identify areas for potential improvements. The lack of adherence to the principles of aseptic technique, which include traffic patterns, maintaining the sterile field, proper wearing of surgical attire, etc., are all potential contributors to exogenous sources of wound contamination. The longer the surgical procedure, the more opportunities for contamination to occur.⁶⁰ Therefore, strict attention to these basic infection control principles cannot be overstated.

Unique to CBGB procedures is the importance of the person responsible for vein harvesting to change his or her gowns and gloves prior to assisting at the chest. In addition, whenever possible the scrub person must not assist or handle instrumentation that has been utilized for vein harvesting. Doing so increases the risk for cross-contamination of these separate surgical wounds. Causative organisms that are commonly found in the groin areas, such as enteric organisms, may appear in chest wound cultures of patients with chest infections. Therefore, a lack of adherence to this principle may be implicated as the causative factor. Appendix A provides an example of an observation tool to utilize while observing a cardiac surgical procedure.

8. **Surgical Technique:** Observing surgeons' practices that are known to have low SSI rates, and comparing them to those of surgeons with higher rates, may be helpful in determining opportunities for improvements. Measuring "bring back" rates (a return to the operating room within 24 hours of surgery), observing the use of bone wax and electrocautery, drain placement, the number of sternal wires, the use of bilateral IMAs, and overall surgical time, are all important factors to consider for process improvement activities.
9. **Post-op Dressings:** All placements and use of dressings should be monitored. Dressing should be applied directly after skin closure and prior to drape removal, utilizing strict aseptic technique, and should not be removed unless there is excessive drainage or they become dirty or damaged. Infections do not typically occur on post-op day one or two. Therefore, leaving the dressing intact for a minimum of one to two days will promote healing, and prevent contamination and disruption of the moist healing environment.⁶¹

Making the Business Case

When SSI rates are consistently higher than expected, process improvements may require work redesign or product changes. These changes may need additional funding and/or capital investment to put new programs or products into place. Justifying the need for additional dollars can be difficult in a healthcare environment where operating margins are shrinking and program dollars must compete with other important initiatives. Therefore, preventionists must use administrative language that frames the argument for additional funding in ways that administrators can relate to, thereby assisting them in making informed decisions.

Calculating Program Intervention Benefits

One of the first questions that an administrator will ask when approached for financial support of a new program or product is what the return on investment (ROI) will be. ROI is an important concept that requires financial analysis of the proposal that will demonstrate a financial return on the investment or cost savings within a reasonable time frame (i.e., when will the program or new product be paid for, become cost neutral, begin to turn a profit, or save the organization money in the long term?). There are several methods of defining program benefits, such as:

1. Revenue increases, generated from positive outcomes and an enhanced reputation with the potential for increases in patient volumes are becoming increasingly important due to the proliferation of pay for performance and public reporting initiatives.
2. Reduction in costs, through a reduction of length of stay, due to decreased incidence of SSI.
3. Cost avoidance through the prevention of future SSI.
4. The societal benefits of reducing morbidity and mortality in the cardiac population through exemplary care, positive outcomes, and the resulting increase in patient quality of life.
5. The reputation of the organization.

There are two important ways to answer the ROI question when developing the business case for mediastinitis prevention programs. The first is to calculate the attributable costs for the outcomes that are contributing to the SSI that the new program has been designed to solve. The second is to develop a cost-benefit analysis of the program proposal to demonstrate the ROI.

One of the challenges in obtaining cost information to answer these important questions is the difficulty in obtaining the direct cost for products and services. Supply chain contracts are variable, depending on volume, price points, etc., and calculating patient provider time, such as nursing, is frequently an educated guess. The indirect cost of lighting, heat, and support services, such as engineering or laboratory, are not allocated to individual services or programs. Therefore, any attributable costs will be underestimated due to the lack of the indirect cost information.

In addition, determining actual cost benefits may be challenging, whereas they are dependent on the cost-accounting methodologies employed by individual institutions. Partnering with the hospital's finance department for accurate data is essential to creating a successful business case. Likewise, fully understanding how the numbers were calculated is important in order to interpret the data for the intended audience. For

example, if costs do not include the patient's stay in the ICU, or additional surgical procedures performed, the numbers will be an underestimation of the total dollars spent caring for the patient during hospitalization.

Attributable Costs

An attributable cost related to mediastinitis is defined as the cost of caring for a patient with mediastinitis, compared to similar cardiac patient populations who did not have mediastinitis.⁶² Calculating these costs is an effective way to assist administrators in understanding how many additional healthcare dollars are spent on this complication that could be saved with the appropriate infection-prevention interventions that would reduce the risk of mediastinitis.

Step One: Calculate the LOS Increase for Mediastinitis

Working with a quality data analyst whenever possible, determine what the average length of stay (LOS) is for all patients who developed mediastinitis after CABG surgery for a predetermined time period (two to three years of data is more accurate than just one year). It is important to ensure that the mediastinitis code (159.2) is linked with CABG surgery DRG codes (located in the NMSN manual Operative Procedures Categories),⁶³ whereas patients may be coded for mediastinitis for reasons unrelated to CABG procedures, such as the diagnosis of a perforated esophagus. Calculations should include the primary LOS (during the initial hospitalization for the surgical procedure) and any additional hospitalizations related to the care and treatment of the patient's mediastinitis.

Step Two: Calculate the Average LOS

Calculate the average LOS for all of the patients who did not experience mediastinitis after a CABG procedure for the identical time period. Do not include patients who had mediastinitis in this group.

Step Three: Subtract the Average LOS

Subtract the average LOS for the control group (the patients who did not have mediastinitis) from the average LOS for the mediastinitis population. The result is the additional LOS attributed to the mediastinitis SSI.

Example:

Saint Hope Hospital has a cardiac surgery program with a mediastinitis rate of 0.66%. Over the last three years, 10 patients were coded as mediastinitis.

1. The average LOS for these 10 patients was 36.6 days.
2. There were a total of 1,500 patients who had CABG procedures during these three years. The average LOS for the patients without mediastinitis (1,490 patients) was 8.9 days.
3. The attributable increase in LOS for each of these 10 patients was 27.7 days ($36.6 - 8.9 = 27.7$).

Step Four: Calculate the Attributable Cost

Calculate the attributable cost related to the LOS by using the hospital's average cost related to one day's hospitalization. Contact the finance department to obtain this cost and multiply this amount by the additional LOS days.

Example:

If the average cost of care per day for an open heart surgery patient is \$2,400, multiply this amount x 27.7 (additional patient care days) = \$66,480 in attributable costs per mediastinitis patient. If Saint Hope Hospital had 10 patients with mediastinitis: $10 \times \$66,480 = \$664,800$ in attributable cost for the mediastinitis complication over the last three years, or \$221,600 per year.

With this information, the argument can be made that if Saint Hope Hospital implemented an effective infection prevention program designed to reduce the incidence of mediastinitis in the CABG population, that hospital would avoid incurring \$221,600 in additional costs annually for the care of patients with mediastinitis SSIs.

Cost-Benefit Analysis

A cost-benefit analysis assists administrators in evaluating the costs associated with new programs. When new products or procedures are implemented, these dollars must be budgeted so that the value of the intervention may be understood from a financial perspective. Working with the finance and supply chain departments, costs for the new products and the labor needed to provide the new services must be estimated using cost data and educated assumptions. Each intervention must include supply and labor costs.

If the new product is replacing an existing product, the cost of the existing product must be subtracted from the cost for the new product. The result is the added cost for this new product. These costs must then be multiplied by the number of times the product is used (total supply costs), or task is performed (total labor costs), to calculate the total costs for one individual patient. The total cost per patient can then be multiplied by the estimated volume of surgical patients who will be receiving care.

The program interventions to reduce mediastinal SSIs that require resources may include antibiotic prophylaxis, increasing hand hygiene compliance, a blood glucose control protocol, skin antisepsis, and hair removal products. Some of the interventions may already be in place but require a new process or product. Therefore, the difference in cost for the change would be utilized for the analysis. Table 8.1 contains example cost calculations for some of these interventions.

Table 8.1. Example Cost Calculations for Sample Interventions.

Intervention	Drugs/Supplies	Labor	Total Cost
Antibiotic Prophylaxis	Cefazolin: \$3.40/one-gram dose 6 doses = \$20.40	Anesthesia time ¹ : \$14.83 (first dose, 5 min) Nursing time ² : \$25.80 (10 min/dose x 5 additional doses) Total labor = \$40.63	\$61.03 per patient
	Vancomycin: \$8.32/one-gram dose 4 doses = \$33.28	Nursing time: \$20.64 (10 min/dose x 4)	\$53.92 per patient
Hand Hygiene ³	Average of 90 hand washes per day @ .025 cents per “dose” of alcohol hand sanitizer = \$2.25/day	20 seconds per hand wash at 90 hand washes per day = 30 minutes Nursing time: \$15.48/day	\$17.73 per day of hospitalization
Insulin Drip	\$1.80 for 100 units of regular insulin in 100cc of NSS	Anesthesia time: 4 hours intra-op management = \$59.33 (5 min/hr x 4 hours) Nursing time: \$103.20 (10 min/hr x 20 hours) Total labor = \$162.53	\$164.33 for 24 hours of IV insulin infusion
Clippers	\$3.00 per disposable clipper head (clipper is free of charge)	Nursing assistant ⁴ time: \$7.00	\$10.00 per patient
Total Costs ⁵	Program cost for a <u>non-diabetic</u> patient with an average LOS of 8 days		\$212.87/patient
	Program costs for a <u>diabetic</u> patient with an average LOS of 8 days		\$377.20/patient

¹ Anesthesiology time was calculated at \$178.00/hour.

² Nursing time was calculated at \$30.96/hour.

³ Hand washing calculations were based on the CDC Guideline for Hand Hygiene (2002)

⁴ Nursing assistant time was calculated at \$14.00 hour.

⁵ The cost of using Vancomycin vs. Cephalosporin for antibiotic prophylaxis is essentially equal if the cost of using an IV pump is taken into account during Vancomycin infusion. (Pumps are generally not used for Cephalosporin administration in the OR setting).

Example:

Saint Hope Hospital averages 500 CABG cases per year at an average LOS of eight days. Approximately 175 patients (35%) were diagnosed with diabetes mellitus. The antibiotic prophylaxis, a hand hygiene program, a blood glucose control protocol, and clippers for hair removal were implemented at the hospital as part of the Infection Control Department's efforts to eliminate mediastinitis SSIs.

The cost-benefit analysis for Saint Hope Hospital's infection control program is provided in Table 8.2.

Table 8.2. Example Cost-Benefit Analysis for Saint Hope Hospital.

Patient Population	Number of Patients Per Year	Cost of Care Per Patient (LOS 8 Days)	Total Cost
Non-Diabetic	325	\$212.87	\$69,183/yr
Diabetic	175	\$377.20	\$66,010/yr
Total Annual Cost for the IC Program			\$135,193/yr

Annual net benefits: Total benefits (\$221,600) – total costs (\$135,193) = **\$86,407**

Cost-benefit ratio: \$221,600 total benefits / \$135,193 total costs⁶⁴ = **1.64**

This ratio means that the mediastinitis prevention program generates \$1.64 for every dollar of cost for the open heart surgery patient at Saint Hope Hospital.

The cost-benefit analysis for Saint Hope Hospital demonstrates that implementing the mediastinitis prevention program would benefit patients and increase the hospital's bottom line by more than \$86,000 annually. Advocacy of the program benefits by Saint Hope Hospital's infection preventionists is as follows:

1. When Saint Hope Hospital's public report card is published, the reduction in CABG mediastinitis rates will enhance the hospital's reputation. It will be publicly acknowledged as a leader in cardiac surgery and positive outcomes, which will attract more patients, physicians, and payers. The net result is increased revenues.
2. The reduction in mediastinitis SSIs will decrease the LOS for the cardiac patient population, thereby reducing associated costs and lack of reimbursement related to an extended LOS. The reduction in LOS will also decrease overall risk of other HAIs. In addition, a decrease in LOS will result in additional patient days that can be utilized for other patients, generating additional revenue.
3. Overall, there is an annual net benefit of \$86,400 in avoidable costs based on the program's implementation and subsequent elimination of mediastinitis SSIs, a significant factor when CMS decreases reimbursement for mediastinitis.
4. Patients who have CABG surgery at Saint Hope Hospital will experience a better quality of life based on the avoidance of the physical, emotional, and financial costs associated with mediastinitis SSI.

Therefore, calculating attributable costs and conducting a cost-benefit analysis will be valuable ways for the preventionist to formulate effective arguments for the financial impact of program interventions that will result in the reduction and elimination of mediastinitis SSIs.

Case Study

General Hospital is a 350-bed tertiary acute-care community hospital that is well-known in its state for exemplary cardiac care services. This well-established program averages approximately 1,300 adult open heart procedures annually. From 1999 through 2001, the hospital experienced an increase in its post-op surgical site infection rates for the cardiac population, and for mediastinitis in particular. Mediastinitis cases averaged six cases per year during this time.

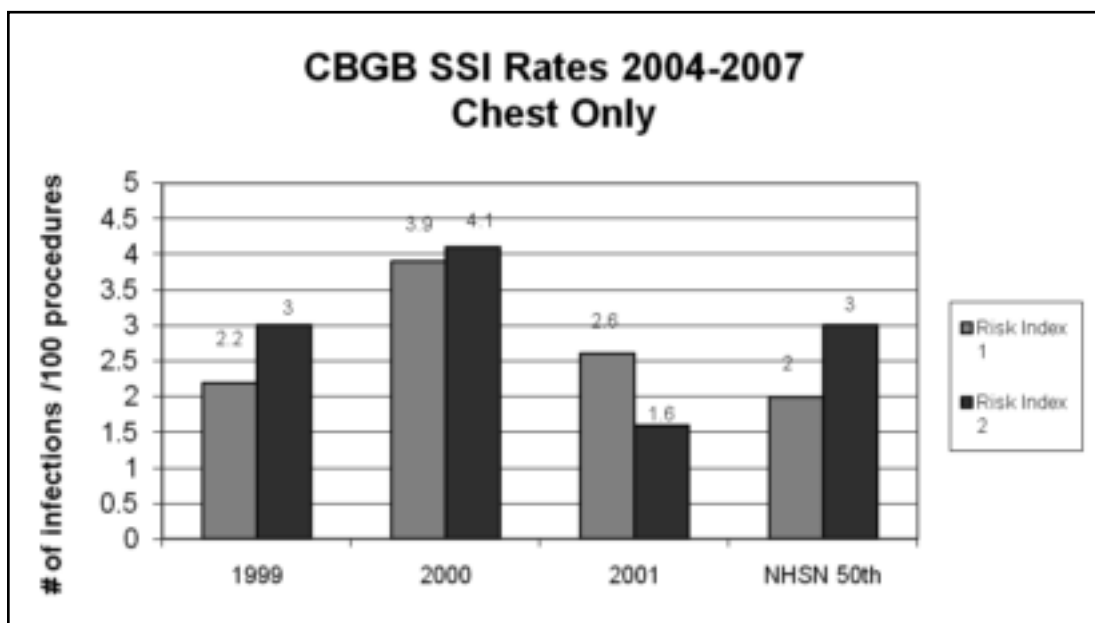


Figure 9.1. CBGB SSI Rates – Chest only.

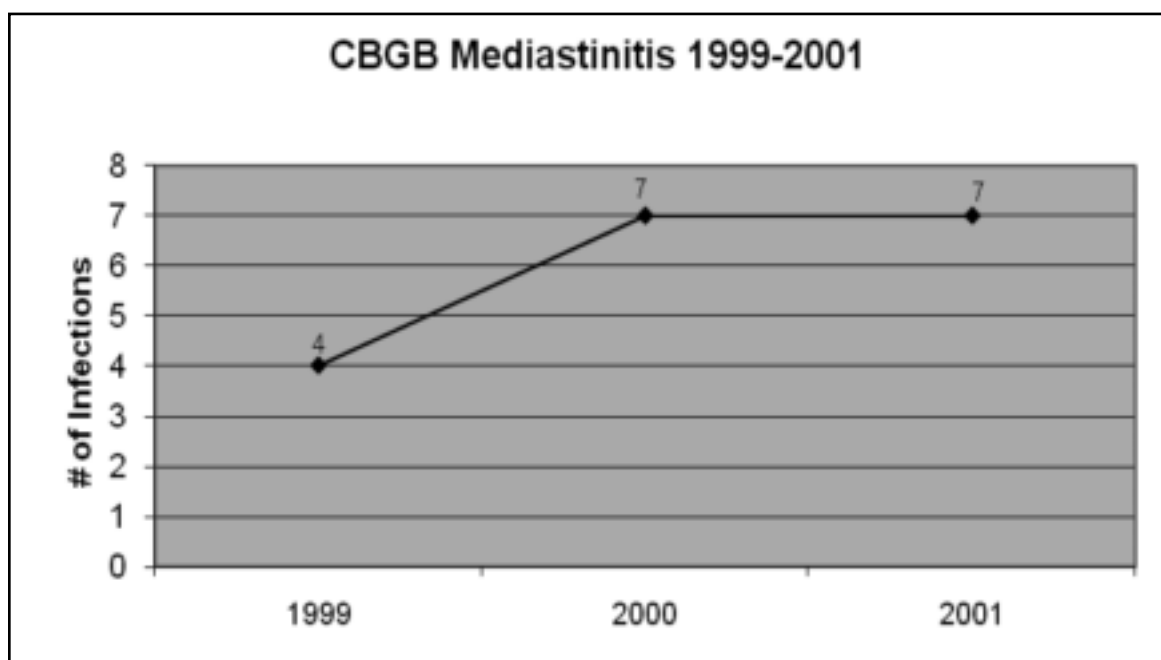


Figure 9.2. Number of CBGB Mediastinitis infections.

A multidisciplinary team was assembled by the Infection Control Department and chartered by the Process Improvement Council and Medical Executive Committee. Members of the team included an administrator, operating room nurses, cardiac ICU nurses, an anesthesiologist, a physician assistant, a cardiac surgeon, an infectious disease physician, an infection preventionist, and a process improvement expert.

The mission of the team was “To reduce the SSI rate below the NNIS 50th percentile.” The team agreed to meet every two weeks for three months and implemented the Plan, Do, Check Act (PDCA) methodology for process improvement.⁶⁵

PLAN

1. Stratify SSI data by chest and leg, chest only, leg only
2. Calculate provider specific SSI rates – surgeon and physician assistant (PA)
3. Assess operating room practices – aseptic technique, surgical technique
4. Collate patient risk factors
5. Evaluate causative organisms
6. Evaluate post-op wound care

The team analyzed the data and identified the following contributing factors:

1. Inadequate skin antisepsis
2. Excessive operating room traffic
3. Inconsistent pre-operative shaving practices
4. Wire sternotomy closure performed by the PAs
5. Suboptimal vein selection and harvesting techniques
6. Inconsistent compliance with timing of prophylactic antibiotics
7. Inadequate glucose control
8. Timing of post-operative showering
9. Cross-contamination of chest and leg wounds based on causative organism reports

DO

The action plan developed included:

1. Sharing surgeon and PA-specific infection rates with individual clinicians
2. Mandatory aseptic technique in-servicing of all surgical staff
3. Implementing a pre-op showering program requiring patients to perform a CHG shower the night before and the morning of the surgical procedure
4. Implementing a nasal decolonization program for all patients with Mupirocin ointment, applied in both nares twice a day for five days prior to surgery, day of surgery, and 48 hours post-op
5. Changing pre-op hair removal technique from razors to clippers and the timing of hair removal to within two hours of the surgical procedure
6. Performing a total body wash preoperatively with a CHG soap solution prior to applying the skin antisepsis
7. Changing the skin antisepsis to an iodine/povacrylex/alcohol-based prepping solution from betadine soap and paint
8. Changing surgical technique by:
 - a. Requiring surgeons to perform the wire closure of the sternotomy
 - b. Increasing the use of the endoscopic vein-harvesting technique

- c. Requiring intra-op gown and glove changes when moving from vein harvesting to assisting at the chest. PAs began harvesting veins independently and scrub nurses were discouraged from participating to prevent cross-contamination of the wound sites.
9. Developing and implementing a glucose management protocol
10. Changing traffic patterns in the operating rooms and restricting traffic to essential personnel only

CHECK

During the course of 2001, the action plan was implemented and surgical site infection rates continued to be collected and reported to the surgical team. Process indicators were developed and collected for antibiotic prophylaxis compliance and glucose monitoring compliance. Improvements were made based on data. The subsequent data for the years 2002 through 2007 demonstrated the significant impact the process improvements had on the mediastinitis rates in the cardiac surgical population.

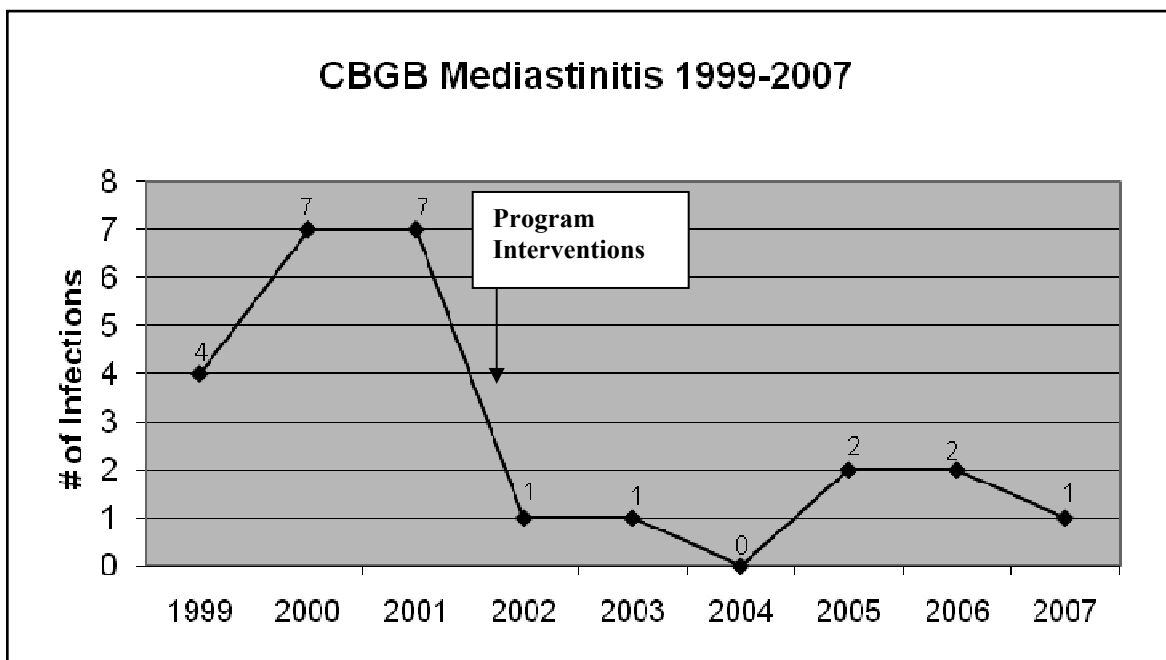


Figure 9.3. Number of CBGB Mediastinitis Infections With Program Interventions.

ACT

During the course of the following five-year process, the outcome data were evaluated for opportunities for improvement. By the year 2005, the majority of vein harvestings were performed utilizing endoscopic technology. In addition, ultrasound technology was adopted to determine the most appropriate sites for vein harvesting. For the future, operating room suite upgrades were planned to expand the size of the ORs to accommodate new video technology and provide a larger space for the sterile field, to reduce the opportunity for intraoperative contamination.

General Hospital's Business Case for the Elimination of Mediastinitis

Calculating Program Intervention Benefits

General Hospital was at financial risk due to the increase in mediastinitis SSIs, because the reputation that it enjoyed as a leader in cardiac surgery was at risk. This could result in a decrease in patient volumes, as well as loss of reputation when the SSI rates are publicly reported. In addition, patients who experienced mediastinitis had an average LOS of 39.2 days. A reduction in costs through a reduction of LOS due to decreased SSI rates would result in increased revenues. Finally, starting in October 2008, General Hospital lost reimbursement monies for the complication of mediastinitis in the cardiac surgery patient population.

Attributable Costs

From 1999-2001, General Hospital had 18 patients coded with mediastinitis.

1. The average LOS for these 18 patients was 39.2 days.
2. There were a total of 3,900 patients who had CABG procedures during these three years. The average LOS for the patients without mediastinitis (3,882 patients) was 8.3 days.
3. The attributable increase in LOS for these 18 patients was 31 days ($39.2 - 8.3 = 30.9$) for each patient.
4. The average cost of care per day for an open heart surgery patient was \$2,400 (calculated by the finance department).
5. Consequently, \$74,400 can be attributed to a single patient with mediastinitis during this time period ($\$2,400 \times 31 \text{ days} = \$74,400$).
6. The overall attributable costs for the 18 mediastinitis patients at General Hospital from 1999-2001 is **\$1,339,200** ($\$74,400 \times 18 \text{ patients}$) or \$446,400 per year.

With this information, the argument can be made that if General Hospital implemented infection control programs designed to reduce the incidence of mediastinitis in the CABG population, the hospital would avoid incurring a minimum of **\$446,400** in additional annual costs associated with the care of patients with a mediastinitis SSI.

Cost-Benefit Analysis

The program interventions General Hospital implemented to reduce mediastinal SSIs included:

1. Enhancing its hand hygiene program
2. Implementing a pre-op showering program with CHG (cost neutral)
3. Requiring the use of Mupirocin for nasal decolonization (cost neutral)
4. Increasing the timing of antibiotic prophylaxis (cost neutral)
5. Implementing a blood glucose control protocol
6. Utilizing an alcohol/iodine povacrylex skin antisepsis product
7. Adding iodine-impregnated adhesive drapes
8. Changing to clippers for hair removal prior to operating room transport

General Hospital averages 1,300 CABG cases per year and the average LOS is eight days. Approximately 455 patients (35%) were diagnosed with diabetes mellitus. The cost-benefit analysis for General Hospital's infection control program is displayed in Table 9.1:

Table 9.1. Cost Benefit Analysis for General Hospital.

Patient Population	Number of Patients Per Year	Cost of Care Per Patient (Average LOS 8 days)	Total Cost
Non-Diabetic	845	\$197.00	\$166,465/year
Diabetic	455	\$362.00	\$164,710/year
Total Annual Cost for the IC Program			\$331,175

Annual net benefits: total benefits (\$446,400) – total costs (\$331,175) = **\$115,225**

Cost-benefit ratio: \$446,400 total benefits /\$331,175 total costs = **1.35**

This ratio means that the infection control mediastinitis prevention program generates \$1.35 for every dollar of cost related to an open heart surgery patient at General Hospital.

The cost-benefit analysis for General Hospital demonstrates that implementing an infection control mediastinitis prevention program was beneficial to both patients and the hospital. An annual net benefit of \$115,225 was realized from the program's implementation. General Hospital's ability to significantly reduce its mediastinitis SSI outcomes benefited the organization as follows:

1. When General Hospital's public report card is published, the reduction in CABG mediastinitis rates will maintain and perhaps enhance its reputation as a leader in cardiac surgery. These positive outcomes will serve to attract more patients, physicians, and payers. The net result will be increased revenues.
2. The reduction in mediastinitis SSIs decreased the average LOS for the cardiac patient population, thereby reducing the associated costs and lack of reimbursement related to the previously extended LOS. In addition, a decrease in LOS resulted in additional patient days that were then utilized for other patients, generating additional revenue.
3. Overall, there was an annual net benefit of \$115,225 in avoidable costs based on the program's implementation and subsequent reduction of mediastinitis SSIs. This is significant, based on the CMS decrease in reimbursement for mediastinitis, which began October 2008.
4. Patients who have CABG surgery at General Hospital experience a better quality of life based on the avoidance of the physical, emotional, and financial costs associated with mediastinitis SSIs.

Conclusions

Mediastinitis is a serious complication of CABG surgery that adversely impacts patients and hospitals alike. Lengthy hospitalizations, multiple procedures, and the fear of unknown health outcomes for patients and families, combined with the financial hardships that may ensue, take an emotional toll as well. The impact for hospitals is substantial, whereas increases in LOS, costs associated with treating mediastinitis, and the loss of reimbursement, such as the CMS pay-for-performance initiative, have major financial implications. This was clearly demonstrated through actual examples of attributable costs. Likewise, the current public reporting initiatives will serve to increase the transparency of healthcare and may result in a loss of reputation for hospitals with high mediastinitis rates. This, too, can result in financial hardship, whereas the potential loss of reputation may result in a decline in heart surgery volumes as patients and payers are able to make more informed choices about their healthcare, and may choose to take their business elsewhere.

Evidence-based infection prevention programs have been developed based on current literature to reduce the incidence of mediastinitis. Program interventions discussed in this document require few resources to implement, and the return on investment is clearly favorable through the cost avoidance associated with preventing mediastinitis complications. Cardiac surgical programs must analyze their outcomes, identify opportunities for improvement, and implement practices that are known to reduce SSIs in general, and mediastinitis in particular.

The cost-benefit analysis demonstrates the challenges when caring for diabetic patients, since this analysis demonstrates that SSI prevention costs in a diabetic patient undergoing open heart surgery is almost double that of a non-diabetic patient. Moreover, diabetic patients comprise a significant portion of any cardiac surgery program. Therefore, diabetes prevention and management through the optimization of glycemic control throughout the patient's hospitalization plays an important role in contributing to healthier patient outcomes.

CMS is leading the way to a culture of value-based purchasing, and private payers are sure to follow. Hospitals cannot afford to ignore the occurrence of SSIs. Infection preventionists must be leaders in changing these cultures. The surveillance and data analysis of open heart surgery SSI programs provide benchmarks for the future, and valuable insight for healthcare providers and their organizations.

Process improvement efforts are driven by surveillance and the preventionist's expert analysis. Therefore, preventionists must partner with surgical services to facilitate this change and when new programs are developed, a financial analysis should be included. The attributable costs underscore the need for such programs and the cost-benefit analysis will engage administrators in the process as the financial impact associated with these programs becomes more readily understood.

In the past, many healthcare providers thought that a significant reduction in central line-associated bloodstream infections was an impossible task. Preventionists now have evidence-based practices and outcome data that demonstrate it is possible. By applying these practices to mediastinitis prevention efforts, there is reason to believe that the same reductions in mediastinitis SSIs are achievable.

Appendix A

Checklist for Cardiac OR Infection Control Observations

Date _____ OR# _____ Observer _____ Type of Surgery _____

OR Personnel:

Surgeon(s) _____ Scrub Nurse(s) _____

Fellow _____ Circulating Nurse(s) _____

Resident _____ Others _____

Anesthesiologist _____ Perfusionist _____

Guidelines for completion:

Indicate number of Yes observations and number of No observations. Enter comments/descriptions for each No observation.

CATEGORY	Not observed	Y	N	Comments on "No" observations
SURGICAL ATTIRE (Observe every person in the room)				
Top is secured at waist, tucked in or close to body.				
All hair is covered.				
Mask is worn (secured with both ties) in the presence of open sterile items and equipment.				
Cover gown/jackets are worn and secured to prevent inadvertent contamination while walking past sterile field.				
STERILE TECHNIQUE				
Sterile field is prepared close to the time of surgery.				
Sterilized items are transported in covered or enclosed cases/carts.				
Sterile field is maintained throughout the procedure with traffic patterns established with a minimum of one foot perimeter respected by unsterile personnel.				
Sterile persons do not turn back to field or sterile supplies.				
Sterile items are presented to scrubbed person or placed securely on field.				
Liquids are poured only once, without splashing, and the remainder discarded.				
Draping is accomplished in a sterile manner. <ul style="list-style-type: none"> • Draping is performed by a minimum of two people. • Hands are "cuffed" while presenting drapes to unsterile personnel. • Anesthesia screen is not dropped prior to placement. • Groin is sufficiently covered. • Drapes are not lifted or moved after placement. 				
Items are flash sterilized only in an emergency situation and a closed container is used for transport to the sterile field.				List any item flash sterilized during procedure:
Primary scrub does not assist with leg vein harvesting.				
Leg harvesting personnel change gown and gloves prior to assisting at the chest.				
Legs are closed and dressed, utilizing sterile technique.				
Legs are draped after dressing placement to protect the incisions/dressings until the end of the case.				
SURGICAL HAND SCRUB				
Scrub is performed according to manufacturer's directions and aseptic technique.				
Scrubbed personnel do not contaminate themselves while gowning and gloving.				
SKIN PREP OF PATIENT				
Hair is removed outside of OR using clippers.				
Skin prep is performed according manufacturer's directions and aseptic technique.				
Agent(s) used: _____				
Sufficient drying time is allowed prior to draping.				
TRAFFIC				
Traffic in and out of the room is kept to essential personnel/tasks.				
The traffic pattern during the case avoids the sterile field whenever possible.				
ENVIRONMENTAL CLEANING				
Horizontal surfaces are free of dust and organic debris.				
After procedure, reusable patient items such as straps are cleaned between uses.				
After procedure, visibly soiled areas of the floor (three-to-four foot perimeter around bed) is mopped free of all blood and debris.				
Total number of YES and NO observations				

Appendix B

Preoperative Surgery Showering Instructions

To keep your skin as clean as possible and to help prevent infection, please follow these instructions:

1. Shower with an antibacterial soap.
Note If using CHG cleanser, do not use it on mucous membranes, such as your genital area. Do not get the soap in ears or eyes. CHG is absorbed by cotton washcloths and may cause discoloration. Follow directions on the package.
2. In the shower, wet skin and wash body from the neck down.
3. Pay special attention to the area where you will have surgery as well as the genital area, belly button, hands and feet.
4. Ask someone for help if you are unable to wash certain areas of your body.
5. Rinse well.
6. Gently dry with a clean towel.

Please Remember:

1. **DO NOT SHAVE ANY BODY PARTS** from the neck down (your legs or underarms). Shaving can increase your risk of infection when you have surgery.
2. **AFTER YOUR SHOWER**, do not use any powder, deodorant, perfumes or lotions prior to surgery.
3. **WEAR FRESHLY LAUNDERED** pajamas to bed that night and sleep on freshly laundered sheets.
4. **SHOWER AGAIN** with antibacterial soap in the morning, following the above instructions.
5. **WEAR FRESHLY LAUNDERED** clothes to the hospital.

Appendix C

Cardiac Surgical Site Infections Worksheet

SSI: Yes No Procedure Code: CARD CBGB CBGC Surgeon: _____

NHSN CODE: SKIN-C SKIN-L ST-C ST-L MED _____

Risk Index: _____

Name _____ Age _____ MR # _____

Date of Surgery _____ Procedure _____ D/C _____

Medical Hx _____ Vein Harvest: Scope _____ Open Skip Incs. _____

Readmit Date _____ DX _____ D/C _____

Date of Culture _____ Site _____ Results _____

Date of Culture _____ Site _____ Results _____

Obtained by: Nursing CT Scan Reoperation

Dehiscence or opened at bedside or I&D by a surgeon? Y N Date _____

Within 30 days of procedure OR one year of procedure involving implant? Y N

S/S: Pain/Tenderness Swelling Redness Heat Fever (>38C)

Purulent Drainage Y N Other _____

Antibiotic Therapy? Y N ABX _____

MD Diagnosis of SSI? Y N Name _____

NOTES _____

1. Height _____ Weight _____ BMI _____ Obese? (≥ 30 BMI)? Y N ABX Prophyl? Y N

2. ABX _____ Time _____ Cut Time _____ Close _____ Redose required? Y N

On Time? _____ Y N Early? _____ Late? _____ Proper Dose? Y N Dosage _____

3. Skin Prep: Betadine Scrub CHG Scrub Alcohol/CHG
Betadine Paint Alcohol/Iodine Other _____

4. Hair Removal: Shave Clip None Not documented

5. Flashing? Y N Item(s) _____ Reason _____

6. + NIDDM + IDDM NO Pre-op _____ 6am POD #1 _____ POD #2 _____

Appendix D

Cardiac SSI Line List

MR # Name	Procedure	Procedure Date	Infection Date	RI	Type	Organism	ABX OK?	Obese	Flash	Glucose	Comments
000000 D.G.	CBGB	12/06/06	1/4/07 28 days	1	SKIN Chest	PM	Yes Ancef 1 gm	No	Yes	3/2/07-182 9/1/07-132	Packed in office + DM
111111 M.B.	CBGB	1/27/07	2/21/07 24 days	1	SKIN Chest	MRSA	Yes Ancef 2 gm	Yes BMI 38.2	Yes	7/16/07 137	Emergent - IABP
222222 W.R.	CBGB	2/23/07	3/5/07 10 days	2	SKIN Leg	SA	Yes Vanc 1 gm PCN -Swelling	No	Yes	12/15/06 241	+DM
333333 R.T.	CBGB	3/30/07	4/9/07 10 days	2	SKIN Leg	CNS	Yes Repeat at 4 hours	No	No	WNL	
444444 S.P.	CBGB	3/9/07	4/2/07 24 days	2	SKIN Leg	SA	No Ancef 1 gm	Yes BMI 43.4	No	WNL	Patient obese
555555 R.D.	CBGB	7/19/07	7/26/07 7 days	1	ST Leg	KP, PM	Yes Ancef 1 gm Repeat at 4 hours	No	No	WNL	L Thigh (scope)
Total Patients = 6			Range = 7-28 days	RI 1 - 3 RI 2 - 3	Skin - 5 ST - 1 Med - 0				# of Flash - 3		

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About This Guide

Post-operative mediastinitis affects as many as 23,000 patients per year and can add more than 30 days to a patient's length of stay. Because of the devastating effects -- and because mediastinitis is preventable -- the Centers for Medicare and Medicaid Services (CMS) no longer reimburses hospitals for costs related to this infection. To help control the far-reaching clinical and financial impacts of mediastinitis, a comprehensive surgical site infection prevention program is imperative. This guide provides the necessary, evidence-based strategies to help infection preventionists in minimizing the risk of mediastinitis following cardiac surgery procedures.

Highlights of this guide include:

- Surveillance Methodology
- Process Improvement
- Making the Business Case
- Case Studies and Worksheets

