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Reducing Morbidity: Establishing a Relationship Between Perioperative Normothermia and Colon Surgical Site Infections

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Walden University
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Abstract

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MPH, Mercer University School of Medicine, 2006

BS, Macon State College, 2003

Dissertation Submitted in Partial Fulfillment

of the Requirements for the Degree of

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Abstract

Healthcare-associated infections (HAIs) are an emerging public health threat. Every day in the United States, HAIs impact 1 in 31 hospitalized patients. Surgical site infections (SSIs) account for over 40% of all reported HAIs and have an increased risk for morbidity and mortality. Surgery associated with colon procedures present an increased risk for infection, morbidity, and mortality. There has been vast work to prevent colon SSIs; however, there remain areas for improvement and exploration. The main research question evaluated the relationship between maintaining perioperative normothermia and colon SSIs. Secondary research questions explored additional risk factors to include age, gender, obesity, and tobacco use. To understand the association, several theories were explored, including the germ theory, germ theory of management, and epidemiologic triad. A quantitative case control study consisting of adult surgical patients (> 18 years of age) was conducted using secondary data (n = 47) from an acute care Level 1 Trauma Center. Multiple logistic regression was used for statistical analysis. Findings suggest that obesity is a significant risk factor for the development of colon SSIs (p = 0.011, 95% CI 1.612, 41.786, *OR* 8.207). Furthermore, obesity confounds the relationship between maintaining perioperative normothermia and the development of a colon SSI (p = .041, *OR* 4.147, 95% CI 1.059, 16.246). Findings may be used to inform public health leaders and health care providers the need for early intervention to reduce the occurrence of colon SSIs and improve patient outcomes among high risk groups. The social change impact by promoting targeted prevention strategies involves a reduction in colon SSIs and associated patient mortality and morbidity, thereby improving population health.

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Dedication

I dedicate my dissertation to my husband and daughter. It is because of their love and support of me that I continue to challenge myself to grow and become a better person. Even during times of stress and apprehension, they continued to show their love and support for me during this journey. Cheers to the next chapter.

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To everyone who was a part of the dissertation review, thank you for your time and feedback. I have continued to grow and learn throughout this entire experience.

To all of my family and friends, you do not know how encouraging it is to hear of your excitement as I share my dissertation journey with you. It makes me proud to see you proud of me.

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Chapter 1: Introduction to the Study

Introduction

Healthcare-associated infections (HAIs) pose a significant threat to both patient safety and public health. In 2002, an estimated 1.7 million HAIs occurred in the United States (Klevens et al., 2002). Despite the work that has been done to combat HAIs, a multistate point-prevalence survey of U.S. acute care hospitals estimated that over 640,000 patients developed over 721,000 HAIs in 2011 (Magill et al., 2014). Such data on the number of HAIs occurring in the United States have indicated the severity of HAIs as a contributor to patients' increased risk of morbidity and mortality as a result of receiving health care, thereby presenting a call to action for public health professionals. To address the increasing risks associated with HAIs, state and federal governments have begun to evaluate quality of care through reported HAI metrics (Magill et al., 2018). An update to the 2011 multistate prevalence survey of U.S. acute care hospitals was recently conducted to assess changes in the prevalence in HAIs after national attention resulted in increased efforts to prevent these infections. Although a decrease in HAIs was reported, with occurrences 16% lower in 2015 than in 2011 ($p = 0.005$), more work is needed for prevention (Magill et al., 2018).

HAIs are infections that occur as a result of health care delivered to a patient. Commonly identified HAIs include catheter-associated urinary tract infections (CAUTIs), central-line-associated bloodstream infections (CLABSIs), surgical site infections (SSIs), and *Clostridioides difficile* infections (CDIs). SSIs are the most commonly occurring HAIs (Magill et al., 2014). The need to prevent SSIs has garnered much attention, leading to considerable research over recent years (Itani et al., 2017). An SSI is an infection occurring at a location where a surgical procedure has taken place (Centers for Disease Control and Prevention [CDC], 2012). SSIs present an increased risk of morbidity, mortality, and growing healthcare costs following an inpatient surgery (Cima et al., 2013; Owens et al., 2014). Among the various types of surgical procedures, colorectal surgical procedures are more frequently associated with higher infection rates (Cima et al., 2013). Reducing colon SSI rates has become a priority for healthcare and governmental leaders, as demonstrated by initiatives tying pay-for-performance to lowering infection rates (Ban et al., 2016).

Strategies to reduce colon SSIs include antiseptic skin prepping, prophylactic antibiotic use (correct antibiotic, timing, and dosing), and intraoperative normothermia, defined as maintaining a core body temperature of at least 36.0°C. When these practices are implemented together, they are referred to as a *prevention bundle*. Implementation of SSI prevention bundles has demonstrated a reduction in colon SSIs (Gabasan et al., 2017). A review of the literature identified limited information on the role of normothermia in reducing infections; however, most of the studies described the role of postoperative normothermia solely (DeGrote, Heather, & Janick, 2015). Therefore, a gap in the literature was identified regarding the role of maintaining perioperative normothermia throughout all surgical phases, along with the role of additional surgical infection risk factors including age, gender, and tobacco use.

Researchers in the European Union estimated the burden of six common HAIs, including SSIs, taking into account the incidence of disease, disabilities associated with complications, and years of life lost as a marker of disability-adjusted life years (DALY; Cassini et al., 2016). Doing so allowed the researchers to make comparisons and identify the true burden of HAIs on the population's health, revealing 501 DALYs per 100,000 general population (Cassini et al., 2016). SSIs represented 16,000 deaths and 57.5 years of life lost (YLL) per 100,000 population (Cassini et al., 2016). Additional research in the United States is needed to determine whether maintaining perioperative normothermia results in a reduction in colon SSIs, thereby promoting population health and adding to years of life. Exploration of the role of normothermia in preventing SSIs would add value to the professional field of health care providers by determining the relevance of implementing core strategies for the prevention of colon SSIs. Research would also offer added value to the field of public health in providing knowledge on best practices for implementation to reduce disability and YLL associated with the development and treatment of HAIs.

Background

The impact of HAIs as a public health threat and patient safety concern has been recognized by key public health stakeholders, including the U.S. Department of Health and Human Services (DHHS). In addition to increased risk of morbidity and mortality, HAIs are linked with an increased financial burden on the healthcare system. It has been estimated that annual costs associated with HAIs reached 9.8 billion between 2011 and 2013, with SSIs contributing to 33.7% of the total (Zimlichman, Henderson, & Tamir, 2013).

The United States spends more on health care every year than any other country; despite these high costs, the overall quality of care remains below average (Kelley & Gravina, 2018). In 2011, DHHS convened a steering committee composed of public health stakeholders specifically targeting a reduction in HAIs (Office of Disease Prevention and Health Promotion [ODPHP], 2018). In addition, funding was given to state and local health departments through the American Recovery and Reinvestment Act (ARRA) to carry out key prevention strategies to achieve and sustain progress toward protecting patients from such infections (Ellingson et al., 2014). In 2017, over $300 million in national funding was distributed to assist state, local, and territorial health departments in combatting infectious disease threats, which included funds for the prevention of HAIs (CDC, 2017).

As patients enter the health care system, they expect to receive the best possible care with no increased risk for infection. However, despite advances in surveillance, surgical techniques, and aseptic practices, SSIs remain commonly occurring HAIs among hospitalized patients. The public health burden of SSIs results in a DALY of 0.5 per incident and 57.5 YLL per 100,000 population (Cassini et al., 2016). Furthermore, colorectal surgery has consistently been associated with a relatively high SSI rate (Cima et al., 2013). With colorectal procedures, there is a high risk for postoperative infections due to the risk for contamination during the procedure (Gabasan, Alvarez-Downing, Smith, & Sordillo, 2017). There continue to be notable challenges with maintaining normothermia, antibiotic prophylaxis, antibiotic dosing, and antibiotic timing, which further elevate the risk for infection.

SSI prevention bundles have been well explored, and a relationship between the implementation of surgical bundles and reduction in colon SSIs has been noted (Cima et al., 2013; Rumberger et al., 2016). Although the benefits of implementing the SSI prevention bundle have been noted (Cima et al., 2013; Rumberger et al., 2016), there has been limited research on each individual element of the bundle, particularly in relation to the role of perioperative normothermia. The role of hypothermia in the risk for infection has been explored. A study conducted by Roig et al. (2009) evaluated colorectal surgeons' perioperative management warming practices, including the use of warming fluids and forced warm air, and intraoperative hypothermia was noted to increase the risk of infections. Additional studies have evaluated the role of warming interventions during the preoperative phase of surgery and discovered that preoperative warming devices did not yield a statistically significant reduction in patients experiencing hypothermia (Nicholson, 2013). Inconsistencies in research findings on the role of maintaining perioperative normothermia for the prevention of colon SSIs have left health care providers and public health leaders without clear recommendations for best practice. These gaps in knowledge may be addressed by closely examining perioperative normothermia and patient outcomes.

It should also be noted that age, gender, and tobacco use are questionable risk factors, both modifiable and nonmodifiable, that are worthy of further exploration for assessment and early intervention for prevention. In addition, the potential risk associated with obesity and SSI should be considered. Research has identified that advanced age, gender, obesity, and tobacco use is a risk for infection. Statistically significant SSI risk factors related to age have been documented (Neuman & Grzebieniak, 2014). In fact, age continues to be independently associated with the prevalence of HAIs (Magill et al., 2018). Understanding the role of age, in addition to other risks factors, for infection prevention is essential for the implementation of targeted prevention strategies. However, no formal recommendations have been made concerning the prevention of SSIs and age, and it has been noted that the relationship may increase secondary to comorbidities or immunosenescence (Anderson et al., 2014). Complications and burdens associated with HAIs have also been seen to occur more commonly in males than in females (Cassini et al., 2016; Muratore, Statz, Glover, Kwaan, & Beilman, 2016). Additional studies have found that modifiable risk factors such as tobacco smoking are independently associated with SSIs (Ghuman et al., 2015). As such, recommendations have been made to encourage smoking cessation within 30 days of a surgical procedure (Anderson et al., 2014). Obesity has also been independently associated with increased risk of SSIs. Evaluating these risks and any potential confounding relationship with perioperative normothermia is essential to inform public health leaders and healthcare providers on recommended preoperative practices for the reduction of morbidity and mortality associated with developing SSIs after colorectal surgical procedures. The implementation of practices informed by such knowledge could reduce the burden of HAIs and their effect on population health.

Statement of the Problem

Despite increased attention and efforts surrounding the reduction of colon SSIs, infection rates only decreased 2% between 2008 and 2014 (CDC, 2016). Although no one strategy has demonstrated effectiveness in reducing colon SSIs (Cima et al., 2012), a literature review showed a gap in understanding the role of maintaining perioperative normothermia. Perioperative normothermia includes maintaining normothermia through all three phases of surgical care (preoperative, intraoperative, and postoperative). Most of the existing literature identified for this study addressed the role of maintaining normothermia only during the intraoperative phase. Organizations are being pressured to improve patient safety and the quality of care (Kelley & Gravina, 2018). A systematic review performed by Zingg et al. (2015) encompassed 92 studies assessing organizations' implementation of best practices, education, training, access to resources, staffing, and workload to create behavioral change, finding that these components introduce manageable ways to reduce HAIs. SSIs represent a financial burden for the public health care system and adversely affect patients' quality of life (Badia et al., 2017).

SSIs are associated with approximately 1 million excess hospital days and have contributed to more than $1.6 million in direct costs related to the care and treatment of infections (Cima et al., 2013). The exploration of the role of perioperative normothermia in reducing colon SSIs could identify the role of perioperative normothermia in the prevention of colon SSIs. Exploring whether maintaining perioperative normothermia reduces colon SSIs may also aid in identifying perioperative best practices aimed to improve patient outcomes, which would add value to the public health field, as the prevention of HAIs is increasingly identified as a public health priority. Implementing best practices for the prevention of SSIs may reduce patient morbidity and enhance patients' quality of life. By reducing the incidence of SSIs, it may be possible to address financial strain due to rising health care costs, decrease the disease burden, and improve patient outcomes.

Purpose of the Study

The purpose of this quantitative research study was to determine whether a relationship exists between perioperative normothermia and colon SSIs and to identify whether additional risks for infection are associated with obesity, tobacco smoking, age, or gender. Information gleaned from this study may guide public health leaders and clinical professionals toward elements of best practices for implementation as a standard of care. The dependent variable, perioperative normothermia, was defined as core body temperature of 36^0C, with the independent variable being the development of SSI as determined by National Healthcare Safety Network (NHSN) surveillance definitions. Additional risk factors for infection include tobacco smoking, age, obesity, and gender.

Nature of the Study

I conducted a quantitative cross-sectional study to explore the relationship between perioperative normothermia and colon SSIs. Study participants included colon surgical procedure patients. Outcomes (infection vs. no infection within 30 days after the date of the surgical procedure) for patients who had perioperative normothermia maintained were compared to outcomes for patients who did not have perioperative normothermia maintained. This quantitative research method offered information on the association between maintaining normothermia during colon surgical procedures and colon SSIs. In addition, I sought to assess whether age, gender, obesity, and tobacco use impact the association between perioperative normothermia and colon SSIs.

Research Questions and Hypotheses

The main research question to be answered by this research was the following: Is there an association between maintaining perioperative normothermia and colon surgical site infections? The research questions and hypotheses are defined below.

1. What is the association between perioperative normothermia and colon surgical site infections?

   Null hypothesis (H_0): There is no statistically significant association between perioperative normothermia and colon surgical site infections.

   Alternative hypothesis (H_A): There is a statistically significant association between perioperative normothermia and colon surgical site infections.

2. Is the association between perioperative normothermia and colon surgical site infections confounded by tobacco smoking?

   Null hypothesis (H_0): The relationship between perioperative normothermia and colon surgical site infections is not confounded by the effect of tobacco smoking.

   Alternative hypothesis (H_A): The relationship between perioperative normothermia and colon surgical site infections is confounded by the effect of tobacco smoking.

3. Is the association between perioperative normothermia and colon surgical site infections confounded by age?

   Null hypothesis (H_0): The relationship between perioperative normothermia and colon surgical site infections is not confounded by age.

Alternative hypothesis (H_A): The relationship between perioperative normothermia and colon surgical site infections is confounded by age.

4. Is the association between perioperative normothermia and colon surgical site infections confounded by gender?

   Null hypothesis (H_0): The relationship between perioperative normothermia and colon surgical site infections is not confounded by gender.

   Alternative hypothesis (H_A): The relationship between perioperative normothermia and colon surgical site infections is confounded by gender.

5. Is the association between perioperative normothermia and colon surgical site infections confounded by obesity?

   Null hypothesis (H_0): The relationship between perioperative normothermia and colon surgical site infections is not confounded by obesity.

   Alternative hypothesis (H_A): The relationship between perioperative normothermia and colon surgical site infections is confounded by obesity.

Theoretical Framework for the Study

The theoretical base for the study was a combination of the following theories: the germ theory, germ theory of management, and epidemiologic triad or triangle, a traditional model for infectious disease. The germ theory and germ theory of management, which provide details on how organisms cause disease and how processes affect patient outcomes, formed a framework for understanding the association between colorectal surgical site infections and the role of maintaining normothermia throughout the surgical care process and the risk for the development of a colon SSI. The epidemiological triad model offers an explanation on disease causation, where the triad consists of an external agent, a susceptible host, and an environment bringing the host and agent together (Dicker, Coronado, Koo, & Parrish, 2006).

Joseph Lister, a physiologist and surgeon; Robert Koch, a physician and scientist; and Louis Pasteur, a chemist, all laid the foundation for the development of the germ theory (Harvard University Library, 2018). The germ theory's premise that specific organisms cause specific diseases, that is without environmental influences, diet, chronic disease, or climate, provided an improved understanding of the cause of disease (Harvard University Library, 2018) and led to advances in public health and hygiene (Egger, 2012).

The germ theory of management expands on the germ theory by bringing together 19th-century medicine with 21st-century management to improve patient outcomes, with implications surrounding the management of system processes (Tribus, 2015), thereby reducing morbidity and mortality. It is well documented that sources of surgical wound contamination can be both endogenous and exogenous (Verwilghen, 2015). Exogenous sources of contamination can stem from the environment, the operating room team and climate, or materials and instruments used during a surgical procedure, while endogenous sources include the patient's own bacterial flora (Verwilghen, 2015). Endogenous measures, such as normothermia, that enhance an individual's immunity for the prevention of SSIs are worthy of exploration. Evidence has provided insight into the role of normothermia for surgical patients, indicating that SSIs occur in 19% of hypothermic patients (Fry, 2013).

The epidemiologic triad model indicates that disease is the result of an interaction between a host and an agent and that agent, host, and environment interconnect in a number of ways to produce disease (Dicker et al., 2006). Although different diseases require different balances and interactions among agent, host, and environment, it is important to understand which public health measures are effective in controlling and preventing disease from occurring (Dicker et al., 2006). In order to understand these measures, an assessment of each component is necessary, thereby providing a model to understand the association between the risk for the development of a colon SSI and the maintenance of normothermia throughout the surgical care process.

Definitions and Key Terms

The following section contains definitions for terms and variables used in this research study. For the definition of HAIs, I consulted CDC materials. Furthermore, NHSN surveillance definitions were used to establish the identification of a colorectal SSI. Hypothermia occurs when core body temperature is less than $36^{O}C$ (Odom, 1999). Therefore, normothermia was set as $36^{O}C$ or greater.

Definition of Variables

To ensure the continuity of the research variables, I established the definitions shown in Table 1.

Table 1

Definition of Variables

Variable	Definition
Perioperative normothermia	Normothermia maintained through all operative phases
Colon surgical site infection	Defined by NHSN, occurring within 30 days of surgery
Tobacco smoking	Patient identified as smoking
Age	Surgical patients greater than 18 years of age
Gender	Male or female
Obesity	Body mass index greater than 30

Key Terms

To assist with the reading of the study, I have provided a list of key terms in Table 2 for reference. The terms provided are commonly used in the medical field. To establish definitions for these terms, I used *Merriam-Webster's Medical Dictionary* (2018).

Table 2

Key Terms

Term	Definition
Preoperative (preop)	Period occurring before a surgical procedure
Intraoperative (intraop)	Period occurring during a surgical procedure
Postoperative (postop)	Period following a surgical procedure
Perioperative	All phases of operative care (pre op, intra op, post op)
Normothermia	Core body temperature maintained at or above $36^{O}C$
NHSN	National Healthcare Safety Network
Infection	Resulting from an infectious agent and susceptible host
Colorectal	Involving the colon and rectum
Colon surgery	Surgical procedure involving the colon (ICD-10-PCS)
Surgery	Branch of medical amenable to operative procedures
SSI rate	The number of SSIs (procedure-specific) divided by the number of procedures performed; multiplied by 100. A rate of infection per 100 surgical procedures.
Electronic medical record (EMR)	Electronic record of patient medical information

Analysis of Data

Multiple logistic regression analysis was used for statistical analysis. This analytic strategy applies when the outcome variable (in this case, colon SSI) is a dichotomous variable and there is more than one independent variable. I used multiple logistic regression to examine the odds of a colon SSI occurring when perioperative normothermia is obtained. The odds ratio provided a measure of association between perioperative normothermia and colon SSI. In addition, multiple logistic regression can be used to examine the effect of maintaining perioperative normothermia on colon SSIs while controlling for age, gender, obesity, and tobacco smoking. It is important to control for the effect of age, gender, obesity, and tobacco smoking because each of these variables has been established as a risk factor for the development of an SSI. In addition, the SSI rate can be used to assess for the number of infections per 100 surgical procedures, indicating an increase or decrease in infections over time.

Delimitations, Assumptions, and Limitations

Delimitations of the research study included the study population. For the purposes of this research, the population was set to include adult surgical patients (18 greater than 18 years of age), and colon surgical procedures that had a wound class of I (clean) or II (clean-contaminated) were included in the sample. Procedures with a wound class of III or IV are associated with contamination and infection, respectively, and therefore were proposed to be excluded from the research. In addition, procedures that were identified as urgent or emergent were also proposed to be excluded. Limiting the scope of the colon surgical procedures to classes I and II would decrease the threat to internal validity and ensured that the variables of interest could remain the focus of the research for generalizability of the outcome data.

Assumptions and a limitation of this study included the possibility of the NHSN surveillance definition being used with subjectivity and not accurately identifying a colon SSI. Although a definition is provided to assist in the determination of an SSI, clinicians must exercise subjective judgment in identifying infections. This may lead to underreporting and, in some cases, overreporting of infections. As a result, assumptions in the study remain to exist that the SSI definition has been accurately applied. The standard for identifying an infection for the surveillance and mandatory public reporting of select HAIs is the NHSN definition (Figure 1). Because this was not a data validation study, it must be assumed that those individuals who met NHSN criteria for a colon SSI were identified accurately.

An additional limitation of this research study was the accessibility of the data. The identified variables for this research included perioperative normothermia (categorical variable) and colon SSI (categorical variable). Additional variables included age, gender, obesity, and smoking status. The available sources for these data included hospital records and nationally reported surgical data. Perioperative normothermia may be assessed through a review of anesthesiology records in which patients' core body temperature is tracked and reported during preoperative, intraoperative, and postoperative phases of surgical procedures. Such data may be available through an acute care hospital's electronic medical record (EMR) system. Systems and processes vary by hospital and may present additional limitations; for instance, records may only include one temperature (generally the highest) during each operative phase of care. Therefore, not all temperatures may be documented in the EMR, and a hypothermic event may not be reflected in the record. Such limitations may introduce study bias. In order to control for study bias, review of the medical records of study participants may be essential for the abstraction of data.

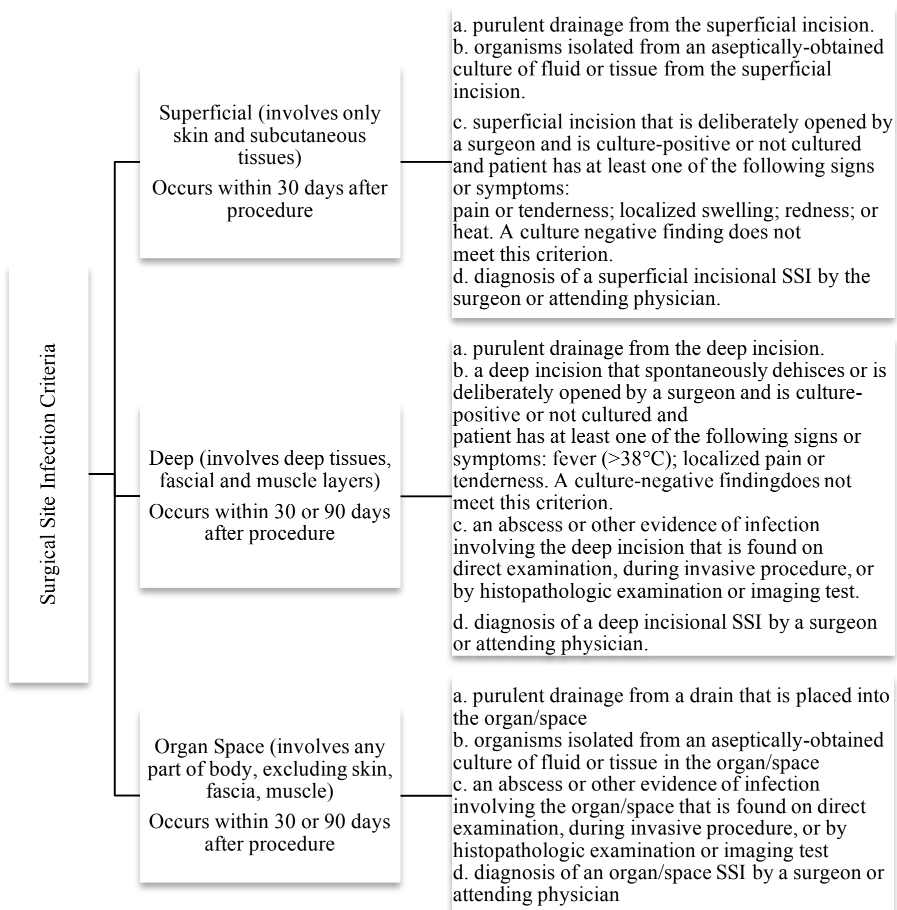

Figure 1. NHSN surgical site infection criteria. Adapted from National health care safety network patient safety component manual: Surgical site infection (SSI) event. CDC, 2019. https://www.cdc.gov/nhsn/pdfs/pscmanual/9pscssicurrent.pdf

Significance

HAIs are an emerging threat to the public's health. Not only do HAIs have a direct impact on health and wellness, but they also have an indirect impact associated with treating these infections. Colorectal SSIs are a significant cause of patient morbidity and mortality (Docherty, 2015). Furthermore, HAIs are associated with increased healthcare expenditure. SSIs accounted for over 33% of the total $9.8 billion U.S. dollars spent to treat those infections between 2011 and 2013 (Zimlichman, Henderson, & Tamir, 2013).

Age has been noted to be a risk factor for surgical complications, including postoperative infections. A study conducted by Anderson et al. (2014) identified age as a risk factor, with risk being dependent upon an individual's comorbidities. Gender differences in the development of SSIs have also been described in the literature. Women have been identified as having significantly lower SSI rates than men (Cohen et al., 2013). Smoking cessation within 30 days of a surgical procedure has also been established as a level I recommendation (i.e., highly recommended based on the quality of evidence) for the prevention of SSIs (Anderson et al., 2014). A study performed by Sharma et al. (2013) found that current smokers were at significant risk for postoperative morbidity (*OR,* 1.3; 95% CI, 1.21,1.40) and mortality (*OR*, 1.5; 95% CI, 1.11,1.94). Such data further establish the need for tobacco cessation programs, as well as the need to control for the variable of tobacco use in the current study. Assessing these risks and allowing for opportunities to intervene before a surgical procedure is essential for the best possible outcome.

Identifying risk factors associated with colon SSIs, including perioperative normothermia, age, gender, and tobacco use, is essential for the implementation of risk reduction strategies. Implementing strategies that have demonstrated a reduction in colorectal SSIs could have significant implications for social change to reduce disease burden and improve population health. Thus, it is important to give public health leaders and providers the information needed to improve the care provided to consumers of health care delivery.

Social Change Implications

This study may assist physicians, hospital leaders, and public health stakeholders by establishing best practices for the prevention of colon SSIs, thereby assisting their efforts to reduce disease burden and costs associated with treating SSIs. There is also an opportunity to further support the public health population-based model, that is identifying the role that public health plays in the prevention of HAIs through identifying and understanding risks associated with colon SSIs, policy development, and implementation of best practices for prevention.

The information and data obtained from this research may be used to stimulate public health collaborative work at local, regional, state, and national levels. Participation in collaboratives has been found to reduce SSIs among participating organizations (Anderson et al., 2014). State health departments are increasingly being established as leaders in supporting efforts to combat HAIs through collaborative work. In addition, state departments of health are gaining access to HAI facility-level data for evaluation and analysis, and they are using these data to drive action for prevention. Communities across the nation benefit when state, local, and territorial public health agencies take action to detect, respond to, prevent, and control infectious disease health threats (CDC, 2017). To respond to colon SSIs, it is important to understand the epidemiology and risks associated with these infections.

Summary

It is estimated that every day, 1 in 25 patients develops an HAI (CDC, 2016). SSIs are the second most commonly occurring HAI type. Colorectal SSIs are associated with higher rates of infection (Cima et al., 2013). Prevention of these infections is essential for the promotion of individual and public health and wellness. This research was conducted in an attempt to understand the association between colon SSIs and maintaining normothermia throughout the surgical care process. Furthermore, risk factors such as age, gender, obesity, and tobacco smoking were considered to determine whether they have a confounding relationship with perioperative normothermia and infection outcome. No one strategy has demonstrated effectiveness in reducing colon SSIs (Cima et al., 2013), and a literature review demonstrated a gap in knowledge on the solitary role of maintaining perioperative normothermia, age, gender, obesity, or tobacco use and the relationship with colon SSIs. In the next chapter, I further explore the research and role of the associations between normothermia, age, tobacco smoking, obesity, gender, and colon surgical outcomes.

Chapter 2: Review of the Literature

Introduction

HAIs are infections that occur as a result of care received while in the health care system. HAIs include infections associated with surgical procedures, medical devices, and multidrug-resistant organisms. HAIs constitute a significant emerging public health threat that has resulted in calls for public health action for prevention. It was estimated that over 720,000 HAIs occurred in just under 650,000 patients in 2011 alone (Magill et al., 2011), making HAIs the most common adverse event occurring during the delivery of health care (Kaier, Mutters, & Frank, 2012).

Further, HAIs result in excess medical costs of over $26 billion each year, resulting in approximately 99,000 deaths annually (Khabbaz et al., 2014). Of the types of HAIs, SSIs have been associated with an increased risk of morbidity, mortality, readmissions, and economic expenditures (Cima et al., 2013). As a result of independent patient risk factors and procedural risk factors, procedures associated with colon and rectal (colorectal) surgery are associated with a higher SSI rate. A call to action has resulted in federal, state, and local health partners joining efforts for targeted SSI reduction strategies. Recommendations for best practices and prevention strategies are now universal; however, there continues to be inconsistency in their implementation. For one prevention strategy, maintaining perioperative normothermia, there remains limited information on the role that perioperative normothermia plays in the prevention of colorectal procedures. Perioperative normothermia occurs when core body temperature is maintained at a minimum of 36^{O}C throughout all phases (i.e., preoperative, intraoperative, and postoperative) of surgical care. In this study, I sought to identify whether any association exists between maintaining perioperative normothermia and colorectal SSIs. The resulting information may inform health care providers and public health leaders of additional potential best practices for the prevention of SSIs.

The review of literature begins with a brief overview of HAIs and from there moves into the public health implications of HAIs by demonstrating the impact on population health and the economic burden associated with these events. An overview of SSIs, including the epidemiology, characteristics, and theory surrounding the development of SSIs, is also introduced. From there, the literature review narrows in on colorectal SSIs and morbidity and mortality associated with this type of HAIs. To facilitate a better understanding of the risk and impact associated with the development of a colorectal SSI, I present information provided related to risk factors and prevention strategies. The literature review chapter concludes by establishing the benefit of determining the role of perioperative normothermia in the development of SSIs.

Review of Literature

A review of the literature was performed by querying public health and medical databases to identify article titles and abstracts containing key search terms such as *healthcare-associated infections (HAIs), surgical site infections (SSIs), colon surgical site infections, public health, age, obesity, gender,* and *tobacco use*. The search results were limited to peer-reviewed journal articles and reports published between January 1, 2013, and December 31, 2018. A search of the Medline with full text database resulted in 1,451 return items. ProQuest Central and Thoreau searches resulted in 88 and 1,393 hits, respectively. To focus on relevant articles, the search was further limited to publications and research conducted in North American and European countries with an emphasis on HAIs, colorectal SSIs, risk factors, and public health implications. After application of the additional filters and further removal of articles not relevant to the current search, 106 remaining peer-reviewed articles were examined for the review of the literature.

An Overview of Healthcare-Associated Infections

HAIs are infections that occur during the delivery of care received in a health care setting. These infections range from central-line-associated bloodstream infections to SSIs and include additional device-associated infections such as catheter-associated urinary tract infections and ventilator-associated pneumonia. HAIs have been deemed to be among the most common adverse events related to healthcare (Moura, Baylina, & Moreira, 2018). These infections are not limited to hospital settings; outbreaks have also been found to occur in outpatient settings and long-term care facilities (CDC, 2018). HAIs represent a common, preventable threat to patient safety and public health (Storr et al., 2016; Zimlichman et al., 2013). HAIs also have a significant financial impact on the U.S. health care system and are associated with patient morbidity and mortality (Storr et al., 2016; Zimlichman et al., 2013). The wide impacts of these preventable sources of harm warrant a public health call to action.

Public Health Implications of HAIs

Consideration of the public health implications of HAIs is a relatively new phenomenon. Therefore, a better understanding of the relative burden of HAIs and the impact that these infections have on public health is essential to inform government officials on best practices and areas in which research is needed to better understand and eliminate these types of infections from occurring (Lewis et al., 2013). The overall burden of HAIs on population health is not well described, although research has been conducted in an attempt to understand HAIs better and inform efforts toward prevention (Badia et al., 2017; Cassini et al., 2016; Magill et al., 2014; Zimlichman et al., 2013). Establishing the burden and impact of these infections for both the U.S. health care system and population health is essential for public health and wellness (Cassini et al., 2016; Zimlichman et al., 2013). Studies have estimated that annual costs associated with HAIs have surpassed $9.8 billion and affected 4% of acute care inpatients within the U.S. health care system (Magill et al., 2014; Zimlichman et al., 2013). SSIs account for a considerable portion of these costs and have an impact on patient safety. SSIs have been identified as a commonly occurring type of HAI (Cassini et al., 2016; Lewis et al., 2014; Magill et al., 2014; Zimlichman et al., 2013). While the severity and risk for the development of an SSI depends upon the type of surgical procedure being performed and the depth of the infection (Cassini et al., 2016), the development of an SSI in general is associated with increased risk for morbidity and mortality (Badia et al., 2017; Barnes, 2018; Edmiston et al., 2011; Hawn et al., 2011).

Additional studies have been conducted to understand better the effect of developing an SSI in terms of the patient's quality of life, potential life lost, and financial burden (Badia et al., 2017; Cassini et al., 2016). Trying to break this impact down further, Cassini et al. (2016) sought to describe the effect that developing an SSI had on actual life lost. In doing so, they described the burden of the development of an SSI in disability-adjusted life years (DALY), translated into 0.5 DALYs per case, 0.8 years lived with a disability per 100,000 population, 58.2 DALYs per 100,000 population, and 57.5 years life lost per 100,000 population (Cassini et al., 2016). The influence of SSIs on quality of life (QoL) has been noted; however, it is also essential to consider broader public health implications associated with SSIs (Badia et al., 2017). These societal impacts include economic costs associated with reduced work and lost income as a result of patients being unable to work while under treatment, in addition to potential negative impacts on patients' mental and physical health (Badia et al., 2017). Estimates indicate that up 50% of SSIs are preventable (Zimlichman et al., 2013; Barnes, 2018). Through prevention activities, reduction in HAIs could result in savings of over $5 billion in health care expenditures, thereby making resources available for other activities improving patient safety (Zimlichman et al., 2013).

SSIs represent a large portion of HAIs and HAI-associated economic costs (Jenks, Laurent, McQuarry, & Watkins, 2014; Zimlichman et al., 2013). Statistics on the frequency of HAI-related events have led to an increased understanding that these infections are a public health threat (Moura et al., 2017) and require the attention of federal and state stakeholders to establish recommendations and requirements concerning the delivery of care for prevention. Policy and prevention efforts are not absolute in targeting SSIs, however, are essential if reductions are to be possible (Zimlichman et al., 2013). Despite associated financial penalties to the facility upon the development of an SSI more work is needed to establish a system for prevention (Jenks et al., 2013).

Federal and State Stakeholders' Response to HAIs

The understanding that HAIs represent a public health threat remains relatively new. The literature review indicated limited knowledge on how vital the response of public health leaders is for the detection and containment of these events. Only over the past decade have HAIs been described as a preventable public health issue (Ellingson et al., 2014b). Recognizing that HAIs lead to increased risk for morbidity, mortality, and economic burden, stakeholders have recommended a coordinated approach to prevention (Ellingson et al., 2014b). In 2008, DHHS convened a steering committee explicitly targeting HAI reduction (Ellingson et al., 2014b; ODPHP, 2018). The steering committee consisted of many public health stakeholders, including but not limited to the CDC, National Institutes of Health (NIH), Office of the Secretary (OS), U.S. Department of Veterans Affairs (VA), Indian Health Service (HIS), and Centers for Medicare and Medicaid Services (CMS). In response to increasing trends associated with the development and harm associated with HAIs, the steering committee was tasked with developing an action plan for eliminating HAIs.

In 2009, Phase 1 of the National Action Plan to Prevent Health Care-Associated Infections: Road Map to Elimination (HAI Action Plan) was launched (ODPHP, 2016). Recognizing that most common HAIs occur inside the acute care setting, the planners of Phase 1 of the action plan focused on inpatient settings (ODPHP, 2016). Phase 1 involved a coordinated research agenda to understand the significance of these infections better, develop an integrated information systems strategy, link policy to the quality of care, enhance regulatory oversite of hospitals, raise awareness of HAIs among the population, and implement best practices among healthcare workers for prevention (ODPHP, 2016).

Through DHHS actions and progress toward the prevention of HAIs, federal stakeholders began investing in state health departments to increase capacity and resources to focus on preventing HAIs (Ellingson et al., 2014) as seen through the American Recovery Reinvestment Act (ARRA) of 2009. The ARRA of 2009 provided grant funding upwards of $35.8 billion to 51 health departments in 49 states, the District of Columbia, and Puerto Rico, through the Epidemiology and Laboratory Capacity (ELC) program of the CDC (Ellingson et al., 2014). Greater capacity for detection and response of HAIs was now deemed essential for prevention, and there was more widespread understanding of the value of public health funding for the prevention of HAIs (Borlaug & Edmiston, 2018; Ellingson et al., 2014; Whittington et al., 2017). State health departments that had not previously been capable of focusing on areas needing attention due to incomplete or inadequate resources were able to launch collaboratives and initiatives with a goal of reducing infections, with many states reporting having developed task forces targeting reduction in SSIs (Ellingson et al., 2014). State health departments focusing on SSI reduction with the goal of reducing patient morbidity were provided with staff and resources to assist health care providers in identifying areas of prevention needing improvement (Borlaug & Edmiston, 2018; Ellingson et al., 2014). With these efforts to increase capacity for surveillance and detection of HAIs among state health departments, significant reductions in SSIs have been seen across all 50 states (Ellingson et al., 2014). Investing in public health partners at the state level for targeting and preventing SSIs is essential for continued infection reduction and promotion of population health.

Reporting of HAIs

The number of surgical procedures performed annually far surpasses the number of births, with approximately 254 million surgeries performed worldwide and more than 15 million performed in the United States (Health Research & Educational Trust [HRET], 2018). With SSIs representing a large portion of HAIs, better coordination, management, and detection of HAIs is essential to understanding the rate at which these events occur as a step toward prevention. Through mandates for the public reporting of specific HAI-related events, the public has become increasingly aware of the frequency at which HAIs occur, with SSIs being of foremost concern. HAI rates are commonly used as a marker of quality performance within healthcare settings (Talbot et al., 2013). Surveillance of HAIs has many uses, including establishing benchmarks, targets for prevention, comparisons between facilities, and, most recently, the application of pay for performance. Just over the past few years have select HAI metrics been made publicly available for consumers of healthcare through mandatory reporting requirements (Talbot et al., 2013).

CMS established the Inpatient Quality Reporting (IQR) program in 2003, with the addition of HAI reporting in 2011. Through the IQR program, CMS recognized top-performing hospitals, paid for quality of care, and penalized organizations that did not meet quality standards (CMS, 2017; Talbot et al., 2013). This requirement was the first attempt at making available to the public a hospital's performance and infection rates.

Additional reporting mandates have been established for outpatient services, end-state renal disease programs, long-term care programs, and inpatient rehab programs (Reagan et al., 2016). Through this reporting, HAIs have been established as a leading cause of death in the United States (McGuckin, Govednik, Hyman, & Black, 2014), and SSIs have been identified as the most commonly recognized type of HAIs (Badia et al., 2013; Jenks et al., 2013; Lewis et al., 2013; Magill et al.,2013; Zimlichman et al., 2013).

Since 2013, 32 states have enacted laws to mandate public reporting of HAIs, meaning that hospitals had to start reporting data on select HAIs to their state department of health, with 37 states having enacted HAI-oriented laws (McGuckin et al., 2014; Reagan et al., 2016). Consumer awareness and access to HAI data have not been identified as important determining factors in hospital selection when seeking medical care (McGuckin et al., 2014). More work is needed to establish effective ways to communicate to consumers the risk associated with HAIs and how to access publicly available reports to inform decision making (McGuckin et al., 2014).

An Overview of Surgical Site Infections

SSIs are infections that occur at the site of a surgical incision or in the organ space after an operative procedure (Berrios-Torres, Umscheid, & Bratzler, 2017). SSIs have been well established as common HAIs with increasing risk of morbidity, mortality, and financial costs associated with treatment. With the number of surgical procedures continuing to rise, establishing process measures for the prevention of these events is essential (Berrios-Torres et al., 2017). Select SSIs are subject to mandatory public reporting (Talbot et al., 2014). Colon SSIs, abdominal hysterectomy SSIs, cesarean sections, as well as hip and knee arthroplasties are all subject to mandatory reporting under the CMS IQR program. Guidelines have been established for the prevention of SSIs, and through the implementation of best practices, nearly half of all SSIs have been deemed preventable (Barrios-Torres et al., 2017).

Epidemiology of Surgical Site Infections

SSIs are occurring at an increasing rate when compared to other HAIs. In the United States, it is estimated that between 2% and 5% of patients who undergo an operative procedure will develop an SSI, equating to 160,000-300,000 SSIs annually (HRET, 2018). By definition, SSIs are infections that occur after an operative procedure involving either the incision, deep tissue, or organ space at the operative site (Berrios-Torres et al., 2017; HRET, 2018; Owens & Stoessel, 2008; Richman & Greenberg, 2009; Savage & Anderson 2012). For HAI surveillance purposes and by definition as set by the CDC's NHSN, these infections may occur up to 30 days after a procedure and, in some procedural cases, up to 90 days after surgery (CDC, 2019; Owens & Stoessel, 2008; Reichman & Greenberg, 2009). With the incidence of a postoperative infection being as high as 20% in some surgical procedures, research on best practices and techniques for infection prevention is essential, so that these may be implemented in practice (Owens & Stoessel, 2008). However, despite increasing awareness of the significant morbidity and mortality associated with the development of SSIs, they remain a common occurrence with complications occurring after operative procedures (Savage & Anderson, 2013). Approaches are needed to prevent the development and spread of these infections as patients increasingly move between healthcare facilities and back out into communities, thereby increasing the risk and potential spread of emerging drug-resistant bacteria that infect surgical wounds (Khabbaz et al., 2014).

Disease Causation

The epidemiological triad model can assist in better understanding the development of an SSI. Assessing and understanding the host, agent, and environment (epidemiological triad) can inform public health providers, stakeholders, and physicians in on infection prevention best practices for prevention of infections. The development of an SSI is multifactorial and often the result of both modifiable and nonmodifiable risks consisting of patient and environmental factors, along with gaps in infection prevention across all phases of an operative care (Savage & Anderson, 2012). In a majority of SSI cases, the patient develops an infection associated with a pathogen that is of their native flora (Reichman & Greenberg, 2009) and as a result, the bacteria contaminate the wound during the surgical incision (Savage & Anderson, 2012). During the operative procedure as a patient's skin is incised the underlying tissue and organ space subsequently become exposed the endogenous skin flora, therefore, contaminates the surgical incision (Reichman & Greenberg, 2009; Savage & Anderson, 2012). Common skin flora includes *Staphylococcus aureus*, methicillin-resistant *Staphylococcus aureus* (MRSA*)*, and other gram-positive microorganisms (Reichmann & Greenberg, 2009) with MRSA identified as a pathogen causing most SSIs (Savage & Anderson, 213).

Additionally, during operative cases where the hollow viscus is entered the surrounding tissue has an increased risk of contamination with endogenous gram-negative bacteria to include Enterobacteriaceae and yeast species (Reichman &

Greenberg, 2009). In the event reporting system, NHSN, there are common community associated organisms that would be excluded as a pathogen associated with the development of an SSI (CDC, 2019). The organisms include *Blastomyces, Histoplasma, Coccidioides, Paracoccidioides, Cryptococcus and Pneumocystis* and are not described as pathogenic in the acquisition of an SSI (CDC, 2019).

Variables that determine the bacterial load required to trigger an infection include the virulence of the bacteria, the condition of the wound, and the patient's host defenses (Savage & Anderson, 2013). In considering Joseph A. Lister's "germ theory" and a connection that microscopic organisms are involved in the pathogenesis of disease arose the diffusion of an aseptic approach in the management of surgical patient's wound to prevent the development of a postoperative infection (Sabbatani et al., 2016). Additional risk factors that are considered in the event of an SSI, in particular, a colon SSI will be described in more detail below.

The role of organizational support in the prevention of infections should also be considered. The germ theory of management as described by Myron Tribus provides context to understand how management coupled with adapting to new processes and techniques are designed to improve patient safety. As best practices for prevention of SSIs are introduced into the healthcare setting they should be evaluated and incorporated into system processes. Best practices to include risk reduction from both endogenous and exogenous factors for the development of an SSI. As an organization, what processes are in place to promote the best outcome for the patient? These processes include evaluation of the operation room environment, cleanliness, sterility, preoperative and postoperative procedures, in addition to the implementation of SSI prevention bundles. Prevention bundles are a key set of best practices to produce the lowest risk for an infection to occur (Cima et al., 2013; Hoang et al., 2019). Colon SSI bundles consists of several factors to include one) maintaining intraoperative normothermia, two) prophylactic antibiotic therapy, three) correct timing and dose of antibiotic, four) perioperative glycemic control, five) minimally invasive surgery, six) short operative duration and seven) clean instruments used for wound closure (Houng et al., 2019). By implementation of the colon SSI bundle a reduction in infections has been documented (Hoang et al., 2019).

Wound classification. There are three classifications of SSIs and include incision, deep incisional, and organ space (CDC, 2019). The incisional wound is further classified as clean (1), clean/contaminated (II), contaminated (III), and dirty/infected (IV) (CDC, 2019). This wound classification is also used to risk stratify for the potential development of a surgical site infection (Reichman & Greenberg, 2009). Therefore, the higher the wound class, the greater the risk for development of a postoperative SSI. Accuracy in the assignment of a wound classification is essential to precisely predict the risk for an SSI as a part of the prevention strategy (Florschutz et al., 2015). Predicting the risk for infection guides physicians and providers on postoperative courses of care to reduce the development of an infection.

Infection prevention. Infection prevention and control programs are essential to better support coordinated prevention efforts to combat HAIs (Price et al., 2018). IPC programs are a fairly consistent fixture within health care systems (Storr et al., 2017). IPC programs consist of evidence-based guidelines that are used to establish the minimum requirements for the prevention of HAIs. Core components of an effective IPC program include the use of care bundles, surveillance, policies and procedures based on evidence-based recommendations, and staff education and training on infection prevention (Price et al., 2018; Storr et al., 2017). Organizational support to ensure that adequate staffing, resources, and expertise in infection prevention knowledge are crucial for an IPC program (Zingg et al., 2015). Infection prevention of HAIs must also be implemented at the organizational level and must be deemed a priority by the organization as a whole including healthcare workers at all levels (Zingg et al., 2015). Ensuring an improved understanding of barriers for HCWs to implement recommended prevention strategies is needed.

An Emphasis on Surgical Site Infections in Colon Procedures

Colon surgery is a procedure that involves the incision, resection, or anastomosis (a surgical reconnection of the intestine) of the large intestines (Gabasan, 2014). Colon surgical procedures have been identified as being associated with an increased risk of infection (Cima et al., 2013; Fry, 2013; Gabasan, 2014). Infection risk has been seen as high as 45% (Cima et al., 2013; Gabasan, 2014). These infections range from superficial infection to infections involving the abdominal cavity where they pose a significant threat to a patient’s life (Fry, 2013).

Pathogenesis of colon surgical site infections. As with the pathogenesis of SSIs, colon SSIs are no different. The inoculum of bacteria at the time of the surgical incision is an important variable in the development of an SSI and the greater the log of bacteria the greater probability that an infection will develop (Fry, 2013). In procedures where the wound class has been designated as clean (I) the source of an incisional infection is likely the patient's skin flora (Edmiston et al., 2018). However, an important consideration is the human colon. The rectosigmoid colon has over 600 species of bacteria and colony counts approaching 10^{12} (Fry, 2013; Gabasan, 2014). These bacteria include both gram-negative and gram-positive microorganisms and with entry into the colon to be inevitable thereby increases the risk of contamination to the surgical site and abdominal cavity to millions of microbes (Fry, 2013). Common organisms encounter in colon procedures include *Escherichia coli*, *Bacteroides fragilis*, *Staphyloccous aureus, Klebsiella pneumoniae*, and *Enterobacter species (*Fry, 2913; Tserenpuntsag et al., 2014). The virulence of the microorganism is another important factor in the development of a colon SSI (Fry, 2013). With certain strains of bacteria having inherit characteristics of drug resistance and endotoxin-producing capabilities they are more difficult to treat and host defenses are weakened (Fry, 2013). Environmental factors also play a significant role in the development of a colon SSI therefore actually decreasing the number of bacteria needed to cause an SSI (Fry, 2013).

Rates of Colon Surgical Site Infections

Infection rates associated with colon surgical procedures have been noted to be higher than among other types of surgical procedures. SSI rates associated with elective colon procedures range from four to 20% and have been identified as an independent predictor for mortality in surgical patients (Fry, 2013; Hewitt et al., 2017; Hübner et al., 2011; Keenan et al., 2014). These increasing infection rates have been associated with varying risk factors both modifiable and nonmodifiable include obesity, age, wound class, smoking, length of the surgery, and male sex (Hübner et al., 2011; Tserenpuntsag et al., 2014; Young et al., 2012). Colon SSIs are often associated with prolonged hospitalization, readmissions to the hospital for continued care, and reoperation (Fry, 2013). Therefore, identifying the increasing costs associated with the acquisition and treatment of infection in addition to associated patient morbidity (Fry, 2013). Quality improvement activities targeting the reduction of colon SSIs have increased (Keenan et al., 2014). However, while there is increasing attention surrounding the awareness of colon SSIs more work needed to improve understanding surrounding the risks of infection.

Surveillance for Colon Surgical Site Infections

Understanding the risk factors associated with colon SSIs will help inform public health leaders, targeted areas for research, and clinical providers are driving infection prevention strategies for the reduction of colon SSIs (Tserenpuntsag et al., 2014). To better inform these key stakeholders of the occurrence of colon SSIs and risk factors contributing to the development of these events, CDC launched NHSN, formerly known as the National Nosocomial Infections Surveillance System (NNIS) in 1970. NHSN serves as a portal for hospitals to conduct surveillance for HAIs, providing standard definitions for the detection of HAIs (CDC, n.d.). In addition, NHSN became a system used for benchmarking against other hospitals for performance and quality improvements and a system used to measure progress with implemented prevention efforts (CDC, n.d.; Tserenpuntsag et al., 2014).

In 2012, CMS implemented mandatory reporting for colon SSIs to better understand the rate at which these infections were occurring. NHSN served as the portal for data and process measure entry as a result of this new mandatory reporting requirement (Gabasan, 2014). For colon surgical site infections, NHSN collects data on American Society of Anesthesiologists (ASA) score, wound classification, duration of the procedure, age, type of anesthesia, hospital size and type (i.e., medical school affiliation), body mass index, and diabetes (Tserenpuntsag et al., 2014). Risk factor data is used to conduct a risk adjustment for the development of a colon SSI and to better direct infection prevention strategies (Tserenpuntsag et al., 2014). Beginning in 2014, the acquisition of a colon SSI became linked to hospital reimbursement as a part of pay for performance (Young et al., 2012). For the first time, hospitals would receive incentives and penalties based on the outcome of patient care (Young et al., 2012). However, this method was disputed by some researchers, indicating that NHSN's model for risk adjustment did not take into consideration additional variables to reporting, therefore, making the risk factors and rates for colon SSI inaccurate and falsely penalizing hospitals and providers (Young et al., 2012). Fry also disputes the ability to compare rates across different hospitals due to inconsistencies in surveillance programs, and the diverse populations and risk profiles the hospitals serve (2013). However, NHSN's risk adjustment model places patients into four distinct risk tiers in an attempt to compare rates across hospitals and for benchmarking as a part of performance improvement (Fry, 2013).

Signs and Symptoms

A key strategy for the prevention of colon SSIs is surveillance (Fry, 2013). This surveillance is generally conducted through an infection prevention program, where one of the main components is surveillance for HAIs. As a part of colon SSI surveillance, NHSN has provided standardized definitions which allows for objective surveillance for the monitoring of SSIs. By following a standardized definition, objective decisions can be made in identifying trends and clusters in SSIs, while also determining where gaps in infection prevention may be occurring (Fry, 2013). For clinical detection of a colon SSI, pus at the incision site is often an indication that an infection has occurred, additional signs and symptoms may include wound dehiscence, erythema, or a positive wound culture (Fry, 2013).

Sequelae of Colon Surgical Site Infections

The development of a colon SSI has been associated with an increase in hospitalization length of stay, increasing costs, 30-day reoperations, morbidity, and a mortality rate of three percent (Hewitt et al., 2016; Huber et al., 2011; Keenan et al., 2014; Martin et al., 2015). Hospitalization days increase by an average of 10 days with two to three folds increase in costs (Hubner et al., 2011). These impacts on care outcomes have been recognized by federal and state leaders with an emphasis being placed on driving quality care.

Risk Factors Associated With Colon Surgical Site Infections

Both modifiable and nonmodifiable risk factors have been found to be associated with colon SSIs. When conducting the literature review focus was on tobacco use, age, and gender. However, interestingly another emerging variable related to the risk for colon SSI was identified, that being obesity. Risk factors associated with increased rates of colon SSI include tobacco use, obesity, age, and gender (Fry 2013, 2016; Gabasan, 2014; Huber et al., 2011; Keenan et al., 2014; Pasam, Esemuede, Lee-Kong & Kiran, 2015; Tserenpuntsag et al., 2014; Young et al., 2012;). These risk factors were deemed important to evaluate the potential public health implication on population health, potentially requiring targeted interventions for the reduction of colon SSIs. Therefore, the following risk factors have been selected as confounders for the research to evaluate their association with maintaining perioperative normothermia and colon SSI outcome.

Tobacco use. Chronic tobacco use has been seen as an intrinsic patient risk factor for the development of an SSI after a colon procedure (Fry, 2016). Additionally, research conducted by Pasam et al (2015) found tobacco use was associated with an increased risk of SSI in patient undergoing colorectal procedures. Recommendations have been made to institute a tobacco cessation program within 30 days of a surgical procedure for prevention of infection (Anderson, 2014).

Obesity. Obesity alone is a significant public health issue and has been associated with an increased risk for HAIs, including surgical site infections (Trivedi, Bavishi, & Jean, 2015). Furthering the public health concern, obesity has also been identified as a modifiable risk factor associated with increasing risk, up to 50%, for the development of a colon SSI despite the depth of infection (i.e., superficial, deep, or organ space) (Tserenpuntsag et al., 2014). It has been suggested that patients with a high BMI (>30 equals obese) have delayed wound healing due to poor vascularization of thicker adipose tissue (Pasam et al., 2015; Tserenpuntsag et al., 2014). In addition, obesity in colon surgical patients has been seen to have a greater risk for wound dehiscence, intra-abdominal infections, and anastomotic leaks (Gabasan, 2014). Understanding that colon surgical procedures are associated with a higher risk for SSI there is a plausible risk that patients who are obese are expected to be at a greater risk for development of an SSI (Pasam et al., 2015). Pasam et al (2015) conducted a multivariable analysis of risk factors associated with SSI in patients undergoing colorectal surgery, finding patients with a BMI > 30 kg.m2 was associated with an increased risk for SSI. A study conducted on over 7,000 patients who underwent a colon procedure found that obese patients had a colon SSI rate of 14.5% (Gabasan, 2014; Wick et al., 2011). However, while obesity is seen as a risk factor, interestingly patients with recent weight loss were also noted to have a greater chance of developing a colon SSI (Fry, 2013).

Gender. Nonmodifiable risk factors such as gender has been significantly associated with an increased risk factor for the development of an SSI. Patients of male sex have been identified as up to 42 percent more likely than females to develop a colon SSI (Tserenpuntsag et al., 2014). Other studies have also demonstrated that male sex is a risk factor for a colon SSI (Hubner et al., 2014; Pasam et al., 2015; Young et al., 2014).

Age. The idea that age is an independent risk for an SSI because of the potential for additional comorbid conditions has been noted (Young et al., 2014). However, increasing age as a risk factor for the development of a colon SSI comes with mixed results. Studies have found that increasing age is an important risk factor for the development of a colon SSI (Huber et al., 2011; Young et al., 2014). However, Tserenpuntsag et al. (2014) found that increasing age (>75) was not a risk for colon SSI; however, those less than or equal to 75 years of age was associated with the development of an SSI (*OR* 1.15). Young et al. (2014) also found that decreasing age was an important risk factor for the development of an SSI with risk increasing with each 10-year increment. That is, a 25-year-old has a higher risk of developing a colon SSI than that of an 85-year-old (Young et al., 2014).

Prevention Strategies for Colon Surgical Site Infections

As previously noted, a key element to the prevention of colon SSIs is conducting active surveillance for infections, in addition to other core components of IPC programs to include education and training of healthcare workers where deficiencies are identified. Ensuring a sterile environment during the operative procedure is also important. These practices consist of the proper preprocedures setting up the sterile field, sterilization, and disinfection of surgical instruments, HCW hand antisepsis, and surgical attire. With the increasing attention surrounding preventing colon SSIs, many hospitals have looked to the development of prevention bundles to reduce rates of infection. These bundles include various evidence-based practices to include antibiotic prophylaxis, dosing, and timing; preoperative skin prep with antiseptic bath; patient warming; closure techniques; appropriate hair removal at the surgical site; and intraoperative normothermia (i.e., core body temperature at $>36^{O}C$). Surgical care bundles promote standardization using practices that are supported by the quality of evidence (Hewitt et al., 2016). The implementation of surgical bundles has demonstrated significant decreases in rates of colon SSIs (Cima et al., 2013; Hewitt et al., 2016).

Role of Perioperative Normothermia as a Prevention Strategy

The role of hypothermia as a prevention strategy comes with mixed results. Mild changes in a patient's core body temperature and the development of hypothermia can result in vasoconstriction and hypoxia which can impact wound health and the subsequent development of an SSI (Anderson et al., 2014; HRET, 2018). Some studies have found that hypothermia has been associated with an increased risk for an SSI (Anderson et al., 2015; Fry 2016). Rates of infections in patients who were allowed to become hypothermic have been seen as high as 19% compared to those who were normothermic (6%) (Fry, 2016). Active warming during colon surgery (intraoperative) has been associated with a reduction in risk for SSI (Lehtimen et al., 2010). Studies had demonstrated that patients who underwent select abdominal procedures were seen to have a lower infection rate when body temperature was maintained at or above 35.5°C (Anderson et al., 2014). Additional studies have also challenged the value in maintaining normothermia as a prevention strategy for a reduction in colon SSIs (Fry, 2016). Research by Lehtinen et al. (2010) found that maintaining normothermia had limited value in preventing SSIs after gastrointestinal surgery (Fry, 2016). However, it is important to note that Lehtinen et al. (2010) did not include preoperative as a phase to collect body temperature in the perioperative timeline. Temperatures were recorded intraoperatively and postoperatively.

The role of preoperative normothermia has been identified as a single strategy associated with the reduction of colon SSI (Kiernan et al., 2016). Intraoperative normothermia has also been a standard recommended practice in surgical procedures

(Anderson et al., 2014). Through the literature review, the role of perioperative normothermia, normothermia throughout all phases of operative care (i.e., preoperative, intraoperative, and postoperative), was not identified as a single intervention evaluated for the reduction of colon SSIs.

Conclusions

HAIs are a significant threat to public health and are associated with increased patient morbidity, mortality, and an economic burden to the health care system as a whole. SSIs are the single most common HAI, representing roughly 30% of all HAIs. Among SSIs, colon procedures are significantly associated with higher rates of SSI. Public health leaders have implemented measures targeting prevention of colon SSI to include implementation of recommended practices, public reporting, and tying pay for performance to drive improved patient outcomes. However, despite these added requirements, SSIs remain to occur.

Risk factors for colon SSIs have been well described in the literature to include both modifiable and nonmodifiable risks. As such, these risk factors should be considered in targeted prevention activities to promote improved patient outcomes. Better understanding of these risks may inform public health leaders on additional areas for research. In addition, surgical care bundles have also been documented to improve patient outcomes. These bundles include antibiotic prescribing, timing, dosing, surgical skin preparation, normal glycemic control, and normothermia. However, there is limited knowledge on the extent of the role that maintaining normothermia through all phases of operative care has on the prevention of colon SSIs. Perioperative normothermia being all phases of operative care (i.e. preoperative, intraoperative, and postoperative).

This study proposes to evaluate if maintaining perioperative normothermia is an effective prevention strategy for colon surgical procedures. In addition, the study will address whether additional confounding variables such as age, gender, tobacco use, and obesity should also be considered for targeted prevention strategies. As a result, informing public health leaders and medical providers of best practices for the prevention of colon surgical site infections.

Chapter 3: Research Method

Introduction

HAIs are a significant public health threat (Magill, Dumyati, Ray, & Franklin, 2015). Although there have been substantial reductions in the occurrence of HAIs (Magill et al., 2018), continued efforts are needed to understand the epidemiology and targeted strategies for prevention. The purpose of this research was to improve understanding of the epidemiology of colon SSIs, which are common HAIs with a notable increased risk for morbidity, and the role of perioperative normothermia as a prevention strategy, with normothermia defined as maintaining a minimum core body temperature of 36^{o}F. An additional goal of this research was to identify risks associated with the development of colon SSIs. Identifying risks associated with colon SSIs may inform stakeholders of targeted areas needing further intervention for reductions in morbidity and mortality.

In this chapter, the overall study is described, including the research design and the rationale for its selection. The data analysis plan is reviewed, along with the study population and the sample size required. Results of the power analysis used to determine an adequate sample size for statistical analysis are also included. The procedures for the collection and acquisition of data are discussed, including the recruiting strategy and a description of the demographics of the health care facility that collected the data. The NHSN surveillance system and definitions are described to establish an understanding of the designation of colon SSI as well as a description of the independent and dependent variables. Lastly, any ethical considerations are reviewed.

Research Design

This quantitative, retrospective, cross-sectional research study was conducted using secondary data. This design was identified to be the most appropriate to explore the relationship between perioperative normothermia and colon SSIs. Colon surgical patients with a known outcome of an SSI and patients without the development of an SSI were considered to determine which subjects to evaluate the exposure (perioperative normothermia, age, gender, tobacco use, obesity) and outcomes (colon SSI). This design choice was supported by prior research conducted to advance knowledge of providers and stakeholders on recommended colon SSI prevention strategies. A cross-sectional study was performed by Fan et al. (2016) to evaluate the culture of safety within an organization and its association with SSIs. Rumberger et al. (2016) conducted a retrospective study to evaluate the outcomes of patients undergoing elective colorectal surgery after adopting a colorectal care bundle intended to prevent SSIs from occurring. The selected research design and the use of secondary data should have limited potential constraints associated with time or available resources, as the data were stored within an existing surveillance database.

Study Variables

The variables for this research study included colon SSI (dependent variable), perioperative normothermia (independent variable), and covariates including age, gender, obesity, and tobacco use. To calculate obesity, body mass index (BMI) was determined using data for height and weight. To determine perioperative normothermia, recorded body temperatures during all phases of operative care (preoperative, intraoperative, postoperative) were reviewed. From the literature review, the identified covariates were illustrated as risk factors associated with SSIs. It was essential that these risks were analyzed to determine if each confounded the relationship between maintaining perioperative normothermia and the development of a colon SSI.

Data Sources

Targeted, disease-specific surveillance data were obtained for the reportable HAI metric, colon SSI, via the hospitals' infection prevention program SSI data, which were used for public reporting through NHSN surveillance system and the facility infection control program (ICP) for surveillance purposes (Figure 2). It is important to note that access to NHSN was not requested or utilized. Under the CMS IQR program, colon SSIs are nationally reportable HAIs. Since 2011, hospitals seeking payment and reimbursement for provided services have been required to report select HAI events. Furthermore, hospital ICPs conduct internal surveillance to establish trends and best practices for the reduction in HAIs that are associated with high rates of infection. To facilitate surveillance priorities, ICPs develop annual infection control risk assessments to identify targeted disease- and procedure-specific events to monitor for performance improvement. Available data sources included medical record abstraction of variable data (e.g., core body temperature, obesity (height/weight), age, gender, tobacco use) through the EMR system, surveillance tracking reports, and logs, or clinical surveillance programs used by ICPs for the tracking and trending of HAIs (e.g., THERADOC ®). Patients entered into EMRs are assigned medical record numbers (MRNs), which are used as identifiers for patients within EMRs and link to patients' hospital encounters for which care was provided. These data sources and the flow of information support the overall surveillance program and reporting of colon SSI events.

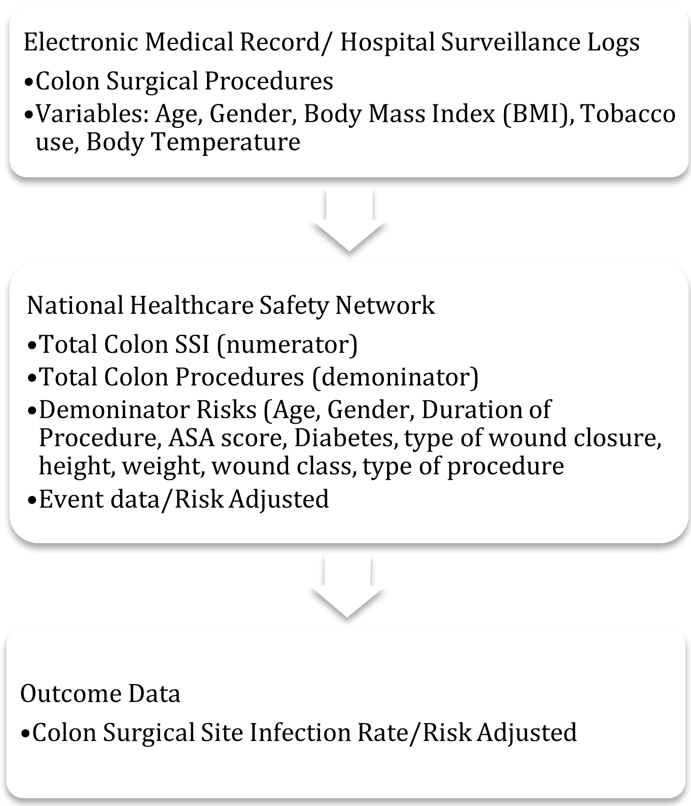

Figure 2. Overview of data acquisition.

Electronic Medical Record Data

As a result of inpatient quality programs and a push to drive technology for quality improvement, hospitals in the United States have made significant advancements with the implementation of electronic medical recordkeeping (Rizer, Kaufmann, Sieck, Hefner, & McAlearney, 2015). Using EMR systems, healthcare facilities can gather and store data on patients' medical history and the delivery of care. The information stored within a patient's EMR allows for continuity of care across the hospital organization or health care system. As a part of the EMR, a patient's complete course of care is documented and available for immediate reference by the healthcare provider to guide medical treatment. The information in the EMR may also be referenced at a later date as archival data containing patient medical history. EMRs include assigned MRNs, patient demographics, comprehensive information on surgical and medical care, physician services, tracking of vital signs, and documented procedures for monitoring of patient care, in addition to routine and procedure-specific progress, operative, and nursing care notes.

Significant challenges have been associated with the implementation of EMRs, including resistance to practice change, induction of new documentation errors, and loss of productivity (Rizer et al., 2015). Despite these barriers, there is an opportunity for the advancement of clinical patient care with the ability to aggregate patient care information to identify trends in care over time for performance improvement initiatives. Patient care information recorded in a patient's medical record, including demographics such as age and gender, can be easily abstracted using the patient’s MRN. Furthermore, additional risk factors, patient care procedures, and processes during operative procedures may be recorded and easily summarized. Within EMRs, data on patient risk factors such as tobacco use, height and weight for calculation of BMI, and recorded body temperatures are readily available.

National Healthcare Safety Network Data

The NHSN is the most widely used surveillance program for the tracking of HAIs (CDC, 2019). To date, over 17,000 healthcare facilities have built in the use of the NHSN surveillance system as a part of their infection prevention strategy for the tracking of HAI events (CDC, 2019). As a component of the CMS hospital IQR, hospitals began using the NHSN as the reporting mechanism for HAI events. Hospital infection preventionists can use NHSN data to compare facility-level data with national data for performance improvement activities (CDC, 2019).

HAI data are also obtainable at regional, state, and national levels to provide public health leaders and key stakeholders with information identifying where issues with HAIs are occurring, while also indicating progress with implemented improvement strategies (CDC, 2019). Information from the NHSN is broken into several components, one of which contains specific guidance for acute care hospitals concerning HAI events. Within the NHSN patient safety component, there is a procedure-associated module with surveillance guidance for the detection of HAIs, including SSIs (Figure 3).

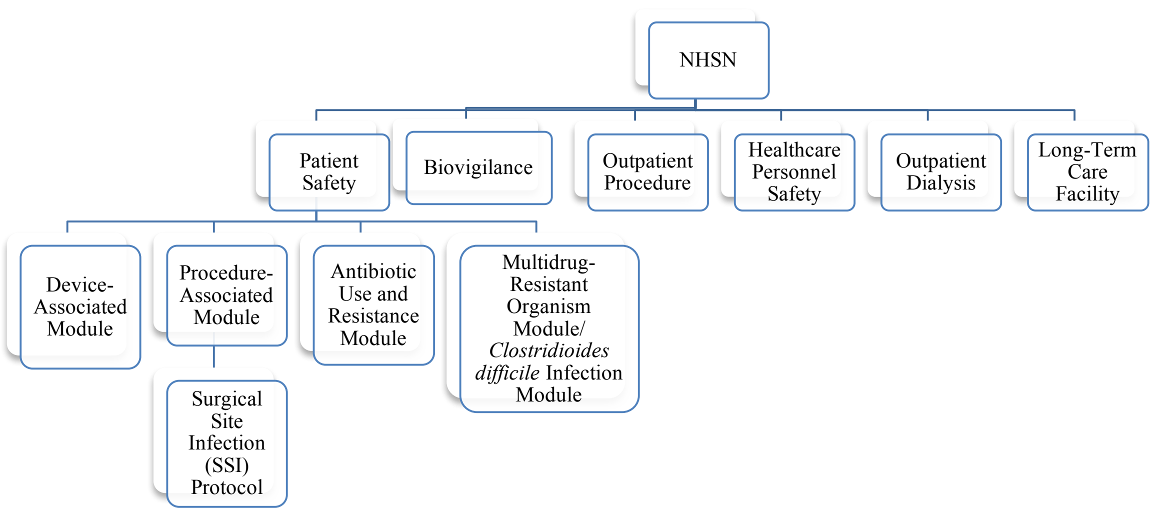

Figure 3. National Healthcare Safety Network (NHSN) patient safety component overview.

Procedure-associated module (surgical site infections). Within the procedure-associated module, there is guidance for conducting NHSN surveillance for SSIs. By providing concrete surveillance definitions for SSI events, hospital surveillance programs can detect and respond to infections, as well as prevent them from occurring. Successful surveillance programs incorporate the use of epidemiologically based definitions for the detection of infectious diseases and use this information to identify risk factors associated with the development of disease processes (CDC, 2019; Haley et al., 1985). NHSN surveillance definitions provide a standard for conducting SSI surveillance and support hospital-based surveillance programs by providing feedback on surgical data to surgeons, hospital leaders, and key stakeholders as a means to reduce SSIs (Berríos-Torres et al., 2017; CDC, 2019; Delgado-Rodríguez et al., 2001; Haley et al., 1985).

In combination with the SSI surveillance definition (Figure 1), SSI surveillance requires active, prospective, patient-based monitoring using methods such review of patient medical records that include admission, operative, microbiology, and radiological test reports (CDC, 2019). The procedure-associated module for SSIs provides concrete guidance for the abstraction of patient surgical data that is required for the input of information to support an effective surveillance program and to provide risk-stratified SSI rates. Guidance on identifying the surveillance period, infection window, event date, and risk factors (e.g., wound class, wound closure, prior infection, ASA score, length of the procedure, height, weight, diabetes, type of anesthesia, emergent procedure) is defined within the protocol. This information is required for submission of the numerator and denominator events into NHSN for risk stratification of SSI event outcome data.

The SSI surveillance definition divides SSIs into three types: superficial, deep, and organ-space. Clear criteria are provided for the classification of infections within these types (Figure 1). When conducting surveillance for colon procedures, the principal operative procedure category is COLO, therefore including procedure codes that fall into this specific category. The reviewer must ensure that the operative code is appropriately classified as a COLO procedure should an SSI be detected to provide for accurate surveillance and reporting. The surveillance period for colon surgical procedures is 30 days. Colon procedures (COLO) are also identified as Priority Level 2, indicating a higher risk of SSI; therefore, if an organ-space infection is detected at multiple sites, the category with the highest risk would be reported into NHSN.

Data analysis using NHSN SSI surveillance. The standardized infection ratio (SIR) is a summary measure used to track SSIs over a period of time by adjusting for both facility- and patient-level risk factors (CDC, 2018b). The SIR is calculated by dividing the number of observed infections by the number of predicted infections (Figure 4).

$$\text{SIR} = \frac{\text{Observed (O) HAIs}}{\text{Predicted (P) HAIs}}$$

Figure 4. Standard infection ratio (SIR) calculation.

The number of predicted (expected) infections is calculated using multivariable regression models gathered from national data collected during benchmark periods (e.g., 2015 re-baseline period data; CDC, 2018). In simpler terms, an SIR > 1 indicates that more infections were observed than predicted, and an SIR < 1 indicates that fewer infections were observed than predicted. An SIR = 1 indicates that the same number of infections predicted were also observed. It is important to know that the SIR is only calculated if the number of predicted infections is at least 1.0 (CDC, 2018b). The *p*-value measure illustrates whether the number of observed infections is statistically significantly different (e.g., $p \leq 0.05$) than the number of predicted infections and is calculated using the mid-P exact test (CDC, 2018b).

It is also important to mention the requirements for the use of the NHSN procedure-associated module. These requirements include the following:

1. Surveillance is conducted following the NHSN operative procedure codes, the International Statistical Classification of Diseases and Related Health Problems (ICD-10-PCS), and/or current procedural terminology (CPT) as defined by the facility's monthly reporting plan.
2. SSI event numerator and operative procedure category denominator data are collected and reported within the facility's monthly reporting plan.
3. The infection event meets the NHSN surveillance definition for an SSI (CDC, 2019).

ICP-10 and CPT codes are used for diagnosing and coding purposes for provider and hospital reimbursement. Hospitals use operative procedure codes for uniformity in reporting of procedures. Additionally, the NHSN requires the use of operative procedure coding to standardize the reporting of SSI surveillance (CDC, 2019). Ensuring that an operative procedure falls within the NHSN operative procedure code provides a safeguard that the procedure category meets criteria for a surveillance event for that procedure and protects against threats to the validity of the data that are used for risk stratification.

Defining an NHSN operative procedure. The NHSN has clearly defined criteria for an operative procedure. Meeting operative procedure criteria is essential for SSI surveillance to be performed in a standardized manner (CDC, 2019). The criteria are as follows:

1. The operative procedure code must be part of the operative category.
2. At least one surgical incision must be made (e.g., laparoscopically) into the skin or mucous membrane or via re-operative procedure through a previously made incision that was left open.
3. The procedure must take place in an operating room (OR) as defined by the American Institute of Architects (AIA) or Facilities' Guidelines Institutes (FGI). (CDC, 2019).

Outcome Data

Surveillance of HAIs is an integral element of a hospital's infection prevention program. The use of targeted HAI surveillance data, particularly colon SSI data, can be important in identifying process measures and areas needing additional focus or intervention. Just as with NHSN data, a hospital infection preventionist can use surveillance data to establish colon SSI rates and set benchmarks for performance improvement. Since NHSN's incorporation of risk-adjusted SIRs, hospital infection preventionists have continued to internally report hospital-based SSI rates for comparison and trending identifying an increase or decrease in infection rates. SSI rates can be calculated by dividing the number of SSIs (procedure-specific) by the number of procedures performed and multiplying by 100; this calculation provides the number of SSIs per 100 operative procedures (Figure 5).

$$\text{SSI rate per 100 operative procedures} = \frac{\text{Number of Colon SSIs}}{\text{Total number of colon procedures}} * 100$$

Figure 5. Calculating colon SSI rate.

While NHSN has become the gold standard for conducting hospital-based surveillance for HAIs and is also required for CMS IQR, it is vital to understand additional potential sources of data. Therefore, recognizing that outcome data (whether or not an infection occurred) for colon SSIs is also available through hospital infection prevention programs on the basis that the same information is needed for reporting into NHSN as a part of CMS IQR.

Research Questions and Hypotheses

The research questions developed for this study were established to identify whether a relationship exists between maintaining perioperative normothermia and patients who develop or do not develop a colon SSI after undergoing a colon operative procedure. Supplementary research questions were established to inform if additional risk factors confound the relationship between perioperative normothermia and development of a colon SSI. These research questions were developed to advise public health leaders and health care providers of any associated risks with the development of colon SSIs for performance improvement. Furthermore, to reduce the morbidity, mortality, and increases in healthcare costs associated with the development of colon SSIs. The research questions are stated below.

1. Is there an association between perioperative normothermia and colon surgical site infections?

   Null hypothesis (H_0): There is no statistically significant association between perioperative normothermia and colon surgical site infections.

   Alternative hypothesis (H_A): There is a statistically significant association between perioperative normothermia and colon surgical site infections.

2. Is the association between perioperative normothermia and colon surgical site infections confounded by tobacco smoking?

   Null hypothesis (H_0): The relationship between perioperative normothermia and colon surgical site infections is not confounded by the effect of tobacco smoking.

   Alternative hypothesis (H_A): The relationship between perioperative normothermia and colon surgical site infections is confounded by the effect of tobacco smoking.

3. Is the association between perioperative normothermia and colon surgical site infections confounded by age?

   Null hypothesis (H_0): The relationship between perioperative normothermia and colon surgical site infections is not confounded by age.

   Alternative hypothesis (H_A): The relationship between perioperative normothermia and colon surgical site infections is confounded by age.

4. Is the association between perioperative normothermia and colon surgical site infections confounded by gender?

   Null hypothesis (H_0): The relationship between perioperative normothermia and colon surgical site infections is not confounded by gender.

   Alternative hypothesis (H_A): The relationship between perioperative normothermia and colon surgical site infections is confounded by gender.

5. Is the association between perioperative normothermia and colon surgical site infections confounded by obesity?

   Null hypothesis (H_0): The relationship between perioperative normothermia and colon surgical site infections is not confounded by obesity.

   Alternative hypothesis (H_A): The relationship between perioperative normothermia and colon surgical site infections is confounded by obesity.

Sampling Design

Due to the number of colon surgical procedures performed at this hospital during 2018 it was determined that participants for this research study would sampled among the noncolon SSI group using a simple random sampling method. However, due to the limited number of patients who developed a colon SSI during the designated timeframe (e.g., 2018 surgical data) all cases were used in order to obtain the minimum number of participants and to meet the eligibility criteria were included in the study. Study participants include those observed during the surveillance period. To further define the study groups, the outcomes of patients who have perioperative normothermia maintained will be compared to the outcomes of patients who did not have perioperative normothermia maintained. Because this is not a data validation study, it must be assumed that the colon SSI surveillance event has been adequately applied to identifying patients as having met criteria for a colon SSI or not meeting criteria.

Population

Study participants for this research study will include all eligible surgical patients at a private not-for-profit hospital located in West Central Florida situated. The hospital services over 12 counties with a combined population of over 4 million. The hospital is a 1,011-bed level one trauma center and medical teaching facility. Based on the facility's community health needs assessment report obtained from the Carnahan Group report, utilizing county demographics, the population which the hospital services are representative of a culturally and financially diverse group with an anticipated growth (22.3%) in the population of adults aged 65 and older by the year 2020. Based on available data, in Q1 of 2018, the facility performed 89 colon procedures. According to the hospital profile for the study site on the CMS website and upon review of the IQR compare care review site, the hospital reported a total of 387 colon procedures over four rolling quarters.

Eligibility Criteria

Study participants for this research included 1) adult surgical patients, defined as >18 years of age, 2) who had an identified colon (COLO) surgical procedure as determined by the ICD-10-PCS and/or CPT NHSN operative procedure code for colon procedures 3) and the operative procedure was performed at a large tertiary academic level 1 trauma medical facility in West Central Florida. The adult population was selected to ensure control for consistency in exposures to operative procedures to the best extent possible. Surgical procedures must have been completed within an operative room. Only adult surgical patients were desired as study participants, recognizing that varying infection prevention surgical bundles may be used for the pediatric patient population compared to adult surgical patients. Additionally, only colon procedures in the COLO ICD-10-PCS or CPT will be used, again for consistency with the surveillance practices and reporting of the numerator and denominator data in the NHSN. Any surgical procedures that are classified as a wound class III or IV were originally planned to be excluded from the study population. In addition, any surgical procedures that were deemed urgent or emergent were also to be excluded. It has been acknowledged that surgical procedures with a higher wound class (III or IV) run a higher risk of developing an infection or have more complex SSIs (Muratore et al., 2016) or already being infected (wound class IV). In addition, urgent or emergent procedures are independently associated with worse outcomes (Lubitz et al., 2017). Therefore, these procedures were not originally planned to be included in the study, however due to case coding by the physicians for these procedures to always be a minimum of wound class II it was decided to include all wound classes in the study population. A colon SSI was defined by the NHSN surveillance definition (Figure 1). Thus, those patients that do not meet the surveillance definition for an SSI will be identified as not having developed an SSI.

Appropriate number of participants. Turning to prior research to establish estimates on sample size found that the average sample size ranging from 296 patients over four years, 393 during a 12-month period and 66 over a six-month period. Prior statistical power conducted in prior research found an adequate sample size of 44 with an effect size of 0.83 (Nicholson, 2013). G*Power 3.1 was utilized to establish the adequate sample size for this research study. Upon review of previous literature, a power level of 0.80, an alpha level of 0.05, with an effect size of 0.83 was utilized. With these input parameters, the sample size of Group 1 is 24, and the sample size of Group 2 is 24, for a total sample size needed of 48 (Figure 6). In understanding the hospital conducted 89 colon procedures in Q1 of 2018, it is anticipated there will be an adequate sample size utilizing all eligible surgical patients who underwent a COLO surgical procedure in 2018.

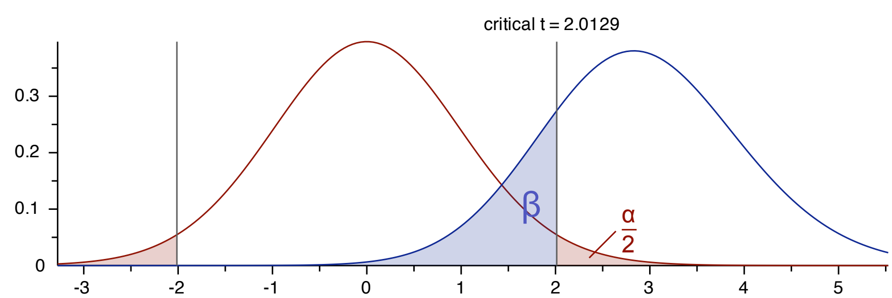

Figure 6. G Power sample size calculation.

Data Collection

For this research study, secondary data was utilized. Due to the requirements of public reporting for CMS IQR, the identified acute care hospital already collects the required data for this research study for purposes of mandatory public reporting and internal performance improvement. Because of reporting requirements extending back to

2011, the required variable data will be available for the time period needed to conduct the research. Both SSI surveillance data and facility EMR data will be accessible through the hospital's collected data as a part of the infection prevention surveillance program. The patient's MRN was used to link the patient's hospital record for which the surgical procedure was performed to collect the variables of interest (e.g., age, gender, obesity, tobacco use, perioperative normothermia).

To gain access to this data, a request was submitted through the Office of Clinical Research (OCR) at the acute care hospital. A research study proposal form (Appendix A) and the credentialing application (Appendix B) was completed for review and consideration. The proposed research study was also reviewed by the facility, and a separate Institutional Review Board (IRB) approval was required. The research was not allowed until the project was approved and both the facility-specific IRB and Walden University IRB were granted. Once approval was granted, it was determined that informed consent was not needed or anticipated since only secondary data was to be used and there was no patient contact.

After obtaining IRB approval from Walden University (Walden IRB approval number 06-04-19-0664975) and approval from the acute care hospital, a line list of colon surgical cases performed during 2018 was requested, along with a listing of patients who developed a surgical site infection for the designated time period to gather the minimum number of patients needed to achieve statistical significance. Data elements included within this source of information included patient MRN, age, gender, height and weight for calculation of BMI, date of surgery, date of admission, operating surgeon, along with additional data needed as a part of NHSN reporting, which removed from the data set as they were not requested or needed. From there, access to the facility EMR was necessary to collect data variables that are not a part of the line list (e.g., recorded body temperature). The patient MRN will be used to review the hospital encounter for the patient in which the surgical procedure was performed to collect additional variable data. Additional data elements to include tobacco use and core temperature recording which is available through the surgical record anesthesiology report.

Operationalization of Variables

Variables for this research study include one dependent variable, one independent variable and several confounding variables (Table 3). It is important to understand that perioperative normothermia is determined on the basis of preoperative, intraoperative, and postoperative normothermia being maintained. Therefore, in order the assess for perioperative normothermia, the variables of preoperative normothermia, intraoperative normothermia, and postoperative normothermia must be included.

To further describe, variables were treated as independent, dependent, and as a covariate based on the intent of the research study and to assess for risks and confounding factors which may be associated with the development of an infection as identified as a result of the literature review. Variables were measured on a nominal-dichotomous or a scale-interval level. For the logistic regression analysis, the scale-interval variables were recoded into new categories.

Table 3

Variables

Variable name	Variable label	Measurement level	Variable type
Age	Baseline age year	Scale-interval	Covariate
Gender	Gender	Nominal-dichotomous	Covariate
Obesity	BMI	Scale-interval	Covariate
Tobacco Use	Use tobacco	Nominal-dichotomous	Covariate
Perioperative normothermia	Normothermia maintained	Nominal-dichotomous	Independent
Preoperative normothermia	Normothermia maintained	Nominal-dichotomous	Covariate
Intraoperative normothermia	Normothermia maintained	Nominal-dichotomous	Covariate
Postoperative normothermia	Normothermia maintained	Nominal-dichotomous	Covariate
Colon SSI	Infection developed	Nominal-dichotomous	Dependent

Analysis of Data

Data was analyzed using IBM SPSS Statistics 25 version 9.6.0.0. A data dictionary is also provided to include the variable name, label, and values (Appendix 3). The output data will be maintained as a part of the data management. As previously discussed the designation of a colon SSI was not be validated as this is not a data validation study. This presumed knowledge of a colon SSI is acceptable as the facility utilizes the NHSN surveillance definition to adequately define without subjectivity if an infection developed post-surgery. The data was cleaned for complete information for each identified variable. For those study participants with any missing data elements, the data sources were reviewed for the availability of variable information. Any missing information or variables not available were to be cleared from the data set, however no missing information was noted.

Multivariate Logistic Regression

Multivariate logistic regression analysis was used for statistical analysis. This analytic strategy applies when the outcome variable (colon SSI) is a dichotomous variable, and there is more than one independent variable. Multivariate logistic regression will examine the odds of a colon SSI occurring when perioperative normothermia is maintained. The odds ratio provided a measure of association between perioperative normothermia and colon SSI. In addition, multiple logistic regression can be utilized to examine the effect of maintaining perioperative normothermia on colon surgical site infections while controlling for age, gender, obesity, and tobacco smoking. It is important to control for the effect of age, gender, obesity, and tobacco smoking as each of these variables have been established as a risk for the development of a surgical site infection.

Data Management

All data was saved in a password protected excel database on a password protected the private computer. Information that is transferred into SPSS will also be maintained in a password protected file. For back up procedures, a separate hard-drive will be used and encrypted ensuring the confidentiality of data. Additionally, the private computer (laptop) and the hard-drive will also be stored in a locked cabinet when not in use. Data files will be saved and backed up on both drives daily. Hard copies of the files will also be maintained and stored in a locked filing cabinet. Patient names will not be retained. The patient MRN will be used as the patient identifier and a unique ID will be reassigned to each record of collected data to ensure patient confidentiality.

Ethical Considerations

This research study consists of secondary data analysis. Therefore, eliminating any direct patient contact and decreasing the potential for any ethical concerns. However, the data collected as a part of this research study required access and review of the surgical patient's medical records. This information includes confidential medical record information that is protected by the Health Insurance Portability and Accountability Act (HIPAA). Colon surgical site infections result in significant morbidity and mortality (Cima et al., 2013). As such, raising the potential for concerns with accessing patient medical records and identifying a lack of adherence to safety practices and identifying risks associated with the development of an SSI. Information conducted from this research study can be used by facility leaders and providers as well as state and federal stakeholders informing them of best practices and risks for development of a colon SSI. Therefore, healthcare providers may have concerns with the disclosure of nonadherence to recommended best practices, which ultimately impact a patient's outcome after surgical procedures. However, it is important to note that patient and provider information will be de-identified and data will be stored in a secure password protected file.

Before the data was requested, collected, or analyzed IRB approval was obtained through the Walden IRB process and the facility ORC study approval process to ensure compliance with all ethical standards.

Summary

The proposed research study intends to establish whether a relationship exists between perioperative normothermia and colon surgical site infections. Therefore, guiding public health leaders and clinical professionals towards implementing elements of best practices as a standard of care and reducing morbidity, mortality, and healthcare costs associated with the development of colon SSIs. To conduct this research study, a quantitative, retrospective case-control research study using secondary data has been proposed. Multivariate logistic regression will be used to examine risk factors and predict the outcome of a colon SSI. Risk factors for analysis and associated variables have been identified to include age, gender, obesity, tobacco use, colon SSI, and perioperative normothermia. After conducting a power analysis, it was determined that the minimally accepted sample size for this research is 48. SPSS software will be used to perform the data analysis.

The next section, Chapter 4, will include the results from the research project. In this chapter results from the study will be described along with the collected data to include the descriptive statistics and statistical analysis from the study findings and tested hypotheses.

Chapter 4: Results

Introduction

The primary purpose of this research study was to establish whether there is a relationship between maintaining perioperative normothermia and colon SSIs. In addition, risk factors including age, gender, obesity, and tobacco usage were analyzed to determine whether certain risk factors confound the relationship between perioperative normothermia and colon SSIs. By improving understanding of the relationship between risk factors and the development of colon SSIs, this study may help to inform public health and health care leaders on potential areas for early intervention. Secondary data from a large Level I Trauma acute care hospital were used to collect the variables of interest consisted of patients who underwent colon surgical procedures during 2018.

To evaluate whether there was a relationship between maintaining perioperative normothermia and colon SSIs, the following research questions and hypotheses were developed:

1. Is there an association between perioperative normothermia and colon surgical site infections?

   Null hypothesis (H_0): There is no statistically significant association between perioperative normothermia and colon surgical site infections.

   Alternative hypothesis (H_A): There is a statistically significant association between perioperative normothermia and colon surgical site infections.

2. Is the association between perioperative normothermia and colon surgical site infections confounded by tobacco smoking?

Null hypothesis (H_0): The relationship between perioperative normothermia and colon surgical site infections is not confounded by the effect of tobacco smoking.

Alternative hypothesis (H_A): The relationship between perioperative normothermia and colon surgical site infections is confounded by the effect of tobacco smoking.

3. Is the association between perioperative normothermia and colon surgical site infections confounded by age?

Null hypothesis (H_0): The relationship between perioperative normothermia and colon surgical site infections is not confounded by age.

Alternative hypothesis (H_A): The relationship between perioperative normothermia and colon surgical site infections is confounded by age.

4. Is the association between perioperative normothermia and colon surgical site infections confounded by gender?

Null hypothesis (H_0): The relationship between perioperative normothermia and colon surgical site infections is not confounded by gender.

Alternative hypothesis (H_A): The relationship between perioperative normothermia and colon surgical site infections is confounded by gender.

5. Is the association between perioperative normothermia and colon surgical site infections confounded by obesity?

Null hypothesis (H_0): The relationship between perioperative normothermia and colon surgical site infections is not confounded by obesity.

Alternative hypothesis (H_A): The relationship between perioperative normothermia and colon surgical site infections is confounded by obesity.

In this chapter, I describe the data collection process, the sample population, and the results, followed by a summary relating the results to the research questions.

Data Collection

As planned, the data used for this analysis were collected from a large Level I Trauma 1,011-bed acute care teaching hospital. The hospital provides care to a large, diverse population. Colon SSI surveillance is an integral component of the hospital's infection prevention program. In addition, the hospital actively conducts surveillance for colon SSIs as a part of the CMS IQR program. As such, data that had already been collected and recorded were available for this analysis. Data were made available via a Microsoft Excel spreadsheet that included the patient MRN, date of procedure, surgical procedure code, date of birth (age), surgical wound class, procedure start and stop time, surgical outcome (e.g., SSI), height and weight (calculated BMI), gender, infection date, days from procedure to infection, and whether infection was present at the time of surgery. Information on tobacco use and core body temperatures were gathered from patients' anesthesia medical records where this information was previously recorded.

Challenges and Discrepancies

After obtaining Walden University IRB approval and executing the hospital's data use agreement, I spent time reviewing the data collected as a part of the infection prevention and patient quality program for colon surgical patients. Data were collected and reviewed over a 1-week period at the hospital. The data set was complete with no missing variables identified. Upon obtaining the data set, I encountered several challenges that were not fully anticipated when planning for the research project and proposed data set. The first unanticipated challenge involved the volume of surgical procedures. It was noted that the hospital performed 422 colon surgical procedures during 2018, for which there were 23 colon SSIs identified (Figure 7).

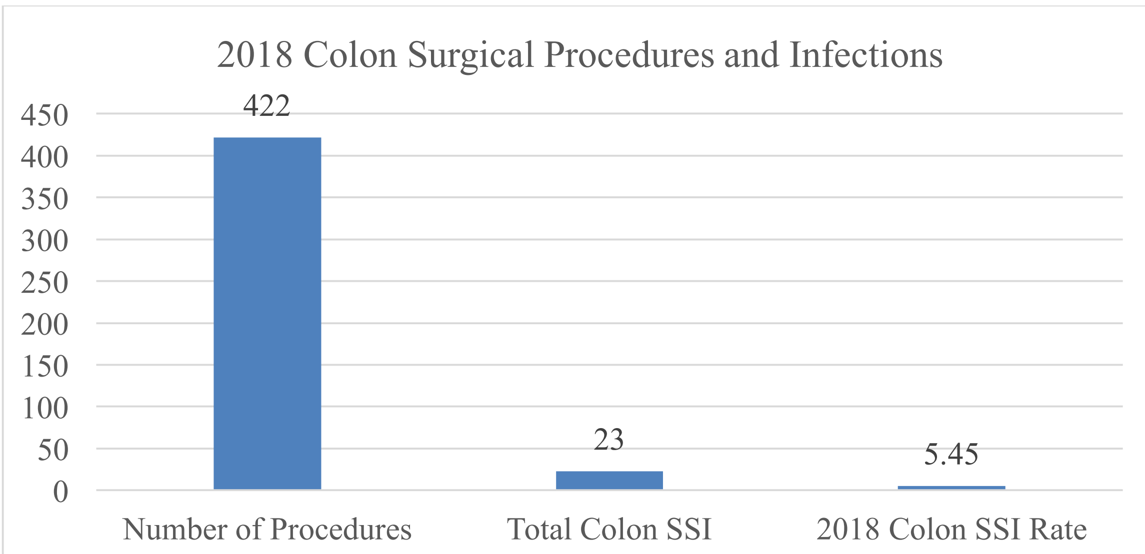

Figure 7. Overview of procedures.

Two issues of concern were identified during the review of data. The first concern involved the volume of procedures performed in 2018. The original research plan was to include all cases performed during 2018 in the analysis; however, understanding that this would not be the best strategy due to the large volume, I determined that simple random sampling would be used to select the 24 cases needed for analysis of noninfected cases. Also of concern was the discovery that there were only 23 infected cases; this number was one case short of the proposed number needed to reach full power, therefore important to understand the result this may have on reaching statistical significance.

After I had reviewed the data and addressed the unexpected challenges, the total population for inclusion in the analysis consisted of 404 surgical procedures. After removing the population 18 years of age and younger, I had a total of 381 cases used for simple random sampling among the noninfected colon surgical procedures, and all 23 colon SSIs were included (Figure 8).

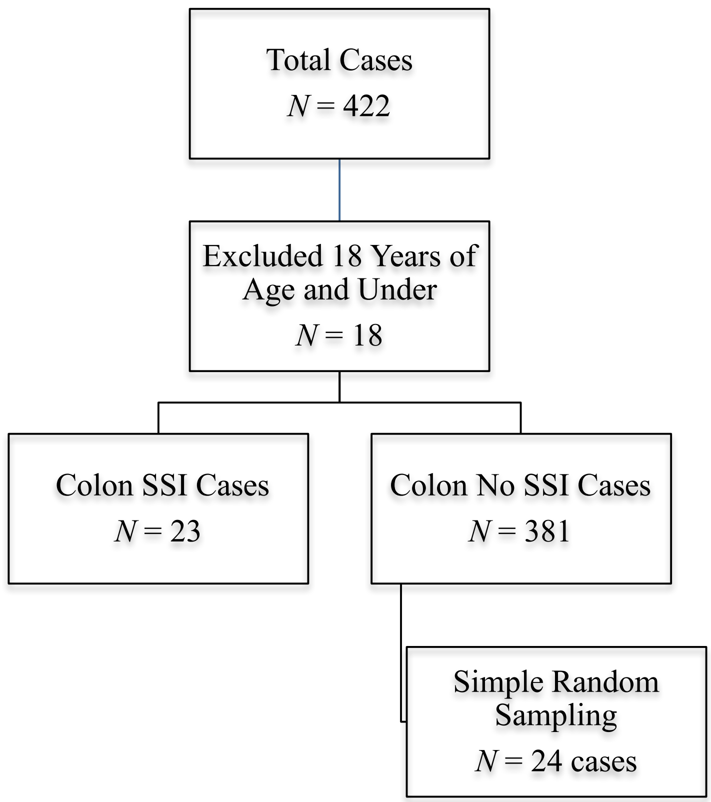

Figure 8. Overview of cases.

An additional finding that raised concern with the proposed data set surrounded the wound class assignment of the surgical cases. Among the 2018 data, all colon surgical procedures performed at this facility were coded with a minimum of a wound class II (clean/contaminated; Figure 9). It was originally proposed to excluded cases with wound classes of III and IV and urgent/emergent cases to help reduce bias with the study findings, as it has been documented that patients with a higher wound class (III or IV) or urgent/emergent procedures have an increased risk for infection and worse outcomes (Lubitz et al., 2017; Muratore et al., 2016).

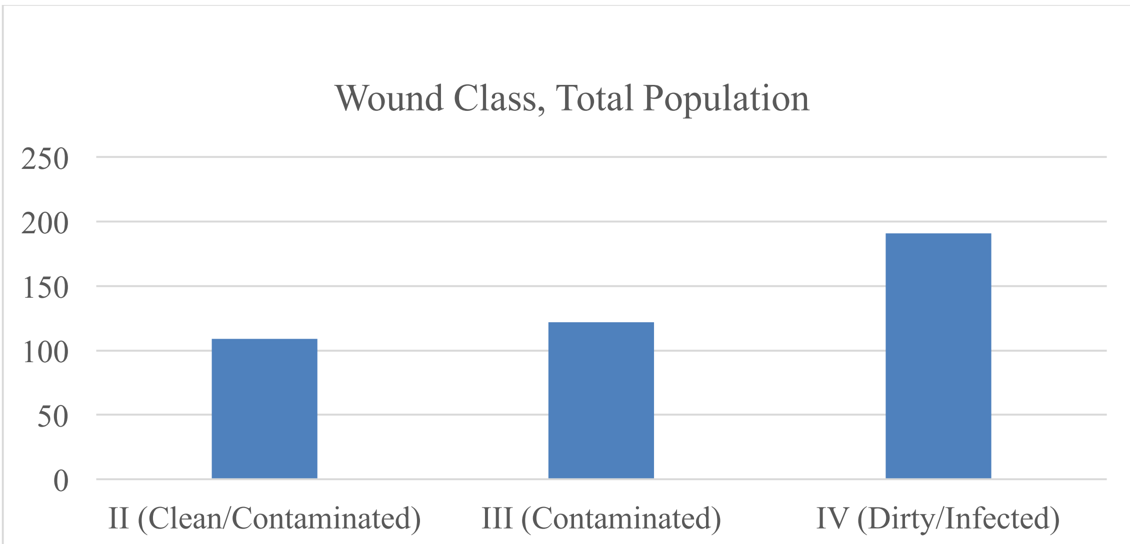

Figure 9. Wound class overview, total population.

Removing the cases with a wound class of III (contaminated) or IV (dirty/infected) would significantly reduce the sample size for both the infected and noninfected cases (Figure 10), not allowing for an adequate sample size (n = 13). Therefore, I determined that I would include all wound classes in the analysis, though understanding that including all wound classes might be a limitation of the study findings.

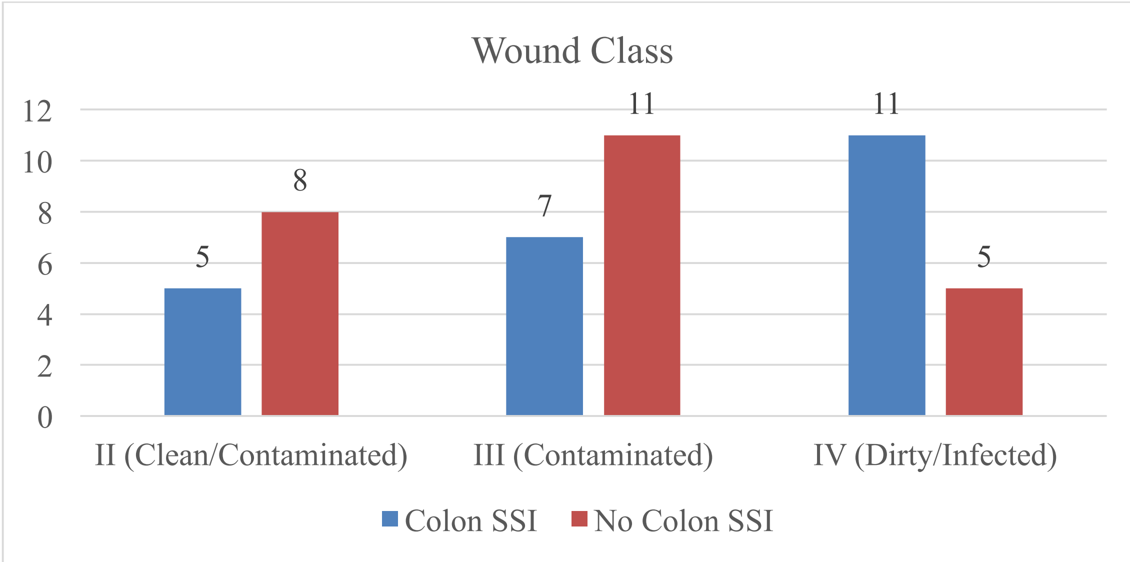

Figure 10. Wound class, study population.

Sample Representation

The sample size used for analysis consisted of 24 noninfected and 23 infected colon SSI cases. The total case count for the noninfected group originated with 381 cases. However, due to the 2018 total population size for the infected group being 23, it was determined that simple random sampling would be used to select 24 cases among the noninfected group. With simple random sampling, each patient in the population had an equal chance of being selected for the noninfected sample group. This method has been an effective way of selecting a sample using nonbiased methods. Using a random numbering system, the noninfected cases were numbered 1-381, and 24 cases were randomly selected using a random number generator. With this method, I anticipated that external validity would be protected and the findings could be generalized to the study population as a whole.

With the findings and changes to the population sample, there were concerns about the potential effect on study power. Despite these challenges, I determined that power would remain at .80, alpha at .05, resulting in a larger effect size. As a result, the findings are interpreted with caution.

Descriptive Epidemiology

As previously discussed, the data and variables of interest were available for all included cases, both infected and noninfected. There was a sample size total of 47 (24 noninfected cases and 23 infected cases). Variables including age, gender, obesity (BMI), tobacco use, perioperative normothermia, and colon SSI were included in the analysis (Table 4). The mean age of the study population was 53.4 years, and the mean BMI was 27.6.

Table 4

Variables

Variable	Level of measurement	Value
Age in years	Scale	Range 26-84; Mean 53.4
Age_Cat	Nominal	1 = 26-39, 2 = 40-84
Sex	Ordinal	1 = Male, 2 = Female
BMI	Scale	Range 18.50-51.80; Mean 27.6
Tobacco use	Nominal	1 = Yes, 0 = No
Perioperative normothermia	Nominal	1 = Yes, 0 = No
Colon surgical site infection	Nominal	1 = Yes, 0 = No

The scale-interval variables were recoded into dichotomous variables (e.g., BMI and age). Age was regrouped into two categories, less than 40 years of age, which included individuals 19-39 years of age (Group 1), and 40 years of age and older (Group

2). BMI was recoded into four new groups, < 18.5 (underweight), 18.5 to 24.9 (normal body weight), 25 to 29.9 (overweight), and above or equal to 30 (obese; Table 5). This recoding also allowed for improved categorical interpretation.

Table 5

BMI Category

Adult body mass index (BMI)
1= < 18.5 = underweight
2 = 18.5 to < 25 = normal
3 = 25 to < 30 = overweight
4 = ≥ 30 = obese

With the variables recoded, the frequencies of the groups could be better evaluated (Table 6). Of the sample population, 32% were considered obese (BMI ≤30), 21% used tobacco, 83% were at least 40 years of age, and 49% had perioperative normothermia maintained. Each hypothesis and the associated variables were tested and analyzed using multiple logistic regression, which allowed for control of confounding variables.

Table 6

Categorical Variables

	Value	Frequency (%)
BMI category	18.5 to 24.9	20 (43%)
	25 to 29.9	12 (25%)
	30-51.80	15 (32%)
Age category	< 40	8 (17%)
	>= 40	39 (83%)
Gender	F	20 (43%)
	M	27 (57%)
Tobacco_Use	No	37 (79%)
	Yes	10 (21%)
Peri_Op_NORM_Maintained	No	23 (49%)
	Yes	24 (51%)
Colon surgical site infection	No	24 (51%)
	Yes	23 (49%)

Association Between Perioperative Normothermia and Colon Surgical Site Infections

The main objective of the analysis was to determine whether there was a relationship between perioperative normothermia and colon SSIs. To test Research Question 1 (Is there an association between perioperative normothermia and colon surgical site infections?), logistic regression was conducted, indicating that there is no statistically significant (p = .061) relationship between maintaining perioperative normothermia (i.e., maintaining a core body temperature of at least 36^{O}C [96.8^{O}F] during all three phases of operative care) and colon SSIs (Table 7). An odds ratio of 3.125 (p = .061, CI .949, 10.286) cannot be adequately interpreted without statistical significance.

Table 7

Variables in the Equation

		B	*SE*	Wald	*df*	Sig.	Exp(B)	95% CI for EXP(B)	
								Lower	Upper
Step 1[a]	PeriOpNORM Maintained(1)	1.139	.608	3.514	1	.061	3.125	.949	10.286
	Constant	-.629	.438	2.062	1	.151	.533		

[a]Variable(s) entered in Step 1: Peri_Op_NORM_Maintained.

The chi-square is borderline statistically significant (p = .056; Table 8). With these findings, I fail to reject the null hypothesis as there is no statistically significant association between perioperative normothermia and colon surgical site infections. Despite no absolute statistical significance (p = .061), it is still worthy to explore if high risk factors to include age, gender, obesity, or tobacco use has any effect on the relationship between perioperative normothermia and colon surgical site infections. Additional tested hypotheses are expanded further below.

Table 8

Omnibus Tests of Model Coefficients

		Chi-square	*df*	Sig.
Step 1	Step	3.659	1	.056
	Block	3.659	1	.056
	Model	3.659	1	.056

Association Between Perioperative Normothermia and Colon Surgical Site Infections and Tobacco Usage

Among the study population 37 (79%) patients were identified as nonsmokers and

10 patients were identified as smokers (Table 6). When evaluating the association between perioperative normothermia and colon surgical site infection and whether tobacco usage confounded the association it was found that tobacco usage is not statistically significant (*p* = .920, CI .217, 3.974; Table 9) and did not affect the relationship between maintaining perioperative normothermia and colon surgical site infections (*p* = .061, CI .950, 10.299; Table 9). The model passed the Hosmer and Lemeshow goodness of fit test (*p* = .480), however I must fail to reject the null hypothesis that the relationship between perioperative normothermia and colon surgical site infections is confounded by the effect of tobacco smoking.

Table 9

Variables in the Equation

								95% CI for EXP(B)	
		B	*SE*	Wald	*df*	Sig.	Exp(B)	Lower	Upper
Step 1[a]	PeriOpNORM Maintained(1)	1.140	.608	3.518	1	.061	3.128	.950	10.299
	Tobacco_Use(1)	-.075	.742	.010	1	.920	.928	.217	3.974
	Constant	-.570	.725	.618	1	.432	.565		

[a]Variable(s) entered in Step 1: Peri_Op_NORM_Maintained, Tobacco_Use.

Association Between Perioperative Normothermia and Colon Surgical Site and Age

The age category was grouped into two separate groups. Group one included patients less than 40 years of age (*n* = 8) and group two including patients 40 years of age and older (*n* = 39). When holding age constant, it can be determined that age is not statistically significant (*p* = .814, CI 0.152, 4.384; Table 10) and does not confound the relationship between maintaining perioperative normothermia and colon surgical site infections (*p* = .089, CI .848, 10.445; Table 10). The chi-square for this model was .814 (*p* = .666) and demonstrates that overall the goodness of fit model passes. With these findings, I fail to reject the null hypothesis that the relationship between perioperative normothermia and colon surgical site infections are confounded by age.

Table 10

Variables in the Equation

		B	*SE*	Wald	*df*	Sig.	Exp(B)	95% CI for EXP(B)	
								Lower	Upper
Step 1[a]	PeriOpNORM Maintained(1)	1.091	.641	2.898	1	.089	2.976	.848	10.445
	Age Category(1)	-.202	.857	.056	1	.814	.817	.152	4.384
	Constant	-.435	.928	.220	1	.639	.647		

[a]Variable(s) entered in Step 1: Peri_Op_NORM_Maintained, Age Category.

Association Between Perioperative Normothermia, Colon Surgical Site Infections, and Gender

When evaluating the association between perioperative normothermia and colon surgical site infections when controlling for gender it was found that gender is not a statistically significant predictor for a colon surgical site infection (*p* = .913, CI .274, 3.181) does not confound the relationship between perioperative normothermia and colon surgical site infections (*p* = .068, CI .919, 10.366; Table 11). Again, I fail to reject the null hypothesis. It is also noted that the goodness of fit is statistically significant (*p* = .033), therefore indicating this model differs from the observed cases and is not a good fit (Table 12).

Table 11

Variables in the Equation

		B	*SE*	Wald	*df*	Sig.	Exp(B)	95% CI for EXP(B)	
								Lower	Upper
Step 1[a]	PeriOpNORM Maintained(1)	1.127	.618	3.323	1	.068	3.086	.919	10.366
	Gender(1)	-.068	.625	.012	1	.913	.934	.274	3.181
	Constant	-.593	.544	1.189	1	.275	.553		

[a]Variable(s) entered in Step 1: Peri_Op_NORM_Maintained, Sex.

Table 12

Hosmer and Lemeshow Test

Step	Chi-square	*df*	Sig.
1	6.799	2	.033

Association Between Perioperative Normothermia, Colon Surgical Site Infections, and Obesity

When evaluating the association between obesity, perioperative normothermia, and colon surgical site infections an interesting finding developed. The relationship between perioperative normothermia and colon surgical site infections changes and is now statistically significant (Table 13). Not only was maintaining perioperative normothermia impacted (p = .041, *OR* 4.147, 95% CI 1.059, 16.246) so was colon surgical site infections among the obese BMI category (p = 0.011, 95% CI 1.612, 41.786, *OR* 8.207; Table 13). With a reported odds ratio of 8.207, for every unit of increase within the obese category, a patient's risk for developing a colon SSI results in an 8x greater chance of developing an infection. Additionally, when evaluating the relationship between maintaining perioperative normothermia and colon SSIs when controlling for obesity, the reported odds ratio of 4.147 identifies a 4x greater chance of developing a colon SSI when perioperative normothermia is not maintained. With these findings, we reject the null hypothesis that the relationship between perioperative normothermia and colon surgical site infections is not confounded by obesity.

Table 13

Variables in the Equation

								95% CI for EXP(B)	
		B	*SE*	Wald	*df*	Sig.	Exp(B)	Lower	Upper
Step 1[a]	PeriOpNORM Maintained(1)	1.422	.697	4.169	1	.041	4.147	1.059	16.246
	BMI Category			6.502	2	.039			
	BMI Category(1)	1.151	.826	1.945	1	.163	3.163	.627	15.952
	BMI Category(2)	2.105	.830	6.425	1	.011	8.207	1.612	41.786
	Constant	-1.734	.706	6.026	1	.014	.177		

[a]Variable(s) entered in Step 1: Peri_Op_NORM_Maintained, BMI Category.

Summary

Multiple logistic regression analysis was utilized to assess the relationship between maintaining perioperative normothermia and colon surgical site infections. In addition, variables of interest to include age, gender, tobacco use, and obesity were included in the analysis to evaluate if the relationship between maintaining perioperative normothermia and colon surgical site infections would be confounded by additional high-risk factors associated with surgical procedures. When holding age, sex, and BMI groups with normal or overweight range constant there is no statistically significant relationship (Table 14). Perioperative normothermia does closely approach statistical significance ($p = .054$), however this can be difficult to interpret and statistical significance was previously set at $p < 0.05$. Also of interest is when holding the BMI obese category (30-51.80) constant, there is statistical significance ($p = .010$) for the development of a colon surgical site infection.

Table 14

Variables in the Equation

		B	*SE*	Wald	*df*	Sig.	Exp(B)	95% CI for EXP(B)	
								Lower	Upper
Step 1[a]	PeriOpNORM Maintained(1)	1.429	.741	3.719	1	.054	4.175	.977	17.844
	Age Category(1)	-.287	.972	.087	1	.768	.751	.112	5.048
	BMI Category			6.690	2	.035			
	BMI Category(1)	1.266	.853	2.202	1	.138	3.548	.666	18.901
	BMI Category(2)	2.196	.854	6.607	1	.010	8.990	1.685	47.971
	Tobacco_Use(1)	.130	.844	.024	1	.878	1.139	.218	5.960
	Gender(1)	-.314	.704	.199	1	.655	.730	.184	2.901
	Constant	-1.402	1.211	1.340	1	.247	.246		

[a]Variable(s) entered in Step 1: Peri_Op_NORM_Maintained, Age Category, BMI Category, Tobacco_Use, Sex.

The Hosmer and Lemeshow test was used as a goodness of fit test. For this model, the test demonstrates a chi-square of 9.223 with a *p*-value of .237 (Table 15). Since the test statistic is not statistically significant, this indicates the model does not differ statically from the observed cases. Therefore, this model passes the goodness of fit test.

Table 15

Hosmer and Lemeshow Test

Step	Chi-square	*df*	Sig.
1	9.223	7	.237

In conclusion, the findings of this analysis identified there is no statistically significant relationship between perioperative normothermia and colon surgical site infections. While this association was disproved, a finding did emerge identifying the association between perioperative normothermia and colon surgical site infections among obese patients (BMI $\geq$ 30). Having identified this information may prove beneficial to both public health leaders and hospital providers for consideration of early interventions, which will be discussed more thoroughly in Chapter 5.

Chapter 5: Discussion, Conclusions, and Recommendations

Introduction

HAIs have become a severe public health concern, representing a threat to both patient safety and quality of care. HAIs develop as the result of care received while receiving treatment in a health care setting (Slayton et al., 2015). HAIs range from the development of antimicrobial-resistant organisms to device-associated urinary tract infections, bloodstream infections, pneumonia, and procedure-associated infections, including SSIs. As they have received increased focus, HAIs have become a priority for many in public health, with health care leaders calling for the implementation of best practices as a prevention strategy. Every day in the United States, 1 in 31 patients are affected by the development of an HAI (CDC, 2018). Furthermore, HAIs remain a leading cause of patient morbidity and mortality (Zuberi et al., 2015). A 2011 U.S. prevalence study conducted identified that there were approximately 722,000 HAIs and 75,000 HAI-related deaths annually (Rodriguez-Acelas, Almeida, Engelman, & Canon-Montanez, 2017). A follow-up point prevalence survey was conducted in 2015 by Magill et al. (2018), who found that fewer patients had HAIs; however, SSIs remain the most common HAIs. While progress has been made, more work is needed to continue advancement toward eliminating HAIs. Many organizations continue to experience a high occurrence of HAIs due to an adverse culture in the areas of patient safety, compliance with recommended practices for infection prevention, and financial support (Popovich et al., 2019).

Among types of HAIs, SSIs have been identified as having a significant impact on quality of life and often result in prolonged hospitalization, readmission, and increased costs associated with provided healthcare services (Savage & Anderson, 2013). These adverse events also have a direct effect of days of life lost associated with the development of an infection. The development of an SSI and its effect on population health has been revealed to result in 501 DALY per 100,000 population, representing 16,000 deaths and 57.5 years of life lost per 100,000 population (Cassini et al., 2016). Among surgical procedures, colon surgical procedures have been identified as having a higher risk of developing an SSI, with an incidence of infection ranging from 5% to 45% (Cima et al., 2013; Tanner et al., 2015).

Strategies have been explored for the prevention of colon SSIs, including the implementation of surgical care bundles. Surgical bundles consist of a set of core interventions that, when implemented in tandem, have been identified to significantly reduce the risk for a colon SSI (Gabasan et al., 2017). While one intervention for the prevention of colon SSIs included the implementation of postoperative normothermia, it was often with mixed results. There has remained a gap in the literature and knowledge in the field concerning the role of maintaining normothermia across all phases of operative care (preoperative, intraoperative, and postoperative) and its association with SSIs in colon surgical patients. An informed understanding of the role of additional significant risk factors, including age, obesity, tobacco use, and gender, and any relationship between maintaining normothermia and colon SSIs would help public health professionals and surgical providers plan and conduct early interventions for the prevention of these infections and improved quality of life, reducing years of life lost and improving population health.

This was a research study of 47 surgical patients who underwent a colon surgical procedure at a large acute care hospital during 2018. Findings from the analysis failed to identify a relationship between maintaining perioperative normothermia and the development of a colon SSI. Among the study population, the patient's core body temperature was not a factor for the risk of developing a colon SSI. However, when assessing the influence of additional risk factors including age, gender, tobacco use, and obesity, a significant finding did emerge. Maintaining perioperative normothermia was associated with the development of a colon SSI among patients with a BMI of 30 or higher. Additionally, a BMI of 30 or higher had a statistically significant association with the development of a colon SSI. These findings may inform the development of prevention strategies at both the hospital level and the national level, providing broader knowledge and guiding future research opportunities for public health stakeholders and providers.

In this chapter, I further review the findings from the research conducted, in addition to describing limitations to generalizability, followed by recommendations, opportunities for future research, and implications for social change. The chapter concludes with a statement of importance surrounding the research and findings.

Interpretation of the Findings

This research study focused on the association between maintaining perioperative normothermia and colon SSIs. Additional risk factors including age, gender, tobacco use, and obesity were also included as covariates to determine whether these preidentified SSI risk factors confounded the relationship between perioperative normothermia and colon SSIs. As the analysis was conducted and findings were interpreted, the theoretical foundations outlined for the research study were reflected upon. Both endogenous and exogenous factors can be risks for the development of a colon SSI. Normothermia, where a patient's core body temperature is within a normal range (endogenous), can be influenced by outside elements (exogenous). Pasteur's germ theory and Tribus's germ theory of management assist in understanding how potential endogenous and exogenous measures may have an impact on a patient's risk of infection. With the germ theory, there is the understanding that specific organisms cause specific diseases without regard to the environment (endogenous factors); however, with the germ theory of management, there is consideration of how the environment, processes, and systems (exogenous) can impact the patient's outcomes. The epidemiological triad model helps in further understanding the multifactorial relationship between a patient and the development of a colon SSI. Understanding the role of the patient, an agent, and the environment and its influence on the development of an infection can be used to establish best practices for prevention. The findings from this analysis are to be used to guide future areas for research and implementation of prevention strategies.

Perioperative Normothermia and Colon Surgical Site Infections

During 2018, the hospital performed 422 colon surgical procedures, of which 23 patients developed a colon SSI, demonstrating a colon SSI infection rate of 5.45 per 100 procedures. A total of 47 patients were used for this study analysis, consisting of 24 patients without the development of a colon SSI and 23 patients who did develop a colon SSI. I looked at the role that maintaining perioperative normothermia had in the development of a colon SSI. It is important to note that the research did not involve evaluating how patients were maintaining normothermia (e.g., active or passive warming interventions), nor did it assess ambient room temperatures and the impact of the patient continuing normothermia. The patient's recorded body temperature collected throughout all phases of operative care (preoperative, intraoperative, and postoperative) was used to assess for the relationship between maintaining normothermia (36^{O}F) and colon SSIs. Multiple logistic regression was used for this analysis.

The logistic regression analysis did not reveal a statistically significant relationship between maintaining perioperative normothermia and the development of a colon SSI ($p = 0.61$). These findings continue to follow previously identified mixed results surrounding the role of normothermia in colon SSI prevention. Although some research studies have demonstrated higher rates of infection upwards to 19% among patients who were hypothermic during a surgical procedure, other studies have challenged normothermia as a prevention strategy (Fry, 2016). Although results concerning normothermia remain mixed, research studies have effectively demonstrated that surgical care bundles incorporating normothermia as an element have resulted in a reduced rate of SSIs ($p = .0005$, CI 0.5; Tanner et al., 2015).

Effect of Age, Gender, Tobacco Use, and Obesity

Risk factors including age, gender, tobacco use, and obesity have been identified to be associated with an increased risk for the development of a colon SSI (Fry 2013, 2016; Gabasan, 2014; Huber et al., 2011; Keenan et al., 2014; Pasam, Esemuede, Lee-Kong & Kiran, 2015; Tserenpuntsag et al., 2014; Young et al., 2012). As such, the effect of age, gender, tobacco usage, and obesity were included as covariates to determine whether there was an effect on the relationship between maintaining perioperative normothermia and colon SSIs. Including these risk factors as potential confounders on the relationship between maintaining perioperative normothermia and colon SSIs was important for evaluating potential public health implications and designing any targeted interventions for prevention.

Age. Age has been identified as a common risk factor for surgical procedures. However, in relation to colon SSIs, age as a risk factor has conflicting findings. Some studies have demonstrated increasing age as a risk factor, whereas some researchers have found that age >75 is not an associated risk factor (Huber et al., 2011; Tserenpuntsag et al., 2014; Young et al., 2014). The mean age of the study population was 53.4 years. In this analysis, age was included as a potential risk factor to determine whether age confounded the relationship between maintaining perioperative normothermia and colon SSIs. Findings from the logistic regression indicated that age did not confound the relationship and was not a factor for the development of a colon SSI (p = .089). These findings fall in line with previous studies and continue to add mixed results to the research field. This variation may be the product of the categorical grouping of less than 40 years of age (Group 1, n = 8) and 40 years of age and above (Group 2, n = 39).

Gender. Prior research has identified that women are at a decreased risk of development an SSI (Cohen et al., 2013; Hubner et al., 2014; Pasam et al., 2015; Young et al., 2014). The study population for this analysis consisted of 27 males (57%) and 20 females (43%). Despite gender being identified through the literature review as an independent risk factor for the development of SSIs, in this analysis, gender did not confound the relationship between perioperative normothermia and the development of colon SSI ($p = .068$).

Tobacco use. Chronic tobacco use has been identified as an independent risk factor for the development of a colon SSI (Fry, 2016). Recommendations have also supported the implementation of tobacco cessation programs within 30 days of surgery as a critical prevention strategy (Anderson, 2014). The study population consisted of 10 individuals (21%) who indicated tobacco use and 37 (79%) who indicated no tobacco usage within their medical history. In this analysis, tobacco usage was not statistically significant ($p = .920$) and did not have an effect on the relationship between the independent (maintaining perioperative normothermia) and dependent (colon SSI) variables ($p = 0.061$)

Obesity. Obesity is a significant public health issue. Obese adults have a great risk of developing chronic conditions and increased medical expenditures, rates of hospitalization, and prescription drug use (Biener & Decker, 2018). In the literature review, obesity was identified as a significant risk factor for the development of an SSI, with SSIs occurring in over 14% of procedures performed (Gabasan, 2014; Wick et al., 2011). Investigation of the effect of obesity on the relationship between perioperative normothermia and colon SSIs brought an exciting finding. For this analysis, obesity was recoded into four separate categories using CDC's (2017) guidance for healthy adult

BMI. A BMI below 18.5 is considered underweight, a BMI range of 18.5-24.9 is normal or healthy, a BMI of 25.0-29.9 is deemed overweight, and a BMI above 30.0 is deemed obese (CDC, 2017). When BMI categories were introduced into the analysis, the relationship between maintaining perioperative normothermia and colon SSIs was affected and became statistically significant ($p = .041$, *OR* 4.147, 95% CI 1.059, 16.246).

Furthermore, with increasing obesity (BMI > 30.0), the development of a colon SSI is statistically significant ($p = .011$). These findings are supported by literature indicating that obesity is a considerable risk factor for the development of an SSI. The additional outcome that obesity confounds the relationship between maintaining perioperative normothermia and colon SSIs is vital for key stakeholders and provides valuable information for population health and consideration of priority prevention strategies specific for this high-risk group.

Limitations of the Study

There were several limitations to this study. The first limitation was the sample size. Although the proposed sample size was 48 (24 infected cases and 24 noninfected cases), there were only 23 colon SSIs detected during 2018. While this small study size may be representative of effective implementation of infection prevention best practices at the organization level, there are implications for study generalizability. As a result of the sample size being shortened by one case, I made the decision to proceed with the analysis, realizing that this would result in a larger effect size and that confidence intervals would widen.

A second limitation to the study was the finding that all of the colon surgical cases performed at this facility were coded a minimum of a wound class II (clean/contaminated), with a majority of the cases coded as III (contaminated; 38%) or IV (dirty/infected; 34%). The initial plan was to remove surgical procedures with a wound class of III and IV from the study sample; however, doing so would have resulted in removing all cases from the study. Of the SSI group, 38% had a wound class above II, and of the nonSSI group, 34% had a wound class above II. As such, I decided to include all wound classes in the analysis, understanding that the literature had identified wound class as predicting the risk for the development of an SSI, with higher wound classes having a higher infection rate. Furthermore, with the inclusion of all wound classes, all operative cases would also be included (e.g., urgent and emergent). These limitations must be taken into consideration when interpreting the study findings. A final barrier was the study's generalizability. The sample population was gathered from a large acute care Level I Trauma Center; however, with a small sample size, the results cannot be generalized to the population as a whole.

An additional limitation of this study was the assumption that all cases were correctly identified as SSI or noninfection following the standard NHSN surveillance definitions. The hospital infection prevention program conducts surveillance for SSIs following the NHSN definitions; however, despite a standard rule for meeting criteria, there remains an opportunity for subjectivity in qualifying criteria. This research study was not a data validation study; therefore, it was necessary to assume that the reported cases were correctly identified as involving infection or not.

Recommendations and Areas for Future Research

Based on nationally reported data, the facility had a reported standardized infection ratio for colon SSIs of 1.032, which is slightly above the national benchmark of 1.0 and the Florida rate of 0.762. An SIR above 1 indicates that the hospital had more infections than expected when compared to similar hospital settings. Of note, these data were based on a rolling four quarters from October 1, 2017 to September 30, 2018, during which there were 390 procedures performed with 12 infections reported and 11.627 predicted infections. Understanding the currently reported infection data may guide hospital leaders toward areas of improvement.

The findings from this research study allow for a pathway to continue to explore the effects of perioperative normothermia and colon SSIs. Although there was no statistically significant relationship identified between the two variables of interest, the limitations described provide an opportunity for a broader analysis to be conducted. Additionally, the finding that obesity does confound the relationship between perioperative normothermia and colon SSIs, and continued support for the notion that obesity is associated with infection outcome, provides valuable information that may guide practitioners, hospital leaders, and public health key stakeholders in evaluating the role of obesity in risk for infection. As patients are being scheduled for elective procedures, additional prevention strategies may be warranted to reduce the risk of infection. Obesity has been identified as an implication and risk for the development of colon SSIs, therefore impacting patient health and overall population health and well-being.

Additionally, although the relationship between perioperative normothermia and colon SSIs was not statistically significant, it is also essential to evaluate the role of normothermia in patient satisfaction. Of the sample population, 23 (49%) of the patients did not have perioperative normothermia maintained during their phases of surgical care. A potential question includes what effect does keeping patients warm during their surgical procedure improve patient satisfaction? Patient satisfaction has become an area of abundant interest among healthcare leaders. The patient experience, as scored by the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS), has also been tied to CMS pay for performance (Tsai, Orav, & Jha, 2015) just as the development of an HAI has also been tied to pay for performance.

A study performed among U.S. hospitals by Tasi et al. (2015) found that patient satisfaction varied in U.S. hospitals and that the patient experience was not directly linked to the quality and efficiency of care. However, it has been found that patient satisfaction is associated with lower surgical readmission rates, mortality rates, and higher quality of processes (Tsai et al., 2015). The findings from this research, along with supportive literature, may be worthy of further exploration to evaluate elements of surgical care for improved patient outcomes, population health, and quality of care and the impact on patient overall satisfaction.

Implications for Positive Social Change

Despite the limitations of this study, there are several implications for positive social change on both the local and national level. Surgical procedures, in particular, colon surgical procedures, are associated with an increased risk of infection (Anderson et al., 2014). Understanding additional risk factors that affect the outcome for the development of infection must be considered to best understand the impact of HAIs on overall patient and population health.

Hypothermia during surgical care has been identified as an adverse event that may be associated with increased cardiac complications, delays in wound healing and poor wound health, blood loss, and SSIs (Allegranzi et al., 2016). The findings surrounding the role of obesity and the relationship between maintaining perioperative normothermia and colon surgical site infections should not go unrecognized.

Obesity has become a national epidemic associated with severe health risks and prevalence among U.S. adults reaching 39.8% (Hales, Carroll, Fryar, & Ogden, 2018). The results of the research identifying that obesity does affect the relationship between maintaining perioperative normothermia and colon SSIs further supports the role that public health plays in the prevention of infections. Early interventions towards reducing obesity among planned surgical patients undergoing colon procedures will produce improved outcomes, promoting population health and wellness while also preventing years of life lost from disability and disease.

Conclusion

Healthcare-associated infections are a significant public health threat and warrant continued efforts for prevention which are essential for elimination. Among the types of HAIs, surgical site infections remain a significant challenge among healthcare providers (Allegranzi et al., 2016). Of the various types of SSIs, colon surgical site infections are associated with a higher risk for morbidity and mortality. Prevention efforts continued to be studied surrounding these high risk surgical procedures.

HAI prevention goals at the federal level have been established to continue progress towards eliminating HAIs. Through HAI reporting mandates, there will be a continued focus on how hospitals are performing and drawing increasing public awareness. Understanding the epidemiology and processes that drive the prevention of infections and risk factors that increase the risk for infection can help inform public health providers, leaders, and practitioners for early interventions. Through a coordinated approach between both public and private sectors, continued collaboratives, and research to establish national best practices, zero HAIs are possible.

The role of perioperative normothermia and colon surgical site infections continues to be met with mixed results, however one key finding continues to be supported. The role of obesity in prevention of colon surgical site infections and maintaining perioperative normothermia is crucial for demonstrating where public health and healthcare intersect. Obesity is a national public health issue, just as HAIs are an emerging public health threat. The role of HAIs on population health has been demonstrated through years of life lost, increasing financial burden, morbidity, and mortality associated with the development of an HAI. To find that obesity further impacts the association and development for HAIs, in particular maintaining perioperative normothermia and colon SSIs, has a significant implication for population health and wellness.

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Appendix A: Hospital Research Study Proposal Form

Research Study Proposal Form

ALL NEW AND ONGOING RESEARCH PROJECT UPDATES MUST BE SUBMITTED TO

[Redacted]

Thank you for your interest in performing/conducting your research project/study at [Redacted] In order for the Office of Clinical Research (OCR) to efficiently conduct our review, the following study documents are required to begin the process. Please select all documents that are included in your submission:

For ALL studies the following documents must be submitted, as applicable:
☐ Research Study Proposal Form ☐ Study protocol (Version date: ____________) ☐ IRB Application **for Investigator Initiated studies (IIT)**. If there is no informed consent, the request for a waiver of Consent and Authorization must submitted with the application ☐ **NA** ☐ Data collection sheet (if applicable) ☐ **NA** ☐ Survey, questionnaires and scripts (if applicable) ☐ **NA** ☐ Current CV, signed and dated for the principal investigator

Informed Consent Form:
☐ **NA** Informed Consent Form **If NA, documentation of/request for Waiver of Consent must be included.** ☐ All Informed Consent/Assent Forms (Version date: ___________________) ☐ Documentation of/request for Waiver of Consent ☐ HIPAA Authorization Forms (if separate document from Informed Consent Form) if applicable ☐ **NA**

Business and Finance:
☐ Sponsor's budget, funding memo/sheet, grant award, etc. (**Required for all funded studies)** ☐ **NA** ☐ CMS Approval Letter (device studies only) ☐ **NA** ☐ FDA Approval Letter for IND/IDE studies. Letters from sponsors are not acceptable ☐ **NA** ☐ Any agreements/contracts: Clinical Trial Agreement, Contracts, Work Order, Statement of Work (SOW), Material Transfer Agreements (MTA), Facility Use Agreements, Purchased Services Agreements, Purchase Agreements, Device Agreements, etc. ☐ **NA** ☐ Purchase Agreement (if applicable) ☐ **NA** ☐ Coverage Analysis (if applicable) ☐ **NA**

Appendix B: Hospital Credentialing Application

In accordance with , and current Joint Commission guidelines, individuals requesting authorization to perform any functions related to patient care at are required to complete an authorization application with the following supporting documentation, and must comply with the Code of Conduct. This authorization gives authority to obtain certain information about you and/or release certain information to your employer upon its/their request.

Documentation that must be submitted with this packet includes:

- Completed application and acknowledgement forms
- Confidentiality and Security Agreement
- Resume/CV
- Copy of valid Driver's License
- Copy of valid license and/or certification (if applicable)
- Proof of health/drug screen (set up upon receiving application)
- Proof of Human Subjects Education (for research)
- Proof of online hospital orientation (set up upon receiving application)
- Proof of Liability Insurance (Licensed personnel only)
- Reference letters (3 of them)
- Supervising Physician/ Supervisor Statement
- Background Release completed through PreCheck (instructions attached)
- **Please turn in completed application as it will not start being processed until all forms are included. Turn into to HR directly or email to**

Please note that completed forms must be submitted to emailed authorization process includes a review of these forms, a background check and drug screening.

Final authorization approval will be granted by the Human Resources Authorization Committee (HRAC) for non-nursing personnel, and by the Professional Nursing Credentialing and Authorizing Committee (PNCAC) for nursing personnel. Approval is conditional upon satisfactory completion of the authorization process. A badge will be issued upon receipt and approval of all documentation. Badges must be worn at all times while on hospital premises.

Appendix C: Data Dictionary

Variable	Position	Label	Measurement Level
Age	1	Age in Years	Scale
Sex	2	Gender	Ordinal
BMI	3	BMI Scale	Scale
Tobacco_Use	4	Tobacco Use	Nominal
COLO	5	Colon Surgical Site Infection	Nominal
Procedure_Date	6	Date of Procedure	Nominal
Wound_Class	7	Wound Class	Ordinal
PreOp_NORM_ Maintained	8	Pre Op Normothermia Maintained	Nominal
PreOp_Temp_C	9	Pre Op Temp in C	Scale
IntraOp_NORM_ Maintained	10	Intra Op Normothermia Maintained	Nominal
IntraOp_Temp_C	11	Intra Op Temp in C	Nominal
Post_Op_NORM_ Maintained	12	Post Op Normothermia Maintained	Nominal
Post_Op_Temp_C	13	Post Op Temp in C	Scale
Peri_Op_NORM Maintained	14	Perioperative Normothermia Maintained	Nominal
Surgical_Site_ Infection	15	Presence of SSI	Nominal
Age_Cat	16	Age Category	Nominal
BMI_Cat	17	BMI Category	Nominal