A Practice-Based Research Approach to Explore the Relationship of Preoperative Warming to the Incidence of Surgical Site Infection in the Ambulatory Surgical Patient

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A Practice-Based Approach to Explore the Relationship of Preoperative Warming to the Incidence of Surgical Site Infection in the Ambulatory Surgical Patient

Krista LaRussa

Submitted to Dr. Barbara Berg, in partial fulfillment of NR706C Doctor of Nursing Practice

Regis University

April 1, 2012
Executive Summary

Problem

Surgical site infections are a financial burden to society and are the second most frequently reported Health Associated Infection (HAI) that increases hospital stays and the chief cause of preventable death (Agency of Health Research and Quality [AHRQ], 2009; National Priorities Partnership [NPP], 2008). It is branded as the top national priority for the United States Department of Health & Human Services (DHHS) and the AHRQ. Unplanned perioperative hypothermia (UPH) is associated with a 68 percent increase in the incidence of surgical site infections (Kurz, Sessler, & Lenhardt, 1996; Pikus & Hooper, 2010). The prevention of UPH and promotion of perioperative normothermia has come to the national forefront as a quality measurement designated by the Surgical Care Improvement Program (SCIP) (2005; n.d). The incidence of SSI’s in the ambulatory surgical population has not been well researched (AHRQ, 2009; Barie, 2010). Therefore, the PICO question that the researcher is trying to solve is: In adult patients undergoing ambulatory surgery, do patients who are prewarmed during surgery have fewer SSIs than those that are not?

Purpose

The purpose of this DNP project was to determine the incidence of UPH and SSI in the ambulatory surgery population. In addition, a relationship of Preoperative patient warming to the incidence of UPH (intraoperatively) and SSI in the ambulatory surgery population was determined.

Goal

The goal of the project was to identify whether the standard of care (the SCIP measures/intraoperative warming methods) was met in an adult ambulatory surgical population and whether there was a relationship between hypothermia occurrence and the subsequent development of an SSI.

Objectives

Specific objectives of the project include: 1) Determine the incidence of UPH in the ambulatory surgery population at the Georgia Health Science University(GHSU); 2) Determine the incidence of SSI in the ambulatory surgical population at GHSU; 3) Determine the relationship of Preoperative patient warming to the incidence of UPH (intraoperatively) in the ambulatory surgical population at GHSU; and 4) Determine the relationship of Preoperative patient warming to the incidence of SSI in the ambulatory surgical population at GHSU.

Plan

The plan involved a review of a cross-sectional, purposive, convenience sample of 100 medical records of adult ambulatory surgery patients at a tertiary hospital. Data from all patient charts meeting inclusion/exclusion criteria was collected via retrospective medical record abstraction (MRA). This data was recorded to a Hypothermia/SSI Research Study In-Hospital Data Report sheet which was based on research of specific items that identify outcomes.

Outcomes

The incidence of unplanned hypothermia in the ambulatory surgical patient was 11% out of 100 cases. The incidence of physician diagnosed surgical site infection in the ambulatory surgery patient was 4% out of 100 cases despite the efforts of warming methods and SCIP measures. Preoperative warming did not affect UPH or surgical site infection in this population.
Acknowledgements

People say it takes a “village” to raise a child…..it definitely takes a “team” who are willing to go the extra mile with love and support of a graduate scholar through the DNP journey. I would like to thank the extraordinary team who was involved in the adventure.

To my family whose love has been instrumental in allowing me to accomplish my dreams.

To my husband who has always allowed me to be the brightest star in our relationship and has sacrificed his own dreams and aspirations selflessly so I could climb tall mountains. His bondless love has no limits and he has been an incredible confidant and cheerleader.

To my children who I love with all my heart who have sacrificed one on one time with their mom and took on extra chores so I could achieve deadlines, work schedules, and homework assignments.

To my faculty mentor…Dr. Pat Mullen, who has a gentle peaceful confidence that held my hand and has inspired me to reflect on the journey and not on the finish line.

To my distance mentor….Vallire Hooper, who is a pioneer in the Perianesthesia realm of nursing, she gave me the foundation to start my project and coaxed me to learn to walk on my own two feet through the process.

To Dr. Berg who has given me immense encouragement through the program and actually saw “this diamond” sparkle as I was chosen for the inaugural DNP program.

To my mother…Norma Combs, who inspired me through her own dogged determination that I have the ability to accomplish my goal. She has been an instrumental precursor in my own hunger to succeed. She always beamed “that I was going to be a doctor”.

To my Preoperative coworkers, whose faith was a supportive backbone in my progression.

To my grandfather, Claude Sherrer, who has given me the inner gentleness of compassion for others and whose spirit with determination lives on in my heart. I miss you everyday.

To my aunt, Betty Smith, who threw caution to the wind and took a secret rendezvous with me to Key West when the stress level was at my breaking point.

To my cousin, Dallas Smith, whose savvy skills at Excel allowed me to begin my project successfully and to Jason Miller whose statistical skills I am indebted to.

To my boss, Endia Veal, who has given me down time and an incredible schedule that allowed me to see the fruits of my efforts.

To my dad and stepmother….Doug and Mackie Combs, thanks for all that you do!
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A Practice-Based Approach to Explore the Relationship of Preoperative Warming to the Incidence of Surgical Site Infection in the Ambulatory Surgical Patient

Healthcare associated infections (HAI), defined as any patient infection acquired during the course of receiving treatment for other conditions within a healthcare setting, are among the leading cause of preventable death in the United States, resulting in up to 99,000 preventable deaths each year (National Priorities Partnerships, 2008; Agency of Health and Qualities, 2009). Due to the significant threat posed to the greater well-being of patients and the financial burden placed on society, the United States Department of Health and Human Services (DHHS) along with the Agency of Research and Quality (AHRQ) have made the prevention of HAI a top national priority, with particular emphasis on the ambulatory care setting (AHRQ, 2009). Surgical site infections (SSI), the second most frequently reported healthcare associated infection after urinary tract infections (UTI), account for 17% of all HAI, totaling approximately 500,000 infections yearly (Dimick, Chen, Taheri, Henderson, Khuri, Campbell 2004; Mlangeni & Babikir, 2005). These additional costs contribute to an estimated financial burden of up to 10 billion dollars annually (Perencivich & Sands, 2003; CDC, 2010). The purpose of the paper is to identify and define the problem, review the evidence, describe the project plan with evaluation, explain the project findings with results, examine the limitations, explore the recommendations, and recognize the implications for change related to the capstone project.

**Problem Recognition and Definition**

**Purpose/Objectives**

The objectives of the proposed project are to determine whether there are a connection between the incidence of hypothermia and the occurrence of post-operative SSI’s.
The data set (exploring available from the medical record) was used to explore the richness of an existing data set and conduct power and sample size calculations for future grant submissions and multi-site studies. The outcomes the researcher is assessing are a condition-specific measure of surgical site infection rates. The tool used for data abstraction are a Hypothermia/SSI Research Study In-Hospital Data Report sheet that was created by the author based on the research of specific items that helped identify outcomes. Data abstracted from ambulatory surgical patients from the medical record of ambulatory surgery patients includes: patient’s age, gender, BMI, ethnicity, time across continuum of care, American Society of Anesthesiology (ASA) patient classification, anesthesia method, associated co-morbidities (cardiovascular disease, diabetes, peripheral vascular disease, renal disease, etc.), Preoperative vital signs including temperature, type of surgical procedure and its duration, type and duration of anesthesia, serial intraoperative temperatures, perioperative/intraoperative warming interventions, ambient operating room (OR) temperature, hypothermia risk factors, Surgical Care Improvement Program Measures employed, and SSI specific data (laboratory findings and specific signs or symptoms) from the postoperative clinical visit.

**Problem Statement**

Surgical site infections associated with ambulatory surgery are a particular concern due the increasing number of surgical procedures conducted in the ambulatory setting. Ambulatory surgical centers are among the fastest growing provider types participating in Medicare, with increases in the number of ambulatory surgery centers of 8.3 percent annually between 1999-2005 (Agency of Health and Qualities, 2009; Barie, 2010). Notably, there are more surgeries conducted on an outpatient basis than inpatient surgeries, with outpatient
procedures comprising 75 percent of all procedures performed (Barie). Unfortunately, there is very little known about the quality of care in these outpatient settings and the incidence of surgical site infections in this population has not been well researched (Agency of Health and Qualities; Barie). The business mentality of quick patient turn-over effects both the patient and reimbursement for services in both Medicare and private insurance companies related to unexpected length of hospital stays or monies attributed to infections. The problem is focused on patient sensitive outcomes that are disseminated as evidence-based practice.

**PICO**

Once an issue has been identified that can be addressed with evidence, a formal evidence-based practice question is constructed that has four elements referred to as PICO. The four elements are: the population of interest, the intervention that is tested, the comparison to the intervention being tested, and the outcome of interest (Houser & Oman, 2011). The PICO frames the evidence-based practice question that drives the conceptual model. The “P” represents the population of interest which is the adult ambulatory patients. The “I” represent the intervention that is tested which is prewarming the patient. The “C” represents the comparison to the intervention being tested which is no prewarming of the patient. The “O” represents the outcome of interest which is surgical site infections. Therefore, the PICO question that the researcher is trying to solve is: In adult patients undergoing ambulatory surgery, do patients who are prewarmed during surgery (normothermic) have fewer surgical site infections than those that are not (hypothermic)?

**Project Significance**

The prevention of surgical site infection has the ability to meet ambulatory surgical consumer needs and has many advantages to include: safety, quality, and cost-effective care.
The overall good health of a consumer with less time lost from work is the first benefit. The second benefit is the reduction of hospitalization admission rates and a decrease in the length of hospital stays related to fewer required hospital stays and shorter stays related to a decline in admission rates associated with surgical site infection. This allows for a more efficient use of health care dollars. In addition, the incidence of new cases of surgical site infections identified each year in the community diminishes. This service will increase community awareness of prevention efforts by improving consumer knowledge of infection, causes, transmission, prevention, and treatment options. Successful business factors include: outstanding quality, a culture of safety, superior research and development, and superior customer service.

**Scope**

To meet the customers’ physiological and safety needs, it is imperative to prevent postoperative surgical site infections. The satisfactions of the consumer needs are met by: the Surgical Care Improvement Program, intraoperative warming methods, a comprehensive Preoperative appointment with an anesthesia provider by walk-in appointment or phone triage, self-scheduling surgery and postoperative appointments. In response to those needs, the ambulatory care surgical customer undergoing anesthesia is offered comprehensive primary care. This endeavor entails: a complete medical history, laboratory testing, patient education related to the prevention of surgical site infections, and directions on surgical site preparation prior to arrival to the ambulatory care site. In addition, a Chlorohexadine or Hibiclens surgical prep is given to each patient upon their Preoperative visit, with instructions for use immediately Preoperatively, as a proactive measure to decrease infection rates.
A standard of care is provided to the customer to ensure safety on the day of surgery. The standard is the Surgical Care Improvement Program (SCIP) measures which are strictly followed by the perioperative staff and physicians. The SCIP measures include: an antibiotic is given in surgery, the right antibiotic is given per standard of care based on type and site of surgery, the antibiotic is given one hour before incision intraoperatively, and the patient is prepped by clipping instead of being shaved. In addition, the patient is kept warm during surgery via intraoperative warming methods per protocol that promotes comfort, patient satisfaction, and has been shown to reduce the incidence of surgical site infection. A follow-up phone call by the nursing staff are performed after the second post-operative day to clarify information, answer questions regarding recovery, and determine if early signs or symptoms of infection may be present. Without such preventative services, medical complications are more likely to occur, possibly resulting in injury or death (Fortenberry, 2010).

Rationale

Evidence-based practice is at the forefront of nursing care that has improved patient outcomes, provided optimal patient safety, and has reduced healthcare costs (Houser & Oman, 2011). Evidence-based practice uses scholarship and inquiry to find the best practices in caring for patients to achieve the greatest outcomes (Houser & Oman). This involves both research and the application of research to find data that supports practice. This discovery is pertinent to Boyer's model in which new knowledge, developed through research and careful inquire, is explored in order to refine existing knowledge. The author will integrate the knowledge gained in this project through interpretation and dissemination in various platforms including journal article publication and presentation of findings at a national
conference of perianesthesia nurses. The knowledge will be used for problem solving, service, and growth. The author identified a problem, performed the research, and documented the outcomes. Through discovery, the author has the most current best evidence for making decisions about the care of individuals in the ambulatory surgical service line specialty. Instead of performing tasks the way we have learned it through the years, evidence-based practice invites opportunities of questioning care with inquiry. It will also make leadership aware of the necessary changes needed to promote best practice and patient safety. The author will also be an instrumental change agent for the perianesthesia specialty and an advocate for patient safety. As a DNP, the author is equipped to: translate research into practice, evaluate practice, use research methods with technology, participate and foster collaborative research, focus on quality improvement with patient-centered care, and disseminate evidence from inquiry. The discovery of new information which could change practice at the bedside further supports the SCIP initiatives which legitimize the role of the DNP-prepared nurse.

**Theoretical Foundation**

The theoretical framework guiding this study is Donabedian’s System’s Theory. Donabedian’s System’s Theory, allows for the evaluation of quality healthcare. This theory uses the concepts of structure, process, and outcome for the evaluation of the quality of healthcare. The Donabedian framework for quality assessment provides a strong basis for the conceptual model of satisfaction dimensions. This model incorporates components of medical aspects for ambulatory care into the structural aspect of satisfaction with care and health services quality into the process aspect of satisfaction with care. Process aspects of satisfaction that align with the identified aspect of this project include both the technical
quality that is focused on the patient’s physical health and continuity/coordination of care reflective of the social side of medicine and important for psychosocial well-being and satisfaction (Kane & Radosevich, 2011).

**Conceptual Model**

This project employed a conceptual model in which the following variables will be examined: hypothermia of the patient during ambulatory surgery, the standard of care or treatment of the patient during surgery, and surgical site infection which is the outcome or the dependent variable. In ambulatory surgery, a patient could be normothermic or hypothermic depending on the hypothermia risk factors when they enter into surgery. Therefore, the standard of care or treatment intervention (SCIP Measures and intraoperative warming methods used) influences the patient’s risk for surgical site infection. In the conceptual model, surgical site infections are confirmed by signs or symptoms of infection (purulent drainage/material, pain/tenderness, localized swelling, redness, heat, fever, incision deliberately opened by surgeon, wound spontaneously dehisces, abscess), laboratory findings (positive culture or positive gram stain when culture is negative or not performed), and a clinical diagnosis of infection. (Appendix A).

**Literature Selection/Systematic Process**

Unplanned perioperative hypothermia (UPH) is associated with a 68 percent increase in the incidence of surgical site infections (Kurz, Sessler, & Lenhardt, 1996; Pikus & Hooper, 2010) as well as multiple other adverse effects associated with increased morbidity and mortality (Kurz, Sessler, & Lendhardt; Scott & Buckland, 2006). The prevention of unplanned perioperative hypothermia and promotion of perioperative normothermia has come to the national forefront as a quality measurement designated as “Surgical Care
Improvement Project” (SCIP) (SCIP, 2005; SCIP, n.d.). These quality measurements are based on the practice recommendations cited in the Clinical Practice Guidelines for the Prevention of unplanned perioperative hypothermia (American Society of Perianesthesia Nurses, 2001) developed by ASPAN, which was recently revised to reflect the most current evidence (Hooper, Chard, Clifford, Fetzer, Fossum, Godden, Martinez, Noble, O’Brien, Odom-Forren, Peterson, & Ross, 2009).

Unplanned perioperative hypothermia (UPH) is caused by heat redistribution intraoperatively or postoperatively. This heat loss occurs because the internal flow of heat is great and because heat applied to the skin requires a considerable amount of time to reach the core compartment (Hooper, Chard et al., 2009). Once established, UPH is difficult to treat, making the maintenance of normothermia an essential priority throughout the course of the surgical continuum (Hooper, Chard et al.). Perioperative warming, defined as the warming of peripheral tissues or surface skin prior to induction of anesthesia (Hooper, Chard et al.), reduces redistribution hypothermia by decreasing the core-to-peripheral temperature gradient, and provoking vasodilatation, switching the body from the typical heat conservation model to heat dissipation (Sessler, 2001). In the absence of prewarming, UPH will typically occur even if active warming is instituted upon induction of anesthesia. Preoperative warming has been shown as an effective means of maintaining perioperative normothermia throughout the surgical continuum, thus possibly contributing to a decreased incidence of surgical site infection (Hooper, Chard et al.). The ASPAN Evidence-Based Clinical Practice Guideline for the Promotion of Perioperative Normothermia (Hooper, Chard et al.) recommends Preoperative warming for a minimum of 30 minutes for all surgical patients, but notes that the evidence supporting this recommendation is based on research on a limited
number of patient populations. The patient populations that have been studied consists of the inpatient population; specifically, cardiovascular, neurological, and gastrointestinal specific service lines.

Patient safety has been recognized by the Institute of Medicine as a key component of evidence-based clinical practice guidelines (CPG) (Kohn, Corrigan et al., 2000). CPG provide a key link between evidence-based knowledge and healthcare practice, offering a mechanism to advance the quality and equity of patient care through the translation of evidence to clinical practice. Both clinical practice and patient outcomes have been influenced positively by practice guidelines across a wide variety of specialties and practice settings (Odem-Forren, 2006). All interventions recommended in the ASPAN perioperative normothermia guideline (Hooper, Chard et al., 2009) are evidence-based. However, a practice-based comparison of the effectiveness of type and combination of guideline recommendations on a diverse population of various patient outcomes; and a diverse ambulatory surgery population, has not been performed. Research regarding the impact of these guideline recommendations on patient outcomes has also been identified by nursing specialty practice organizations as a research priority (Hooper, Chard et al.).

**Review of Evidence**

**Background of the Problem**

Before the mid-19th century most surgeries performed was met by sepsis and often death (Zoutman, 2005). The history of surgical site infection prevention and control has been set by four different precedents to include: Oliver Wendell Homes published the paper on “dirty hands” in 1843, Ignaz Semmelweis discovered hand washing techniques with chloride lime solutions in 1861, Louis Pasteur founded the germ theory in 1863, and Joseph Lister
established antiseptic principles in 1867 (Zoutman). Currently, surgical site infections are combated with aseptic technique, hand washing, antibiotics, surgical cleansers, cavity irrigations, and prepping procedures. Many factors can contribute to the development of surgical site infection to include: age, co-morbidities, immune status, surgical technique, and intra-operative contamination.

**Social.** The Surgical Care Improvement Program (SCIP) is a national quality partnership of organizations committed to improving safety of surgical care through the reduction of postoperative complications (Bratzler & Hunt, 2006). A meeting was initiated aimed at reducing surgical complications and mortality. This meeting, that included representatives of the Centers Medicare and Medicaid Services (CMS) and the Centers for Disease Control and Prevention (CDC), together with representatives of the Veterans Administration, the American College of Surgeons, The American Society of Anesthesiologists, the Agency for Healthcare Research and Quality, the American Hospital Association, and the Institute for Healthcare Improvement, resulted in the SCIP measures (Bratzler & Hunt).

**Ethical.** The ethical principles that should be considered related to surgical site infections include: beneficence, nonmaleficence, and justice. As a health provider, beneficence involves the promotion of good and the prevention of harm (McCann, 2004). This ethical principle is a hallmark of the prevention of surgical site infections which could cause mortality if strict guidance to aseptic procedures is not followed. Nonmaleficence is described as the obligation to do no harm which is in the Hippocratic Oath that nurses uphold in their practice (McCann). Justice is described as the fairness and equality of distributed health care resources which means that each patient receives the same standard of care (McCann).
**Political.** Political commitment will help catalyze leadership, commitment, and action into funds, policies, and multispectral involvement (World Alliance for Patient Safety, 2006). Politically, health professional bodies and associations can urge members to promote the highest standards of practice and behaviors (World Alliance for Patient Safety, 2006). Senate Bill 1058, chaptered in September 2008 states that each facility shall report quarterly to the Department of Public Health all health-care-associated surgical site infections of deep or organ space surgical sites, health-care-associated infections of orthopedic surgical sites, cardiac surgical sites, and gastrointestinal surgical sites designated as clean and clean-contaminated, and the number of surgeries involving deep or organ space, and orthopedic, cardiac, and gastrointestinal surgeries designated clean and clean contaminated (Surgical Site Infection, 2008). Infection control is an overlap area between a Quality Indicator (QI) and public health (Saginur, 2009). Recent legislative and regulatory changes mandate that healthcare institutions and government implement surveillance programs and report certain infection rates (Saginur). Public health surveillance is exempt from ethics review; however, if the information that is obtained is for research purposes, then an informed consent is needed with IRB review (Saginur). Surveillance of personal health information is an obligation of hospitals to maintain accreditation status and is a legal requirement at the provincial, state, national, and international level (Saginur).

**Legal.** There are two regulatory bodies to which the organization is accountable. The first regulatory body is the Joint Commission which is a not-for-profit nongovernmental professional agency that is the largest standard setting accrediting and certification body for quality and safety efforts (About the Joint Commission, n.d.). The next regulatory body is the governmental agency of the Centers for Disease Control (CDC) and Prevention which protects
the health of the population and promotes quality of life (Vision, mission, core values, and pledge, n.d.). It is charged with implementing strategies for the prevention and control of disease, injury, and disability.

**Systematic Review of the Literature**

Research studies are needed to establish effective guidelines and standards for temperature monitoring and warming (Weirich, 2008). Scott and Buckland (2006) found that preventing intraoperative hypothermia should be routine practice in all perioperative departments, especially for patients undergoing major surgery which reduced postoperative complications (wound infection, pressure ulcers, blood transfusion need, and cardiac events). Hasankhani, Mohammadi, Moazzami, Mokhtari, and Naghgizah (2007) assert that shivering causes: increased metabolic demand/cardiac output, decreased drug metabolism, impaired coagulation, and decreased immune response. Weirich (2008) affirms that hypothermia increases recovery time, increases patient health facility costs, and decreases patient satisfaction. Kumar, Wong, Melling, and Leaper (2005) found maintenance of normothermia has been shown to be an effective way to avoid complications of homeostatic functions and improving outcomes.

A Clinical Guideline for the Prevention of Unplanned Perioperative Hypothermia has been produced to improve patient care and patient satisfaction (Hooper, 2011). Pikus and Hooper (2010) argue that the most effective and safe method of rewarming in the PACU is force-air warmers which are supported by the ASPAN clinical guideline. Sessler (2001) concluded that methods of rewarming such as forced-air and resistive-heating are currently the most effective noninvasive options. In fact, Braur, Weyland, and Kazinaier (2004) discovered that forced air warming is more effective than radiative warming in rewarming
hypothermic patient’s after cardiac surgery. Vanni, Braz, Modolo, Amorim, and Rodrigues (2003) emphasize that one hour of Preop warming combined with intraoperative warming alone, avoided hypothermia caused by general anesthesia during the first two hours of surgery while preventing shivering and offered favorable conditions for early extubation. However, Galvao, March, Sawada, and Clark (2009) contend that fiber blankets are as effective as the forced-air warming system to prevent hypothermia and the circulating water garments are the most effective method.

Prewarming and heat distribution may be the key to the treatment of hypothermia (Weirich). Forbes, Eskicioglu, Nathens, Fenech, Laflamme, McLean, and McLeod (2009) established that forced air be used for procedures expected to last greater than 30 minutes both Preoperatively and intraoperatively for the prevention of surgical site infections. Intraoperative IV fluid warming reduces perioperative changes to the hemodynamic situation, postoperative shivering, and recovery time (Hasankhani et al.). Melling, Ali, Scott, and Leeper (2001) declare warming patients before clean surgery (breast, varicose veins, and hernia) seems to aid in the prevention of postoperative wound infection and may provide an alternative to prophylactic antibiotic in this type of surgery. Brox (2004) claims that with improvements in timing, prophylactic antibiotic selection, and the maintenance of perioperative normothermia through a series of system level changes allowed for a decrease in surgical site infection rates. Forbes, Stephen, Loeb, Smith, Christoffersen, and McLean revealed in their study that patients receiving their Preoperative antibiotics within 60 minutes improved from 5.9% to 92.6% (p<0.001); perioperative normothermia rates improved from 60.5% to 97.6% (p<0.001) between cohorts; whereas, there SSI rates improved but did not reach statistical significance (14.3% vs. 8.7%; p=0.21). However, Walsh and Whitman
Burger and Fitzpatrick (2009) shared the risk factors for the development of inadvertent hypothermia which include patient’s intrinsic factors: age (neonate/over 70), systemic disease (diabetes, peripheral vascular disease, poor nutritional status), surgery factors (preoperative fasting, administration of cool IVFs, large area of exposure, evaporative heat loss due to skin Preops/solutions, type/length of surgery (abdominal surgery greater than 2 hours), general anesthesia, thermoregulation impaired, volatile agents (cause vasodilation leading to heat loss by radiation), muscle relaxants (prevent shivering of skeletal muscles). Burger and Fitzpatrick discovered environmental factors linked to inadvertent hypothermia which includes: thin gown, transfer, skin exposure, cool operating room temperature, and minimal covering.

Dimick, Chen, Taheri, Henderson, Khuri, and Campbell (2004) found that reducing morbidity may provide sufficient cost savings to offset the resources needed to participate in the private-sector expansion of the National Surgical Quality Improvement Program. Median hospital costs were lowest for patients without complications ($4,487 dollars) compared with those with minor ($14,094 dollars) and major complications ($28,356 dollars) (p<0.001) (Dimick et al.). After adjusting for differences in patient characteristics, major complications were associated with a cost increase of $11,626 dollars which was statistically significant (Dimick et al.). Khan, Quan, Bugar, Lamaire, Brant, and Ghali (2005) exposed that postoperative and surgical complications increased hospital costs by 78% and LOS by 114%. Odom-Forren (2006) found recommendations of the Institute for Healthcare Improvement, CDC, and other organizations with infection control expertise, postoperative patients can
avoid and prevent costly fatal surgical site infections by the use of warmed intravenous fluids, increase ambient temperature in the operating room, the use of wearing a hat and foot socks perioperatively, the use of active external warming devices, the uses of showering with an antiseptic soap before surgery, cover the incision, hand hygiene, and individualized patient education before discharge.

Perencevich, Sands, Cosgrove, Guadagnoli, Meara, and Platt (2003) support the need to prevent surgical site infections that occur after discharge which are associated with incurred substantial excess across the spectrum of health care. Scott and Buckland (2006) discovered through systematic review that there is a relationship between wound infection and hypothermia. Warming therapy has been effective in preventing infection in surgical wounds, healing chronic wounds, and used as an alternative to prophylactic antibiotics in certain types of surgery (Scott & Buckland).

CDC acknowledged criteria that should be used when identifying and reporting National Health Safety Net events so that rates between hospitals can be compared. Rivers, Coba, and Whitmill (2008) affirm that overcoming logistical, institutional, and professional barriers to the implementation of goal-directed therapy can save the life of every six patients presenting with severe sepsis and septic shock. Vogel, Dombrovskly, and Lowry contend that the development of sepsis has increased significantly after elective and nonelective procedures over the past 17 years with disparities found in age, sex, and ethnicity.

Little is known about infection control practices in ambulatory surgery centers (Schaefer, Jhung, Dahl, Schillie, Simpson, Llata, Link-Gelles, Sinkowitz-Cochran, Patel, Bolyard, Sehulster, Srinivasan, & Perez, 2010). The authors found that among a sample
of United States ambulatory surgical centers assessed in three states, lapses in infection control (hand hygiene, infection safety, medication handling, equipment reprocessing, environmental cleaning, and handling of glucose monitoring equipment) were common (Schaefer et al.). The AMBU-KISS is a protocol designed to create a reference database on surgical site infections for institutions involved in ambulatory surgery (Mlangeni, Babikir, Dettenkofer, Daschner, Gastmeier, & Ruden, 2005). (Appendix B).

**Project Plan and Evaluation**

**Market/Risk Analysis**

Marketing plans serve as road maps that guide marketers, allowing them to proactively, rather than reactively, address and manage pursuits (Fortenberry, 2010). A market analysis allows for planning, strategizing, and forecasting. These insights can greatly improve the performance of the organization.

**Strengths, Weaknesses, Outcomes, Threats (SWOT) Analysis**

The SWOT Analysis provides an effective method for assessing the internal and external factors associated with products and the organizations that produce and provide them (Fortenberry, 2010). It is a tool that assists with the environmental analysis and competitive assessment of the organization. It allows marketers to analyze the strengths, weaknesses, opportunities, and threats associated with product offerings. First, the internal strengths of the organization are: advanced research development, patient protection by a culture of safety, exceptional quality, brilliant marketing management with a diverse abundant advertising market, reputable physicians and nurses, tremendous customer service, a greater capacity than competitors, medication reconciliation, a new CEO who is a visionary, and an academic medical center where teaching is valued (Fortenberry). The
internal weaknesses of the organization are: poor brand identity, inconvenient access to offerings, declining market share, nurse attrition, patient rooms not as elaborate as competitors, infancy of patient information system, and behind on the technological advancements (Fortenberry). The external opportunities of the organization are: a newly discovered product use with developed technologies, favorable governmental regulation, information system streamlined, and the increased demand for ambulatory surgical services and elective medical procedures (Fortenberry). The primary threats to the organization are: market attrition, changing consumer preferences, superior substitute products, economic decline, and the competitors equipped with superior technologies.

**Driving Forces**

The driving forces of the project proposal is to create a healthier population by decreasing the incidence of surgical site infections as assessed by identified new cases each year. Decrease the overall health care cost which will render a more efficient use of health care dollars. Lastly, to increase community awareness of prevention efforts for the cause, transmission, prevention, and treatment of surgical site infections.

**Restraining Forces/Barriers**

Barriers are negative product and product-related attributes that adversely impact exchange (Fortenberry, 2010). Some of the barriers to the organization are: poor brand identity, inconvenient access to offerings, declining market share, high nurse employment turnover rate, patient rooms are not as elaborate as competitors, infancy of patient information systems, technological advancement weaknesses. The first barrier to the organization is poor brand identity because of the lack of consistency in the marketplace evidenced by a recent name change of the institution (Fortenberry, 2010). Inconsistent
imagery is confusing to customer and conveys the impression of disorder (Fortenberry). The next barrier is the inconvenience of the location of offerings because the organization is located downtown fifteen miles from the interstate and among five competing hospitals within a five mile radius which impedes market share. In addition, the instability of the economy has led to both a high unemployment rate and increases in the number of uninsured consumers. Even though the nurses at the organization are paid higher than the competitors, the operating room nurses have to be extensively trained for several months before competence, undergo environmentally challenging situations with physicians, and taking a rotating call schedule. Therefore, these circumstances are reflected in the high attrition rates which decrease the number of staff available to perform the surgical cases and squelch the potential revenue made by the hospital. In addition, the organization is an older hospital that does not have a distinguishable front entrance to the hospital and lacks elaborate rooms or decor as the rival which signifies being outdated. Moreover, the lack of technological advances and the infancy of the patient information convey to the public that these areas are insignificant. There are many opportunities that could be improved; whereby, increasing the likelihood of growth and prosperity.

Need

A need is described as something that a person requires for survival or wellbeing (Fortenberry, 2010). To meet the customers’ physiological and safety needs, it is imperative to prevent post operative surgical site infections. The overall good health of a consumer is the first need that is met that equates to a healthier population. In addition, a healthier population translates to less time lost from work with the ability to continue earning a living. This allows for a more efficient use of health care dollars. There is also a reduction in the
incidence of new cases of surgical site infections identified each year in the community which is also an advantage. This service will increase community awareness of prevention efforts by improving consumer knowledge of infection, causes, transmission, prevention, and treatment options. Also, the reduction of hospitalization rates of a consumer because of fewer and shorter stays related to a decline in admission rates associated with surgical site infection. Without such preventative services, medical complications are more likely to occur, possibly resulting in injury or death (Fortenberry).

**Resources Used for Attraction and Retention of Customer Base**

Interdisciplinary collaboration and community partnership involves coordination, networking, and cooperation (Zaccagnini & White, 2011). Collaboration involving the broader community of the entire organization and its patterns of function and operation are needed for successful achievement of system-wide benchmarks and goals. Resources that customers might find helpful to ensure that quality and safety are provided during the surgical encounter include: trade associations, the organization’s mission statement, governmental websites (CDC and Joint Commission), quality indicator websites (Agency for Health Care and Quality Research, Quality Net, and Surgical Care Improvement Program Measures), and local customer directories.

**Sustainability/Market Share**

Healthcare marketers must be continually concerned with how their organization and related products are perceived by target audiences because this safeguards the vitality of the organization (Fortenberry, 2010). There are currently 300 to 400 surgical patients (consumers) who are serviced monthly by the ambulatory surgical service line in the organization. To increase the surgical market share some important considerations must be
employed: new specialty surgeons hired that will increase the volume of patients and
provide entry into new markets, consistent corporate structure, customer loyalty, progressive
branding with consistency that safeguards identity, identity management, strategic planning
that involves a pulse on the competition, market place intelligence, and marketing warfare
(Fortenberry).

Stakeholders/Project Team

A stakeholder is described as a person, group, or organization that has direct or
indirect stake in an organization because it can affect or be affected by the organization's
actions, objectives, and policies (BusinessDictionary.com, n.d.). The key stakeholders
include: the consumers (ambulatory surgical patients), perioperative staff, the researcher,
and the project team. Other stakeholders in a business organization include creditors,
customers, directors, employees, government (and its agencies), owners (shareholders),
suppliers, unions, and the community from which the business draws its resources. The
project team includes: the DNP faculty mentor, Regis Capstone Chair, and the primary
investigator (the researcher).

Cost-Benefit Analysis

Cost information provides data for identifiable and specific decision-making groups,
such as budgetary cost variance reports to department managers, cost reports to third-party
payers, and forecasted project cost reports to planning agencies (Cleverley, Song, &
Cleverley, 2011). This allows management to decide whether the healthcare organization
services are profitable or to forego certain aspects of care. The purpose of the cost-benefit
analysis is to identify the service and costs that will be provided in regards to surgical site
infections such as: the charge for the service, the resources required to produce the service,
the fixed costs, the variable costs, the direct costs, the indirect costs, and the break-even point of the service.

A cost-oriented assessments or evaluation can be especially important in the search for policies that provide value for public dollars. An organization needs to select the projects that contribute most to the attainment of its objectives, given resource constraints (Cleverley, Song, Cleverley, 2011). A cost-benefit analysis is based on the relationship between the benefits and costs of a particular policy, where all costs and benefits are expressed in monetary terms (Longest, 2010). The result of the analysis is a measure of net benefits (Longest).

The consumer demands quality, safety, convenience, timely service, and cost-effective care which can be satisfied by the Surgical Care Improvement Program, intraoperative warming methods, and a comprehensive Preoperative assessment with prevention education. In turn, the consumers will have a more efficient use of their health care dollars, increase survival rates, and the population will be healthier creating community awareness of prevention efforts related to surgical site infections. The health issue offers a tactic for the service of superior quality while maintaining competitive prices that secures human longevity and business profitability. In the simplest terms, the value of life attained in the prevention of postoperative infection is far greater than the costs spent.

Surgical site infections (SSI), the second most frequently reported healthcare associated infection next to urinary tract infections (UTI), account for 17% of all HAIs, totaling approximately 500,000 infections yearly (Dimick, Chen, Taheri, Henderson, Khuri, Campbell, 2004; Mlangeni & Babikir, 2005). Zoutman (2005) found that 1.39% patients are admitted per 100 admissions for surgical site infections. Each infection accounts for 8.2
extra days per surgical case in the hospital (Zoutman). Therefore, 438,052 patients are hospitalized related to infection for extra bed days per year that would have normally been discharged after the surgical procedure (Zoutman). The associated hospital costs ranging from $3,500 to $18,000 dollars with an increased length of stay of four to 14 days for each surgical site infections have been found (Dimick et al., 2004; Mlangeni & Babikir, 2005; Zoutman). The estimated costs per year for surgical site infections are $219,000 per hospital (Zoutman). These additional costs contribute to an estimated financial burden of up to 10 billion dollars annually (Perencivich & Sands, 2003; CDC, 2010).

Vision/Mission

Professional focused vision statement. Vision gives direction. Vision represents values that are important to a person, project team, organization, or a country. Moreover, a vision statement defines the desired future state of an organization in terms of its fundamental objectives (Houser & Oman, 2011). The vision statement should resonate with all members and make them feel part of something bigger than themselves. It provides a long-term view of the organization and what the organization wants to become (Houser & Oman). The professional focused vision statement for the organization is: Quality and safety above all, in the quest to be an acknowledged leader in compassionate patient-centered care with interdisciplinary collaboration to treat, cure, and prevent diseases or infection through educational inquiry, research discovery, and evidence-based clinical practice. The vision statement was revised to include quality and safety as the focus of the organization which depicts the overall goal in the eradication of infection and disease states. The vision statement for the project is: Quality and safety above all, in the quest to be an acknowledged leader in the prevention of infection through the use of evidence-based clinical practice.
**Professional focused mission statement.** The mission statement defines the fundamental purpose of an organization or project team which describes why an organization exists (Houser & Oman, 2011). A mission statement is intended to guide the organization into the future by identifying the unique attributes of the organization, why it exists, and what it hopes to achieve (Cleverley, Song & Cleverley, 2011). The professional focused mission statement for the organization is: As a comprehensive Health Science University, we strive to be a leader in the highest quality by:

- Being a pioneer in the surgical service arena.
- Providing excellence in both biomedical and social sciences through discovery and innovation.
- Modeling evidence-based practices in clinical care and public health.
- Educating health professionals.
- Empowering staff, patients, and families in decision-making.

The mission statement of the project team is: being a pioneer in the surgical service arena”.

The mission statement now embodies a holistic view of the attributes that the project team is striving to achieve.

**Project Goals**

The goals of the DNP capstone proposal is to create a healthier population by decreasing the incidence of surgical site infections as assessed by identified new cases each year. Decrease the overall health care cost which will render a more efficient use of health care dollars. Lastly, to increase community awareness of prevention efforts for the cause, transmission, prevention, and treatment of surgical site infections.
Outcome Objectives/Specific Aims of the Study

There are four specific aims for the study. The specific aims of this project include:

- To determine the incidence of unplanned postoperative hypothermia in the ambulatory surgery population at the Georgia Health Science University.
- To determine the incidence of surgical site infection in this ambulatory surgical population at the Georgia Health Science University.
- To determine the relationship of Preoperative patient warming to the incidence of unplanned postoperative hypothermia in the ambulatory surgical population at the Georgia Health Science University.
- To determine if the relationship of Preoperative patient warming to the incidence of surgical site infection in the ambulatory surgical population at the Georgia Health Science University.

Identified factors. The variables were identified using the proposed conceptual model. The conceptual model drives the analysis plan. The first major factor is unplanned postoperative hypothermia. There are several different hypothermia risk factors or co-variates. Risk factors for the development of perioperative hypothermia include:

- Physical status/co-morbidities
- Anesthetic agents
- Age (children/elderly)
- Exposure of a large body cavity
- Major blood or fluid loss
- Environment/temperature of the operating room
- Length and type of the surgical procedure
• Infusion of cold fluids, blood products, or irrigation into the body cavity
• Body size of the patient (thin/small)

The next major factor has other items that need to be considered. There are three separate factors that fall under this category which include: the Surgical Care Improvement Program, intraoperative warming methods used, and the patient’s medical history. The SCIP program has several factors that reflect the care of the patient which include:

• Patient is prepped appropriately by being clipped for hair removal prior to surgical intervention.
• Antibiotic given one hour before surgical incision.
• Right antibiotic is initiated based on the type of surgical procedure.

The last major factor to be considered is surgical site infection which is diagnosed by three different methods. The first method in this category are the signs and symptoms of infection which include: purulent drainage, pain or tenderness, localized edema, redness, heat, fever, the incision deliberately opened by surgeon, the wound spontaneously dehisces, abscess, or other evidence of infection found on direct exam, during surgery, or by diagnostic tests. The second method is laboratory findings that consist of a positive culture or positive gram stain when the culture is negative or not completed. The third method is the clinical diagnosis of infection by the physician after the event, with the initiation of appropriate antimicrobial therapy. Lastly, the dependent factors will be the short-term findings of patient temperature on return from the operating room and the long-term findings are identified as the incidence of surgical site infections.
Logic Model

The Logic Model illustrates an inventory of what you are starting with and what you need to operate a program. It gives a systematic and visual method for program management and assessment while supporting a strong case for how and why a program will produce desired results (W. K. Kellogg Foundation, 2004). The inputs include: the team, ready access to affected population (retrospective chart abstraction), time (abstraction of data from charts), and materials (data sheet). The activities involved in the project include: comprehensive primary care of the ambulatory surgical patient undergoing anesthesia [comprehensive medical history, laboratory testing, prevention of infection education, Hibiclens soap provided, and strict adherence to the SCIP measures (the right antibiotic, antibiotic given one hour before incision, antibiotic given in surgery, and Preoperative clipping with no shaving)], chart abstraction of data (lab results, clinical notes, anesthetic record, PACU record, ambulatory surgical record, and operating room notes), and intraoperative warming methods. The outputs related to the Logic Model include: patient laboratory results (white blood cell count and blood or wound culture), clinical diagnosis of infection related to signs or symptoms (elevated temperature, wound dehisce, edema at the site), adherence to prescribed therapeutic regimen (Preoperative appointments, laboratory appointments, and antibiotic/prophylactic medication prescription), infection control (infection rates monitored), patient satisfaction surveys, consumer participation in Preoperative education, consumer participation in Preoperative showering with cleanser, insurance status (ability to obtain Medicaid, SSI, or private insurance), and infection control (hand washing protocol). The project outcomes of the Logic Model include: decreased infection rates, increased survival rates, decreased hospitalization rates (fewer/shorter
hospitalizations and a decrease in readmission rates related to postoperative infection), ability of consumer to continue to work (less time loss from work), more efficient use of health care dollars, improved consumer knowledge related to infection, causes, transmission, prevention, and treatment. The project will have an impact to society that includes: increased community awareness of prevention efforts, decreased incidence of surgical site infection in the community as assessed by identified “new cases” per year, decrease in overall healthcare costs, and a healthier population. The constraints of the project include: budget, timeframe, stake-holder buy-in, and IRB approval. (Appendix C).

Population

Recruitment. The 100 medical records came from an institutional Preoperative warming device performance improvement (PI) project of 600 patients during the period of October 2009 to November 2009. In this project, patient medical record numbers and serial Preoperative, intraoperative, and postoperative patient temperatures were collected prior to, and following the implementation of routine Preoperative warming on all ambulatory surgical patients. Data were collected for a two-month period. The purpose of the PI project was to evaluate the impact of a minimum of 30 minutes of Preoperative warming on serial temperature trends throughout the surgical continuum; however, data regarding confounding variables and SSI were not collected. An analysis of the impact of these variables on patient outcome was not conducted at the time. This project identified whether the standard of care was met and whether there was a relationship between hypothermia (occurrence) and the subsequent development of an SSI. The standard of care for the ambulatory surgical patient is the Surgical Care Improvement Program and the use of intraoperative warming methods.
Sample size/sampling methods. A cross-sectional, purposeful, convenience sample of 100 medical records (50 prior to initiation of pre-warming and 50 post initiation of pre-warming) was used. The sample size must include enough participants to provide sufficient representation of relevant characteristics, and negative or disconfirming cases or viewpoints should be reflected in the sample. A larger sample size helps to decrease standard error and increases statistical significance (Kane & Radosevich, 2011). The sample size was determined based on the available population and the time allotted for completion of the study. An extensive number of patient charts were available for analysis and the project team determined that a larger sample size would result in more meaningful analysis. Inclusion criteria include medical records of adult patients greater than 18 years of age having non emergent, elective ambulatory surgery under general or regional anesthesia, who were discharged on the day of surgery. Records of pediatric patients and any patients admitted to the hospital postoperatively were excluded.

Setting/Service

The setting captured the surgical service experience of an ambulatory surgical patient retrospectively from an institutional Preoperative warming device Performance Improvement project of 600 patients. The service was provided in an ambulatory surgery unit within an academic medical center in Augusta, Georgia. The services that are provided are for surgical patients who are undergoing non-emergent elective anesthetic care. The services are for consumers that have surgery without post procedure admissions.

EBP Design Methodology

Measures/instruments. A retrospective, exploratory research design was proposed, using practice-based research methodologies. Medical records were abstracted for
demographic, anesthesia, and surgery specific information related to the development of unplanned postoperative hypothermia and/or SSI as outlined by the ASPAN perioperative normothermia guideline (Hooper, 2011) and the CDC National Healthcare Safety Network’s (NHSN) (2010) data elements related to SSI. The tool used for data abstraction was a Hypothermia/SSI Research Study In-Hospital Data Report sheet that was created by the author based on the research of specific items that will help identify outcomes. The independent variables are the intraoperative warming methods and SCIP measures. Dependent variables include patient temperature and incidence of surgical site infection. Measures that is included: patient discharge temperature from the OR, discharge temperature from the post anesthesia care unit (PACU), and report of SSI as quantified by the CDC National Healthcare Safety Network Surgical Site Infection data components. (Appendix D).

**Use of Human Subjects and/or Human Derived Materials**

Because this research proposal involves chart abstraction with minimal risk, IRB Form A was submitted with a request for an exempt status review to Regis University and Georgia Health Science University. Approval for exempt status was granted by Regis University. Approval for exempt expedited status was granted by Georgia Health Science University. CITI (Collaborative Institutional Training Initiative) was completed in regards to Human Research Curriculum Completion Training. Research methodology for all phases of the proposed study employed a retrospective medical record abstraction approach involving no direct social, legal, financial, physical, psychological, and/or emotional risk to participants. All data was de-identified and there was no direct interaction with patients.
Validity and Reliability

The goal is to detect a true effect. However, the potential threats to validity and reliability that were explored and were minimized during the study include: a study design, data entry, the over interpretation of results, measurement tool may not capture the needed data to be analyzed, bias (mentor and researcher are both trained in perianesthesia nursing), data collection/abstraction by researcher, instrumentation (data collection/report sheet), subject selection (ambulatory surgical population which are elective quick cases), history (related to retrospective study), testing (abstraction of nurse’s notes, anesthesia notes, and clinical notes), timeframe for collection of data (100 charts), a retrospective document (not assessing data in real time), limitations of charting (the researcher had to assume the accuracy of the data), the generalizability of findings to other settings or populations, error rate problems, handling of missing data, decreased statistical power, and violated assumptions of statistical tests. To minimize these issues, the researcher was the sole person responsible for the timeframe, data collection, interpretation of data collected, the method of collecting data, and the author of the tool used for data collection. The researcher was involved in the entire abstraction of data collection which eliminated bias. In addition, the researcher recorded data in the same way each and every time for each chart. Also, an expert in Excel was involved with data entry into a workable document for statistical analysis. A statistician was used for the expert interpretation of data collection with results.

Statistical Tests/Statistical Program

A statistician was involved related to the volume of data collected and the sample size. SPSS software was used for the statistical analyses. Statistical significance will be set at a probability (p) value of less than 0.05 for all analyses. Descriptive statistics will include
measures of central tendency and frequency measures, and will be calculated for the entire sample. Frequency distributions will be analyzed for normal distribution, outliers, and missing data. Analysis of variance and chi-square analyses will be used to compare continuous and categorical variables among groups. Multiple binary logistic regressions will be used for analysis of dichotomous dependent variables and multiple linear regressions for continuous dependent variables.

**Data Collection**

Data from all patient charts which met inclusion/exclusion criteria was collected via medical record abstraction. Then, the data was recorded to a source document (data report sheet). All data collection was performed solely by the primary investigator.

**Handling missing or incomplete data.** The handling of missing or incomplete data was accomplished by using dummy variable codes. The employment of interpolation of outcomes values which is described as carrying the last observed outcome forward is used. Ineligibility of patients was determined if essential data was missing for abstraction of data, if the patient was admitted, or if a chart is unavailable.

**Safe storage/de-identified.** Storage of the data was performed by the researcher under a locked file in which no one had the ability to access the information. Because this research proposal involves chart abstraction with minimal risk, it was submitted with a request for an exempt status review. The exempt status was granted at the educational institution of Regis and Georgia Health Science University where the project took place. Research methodology for all phases of the proposed study will employ a retrospective medical record abstraction approach involving no direct social, legal, financial, physical,
psychological, and/or emotional risk to participants. All data was de-identified and there was no direct interaction with patients.

**Project Findings and Results**

**Objective**

- **Incidence of unplanned postoperative hypothermia.** The incidence of unplanned postoperative hypothermia in the ambulatory surgical patient is 11% out of a 100 cases.

- **Incidence of surgical site infection.** The incidence of physician diagnosed surgical site infection in the ambulatory surgical patient is 4% out of a 100 cases despite the efforts of warming methods and SCIP measures.

- **Relationship of preoperative patient warming to UPH.** Preoperative warming does not affect UPH in this population.

- **Relationship of preoperative patient warming to surgical site infection.** Preoperative warming does not affect Surgical Site Infection in this population.

**Key Elements/Instrumentation Findings Detailed**

- **Patient characteristics.** The cohort consisted of 45% male participants and 55% female participants. The ethnicity of the cohort include: 66% Caucasian, 29% African American, 4% Asian, and 1% Latino or Mexican. There were no participant representations of Native American, Alaska Native, Native Hawaiian, or Pacific Islander.

- **Pertinent medical history.** The American Society of Anesthesiologist (ASA) scores of the participants include: 49% II’s, 37% III’s, 13% I’s, and 1% IV’s. There was no representation of V’s in this cohort which included patients with a high acuity or morbidity rate. The pertinent medical history of the participant does include: 39% with Cardiovascular
Disease, 11% with Diabetes, 5% with Bleeding disorders, 3% with Peripheral Vascular Disease, and 2% with Renal Disease.

**Surgical procedure.** The surgical procedures range in different service arenas in the ambulatory surgical population. The service lines include: 26% Otolaryngology, 22% Orthopedics, 11% Plastics, 10% Gynecology, 9% Gastroenterology, 6% Urology, 5% Ophthalmology, 4% Surgical Oncology, 3% Oral Surgery, 2% Neurosurgery, 1% Gynecology Oncology, and 1% Vascular Surgery. It was very interesting to find that both the Plastic Surgery and Orthopedic service lines have the most surgical site infections. In the 100 participant cohort, the Plastic surgery service line had three patients diagnosed with surgical site infection; whereas, the Orthopedic service line had one diagnosed surgical site infection.

**Hypothermia risk factors.** The hypothermia risk factors that were being researched include: anesthetic agents, length/type of surgical procedure, body size (thin/small), infusion cold fluids/blood products, age (elderly), large volumes irrigation into body cavities, and cold OR environment. The chart review revealed that 97% of the sample received anesthetic agents. An increased length of time during the procedure or had a type of procedure that exposed most of the body during the surgical procedure was found in 14% of the sample. A thin or small body size which increased the chances of becoming hypothermic was found in 7% of the sample. The factor of being elderly which is classified as being 65 years or older was found in 28% of the sample. The researcher was unable to determine the temperature of the OR room because this was not documented on any of the medical records which include the anesthetic and OR records. There was also no documentation of the infusion of cold fluids, blood products, or large volumes of irrigation into body cavities.
**Preoperative and intraoperative warming measures.** Some form of perioperative warming was employed in 89% of the cohort compared to 11% that did not. The perioperative warming measures include: warm cotton blankets or a gown (an institutional Preoperative warming device). The intraoperative warming methods that were assessed for each data abstraction include: warmed irrigation fluids, warmed IV fluids, gel pad surface warming, warm cotton blankets, warm forced air, circulating water mattress, foot socks, head covers, hypo/hyperthermia unit, room temperature adjustment, and transwarmer infant warming mattress. The researcher found that the gel pad surface warming and circulating water mattress was not used during this data collection. However, foot socks and head covers were used for all the participants in the study. In addition, the researcher found that 98% of the participants used a warm cotton blanket during surgery. The cohort participated in intraoperative warming methods to include: warmed irrigation fluids (61%), warm forced air (53%), room temperature adjusted (24%), hypo/hyperthermia unit (21%), warmed IV fluids (3%), warm air (1%), and transwarmer infant warming mattress (1%).

**SCIP measures.** The assessment of the SCIP measures include: the patient was prepped by clipping instead of shaved with a razor, an antibiotic was given one hour before surgical incision, the right antibiotic was uninitiated in surgery based on the type of surgical procedure. The data abstraction found that 95% of the cohort was given the right antibiotic. However, 5% of the cohorts were given a different antibiotic from what was suggested by the surgical prophylactic antibiotic physician order form. There were 92% of the cohorts that was given an antibiotic in surgery. There were only 8% of the patient’s that were not given an antibiotic at all. Therefore, the standards of the surgical prophylactic antibiotic orders were not followed appropriately. In addition, there were 3% of the cases where the right
antibiotic was given, but the recommended dosage was not followed. There was 8% of the cohort that was prepped by clipping. The researcher found that no antibiotic was given one hour before the incision time. Instead the antibiotics were given intraoperatively during the case by the anesthesiologist.

**Surgical site infection.** The criteria used for the assessment of surgical site infection included: laboratory (white blood cell counts, positive cultures, or a positive gram stain when culture is negative or not done), signs and symptoms (purulent drainage, pain/tenderness, localized swelling, redness, heat, fever, incision deliberately opened by surgeon, wound spontaneously dehisces, abscess, and other evidence of infection found on direct exam or during surgery. No documentation of a positive culture or positive gram stain was found. However, 2% of the cases had physician documented pain or tenderness at the site and wound spontaneously dehiscence. Plastic Surgery was the only service to report purulent drainage and wound dehiscence spontaneously at the site. Purulent drainage, redness, and localized swelling were noted in one case. There was no documentation of heat, fever, abscess, incision deliberately opened by surgeon, or other evidence found on direct exam, during surgery, or by diagnostic testing. Within the sample, a surgical site infection was diagnosed in (4%). Three of these cases were the service line of Plastic Surgery and one of the cases was Orthopedics. However, only in 2% of the cases, the physician instituted the appropriate antimicrobial therapy (SCIP, 2005). This was found to be the case in both Orthopedic and Plastic Surgery service line.

**Statistical Data Clear/Reliability of Findings Addressed/Results Discussed**

Based on the results of this study, the researcher was unable to reject either of the null hypotheses. 1st Null Hypothesis: Preoperative warming does not affect Hypothermia in this
population.  2nd Null Hypothesis: Preoperative warming does not affect Surgical Site Infection in this population. This may be due to the low statistical power of the test as well as the high level of variability inherent in the data. The review of the results of the analysis in detail will be given.

While missing data was initially an issue, particularly for temperature data, this was overcome by using an index of temperature (Mean Temp) which is described in Table 1.

| Table 1. Mean_Temp |
|-------------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|
|                   | N   | Minimum | Maximum | Mean  | Std. Deviation | Variance | Skewness |
| Mean_Temp         | 100 | 30.400   | 37.220   | 36.00612 | .082071 | .820712 | .674  | -3.766 |

This table shows that the missing data problem was eliminated (since n=100 and there were 100 observations in the sample). It also shows that there is a moderately high level of variability (a standard deviation of 0.82) and skewness. The large, negative skewness shows that the mean was less than the median, thus the variable Mean_Temp was skewed to the left. Kurtosis was also calculated but not reported due to space constraints -the values was 22.624 with a standard error of 0.478, thus the distribution of Mean_Temp had fat tails. For a graphic depiction of this information it is useful to look at a histogram, such as Figure 1.
Despite the skewness, the data is clearly still approximately normal upon visual inspection. A Stem-and-Leaf Plot of these results is found in Figure 2. All of these deviations from normality will make identification of a causal effect more difficult. This provides part of the motivation for the recommendation that future researchers use a much larger sample.
Temperature was a key variable of interest since it was used to define hypothermia (Hypothermia), where hypothermia was defined as a mean temperature below 36 degrees Celsius. This descriptive statistics for the variable Hypothermia are given in Table 2.

<table>
<thead>
<tr>
<th>Hypothermia</th>
<th>N</th>
<th>Minimum</th>
<th>Maximum</th>
<th>Mean</th>
<th>Std. Deviation</th>
<th>Variance</th>
<th>Skewness</th>
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<td>.3600</td>
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<td>.48242</td>
<td>.233</td>
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</tbody>
</table>

Other key variables where the dummy variable used to indicate the presence of Preoperative warming (Preop Warming) and dummy variable used to indicate diagnosis of surgical site infection (SSICD_recode). Preop Warming is described in Table 3 and the binary indicator of surgical site infection is described in Table 4.
The incidence of hypothermia, preoperative warming, and surgical site infection was determined in our sample. Table 5 shows that 89 of the 100 cases involved in preoperative warming. Surprisingly, over a third of our sample experienced hypothermia. Only 4 out of the 100 cases (4%) were diagnosed with a surgical site infection (Table 7), which may have provided an unusable small number of cases to test the hypothesis with appropriate statistical power and precision.
Table 6: Hypothermia Incidence

<table>
<thead>
<tr>
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<th>Frequency</th>
<th>Percent</th>
<th>Valid Percent</th>
<th>Cumulative Percent</th>
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<td>64.0</td>
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<td>1.00</td>
<td>36</td>
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<td>36.0</td>
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<tr>
<td>Total</td>
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<td>100.0</td>
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</table>

Table 7: Surgical Site Infection Incidence

<table>
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<th>Frequency</th>
<th>Percent</th>
<th>Valid Percent</th>
<th>Cumulative Percent</th>
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<tr>
<td>1.00</td>
<td>4</td>
<td>4.0</td>
<td>4.0</td>
<td>100.0</td>
</tr>
<tr>
<td>Total</td>
<td>100</td>
<td>100.0</td>
<td>100.0</td>
<td></td>
</tr>
</tbody>
</table>

It was determined that the most appropriate statistical tool for this analysis was regression because of observations on all three of the key variables and information on important covariates such as age and health status. Regression analysis allows us to examine the effect of an independent variable on a dependent variable. The researcher is seeking to determine the effect of Preoperative warming on hypothermia and on surgical site infection. While it is impossible to get a true ceteris paribus effect, particularly with observational and archival data such as this, it is possible to approximate such a relationship by holding confounding factors constant without introducing perfect multicollinearity.

Since the dependent variables are binary, the appropriate form of regression must be either probit or logit. Since logit is used by convention in the statistician field, it was selected for this analysis. The key models are those which included several right-hand side terms which the researcher believes should be held constant a priori; however, simple regressions with only Preoperative warming as the regressor was included. This will assist in
consistency and determining if the results were driven by specification. The four regression
models (simple and multivariate, for each of the two hypotheses) are included in the Table
section. Table 8 is the simple regression on hypothermia and Table 9 is its multivariate
counterpart. Table 10 is the simple regression on surgical site infection and Table 11 is its
multivariate counterpart.

**Table 8: Simple Hypothermia Logit**

<table>
<thead>
<tr>
<th></th>
<th>B</th>
<th>S.E.</th>
<th>Wald</th>
<th>df</th>
<th>Sig.</th>
<th>Exp(B)</th>
</tr>
</thead>
<tbody>
<tr>
<td>PreopWarming</td>
<td>1.023</td>
<td>.812</td>
<td>1.589</td>
<td>1</td>
<td>.207</td>
<td>2.782</td>
</tr>
<tr>
<td>Constant</td>
<td>-1.504</td>
<td>.782</td>
<td>3.702</td>
<td>1</td>
<td>.054</td>
<td>.222</td>
</tr>
</tbody>
</table>

**Table 9: Multivariate Hypothermia Logit**

<table>
<thead>
<tr>
<th></th>
<th>B</th>
<th>S.E.</th>
<th>Wald</th>
<th>df</th>
<th>Sig.</th>
<th>Exp(B)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preop Warming</td>
<td>.949</td>
<td>.823</td>
<td>1.328</td>
<td>1</td>
<td>.249</td>
<td>2.582</td>
</tr>
<tr>
<td>HRF Age</td>
<td>.686</td>
<td>.471</td>
<td>2.124</td>
<td>1</td>
<td>.145</td>
<td>1.987</td>
</tr>
<tr>
<td>HRF Body Size</td>
<td>1.041</td>
<td>.776</td>
<td>1.802</td>
<td>1</td>
<td>.180</td>
<td>2.833</td>
</tr>
<tr>
<td>Constant</td>
<td>-1.721</td>
<td>.806</td>
<td>4.558</td>
<td>1</td>
<td>.033</td>
<td>.179</td>
</tr>
</tbody>
</table>

**Table 10: Simple Surgical Site Infection Logit**

<table>
<thead>
<tr>
<th></th>
<th>B</th>
<th>S.E.</th>
<th>Wald</th>
<th>df</th>
<th>Sig.</th>
<th>Exp(B)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preop Warming</td>
<td>18.147</td>
<td>12118.638</td>
<td>.000</td>
<td>1</td>
<td>.999</td>
<td>76022349.482</td>
</tr>
<tr>
<td>Constant</td>
<td>-21.203</td>
<td>12118.638</td>
<td>.000</td>
<td>1</td>
<td>.999</td>
<td>.000</td>
</tr>
</tbody>
</table>
Table 11: Multivariate Hypothermia Logit

<table>
<thead>
<tr>
<th></th>
<th>B</th>
<th>S.E.</th>
<th>Wald</th>
<th>df</th>
<th>Sig.</th>
<th>Exp(B)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preop Warming</td>
<td>17.234</td>
<td>11333.692</td>
<td>.000</td>
<td>1</td>
<td>.999</td>
<td>30536270.782</td>
</tr>
<tr>
<td>HRF Age</td>
<td>1.420</td>
<td>1.078</td>
<td>1.736</td>
<td>1</td>
<td>.188</td>
<td>4.138</td>
</tr>
<tr>
<td>Anesthesia</td>
<td>-.764</td>
<td>1.200</td>
<td>.406</td>
<td>1</td>
<td>.524</td>
<td>.466</td>
</tr>
<tr>
<td>IWFAu</td>
<td>.675</td>
<td>1.201</td>
<td>.316</td>
<td>1</td>
<td>.574</td>
<td>1.964</td>
</tr>
<tr>
<td>Temp Monitor</td>
<td>.364</td>
<td>.458</td>
<td>.632</td>
<td>1</td>
<td>.426</td>
<td>1.439</td>
</tr>
<tr>
<td>Constant</td>
<td>-22.084</td>
<td>11333.693</td>
<td>.000</td>
<td>1</td>
<td>.998</td>
<td>.000</td>
</tr>
</tbody>
</table>

The first two models (Table 8 and 9) test the hypothesis that Preoperative warming predicts hypothermia. They are consistent in that the Preoperative warming term, Preop Warming, is statistically insignificant in both cases. In fact, it actually appears to be less significant in the multivariate model, which indicates that some of the trivial amount of variation it did explain was actually proxying for other terms. Thus, we must fail to reject the null hypothesis of no relationship between Preoperative warming and hypothermia.

The second two models (Table 10 and 11) indicate that there was insufficient variation in the data to estimate a meaningful parameter estimate and clearly, we again must fail to reject the null hypothesis. In this case estimation was not valid simply because all four of our observations on surgical site infection involved Preoperative warming. So, there were no cases of surgical site infection without warming. This underscores our key takeaway that future researcher’s need substantially more data than which was sampled.

Limitations, Recommendations, Implications for Change

Limitations

The biggest limitation was the size of the sample used for abstraction of the data. The statistician suggested the use of 600 charts would allow adequate power to detect a difference. A recommendation is being suggested for future researchers to use a much larger
sample because of the deviations from normality which make identification of a causal effect more difficult. The sample size must include enough participants to provide sufficient representation of relevant characteristics, and negative or disconfirming cases or viewpoints should be reflected in the sample. A larger sample size helps to decrease standard error and increases statistical significance (Kane & Radosovich, 2011). The sample size of 100 participants was determined based on the available population for study and the limited time allowed for data abstraction based on IRB approval. An extensive number of patient charts were available for analysis and the project team determined that a larger sample size would result in more meaningful analysis because a low number yields lack of statistical power.

Other challenges include: the novice researcher interpreting results (drawing the incorrect conclusions), the influence of extraneous variables or the abundance of the different variables to analyze, the absence of charting, and the timeframe needed to abstract data for analysis. Great care was taken to minimize the limitations associated with data analysis.

**Recommendations/Contribution to Nursing**

**Consequences (intended, unintended, impact of not having a policy).** Integrated forecasting is used to facilitate the exploration of possible global futures through the creation and analysis of alternative scenarios (Hughes, Kuhn, Peterson, Solorzano, Mathers, & Dickson, 2011). Based on the findings from Hughes et al. (2011), deaths from surgical site infections will decline by 50% in the next 10 years. Life expectancy will increase about one year for every ten years (Hughes, et al.) With the increase of life expectancy, the healthcare expenditures will increase by 10% each year (Shi & Singh, 2011). The increase in spending is attributed to the fragmentation of healthcare financing, the delivery of care, and medical technology advancement (Shi & Singh). However, the uninsured will have a 10% increase in
mortality rate because of the lack of access to primary care and fewer services received upon entering the hospital setting (Shi & Singh). Surgical procedures will increase related to the increase in mortality. The integrated forecasting model projects that deaths from non-communicable disease and injuries will more than double over the next 10 years (Hughes et al.). This finding will attribute to an increase for the need of surgical intervention. In addition, road traffic accident deaths will increase based on the growth of the vehicle fleet which is strongly tied to income growth (Hughes et al.). In addition, unsafe water and poor sanitation will also decrease with rising income which decreases the overall infection rate in the next five years (Hughes et al.). These advances will lead to enhanced sterilization innovations which will decrease the potential for surgical site infections. However, the uninsured will most likely not be able to take advantage of surgical interventions related to the inability pay or no source of payment which will continue to alienate the patient from proper access to care that plagues the mortality rate.

If a health policy is not in place, the increase of surgical site infections has the potential to exacerbate several problems in society. First, the problem of inflated or needless health care costs will be worsened by a boost in readmission rates from infection. In addition, consumers will have a lengthy recovery with a potential for greater mortality from a surgical intervention. Health care personnel will not be held accountable for strict procedures for the prevention of surgical site infections as a standard of care which will intensify unsafe practices in regards of consumers receiving substandard care. Through the lack of marketing efforts related to surgical site infection, the deficit of knowledge will persists in regards to infection in the population.
Alternatives (policy options). The risk to the patient can be minimized by leadership and commitment at all levels of the patient safety chain with well designed process systems, clean hygienic environment, and safer practices. One policy alternative is to develop an organizational infrastructure for a dedicated nurse reviewer to capture necessary clinical data regarding 30-day events to appropriately measure risk-adjusted outcomes (Bratzler & Hunt, 2006). Zoutman (2005) suggests that a full-time infection control nurse reviewer is required to specifically monitor patient readmits with infections, review charts related to patient care, classifying wound infections based on the CDC definition, and examine wounds every 48-72 hours with suspicious infections. Sharing surveillance data between institutions and surgeons helps assist with interdisciplinary and community collaborations (World Alliance for Health Safety, 2006; Zoutman). The next alternative is to pursue global or operation-specific outcomes, such as 30-day readmissions and 30-day mortality rates (Bratzler & Hunt). The availability of reliable health care associated infection information at the community and district level fosters action (World Alliance for Health Safety, 2006). Another alternative involves the development of an information data collection tool for the Surgical Care Improvement Program for the process of care (Bratzler & Hunt). Another alternative involves specific education programs promoting safety in surgical procedures tailored to the needs of the health care facility (World Alliance for Health Safety). In addition, health care workers need to have access to best practice protocols on clinical procedures and equipment with adherence to safe clinical practice (World Alliance for Health Safety). Surgeons need to use optimal surgical antimicrobial prophylaxis that includes: limiting the duration of antimicrobial administration following surgery, proper timing of administration prior to incision, and the appropriate choice of antimicrobial agent (Zoutman). The last alternative is
to abide by the SCIP measures instead of the focus being on a comprehensive surgical visit which includes intraoperative warming methods.

**How does it fit with established goals/priorities?** The driving forces of the health policy is to create a healthier population by decreasing the incidence of surgical site infections as assessed by identified new cases each year. Decrease the overall health care cost which will render a more efficient use of health care dollars. Lastly, to increase community awareness of prevention efforts for the cause, transmission, prevention, and treatment of surgical site infections. The planned policy alternatives will not render the same benefits of eradicating infection because some of the options are concerned with data capture or collection, collaboration efforts, education strategies, protocols, prophylaxis medication. However, they are all concerned with taking steps to decrease overall surgical site infection rates.

**Options and rationale for recommendations.** The rationale for the recommendations are based on research related to expert opinions, professional organizations, regulatory bodies, governmental agencies, and quality indicator organizations in regards to surgical site infection. Experts have researched the topic and have many years of experience dealing with the subject matter. Professional organizations seek to further both the public and member interests. Regulatory bodies are in charge of accreditation and certification for quality and safety efforts. Governmental agencies protect the health of the population and promote quality of life. Quality indicatory organizations focus on the quality of consumer health care.
Implications for Change

Legal, administrative, and political feasibility. Legal feasibility determines whether the proposed system conflicts with legal requirements. Administrative feasibility is how possible it would be to implement any given intervention given a variety of social, political, and administrative constraints (Shi & Singh, 2011). Political feasibility is politically acceptable this policy is to key officials, stakeholders inside and outside of government, and voters (Shi & Singh). In the simplest terms, the value of life attained is far greater than the costs spent. Legally, safety efforts will prevent needless lawsuits. Administrative commitment and leadership at all levels with well designed processes and systems will minimize risk to the patient. The policy is political feasible based on the fact that consumers (voters) demand safety in healthcare. Political figures will advocate for policies that safeguard consumers’ welfare.

Conclusion

In summary, SSIs associated with ambulatory surgery are a particular concern due to increasing number of surgery procedures performed in the ambulatory setting. Preoperative warming has been identified as a possible means of preventing SSI through the maintenance of perioperative normothermia (Vanni, Braz, Modolo, Amorim, Rodrigues, 2003; Hooper, Chard et al., 2009). The relationship of Preoperative warming to the incidence of UPH and SSI in the ambulatory surgical patient population, however, has not been well researched. Therefore, a capstone project was proposed to explore the relationship of Preoperative warming to the incidence of surgical site infection in the ambulatory surgical patient. This project found that Preoperative warming does not affect UPH or surgical site infection. In fact, the incidence of unplanned hypothermia in the ambulatory surgical patient was found in
only 11% of cases; whereas, physician diagnosed surgical site infection was found in 4% despite efforts of both warming methods and SCIP measures. This capstone project identified a problem, reviewed the evidence, described the project plan with an evaluation, explained the project findings with results, examined the limitations, explored the recommendations, and recognized the implications for change.
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Appendix A

Conceptual Diagram

Donabedian’s Systems Theory (Theoretical Foundation)

Introduced the concepts of structure, process, and outcome for the evaluation of the Quality of Healthcare.

<table>
<thead>
<tr>
<th>Conceptual Model (Landscape View)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hypothermia (Patient Exposure during Ambulatory Surgery)</td>
</tr>
<tr>
<td>Hypo-thermic Risk Factors—&gt;</td>
</tr>
<tr>
<td>{Infusion Cold Fluids/Blood}</td>
</tr>
<tr>
<td>{Age (Children/Elderly)}</td>
</tr>
<tr>
<td>{Cold OR Environment}</td>
</tr>
<tr>
<td>{Length/Type Surgical Procedure}</td>
</tr>
<tr>
<td>{Body Size}</td>
</tr>
<tr>
<td>Anesthetic Agents</td>
</tr>
<tr>
<td>Large Volume of Irrigation Into Body Cavity</td>
</tr>
<tr>
<td>Exposure of Large Body Cavity</td>
</tr>
</tbody>
</table>

SCIP (Surgical Care Improvement Program) Measures

<table>
<thead>
<tr>
<th>The Right Antibiotic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antibiotic Given in Surgery</td>
</tr>
<tr>
<td>Antibiotic Given One Hour before Incision</td>
</tr>
<tr>
<td>Clipped (Prep)/No Razor</td>
</tr>
</tbody>
</table>

Intraoperative Warming methods used

Patient’s Medical History

Conceptual Model: Interpretation

**Concepts:** Hypothermia (Patient Exposure during Ambulatory Surgery), the Standard of Care or Treatment of the Patient, and Surgical Site Infection (outcome/dependent variable).

The arrows by their directionality, indicate that the patient exposure during ambulatory surgery (a patient could be normothermic or hypothermic depending on the hypothermia risk factors when they enter into surgery). This therefore, combined with the standard of care or treatment/intervention (SCIP Measures, intraoperative warming, patient’s medical history) influences the patient’s risk for surgical site infection (confirmed by: signs/symptoms of infection, laboratory findings, & clinical diagnosis of infection). Using Donabedian’s Systems Theory, allows for the evaluation of quality healthcare.

**PICO:** In adult patients undergoing ambulatory surgery, do patients who are prewarmed during surgery (normothermic) have fewer surgical site infections than those that are not (hypothermic)?

**Selected Evidence-based outcome indicators for Advanced Practice Nursing:**

- **Patient Satisfaction:** (no infection/speedy recovery)
- **Risk** (morbidity/mortality)/Infection: reports (clinical notes with signs & symptoms of infection/follow-up care/lab reports/clinical diagnosis of infection per MD).
- **Infection Control:** Surgical Procedures: Hand washing; nosocomial infection rates.
- **Knowledge:** antibiotic medication/taking antibiotics until completion of prescription.
## Appendix B

### Systematic Review

<table>
<thead>
<tr>
<th>Article Title &amp; Journal</th>
<th>Author/Year</th>
<th>Database/Keywords</th>
<th>Research Design</th>
<th>Study Aim/Purpose</th>
<th>Population Studied/ Sample Size/ Criteria/ Power</th>
<th>Methods/Study Appraisal Synthesis Methods</th>
<th>Primary Outcome Measures &amp; Results</th>
<th>Author Conclusion Implications Key Findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hypothermia Warming Protocols: Why Are They Not Widely Used in the OR?</td>
<td>Weirich, T. February 2008</td>
<td>Hypothermia Infection</td>
<td>Protocols II</td>
<td>To offer guidelines for the prevention of hypothermia</td>
<td>Surgical patients undergoing anesthesia-3 studies (RCT)</td>
<td>RCT/blinded outcome assessment-temp measurements/wound cxs (3 weeks after surgery)- RCT 421 pts-3 groups (local warming, systemic warming, or unwarmed)- Blinded study- Schmied conducted study for evaluation of warming to reduce blood loss (operative).RCT-60 pts undergoing hip arthroplasty-Higher transfusion rate for hypothermic group.</td>
<td>Discussed the cause and effects of hypothermia, the lack of consistent normothermia practices among institutions, and the obstacles to achieving normothermia in the OR-offering suggestions for improved hypothermia prevention procedures.</td>
<td>Hypothermia: Increase recovery time, increase pt. health facility costs, decrease pt satisfaction. Research studies are needed to establish effective Guidelines and Standards for temp monitoring &amp; warming. Prewarming and heat distribution may be the key to treatment of hypothermia. Wound infection 3x higher in hypothermic pts./Melling-study of wound infection rates after clean surgical procedure. Results indicated pts. had 4% rate of...</td>
</tr>
<tr>
<td>2. The Effects of Intravenous Fluids Temperature on Perioperative Hemodynamic Situation, Post-Operative Shivering, and Recovery in Orthopedic Surgery</td>
<td>Hasankhani, H., Mohammadi, E., Moazzami, F., Mokhtari, M., Naghizad, M.</td>
<td>Intravenous Fluids Temperature Hemodynamic Situation, Shivering, Recovery</td>
<td>Randomized Controlled trials</td>
<td>None Noted</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>---</td>
<td>---</td>
<td>---</td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| | | | Evaluate the effects of warming intravenous fluids on perioperative hemodynamic situation, post-operative shivering and recovery in orthopedic surgery | I
IVF warming has been studied in other surgeries, but rarely in orthopedic surgeries. Offered information on the effects of hypothermia: morbid cardiac events, wound infections, increased blood loss, and transfusion requirements, and delay discharge from the PACU. Shivering causes: increased metabolic demand/cardiac output, decreased drug metabolism, impaired coagulation, and decreased immune response. |
| | | | 60 Orthopedic surgical patients-randomly divided into 2 groups according to intraoperative IVF management. 30 pt (hypothermia group) all IVFs infused at room temperature/30 pts (normothermia group) all IVFs warmed using a dry IV fluid warmer. |
| | | | Analyzed by T-test/chi-square analysis, ANOVA Perioperative pulse rate, blood pressure, intraoperative esophageal and skin temperature were measured. |
| | | | The core and skin temperatures of the hypothermia and normothermia groups decreased significantly between the induction of anesthesia and the end of surgery, but the drop was greater in the hypothermia group (P<0.005). Shivering was observed in 21-30 in the normothermia group (p<0.005) and recovery time was significantly lower in the normothermia group (36+/1 vs. 26+/3 min, p<0.005). |
| | | | Intraoperative IV fluid warming reduces perioperative changes to the hemodynamic situation, post-operative shivering and recovery time |

| 3. Reducing Surgical Site Infection Through Process | Brox, N. & Ghazarian, P. | Surgical site Infections, CDC, Normothermia Centers for Medicare and Medicaid/CDC | Independent randomized Study | I
A national collaborative with 55 other hospitals and Quality Improvement Organization aimed at reducing surgical infections via utilizing the IHI Breakthrough Model of Improvement Via Christi Regional Medical Center participated in a national collaborative with 55 other hospitals. Implementation evidence-based practices at both the system level and IHI Breakthrough Model of Improvement-13 month project. Prevention strategies focused on the appropriate use of prophylactic antibiotics, avoiding shaving of the operative site, prevention of perioperative hypothermia, |
| | | | Antibiotic timing & selection (Administration to a specific group, standardized location for documentation, standardized antibiotic protocol, implementation of antibiotic administration orders, |
| | | | Improvements in the timing and selection of prophylactic antibiotics & maintenance of perioperative normothermia through a series |
| Improvem ent  | Strengths: Focused on a system level change within a hospital which is similar to the efforts I will be conducting. Recommendations similar to SCIP measures. for the focus of improving the quality of care delivered to surgical patients. Using a pilot study population which I intend to do in my own project. | Kansas Nurse | individual surgeon level. Process improvements and patient outcomes were tracked in a pilot population of neurosurgery patients to evaluate the impact of these changes. and behaviors (traffic control, hair covering, nails, etc.). Process changes were trialed and implemented within this pilot population. | education on antibiotic timing with rationale, reminders implemented, feedback to staff) Perioperative Normothermia (Initiated patient warming, standardized location for warmers, room temp. OR suites as degree F.). Avoid shaving operative site (Initiated Hair removal procedures/clippers, educate patients not to shave themselves), and Traffic control. |
| Initiatives | | | of system level changes. |
| **4. Hospital costs associated with surgical complications: a report from the private-sector National Surgical Quality Improvement Program** | Surgical Site Infections Complications Quality Improvement | Descriptive study II | The objective of the current study was to calculate hospital costs associated with postoperative complications because reducing morbidity may offset the costs of using the National Surgical Quality Improvement Program. Looking at the cost factors for postoperative wound infection (surgical site infection) will be a huge factor in the support of my project. | Patient data were obtained from a single private-sector center involved in the NSQIP from 2001-2002 (n=1,008). | Cost data were derived from the hospital’s internal cost-accounting database (TSI: Transition Systems, Inc). Total hospital costs associated with both minor complications and major complications were calculated. Multiple linear regressions were used to determine the cost of each type of complication after adjusting for patient characteristics. | Rates of minor complications (6.3%, 64 events) & major complications (6.6%, 67 events) were similar. Median hospital costs were lowest for patients without complications (4,487 dollars) compared with those with minor (14,094 dollars) and major complications (28,356 dollars) (p=0.001). After adjusting for differences in patient characteristics, major complications were associated with an increase of 11,626 dollars (95% CI, 9,419 dollars to 13,832 dollars; p<0.001). Minor complications were not associated with increased costs in the adjusted analysis. | Given the substantial costs associated with major post-operative complications, reducing morbidity may provide sufficient cost savings to offset the resources needed to participate in the private-sector expansion of the NSQIP. |
| **5. Prevention of inadvertent** | Hypothermia Nurse’s Role Nursing Implications, Prevention | Flawed randomized study II | Educate on precautionary measures that can reduce the amount of heat loss, minimize the Patients at risk for hypothermia-surgical | The inadvertent perioperative hypothermia algorithm (based on National Institute for Health and Clinical Excellence | Author shared the risk factors for the development of inadvertent hypothermia: pt’s intrinsic | Precautionary measures can reduce amount of heat lost, minimize the risk of adverse |
### 1. Perioperative Hypothermia

**Journal of Nursing 2009**

None Noted

A perioperative hypothermia algorithm (based on the National Institute for Health & Clinical Excellence (2008) guidelines for hypothermia management) came out of the article. This allows the healthcare provider specific guidelines for treatment/prevention of hypothermia. It also gave specific principles associated with hypothermia: prolonged recovery, increased blood loss, arrhythmias/cardiac arrest, impaired immunity, delayed wound healing, and wound infection. Recent evidence:

- Risk of adverse complications associated with low core temperature, and improve patient’s recovery. Also, used to educated nurses that hypothermia is preventable.
- I will need to know the mechanisms to prevent hypothermia—this will help me establish my tool for hypothermia risk factors.


Factors include: age, neonate/over 70, Systemic disease (diabetes, peripheral vascular disease, Poor nutritional Status), surgery Factors: pre-operative fasting, Administration of cool IVs, large area of body exposure, evaporative heat loss due to skin preps/solutions, type/length of surgery (abdominal surgery >2 hrs) General anesthesia Thermoregulation Impaired, volatile Agents cause Vasodilation leading to heat loss by radiation, muscle relaxants prevent shivering of skeletal muscles. Environment: thin gown, transfer, skin exposure, cool temp, & minimal covering.

### 2. Preventing Surgical Site Infections

**Odem-Foren, J. June 2006 Nursing 2006**

None Noted

Practice guidelines (Best practice interventions for preventing surgical site infections) This article is the 6th in Nursing 2006 that examines the IHI’s suggested 100,000 Lives campaign interventions from a risk of adverse complications associated with low core temperature, and improve patient’s recovery. Also, used to educated nurses that hypothermia is preventable.

- Educate on four evidence-based components of care endorsed by the IHI for preventing surgical site infections.
- This article will assist me on the variables of surgical site infection for my tool for capturing the data.

Surgical patients

Informative-IHI (1000 Lives Campaign) & CDC definition of surgical site infections and how to classify.

Surgical patients

Informative-IHI (1000 Lives Campaign) & CDC definition of surgical site infections and how to classify.

Surgical patients

Informative-IHI (1000 Lives Campaign) & CDC definition of surgical site infections and how to classify.

Educate practitioner on THE CDC Classification of Surgical Wounds: Class 1: Clean wounds (no inflammation, closed by primary intention, closed drainage system, does not involve respiratory, alimentary, genital, or uninfected urinary tract. Class 2: Clean-Contaminated Wounds (operative wounds in which respiratory, alimentary, genital, or

Following recommendations of the IHI, CDC, and other organizations with infection control expertise, postoperative pts can avoid and prevent a costly fatal SSI.
nurses point of view. The key strategies have proven to prevent avoidable deaths (deploying rapid response teams, preventing ventilator-associated pneumonia, preventing adverse drug events with medication reconciliation, preventing central line infections, prevention surgical site infections, and delivering evidence-based care to treat acute myocardial infection. Note to be similar to the SCIP Measures.

**Class 3: Contaminated Wounds**
- Open, fresh, accidental wounds
- Surgeries with major breaks in sterile technique or gross spillage from GI tract, incision which acute, nonpurulent inflammation is visible.
- Surgical site infections
- Prevention surgical site infection (Superficial, Deep, or Infection of Organ Space).

### 7. Effects of preoperative warming on the incidence of wound infection after clean surgery: a randomized controlled trial

*The Lancet*

| Melling, A., Bagar, A., Scott, E., & Leaper, D. | Surgical Site Infection, Hypothermia, Normothermia | Randomized controlled trial |
| Professional Unit of Surgery, North Tees and Hartlepool NHS Trust, university hospital of North Tees, UK | I | Weakness: The article itself was on the end of being outdated. Strengths: Had a good population size. |

Wound infection after clean surgery is an expensive and often underestimated cause of patient morbidity, and the benefits of using prophylactic antibiotics have not been proven. Warming patients during colorectal surgery has been shown to reduce infection. The aim of the study is to assess whether warming patients before short duration, clean surgery would have the same effect.

This article will help me see how

| 421 patients having clean surgery (breast, varicose vein, or hernia) | 421 patients having clean surgery (breast, varicose vein, or hernia) were randomly assigned to either a nonwarmed (standard) group or one of two warmed groups (local & systemic). Applied warming for at least 30 min before surgery. Patients followed up and masked outcome assessments made at 2 to 6 weeks. |

- Identification 19 wound infections in 139 nonwarmed pts (14%) but only 13 in 277 who received warming (5%, p=0.001). Wound scores significantly lower (p=0.007) in warmed pts. There were no significant difference in development of seromas/hematotomas after surgery but the nonwarmed groups were prescribed.

- Analysis was done on an intention to treat basis. Identification 19 wound infections in 139 nonwarmed pts (14%) but only 13 in 277 who received warming (5%, p=0.001). Wound scores significantly lower (p=0.007) in warmed pts. There were no significant difference in development of seromas/hematotomas after surgery but the nonwarmed groups were prescribed.

- Warming pts before clean surgery seems to aid in prevention of postop wound infection. May provide an alternative to prophylactic antibiotics in this type of surgery.
<table>
<thead>
<tr>
<th>8. Identifying Healthcare-associated Infections (HAI) in NHSN</th>
<th>CDC</th>
<th>None Noted</th>
<th>Published practice guidelines (federal agency)</th>
<th>CDC/NHSN surveillance definition of healthcare-associated infection and criteria for specific types of infections in the acute care setting. A great source for me because it used data abstraction from medical records which I will be involved in as my method of data collection. Recent evidence.</th>
<th>Patient’s with healthcare-associated infections having surgery.</th>
<th>Clinical evidence from direct observation of the infection site or review of information in the patient chart/clinical records</th>
<th>Identification of HAIs that should be used when identifying and reporting NHSN events so that rates between hospitals can be compared. Infection definition.</th>
</tr>
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<tbody>
<tr>
<td>9. Exercising in Environmental Extremes</td>
<td>Walsh, N, Whitham, M</td>
<td>None Noted</td>
<td>Field studies/Evidence based practice</td>
<td>Discussion of the research evidence to date from studies examining the effects of environmental extremes (heat, cold, high altitude, and space flight) on immune responses at rest and after exercise to determine if exercising in environmental extremes poses a greater threat to immune function than exercising in more favorable conditions. Different author’s studies (8 studies) are examined &amp; compared with participants of 3-11 people which are looking at both the effects of whole-body passive heating &amp; environmental temperature on</td>
<td>Environmental extremes related to exercise</td>
<td>Lab and field studies</td>
<td>The author reviewed stress-induced mediators of immunity, heat stress and immune function, cold stress and immune function, high altitude and immune function, and space flight and immune function. Recent lab studies show a limited effect of Exercise in the heat on immune function. Evidence does not support the belief that exercising in The heat poses a greater threat to immune function (vs. thermo neutral conditions). The available evidence does not support the popular belief that short-or long-term cold exposure, with or without exercise suppresses immunity and increases infection. Lab studies show immune-stimulatory effects of cold exposure. Clear conclusions difficult</td>
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circulating leukocyte, differential leukocyte and lymphocyte subset counts
It has the least congruency with my study population. It will help give me proven data to support my hypothesis.

to make because of overlap with symptoms of acute motion sickness in regards to high altitudes increases infection. Some limitations in lab and field studies have attempted to identify if residing or exercising in environmental extremes poses a greater threat to immune function. Evidence does not Fully support the belief that residing or exercising in environmental extremes poses a greater threat to immune function.

10. Early goal-directed therapy in severe sepsis and septic shock: a contemporary review of the literature

Rivers, E., Coba, V., Whitmill, M. 2008

Sepsis
National Institute of Allergy and Infectious Disease, Biosite (Inverness), Edwards Lifesciences, and Hutchinson Technologies.

Systematic Review
I
Strength: Large sample size- Validity of information.

Aggressive approaches to acute diseases such as acute myocardial infarction, trauma, and stroke have improved outcomes. Early goal-directed therapy for severe sepsis and septic shock represents a similar approach. An analysis of the literature assessing the external validity & generalizability of this intervention is lacking. This article will help

Eleven peer-reviewed publications (1569 patients) and 28 abstracts (4429 patients) after the original early goal-directed therapy study were identified from academic, community, and international settings. These publications total 5998 patients (3042 before and 2956 after early goal-directed therapy).

The mean age, sex, APACHE II scores and mortality were similar across all studies. The mean relative and absolute risk reduction was 0.46+/−26% and 20.3+/−12.7%.

These findings are superior to the original early goal-directed therapy trial which showed figures of 34% and 16%. A consistent and similar decrease in healthcare resource consumption was found also.

Early goal-directed therapy modulates systemic inflammation and results in significant reductions in morbidity, mortality, and healthcare resource consumption. Early goal-directed therapy has been externally validated and is generalizable across multiple healthcare settings.
<table>
<thead>
<tr>
<th>Current Opinion in Anesthesiology</th>
<th>me the least because it is concerned with sepsis and not specifically surgical site infection.</th>
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</table>

| 11. Association of Postoperative Complications with Hospital Costs and Length of Stay in a Tertiary Care Center | Khan, N., Quan, H., Bugar, J., Lemaire, J., Brant, R., Ghali, W. | October 2005 | Well-controlled without randomization |
| Perioperative Surgery Cost Complications | II Strength: Large sample size-results of study had more validity. Information based on discharge data (I will be looking at discharge data and clinical visits to see if pt developed SSI infection). This article helps support the need to decrease surgical site infection related to the cost of each infection. | Retrospective-The study population was derived from administrative hospital discharge data of an urban, 750-bed tertiary care center and teaching hospital in Calgary, Alberta, Canada, for patients discharged from July 1, 1996 & March 31, 1998. Patients aged 16 or older admitted for elective or urgent noncardiac surgery. Excluded patients were those undergoing day procedures, had surgery cancelled, or who had no recorded procedure case (2,151 pts excluded in total). Using a detailed administrative hospital discharge database, the determination of total hospital costs and LOS were found. Total hospital costs and LOS were adjusted for pt postoperative and surgical characteristics. |
| Journal of General Internal Medicine | Of 7,457 pts who underwent noncardiac surgery, 6.9% developed at least 1 of the postoperative complications. These complications increased hospital costs by 78% (95% confidence interval [CI]:68% to 90%) and LOS by 114% (95% CI: 100% to 130%) after adjustment for pt postoperative and surgical characteristics. Postoperative pneumonia was the most common complication (3%) and was associated with a 55% increase in hospital costs (95% CI: 42% to 69%) and an 89% increase in LOS (95% CI: 70% to 109%). Postoperative complications consume considerable health care resources. Initiatives targeting prevention of these events could significantly reduce overall costs of care and improve patient quality of care. |

<p>| Infection Ambulatory Surgery | Stratified Random Sample | Seven states volunteered; 3 were selected based on geographic dispersion, number of ASCs each state committed to | 46 of 68 ASC (67.6%; 95% CI, 55.9%-77.9%) had at least 1 lapse in infection control; 12 of 68 ASC (17.6%; 95% CI, 9.9%-28.1%) had lapses |
| Ambulatory Surgery | II Strength: This is | (Retrospective Chart study). The Centers for Medicare and Medicaid Services (CMS) piloted an infection control audit tool in a sample of ASC inspections | Among a sample of US ASCs in 3 states,lapses in infection control were common. |</p>
<table>
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<th><strong>Ambulatory Surgical Centers</strong></th>
<th><strong>JAMA</strong></th>
<th><strong>AORN Journal</strong></th>
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<tr>
<td>Medicaid Services</td>
<td>Randomized Controlled Trials. Systematic Review</td>
<td>May 2006</td>
</tr>
<tr>
<td>the study population</td>
<td><strong>Randomized Controlled Trials. Systematic Review</strong></td>
<td>Actamed Limited, Pegasus Limited</td>
</tr>
<tr>
<td>I will focus on &quot;ambulatory surgical pt&quot; r/t infection control. Weakness: Did not specifically focus on surgical site infections. The most recent evidence.</td>
<td>Primary outcomes included: 26 RCT (n=2070) were included. Sample sz ranged from 16-324. Study of patients of any age who were undergoing noncardiac surgery under general anesthesia was eligible for inclusion. Most of the participants were undergoing major surgery and were classified as 1 to 3 on the American Society of Anesthesiologists (ASA) Physical Status Classification System. Other participants were undergoing minor or intermediate procedures requiring a short hospital stay and had ASA scores of 1 or 2. The majority of participants were aged over 50yrs old (range: 18-85). General anesthesia was used in most studies: other studies used spinal to assess facility adherence to recommended practices. Surveyors from CMS, trained in used of the audit tool, assessed compliance with specific infection control practices. Assessments focused on 5 areas of infection control: hand hygiene, infection safety and medication handling, equipment reproprocessing, environmental cleaning, and handling of blood glucose monitoring equipment. Identified in 3/5 more of the 5 infection control categories. Common lapses included using single-dose medication vials for more than 1 pt (18/64; 28.1%; 95% CI, 18.2%-40%), failing to adhere to recommended practices regarding reproprocessing of equipment (19/67; 28.4%; 95% CI, 18.6-40%), and lapses in handling blood glucose monitoring equipment (25/54; 46.3%; 95% CI, 33.4%-59.6%).</td>
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<tr>
<td>US participate in the Medicare program. Little is known about infection control practices in ambulatory surgery centers.</td>
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<td>I am not sure if this will help prove my point related to the lack of focus on surgical site infection.</td>
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<td>To evaluate the effect of interventions to prevent hypo-thermia during surgery on post-operative complications.</td>
<td>Studies that evaluated interventions to prevent hypothermia during surgery were eligible for inclusion. Studies in which hypothermia was induced were excluded, as were studies of the efficacy of the intervention. All of the included studies compared standard care with one or more methods of preventing hypothermia. More than half of the included studies evaluated forced air or intravenous fluid warming; other studies used electric blankets, irrigation fluid warming, warming of insufflation gas, circulating water mattresses, reflective (space) blankets and warming of anesthetic gas; some studies evaluated combinations of methods. All interventions were used intra-operatively; some studies also used interventions pre-operatively or post-operatively.</td>
<td>Preventing intra-operative hypo-thermia should be routine practice in all peri-operative departments, especially for patients undergoing major surgery.</td>
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The studies had to assess outcomes beyond the intra-operative phase to the post-anesthesia care unit and/or the total hospital stay; other than that no inclusion criteria were specified. The review assessed post-operative complications such as shivering, cardiac events, need for blood transfusion, wound infections and pressure sores, pain and thermal comfort. 2 Reviewers extracted the data. Shivering in the PACU (14 studies) less common in intervention group than control group, morbidity cardiac events (2 studies) less common in intervention group than in control group, Thermal comfort (1 study, n=29) Pts intervention group warmer compared with control group.
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<td>Hooper, V. March 18, 2011</td>
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<td>ASPAN</td>
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15. ASPAN’s Evidence Based Clinical Practice Guideline for the Promotion of Perioperative Normothermia

<p>| Hooper, V. Chard, R. 2009 | Hypothermia Normothermia Infection SCIP measures | Published Practice Guidelines II | Designed to guide (practical bedside tool) perianesthesia, perioperative, and anesthesia health care providers in the prevention and/or management of perioperative hypothermia and optimize pt outcomes. My mentor is Vallire, who can be instrumental in | The perioperative patient | Multidisciplinary Strategic Work Team (12 experts-representatives from ASPAN, the American Association of Nurse Anesthetists (ANNA), the American Society of Anesthesiologist (ASA), and the Association of perioperative Nurses (AORN)) implemented to revise the 2001 hypothermia guideline for current practice (consensus-based, multimodal practice recommendations supported) | Up-to-date clinical practice guidelines for the promotion of normothermia | Critical tool for the advancement of evidence-based, safe, quality pt care to improve pt assessment, management, &amp; satisfaction with care. Improvement of safety &amp; pt outcomes. Also, To spur future research in areas of perioperative thermoregulation |
| ASPAN | | | | | | | |</p>
<table>
<thead>
<tr>
<th>Publication</th>
<th>Author</th>
<th>Article Title</th>
<th>Summary</th>
<th>Reference</th>
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**Thermia**

**Journal of Peri-anesthesia Nursing**


**16. Surgical Site Infection Event**


**Surveillance of SSI** with feedback for appropriate data to surgeons has been shown to be an important component of strategies to reduce SSI risk. Surveillance program includes the used of epidemiologically sound infection definitions and effective surveillance methods, stratification of SSI rates according to risk factors associated with SSI development and data feedback. This also helped me

Surveillance will occur with surgical patients in any input/output setting where selected NHSN operative procedures are performed.

The SSI rates per 100 operative procedures are calculated by dividing the number of SSIs by the number of specific operative procedures and multiplying the results by 100. SSI will be included in the numerator of a rate based on the date of procedure, not on the date of event. Rate calculations will be performed separately for the different types of operative procedures and stratified by risk index. Standardized infection ratios are also calculated using indirect standardization or multivariate models. Basic SSI Risk Index (used in NHSN assigns surgical patients into categories based on the presence of SSI development and data feedback. This also helped me

Definitions of criteria need to meet superficial incisional SSI, deep incisional SSI, & organ/space SSI w/reporting instructions

Ability to Distinguish criteria for surgical site infection.
<table>
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<tr>
<th>Perencevich, E., Sands, K., Cosgrove, S., Guadagnoli, E., Meara, E. Platt, R.</th>
<th>Surgical Wound Infection Control Medical Costs/ Economics Research</th>
<th>Matched Cohort Design</th>
<th>Study the impact of infections diagnosed after discharge which constitute the majority of SSIs.</th>
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<tr>
<td>February 2003</td>
<td>Grant from the Harvard Pilgrim Health Care Foundation and by the CDC &amp;Prevention Eastern Massachusetts Prevention Epicenter cooperative agreement</td>
<td>Study participants nonobstetric input/output operating room procedure at Brigham and Women’s Hospital from May 18, 1997 to October 31, 1998. (Questionnaire &amp; administrative databases)The assessment of clinical outcomes and resource utilization in the 8week postoperative period associated with SSIs recognized after discharge. Cases of SSI were identified prospectively by using an established method of automated medical record screening for 102 diagnostic, testing, or treatment codes that may have indicated the occurrence of an SSI in the outpt setting. Pharmacy records were screened for antibiotic dispensing, and claims were screened for hospital readmissions or emergency room visits pertaining to an SSI. Surgeries were identified in 2-week cycles, and a total of 38 cycles were completed. An investigator reviewed those records judged to indicate a post discharge SSI by initial screening, using the National Nosocomial Infections Surveillance criteria during the 30-day postoperative period to confirm infection. Patients who had SSI that occurred during the index hospitalization were excluded. Case-patients were individually matched</td>
<td>SSI recognized after discharge was confirmed in 89 (1.9%) of 4,571 procedures from May 1997-Oct 1998. Patients with SSI, but not controls, had a significant decline in SF-12(Medical Outcomes Study 12 Item Short Form Health Survey) mental health component scores after surgery (p=0.004).Pts required significantly more outpt visits, ER visits, radiology services, readmissions, and home health aide services than did controls. Avg total costs during the 8weeks after discharge were US $5,155 for pts with SSI and $1,773 for controls (p&lt;0.001). Findings support the need to prevent SSIs that occur after discharge. SSI diagnosed after hospital discharge which were associated w/significant impairment of physical &amp; mental health. These SSIs also incurred substantial excess across the spectrum of health care.</td>
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17. Health and Economic Impact of Surgical Site Infections Diagnosed after Hospital Discharge

Emerg Infect Dis
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<tr>
<th>18. Effects of Perioperative Hypothermia and Warming in Surgical Practice</th>
<th>Kumar, S., Wong, P., Melling, A., Leaper, D.</th>
<th>Systematic Review</th>
<th>Perioperative patients</th>
<th>The primary beneficial effects of warming are mediated through increased blood flow and oxygen tension at tissue level. Reduction in wound infection, blood loss and perioperative pain with warming is promising. Article had key points r/t: perioperative thermal homeostasis, effects of hypothermia, hematological effects, effects on the immune system, effects on CV/Solid Organs, Measuring &amp; Delivering Heat, Effects on Warming on Cells/tissues, &amp;Clinical Applications of Perioperative Warming.</th>
<th>More evidence from good-quality prospective randomized controlled trials is needed to evaluate the role of warming in improving overall morbidity, mortality and hospital stay as well as to clarify its role as an adjunct to resuscitation and during the pre-hospital transport phase of critically ill patients. Awareness of the risks of perioperative hypothermia is the key to prevention. Maintenance of normothermia has been shown to be an effective way to avoid complications &amp; improving outcomes.</th>
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<tr>
<td><strong>Kumar, S.</strong>, <strong>Wong, P.</strong>, <strong>Melling, A.</strong>, <strong>Leaper, D.</strong></td>
<td>Hypothermia, Perioperative Warming Infection Wound Infections</td>
<td>Systematic Review</td>
<td>Perioperative hypothermia is a common and adversely affects clinical outcomes due to its effect on a range of homeostatic functions. The adverse consequences are preventable by the use of warming techniques. It will help me distinguish the effects of hypothermia &amp; warming the surgical patient. It will help determine if this decreases surgical site infection?</td>
<td>Lit search for identification relevant published articles on perioperative hypothermia and warming (MEDLINE-1966 to Feb 2005), EMBASE (1974-Feb 2005), CINAHL, the Cochrane library and the health technology assessment database. Reference lists of key articles were searched.</td>
<td>2005</td>
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<tr>
<td>19. Postoperative Rewarming: Are There Alternatives to</td>
<td>Pikus, E. Hooper, V.</td>
<td>Systematic Review</td>
<td>Perioperative patients</td>
<td>Perioperative patients-3 articles in OVID &amp; 12 articles in CINAH</td>
<td>All 11 of the identified articles were published between 1997 and 2008. Eight articles (73%) were published in medical journals and the other 3 were published in Nursing journals. Nine of the selected articles were Forced-air warmers appear to be the Most effective &amp; safe method of re-warming pts in the PACU when used in accordance to manufactures instructions. This</td>
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<td><strong>Pikus, E.</strong> <strong>Hooper, V.</strong></td>
<td>Systematic Review, Perioperative Complications Perioperative Hypothermia Postoperative Warming</td>
<td>Systematic Review of eleven studies comparing different methods of postoperative rewarming to identify the most effective methods of rewarming surgical patients</td>
<td>Medline (OVID) and CINAHL databases were searched for relevant articles. Search terms included &quot;postoperative hypothermia, postoperative rewarming, rewarming in PACU, methods of rewarming, and</td>
<td>2010</td>
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<tr>
<td><strong>Pikus, E.</strong></td>
<td>Systematic Review, Perioperative Complications Perioperative Hypothermia Postoperative Warming</td>
<td>Systematic Review of eleven studies comparing different methods of postoperative rewarming to identify the most effective methods of rewarming surgical patients</td>
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<td>2010</td>
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<td>Warm Hospital Blankets</td>
<td>ASPAN</td>
<td><strong>Journal of Perianesthesia Nursing</strong></td>
<td>was recent (in the past 14 years)/most current research. Strong level of evidence: Most RCTs. Recent evidence. This study looked at warming blankets which is a protocol that is applied to each surgical patient. eliminated. Studies including pediatric populations were excluded. Studies discussing rewarming of surgical patients after cardiac surgeries were included in this review. postanesthesia rewarming. The search was limited to articles published in the English language from 1997 through 2008. Reference lists of the related articles were also examined. After conclusion of the eval-11 articles were identified as appropriate for analysis. Articles were evaluated according to Stetler et al’s evidence hierarchy and quality ratings, ranging from Level I, a meta-analysis, to Level VI, expert opinion. The quality of the studies was rated from A to D, where A indicates a well-designed study and D marks a study with multiple deficiencies in scientific merit.</td>
<td>randomized controlled trials, one was a systematic literature review, and one used a quasi-experimental design. conclusion supports current recommendations provided by the ASPAN guidelines. Also, the expansion of the current definition of active warming by the guidelines should include methods of postoperative rewarming.</td>
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<td><strong>20. Efficacy of postoperative rewarming after cardiac surgery</strong></td>
<td><strong>Annuals of Thoracic and Cardiovascular Surgery</strong></td>
<td>Brauer, A., Weyland, W., Kazmaier, S. October 2004</td>
<td>Hypothermia Surgical Patient Rewarming Hypothermia Normothermia</td>
<td>Randomized controlled trial II Strengths: Two different systems for each intervention were used to determine differences in efficacy of similar devices (WT vs. BH, and TC vs. HY). Weakness: Small sample size. To compare the efficacy of two forced-air warmers and two radiant heaters on rewarming and oxygen uptake in hypothermic patients after cardiac surgery. This study may not be able to assist me because it is looking at primarily cardiac patients (inpt population) whereas, my focus is ambulatory patients that are discharged after surgery. Surgical patients, ASA III, after cardiac surgery N=50</td>
<td>Inclusion: Pre-Operative left ventricular ejection fraction &gt;40%, postoperative T&lt;35.5°C, absence of endocrine diseases, low dose of inotropic support on arrival to ICU, with weight deviation -10% to +30% of normal wt. Control group n=10, patient covered with standard hospital polyester-filled blanket. Group 2 treated with forced air system Warm Touch, n=10. Group 3 treated with forced air system Bairhugger, n=10. Group 4&amp;5 treated with overhead radiant heaters - Thermal Ceiling n=10, and Hydro sun 500, n=10. The rate of core temperature rise was doubled with forced-air warming compared with control group. The radiant heaters accelerated core rewarming by 50%. Forced air warming is more effective than radiative warming in rewarming hypothermic patients after Cardiac surgery.</td>
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<td><strong>21. Complications Hypothermia</strong></td>
<td><strong>Complications Hypothermia</strong></td>
<td>Review of the literature</td>
<td>To discuss current definition of mild</td>
<td>Wide varieties of adult surgical patients were The results of prospective, randomized trials that Active and passive methods of rewarming The author concluded that</td>
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<tr>
<td>Year</td>
<td>Journal</td>
<td>Study Type</td>
<td>Strengths</td>
<td>Weaknesses</td>
<td>Hypothermia, complications of this widespread phenomena and discuss available methods of perioperative rewarming in surgical patients.</td>
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<tr>
<td>August 2001</td>
<td><em>Surgical Patients Rewarming</em></td>
<td>I</td>
<td>I</td>
<td>None Noted</td>
<td>Cations and treatment of mild hypothermia was not indicated. Most of current existing rewarming methods were discussed.</td>
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<tr>
<td>March 2010</td>
<td><em>Normothermia Temperature Hypothermia</em></td>
<td>Prospective, Randomized, Blind Study</td>
<td>I</td>
<td>None Noted</td>
<td>To evaluate the effects of intraoperative skin-surface warming with and without one hour of Preoperative warming, in preventing intraoperative hypothermia, and postoperative hypothermia, and shivering, and in offering optimal conditions for early tracheal extubation.</td>
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<td>Scott, E., Buckland, R.</td>
<td>A Systematic Review of Intraoperative Warming to Prevent Postoperative Complications</td>
<td>Systematic Review - Randomized Controlled Trials</td>
<td>Examines whether preventing hypothermia during surgery prevents postoperative complications and thereby improves outcomes for patients. I Strength: Statistically significant because of the large population studied which validates the research. It also included beyond the intraoperative phase to include the entire hospital stay (this data important related to potential of infection).</td>
<td>26 Randomized controlled trials, data extraction, &amp; assessment of study quality were carried out by two researchers independently. Studies included: RCT, human participants of any age having surgical procedures (other than cardiac) under general/regional anesthesia, evaluated interventions that aimed to prevent hypothermia during surgery, included pt follow-up that extended beyond the intraoperative phase to the PACU and/or total hospital stay. Excluded: (efficacy studies, hypothermia induced, &amp; pts undergoing cardiac surgery). Researchers searched the Cochrane Wounds Group Specialized Trials Register and Cochran Central Register of Controlled Trials (Medline, CINAHL, EMBASE, &amp; national Research Register for studies published from Jan 1948 to May 2003. (search terms: anesthesia, hypothermia, normothermia, warming, thermoregulation, postoperative complications.</td>
<td>Outcomes measured included postoperative pain levels, thermal comfort, and treatment costs. Postoperative complications identified were shivering, cardiac events, need for blood transfusion, wound infections, and pressure ulcers. The majority of the studies favored treatment.</td>
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<td>Journal of Clinical Nursing</td>
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<td><strong>25.</strong> The Role of Perioperative Warming in Surgery: A Systematic Review</td>
<td>Sajid, M., Shakir, A., Khatri, K., Baig, M.</td>
<td>Systematic Review</td>
<td>Systematic Review - RCT</td>
<td>None Noted</td>
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<td>Sao Paulo Med</td>
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</table>
Journal terms used “randomized trials on perioperative warming, trials on perioperative warming, warming surgical pts were used in combination with headings of surgical pts, forced air warming, thermoregulation in anesthetized pts, warming blankets”.

| | Strengths: Recent inquiry of the body of evidence (Lit. Review) of over 60 years of data related to the prevention hypothermia. Level of evidence is strong r/t grading that was enclosed in the study. | These guidelines are for the prevention of unplanned perioperative hypothermia in patients undergoing abdominal operations, including general, vascular, gynecologic, & obstetric procedures. Prepared for surgeons and anesthesiologists in order to consolidate the evidence supporting avoidance of unplanned PH. Guidelines focus on how avoidance of PH prevents SSI and cardiac morbidity, how best to monitor perioperative temperature, and what devices readily available in North American Hospitals are most effective in prevention PH. Specific questions of inquiry focused on the answers that I am striving for in my own ways. | Only randomized controlled trials and meta-analysis for studies on diagnostic accuracy. Only adult human patients were included. | Systematic review of lit. from Jan 1950-Jan. 2008 performed. Address 3 questions: 1. Is there direct evidence that preventing PH can reduce risk of SSI and morbid cardiac events? What is most accurate tool for monitoring perioperative temperature? Do warming devices (fluid warmers & forced air devices) help to maintain core body temperature? | Level 1 (RCT) Evidence is recommended that active measures be taken for prevention of PH to reduce risk of SSI and morbid cardiac events (Grade B). Use of Esophageal/oral thermometry in anesthetized & awake pts (Grade B recommendation). Use of Level 1 Evidence – recommendation IVF Warmers for abdominal procedures. | PH rates remain unacceptably high 46% general surgery.

English publications from Medline, EMBASE, & Cochrane Database were collected. Level 1 (RCT) Evidence is recommended that active measures be taken for prevention of PH to reduce risk of SSI and morbid cardiac events (Grade B). Use of Esophageal/oral thermometry in anesthetized & awake pts (Grade B recommendation). Use of Level 1 Evidence – recommendation IVF Warmers for abdominal procedures. Level 1 evidence recommend use Warmed forced air both Preoperatively (Grade B) & Intraoperatively When procedures Expected to last >30 minutes.

Evidence-based Guidelines for Prevention of Perioperative Hypothermia 2009

Hypothermia Randomized Controlled Clinical Trials

None Noted

Randomized Control Trial Evidence/Evidence-based Guidelines

I

Strengths: Recent inquiry of the body of evidence (Lit. Review) of over 60 years of data related to the prevention hypothermia. Level of evidence is strong r/t grading that was enclosed in the study.

These guidelines are for the prevention of unplanned perioperative hypothermia in patients undergoing abdominal operations, including general, vascular, gynecologic, & obstetric procedures. Prepared for surgeons and anesthesiologists in order to consolidate the evidence supporting avoidance of unplanned PH. Guidelines focus on how avoidance of PH prevents SSI and cardiac morbidity, how best to monitor perioperative temperature, and what devices readily available in North American Hospitals are most effective in prevention PH.

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PH rates remain unacceptably high 46% general surgery.
<table>
<thead>
<tr>
<th>27.</th>
<th>Trends in Postoperative Sepsis: Are We Improving Outcomes?</th>
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<tbody>
<tr>
<td></td>
<td>Surgical Infections</td>
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<tr>
<td></td>
<td>Vogel, T., Dombrovskly, V., Lowry, S. November 2009</td>
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<tr>
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<td>AHRQ Surgical Site Infections None Noted</td>
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<td></td>
<td>Meta-analysis I</td>
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<td></td>
<td>Strengths: Recent strong evidence. Analysis of data from hospital discharge for over 15yrs (r/t infection).</td>
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<td>To determine recent trends in sepsis incidence, severity, and mortality rate after surgical procedures and to evaluate changes in the pattern of sepsis pathogens over time. A total of 1,276,451 surgery discharges 537,843 elective (42.1%) &amp; 738,608 non-elective (57.9%) procedures were identified.</td>
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<td>This will assist in looking at sepsis in a hospital population and whether this was related to surgical site infection.</td>
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<td>Surgical patients after surgery greater than 18yrs who developed sepsis after surgery.</td>
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<td>Analysis of the 1990-2006 hospital discharge data from the Healthcare Cost and Utilization Project State Inpatient Databases for New Jersey. International Classification of Diseases, Ninth Revision, Clinical Modification Codes as defined by the Patient Safety Indicator &quot;Postoperative Sepsis&quot; developed by the agency for Healthcare Research &amp; Quality. Severe sepsis defined as sepsis complicated by organ dysfunction.</td>
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<td>After elective surgery, 5865 pts (1.09%) developed postoperative sepsis, of whom 2,778 (0.52%) had severe sepsis. The incidence of postoperative sepsis after elective surgery from 0.22% to 1.12% (p&lt;0.0001). The sepsis mortality rate for elective procedures showed no significant change over time. The proportion of severe sepsis after elective cases increased from 32.9% to 64.4% (p&lt;0.0002). The rates of postoperative sepsis (3.74% to 4.51%) and severe sepsis (1.79% to 3.15%) overtime (p&lt;0.0001) with the proportion of severe sepsis increasing from 47.7% to 69.9% (p&lt;0.0002). The in-hospital mortality rate after non-elective surgery decreased from 37.9% to 29.8% (p&lt;0.0001). Sepsis &amp; death were more likely after non-elective than elective surgery. The incidence of postoperative sepsis after non-elective procedures over the past 17 Yrs. The hospital mortality rate was reduced after non-elective surgery, but no improvements were found for elective surgery. Pts who developed sepsis. Disparities in age, sex, &amp; ethnicity and development of postoperative surgical sepsis were found.</td>
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<td>(abdominal) have Temp&lt;36C at start operation &amp; 1/3 Will be hypothermic on arrival to PACU. End result decreased resistance to SSIs SSI increased risk Of death-RR2.2, 95%CI, increase Length of stay (median 6.5days, 95%CI, 5.8), Increase direct hospital costs.</td>
</tr>
<tr>
<td>28. Implementation of evidence-based practices for surgical site prophylaxis: results of a pre-and post intervention study</td>
<td>Forbes, S. Stephen, W., Loeb, M., Smith, R., Christoffersen, E., McLean, R.</td>
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<tr>
<td>29. Perioperative Normothermia to reduce the incidence of surgical wound infection and shorten hospitalization</td>
<td>Kurz, A., Sessler, D., &amp; Lenhardt, R.</td>
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<tr>
<td>Medicine</td>
<td>to new research in the area.</td>
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<tr>
<td>AMBU-KISS: Quality control in ambulatory surgery</td>
<td>AMBU-KISS is a protocol designed to create a reference database on surgical site infections for institutions involved in ambulatory surgery.</td>
</tr>
<tr>
<td>Mlangeni, D., Babikir, R., Dettenkofer, M., Daschner, F., Gastmeier, P., Ruden, H.</td>
<td>Protocols/Tool III</td>
</tr>
<tr>
<td>February 2005</td>
<td>Strength: This tool is a different way and helpful option/tool in the assessment of surgical site infections</td>
</tr>
<tr>
<td>Quality, Ambulatory Surgery Surgical Site Infection</td>
<td>Weakness: Questionnaires are not as valid as other measures or tools. My study population will focus on a variety of ambulatory surgical pts; whereas, this study focused on 3 different procedures.</td>
</tr>
<tr>
<td>None Noted</td>
<td>Physician questionnaire which compared surgical site infection rates for 3 indicator procedures in the ambulatory setting to those observed in the inpt setting.</td>
</tr>
<tr>
<td>AMBU-KISS Protocol is suitable for assessing and defining the magnitude of surgical site infections in ambulatory surgery preliminary results show no significant differences for the indicator procedures.</td>
<td>AMBU-KISS Protocol is suitable for assessing and defining the magnitude of surgical site infections in ambulatory surgery preliminary results show no significant differences for the indicator procedures.</td>
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</tbody>
</table>

**Note:** The table above includes a summary of a study by Mlangeni et al. on the quality control in ambulatory surgery and the use of AMBU-KISS protocol for assessing surgical site infections. The study compared infection rates between ambulatory and hospital settings for different procedures, finding no significant differences except in vein stripping procedures.
# Appendix C

## Logic Model

<table>
<thead>
<tr>
<th>Resources/Inputs</th>
<th>Activities</th>
<th>Outputs</th>
<th>Outcomes</th>
<th>Impacts</th>
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</thead>
<tbody>
<tr>
<td><strong>Team:</strong> PhD student, mentor, &amp; Regis faculty</td>
<td>Comprehensive Primary Care of Ambulatory Surgical Patients undergoing Anesthesia (Complete comprehensive medical history, Laboratory testing-Preoperative, prevention of infection education (patient), clip (no shave), &amp; Hibiclens soap provided with education)</td>
<td>Patient Laboratory Results (e.g. WBC levels) &amp; Clinical Diagnosis of Infection r/t signs &amp; symptoms of infection.</td>
<td>Infection Rates (Decreased)</td>
<td>Increased Community Awareness of Prevention Efforts</td>
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<tr>
<td><strong>Ready Access to Affected Population (Retrospective Chart Abstraction)</strong></td>
<td>SCIP measures followed (perioperative &amp; OR staff/physicians) 1. The Right Antibiotic 2. Antibiotic given 1 hour before incision 3. Antibiotic given in surgery 4. Prep-Clip only/no razor</td>
<td>Adherence to Prescribed Therapeutic Regimen (Preop Appointments, Lab Testing Appointments, &amp; Antibiotic/Prophylactic Medication Prescription)</td>
<td>Survival Rates (Increased)/Death Rates (Decreased)</td>
<td>Decreased incidence of surgical site infection in the community as assessed by identified “new cases” per year. Decrease overall health care costs.</td>
</tr>
<tr>
<td><strong>Grant proposal/Financial</strong></td>
<td>Chart abstraction of data (lab results, clinical notes, anesthesia record, PACU records, 8West records, &amp; OR record</td>
<td>Infection control: infection rates monitored</td>
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<tr>
<td><strong>Time: Chart Abstraction</strong></td>
<td>Right Antibiotics given per standard of care (surgery &amp; location/site)</td>
<td>Patient Satisfaction Surveys</td>
<td>Hospitalization Rates (Fewer and Shorter Hospitalization-decrease readmission rates related to postoperative infection)</td>
<td>Healthier population</td>
</tr>
<tr>
<td><strong>Materials Management</strong></td>
<td>Intraoperative warming methods per protocol</td>
<td>Participation in Preoperative Education</td>
<td>Ability to Continue to Work; Less Time Lost From Work</td>
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<tr>
<td><strong>Patient’s medical history</strong></td>
<td>Participation in Preoperative showering with Hibiclens</td>
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<td>More Efficient use of Health Care Dollars</td>
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<tr>
<td><strong>Insurance Status (ability to obtain Medicaid, SSI, private insurance)</strong></td>
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<td></td>
<td>Improved Knowledge of Infection, Causes, Transmission, Prevention, &amp; Treatment</td>
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<tr>
<td><strong>Infection control: Hand washing protocol/regimen</strong></td>
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</table>
The *constraints* that are foreseen are: Budget, Timeframe, Stakeholder Buy-In, and IRB approval.

**Project:**
**PICO:** In adult patients undergoing ambulatory surgery, do patients who are prewarmed during surgery (normothermic) have fewer surgical site infections than those that are not (hypothermic)?

- **P- Population** Patients (Adults undergoing ambulatory surgery)
- **I-Intervention** Prewarming the patient
- **C-Comparison** Not prewarming
- **O-Outcome** Surgical site infection

**Problem Identification:**
Increased Length of Stay in the Hospital
Increased Health care dollars
Increased risk of mortality
Increased risk of disability
Increased loss of work

<table>
<thead>
<tr>
<th>Team</th>
<th>Budget</th>
<th>Comprehensive Assessment</th>
<th>Lab results</th>
<th>Infection Rates</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ready Access to Affected Population</td>
<td>Timeframe</td>
<td>SCIP measures followed</td>
<td>Adherence to Prescribed Regimen</td>
<td>Survival Rates</td>
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<tr>
<td>Grant Proposal/Financial</td>
<td>Stakeholder Buy-In</td>
<td>Chart abstraction of data</td>
<td>Infection Control</td>
<td>Death Rates</td>
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<tr>
<td>Time/Abstraction of data from charts</td>
<td>IRB approval</td>
<td>Right antibiotic</td>
<td>Patient Satisfaction Surveys</td>
<td>Hospitalization</td>
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<tr>
<td>Materials</td>
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<td>Intraoperative warming methods</td>
<td>Participation Preop Education</td>
<td>Loss of Work</td>
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<td>Patients Medical History</td>
<td>Participation Preop Showers</td>
<td>Use Healthcare Dollar</td>
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<td>Insurance Status</td>
<td>Improved Knowledge</td>
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</table>
Appendix D

Measurement Tool/Instrument

Hypothermia/SSI Research Study
In-Hospital Patient Data Report Sheet

Article I. Patient Characteristics – Patient’s Study ID#: _______

<table>
<thead>
<tr>
<th>Age:</th>
<th>O male</th>
<th>O female</th>
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<tbody>
<tr>
<td>Height [cm]</td>
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<tr>
<td>Weight [kg]</td>
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</tbody>
</table>

Ethnicity: O Latino or Mexican – O Native American or Alaska Native – O Asian – O African American
O Native Hawaiian or Other Pacific Islander – O White – O Other

ASA: O I O II O III O IV O V

Article II. Patient Information

Pertinent Medical History:
O Diabetes   O Cardiovascular disease   O Bleeding disorders   O Peripheral Vascular disease   O Other
O Renal disease

Preoperative Vital Signs:
BP: P: T:

Article III. Surgical procedure

Surgical Dept.: Date of procedure:

Procedure (incl. approach: open/laparoscopic):

Hypothermia Risk Factors
O Anesthetic Agents
O Length/type of Surgical Procedure
O Body size (Thin/Small)
O Infusion cold fluids/blood products
O Age (Children/Elderly)
O Large Volumes Irrigation into Body Cavities
O Cold OR environment

Pre-op Warming
O Yes  Duration: ___
O No

Article IV. Intraop

Article V. OR Room Temperature: O High  O Medium  O Low (Actual Degrees)

Time in the room: Surgery start: Surgery end: Out of the room:

Crystalloid fluids Administered [ml]: _______ Urine output: Blood loss:
Blood Administered: _______

Temp Monitor: O used  O not used

Mode of Intraoperative Temperature Monitoring:
O PA  O Esophageal  O Skin  O Foley  O Other

Intraoperative Warming Measures:
O Warmed Irrigation Fluids
O Warmed IV Fluids
O Gel Pad Surface Warming
O Warm Cotton Blankets
O Forced Air used
O Circulating Water Mattress
O Foot Socks
O Head Covers
O Other

PACU Arrival Time: _____

Anesthesia:
- O General
- O Combined
- O MAC

O Regional Time: _____

Types:
- O Spinal
- O Epidural
- O Nerve blocks

8 West Holding O.R Start O.R. Finish PACU Finish

Temperature

SCIP Measures:
- O The Right Antibiotic
- O Antibiotic given in surgery
- O Antibiotics one hour before incision
- O Clipped (Prep)/ No razor

Surgical Site Infection (SSI) Specify Criteria Used (check all that apply):

Laboratory
- O Positive Culture
- O Positive Gram stain when culture is negative or not done

Signs & Symptoms
- O Purulent drainage or material
- O Pain or tenderness
- O Localized swelling
- O Redness
- O Heat
- O Fever
- O Incision deliberately opened by surgeon
- O Wound spontaneously dehisces
- O Abscess
- O Other evidence of infection found on direct exam, during surgery, or by diagnostic tests

Clinical Diagnosis
- O Physician diagnosis of this event type
- O Physician institutes appropriate antimicrobial therapy
### Timeframe/Timeline

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Appendix F

Budget & Resources

Budget: $225.00 (Data Excel) 0 (Statistics Calculation)/Webpage Recommendation

Resources: DNP Faculty-Pat Mullen-Time
Faculty Mentor-Vallire Hooper-Time
Chair of the Program-Dr. Berg-Time
Statistics Major-Jason Miller-Time
Excel Expert (Data Input)-Dallas Smith-Time
Appendix G

IRB Approval Letters

October 18, 2011

Krista LaRussa
c/o Regis University
School of Nursing, G-8

RE: IRB #: 11-299

Dear Krista:

Your application to the Regis IRB for your project “Surgical Site Infections Related to Unplanned Hypothermia” was approved as exempt on October 18, 2011.

Supporting reference information from the chair: “…approved as an exempt study under 45CFR46.101(b)(4) (study of existing data).

The designation of “exempt,” means no further IRB review of this project, as it is currently designed, is needed.

If changes are made in the research plan that significantly alter the involvement of human subjects from that which was approved in the named application, the new research plan must be resubmitted to the Regis IRB for approval.

Sincerely,

Daniel Roysden, Ph.D.
Chair, Institutional Review Board

cc: Patricia Mullen, Ph.D.

REGIS UNIVERSITY
Hi Dr. LaRussa,

Attached is the notice from OCIS that HI has approved your study and we have noted their approval in eIRB.

Please let me know if you have any questions.

Thanks,
Lindsley Goodpasture
Dear Krista,

Your Chart Review was approved by HI on: January 13, 2012. I have made the appropriate note in the eIRB.

Thank you,
Teresa Callahan

Georgia Health Systems University
OCIS Review Office
1120 15th Street, BB8514
721-6247 (Phone)
721-8335 (Fax)
OCIS@georgiahealth.edu
http://www.georgiahealth.edu/OCIS/review.htm

****

https://owa.georgiahealth.edu/owa/?ac=Item&t=IPM.Note&id=RgAAAAAF7KPARUhsQ... 1/21/2012
Krista LaRussa - HAC Study # Pro00000330 - Approved - Storing Research Data - no ePHI

From: Angela Long
To: Krista LaRussa
Date: 1/14/2011 9:40 AM
Subject: HAC Study # Pro00000330 - Approved - Storing Research Data - no ePHI
CC: HAC Notify

ID: Pro00000330
Title: Surgical Site Infections

ITSS Security Administration has reviewed the following protocol for HIPAA compliance, with an emphasis on the storage of electronic protected health information (e-phi), and has released it for HAC approval. Based on the study information, no ePHI is being collected and stored.

This ITSS release does NOT approve the study, only the methods used to secure the electronic data collected from the study. HAC approval is required prior to implementing the study. NOTE: Other approvals such as a fully executed contract for funded protocols may also apply.

Protected Health Information (PHI) pertains to:
*Present past, present or future physical or mental health
*Provision of health care to the person
*Past, present or future payment for health care
*AND includes any of the data elements listed in Form 101 that taken together could be used to identify a person.

GHSU requires that all such data be stored in an ITSS approved location that would protect it from a breach of confidentiality, loss or theft, or inappropriate modification.

At no time, should electronic PHI or research data be stored locally on a workstation, laptop, USB/thumb drive, external hard drive, CD-ROM, DVD, SD Chip, handheld device (e.g. Blackberry), or e-mail.

In the event a storage device listed above is lost or stolen, and you have reason to believe it to contain e-phi or research data, you must immediately file a report with Public Safety and notify ITSS Security Administration.

As part of your research protocol, you have requested secure file storage space for you and your colleagues to store research data electronically. Once you receive notification this request is complete, you will need to verify access for you and your colleagues. You may request additional people to have access to this space, however, they must be formally listed on the protocol and verified with the HAC office before the request will be processed.

Accessing your Data:
1. From on campus, if you are using a Windows computer with the Novell login, you will need to reboot your computer. Once you login with your GHSU NetID you will find the folder for your protocol listed in the R: drive. Please DO NOT rename this folder.
2. With a web browser https://net.mcu.edu/NetStorage/
3. WebDAV for Windows - see online instructions @ http://www.georgiahealth.edu/itss/computing/storage/webdawin.html
4. WebDAV for Macintosh - see online instructions @ http://www.georgiahealth.edu/itss/computing/storage/webdavmac.html

If you are unable to access your protocol data folder, or for additional assistance, please contact the IT Service Desk at 706-721-4000 or email ITSERVICE@mcu.edu.

ITSS Security Administration
Georgia Health Sciences University

All information in the communication, including attachments, is strictly confidential and intended solely for delivery to the addressee(s) identified above (ie, To/cc/bcc), and may contain privileged, confidential, proprietary and /or intellectual property entitled to protection from disclosure under applicable law. If you are not the intended recipient, please take note that any use, distribution or copying of this communication is unauthorized and may be unlawful. If you have received this communication in error, please notify the sender, delete this correspondence from your computer, and destroy any printed copies of this communication.
Appendix H

CITI Collaborative Institutional Training Initiative

Human Research Curriculum Completion Report
Printed on 2/18/2011

Learner: Krista LaRussa (username: klarussa)
Institution: Georgia Health Sciences University
Contact Information:
  3 Bolin Court
  North Augusta, SC 29841 United States
  Department: preop
  Phone: 706-721-3005
  Email: klarussa@mcg.edu

Group 3 - Human Derived Materials Research:

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For this Completion Report to be valid, the learner listed above must be affiliated with a CITI participating institution. Falsified information and unauthorized use of the CITI course site is unethical, and may be considered scientific misconduct by your institution.

Paul Braunschweiger Ph.D.
Professor, University of Miami
Director Office of Research Education
CITI Course Coordinator

https://www.citiprogram.org/members/learners/crbystage.asp?strKeyId=276050BF-77F... 2/18/201
# CITI Collaborative Institutional Training Initiative

## Human Research Curriculum Completion Report

*Printed on 2/18/2011*

**Learner:** Krista LaRussa (username: klarussa)  
**Institution:** Georgia Health Sciences University  
**Contact Information**  
3 Bolin Court  
North Augusta, SC 29841 United States  
Phone: 706-721-3005  
Email: klarussa@mcg.edu

### Group 7 - Social and Behavioral Research:

#### Stage 1. Basic Course Passed on 02/18/11 (Ref # 5661331)

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Paul Braunschweiger Ph.D.  
Professor, University of Miami  
Director Office of Research Education  
CITI Course Coordinator

Appendix I

Agency Letter of Support (Manager)/Project Approval

Re: DNP Project
Andrews, Susan
Sent: Tuesday, December 06, 2011 5:52 PM
To: laRussa, Krista

OK, just let me know when everything comes through.
Sue

Susan M. Andrews, RN, BAN, MA, CAPA
Perioperative Manager
MCGHealth
1120 15th Street
Augusta, GA 30912
(706) 721-7225 Phone
(706) 434-5007 Fax

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>>> Krista laRussa 12/6/2011 5:32 PM >>>
I appreciate you responding so quickly-I have received IRB approval from Regis University for exempt status related to retrospective chart abstraction (from the PI study). I have requested IRB approval through GHSU-expedited and awaiting approval. CITI has been completed, also. So, we are very close to being ready for the start of research after x2 IRB approval. Thank you for your support-Krista

>>> Susan Andrews 12/06/11 4:35 PM >>>
Krista,
Depending on how you are going to use this data IRB may be needed. I don't think we did an IRB since we collected it as PI.
Sue

Susan M. Andrews, RN, BAN, MA, CAPA
Perioperative Manager
MCGHealth
1120 15th Street
Augusta, GA 30912
(706) 721-7225 Phone
(706) 434-5007 Fax

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>>> Krista laRussa 12/5/2011 8:58 PM >>>
Vallire Hooper and I are ready to start the project related to Surgical Site Infections. We would like to use the data from the hypothermia study done in the unit from Feb-April and expand on it...to see if there is a correlation between surgical site infections and hypothermia. I would like to ask if it is okay to use this data? Thanks-Krista

3/2/2012 6:29 AM