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Evidence-Based Guidelines for Prevention of Inadvertent Hypothermia in Total Joint Arthroplasty

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Abstract

Hypothermia is a core body temperature below 36 degrees Celsius. Hypothermia is a common occurrence for many surgical patients that presents with many complications. When patients experience hypothermia during the perioperative setting, it is defined as Inadvertent Perioperative Hypothermia (IPH). During surgery, the patient typically has large body areas exposed to perform surgery in a room that is kept cool leading to lower body temperature and under general anesthesia the body's ability to regulate body temperature is impaired. Patients who are undergoing total joint arthroplasties (TJA), a hip or knee replacement, are a high-risk population for IPH, therefore, increasing their overall length of stay postoperatively. Complications that can result from hypothermia include decreased wound healing with a high risk of surgical site infection, decreased coagulation ability leading to excessive blood loss, and delayed awakening from anesthesia due to decreased metabolism of medications. Currently, there are measures in place perioperatively to help regulate patient's temperature such as heated intravenous fluids, warm blankets, or forced air warmers. With these interventions there are roughly 20 to 70% of TJA patients that unintentionally suffer from IPH. Due to the high incidence of IPH and the associated complications, it is increasing the overall cost to the patients and healthcare systems. Many facilities lack compliance with overall policy and clinical guidelines to prevent IPH in the at-risk population of TJA patients. The goal of this project is to implement evidence-based practice guidelines for perioperative management of hypothermia and maintenance of normothermia with the use of qualitative and quantitative data and assess the effectiveness in a rural hospital in the Midwest.

Key words: hypothermia, inadvertent perioperative hypothermia, complications, length of stay, total joint arthroplasty, perioperative

Clinical Problem

On average, 40 to 50 million surgeries in the United States are performed yearly from orthopedic surgeries to minor laparotomies from lifesaving organ transplants to removal of cancer (Dobson, 2020). When a patient undergoes any type of surgical intervention whether minor or major there are many known complications, such as blood loss, infection, deep vein thrombosis, or pain (The John Hopkins University, 2021). One of the most common complications that individuals may be unaware of is hypothermia. Hypothermia is a condition that can occur at any phase of the patient's operative course.

Hypothermia is a common side effect that can happen at any point in the perioperative setting (Ukrani et al., 2021). "Inadvertent perioperative hypothermia is defined as a drop in core temperature to less than 36 degrees Celsius" (Rauch et al., 2021, p. 1). As a result, hypothermia can lead to many adverse complications, especially for complicated surgical patients (Rauch et al., 2021). In addition, when a patient undergoes anesthesia, the body can no longer regulate body temperature adequately, causing hypothermia to set in quickly (Simegn et al., 2021). As a result, hypothermia can lead to adverse side effects and complicate the patient's postoperative course (Torossian et al., 2015). Complications that can result from hypothermia include coagulation issues, decreased wound healing, increased risk of postoperative infection, cardiac dysrhythmias, and impaired drug metabolism, which may result in increased length of stay postoperatively (Rauch et al., 2021). Therefore, hypothermia should be avoided at all costs during the perioperative course.

Problem Statement

Proper patient body temperature management is imperative in the preoperative, intraoperative, and postoperative settings to avoid any potential adverse outcomes. Currently, there are several recommendations as to how to prevent hypothermia and maintain normothermia. However, the uniformity and clarity in the policy and procedure available to healthcare workers in the perioperative settings are lacking. Education and implementation of best practice protocols and guidelines to avoid and treat perioperative hypothermia are necessary to provide better patient outcomes and decrease the occurrence of complications. Overall, hypothermia can lead to many complications that result in increased length of hospital stay, higher costs for the patient, decreased patient satisfaction and outcomes, and even death.

Background

Hypothermia

Hypothermia is a core body temperature of less than 36 degrees Celsius or 96.8 degrees Fahrenheit (Senkal & Kara, 2020). Hypothermia can be classified as mild (34° - 36° C), moderate (32° - 34° C), or severe (<32° C), with higher mortality rates associated with more severe hypothermia (Association of Surgical Technologists, 2019). When an individual is not under anesthesia, they are able to autoregulate their body temperature through many internal mechanisms to stay around 37 degrees Celsius or 98.6 degrees Fahrenheit (Rauch et al., 2021). However, when a patient undergoes surgery under anesthesia, many factors can contribute to the body temperature dropping, commonly referred to as Inadvertent Perioperative Hypothermia (IPH). It is estimated that anywhere from 20 to 70% of surgical patients experience IPH (Ruetzler & Kurz, 2018).

The human body can lose heat in one or more of the four following ways: conduction, convection, evaporation, or radiation (Association of Surgical Technologists, 2019). Conduction is the transfer of heat when in contact with a surface or a cooler object, such as a metal operating room table (Association of Surgical Technologists, 2019). Convection is the transfer of heat via the flow of air (Association of Surgical Technologists, 2019). Evaporation is heat loss to the atmosphere from fluid loss, such as sweating (Association of Surgical Technologists, 2019). Radiation is the transfer of heat when the skin is warmer than its environment, being the most common cause of heat loss (Association of Surgical Technologists, 2019).. These physics principles explain why a surgical patient is at such a high risk of heat loss.

Many external conditions can play a role in the development of IPH. Typically, an operating room is kept around 68 to 73 degrees Fahrenheit (20 to 23° C) with a humidity of 30 to 60% and can be fluctuate due to the operating room staff preferences (Allen, 2017). These parameters are kept tightly controlled to reduce the risk of infection and condensation that can break the sterility of the environment but can expose vulnerable patients to cool temperatures (Allen, 2017). “Core temperature is tightly regulated by keeping a balance between heat gain and heat loss (Rauch et al, 2021, p.2)”. Many surgeries, such as TJA, require large surface areas of the patient's body to be exposed, cleansed, and sterilely prepped with room temperature liquid in to perform the operation safely (Williams & El-Houdiri, 2018). Under these conditions, heat can escape too quickly to be replaced externally and limits the amount surface area left to rewarm with supplemental warming devices such as forced air warmers or blankets (Rauch et al., 2021). Additionally, surgery can have minimal to substantial blood loss; the more blood loss, the quicker it can result in decreased body temperature from lack of circulating volume (Rauch et al., 2021). If blood loss is substantial enough to result in fluid or blood replacement therapy, the use of room temperature intravenous fluids or blood can cool the patient body temperature even quicker (Williams & El-Houdiri, 2018). Patients who are smaller with less subcutaneous tissue have less protection from hypothermia and less circulating blood volume to compensate for blood loss (Rauch et al., 2021) Finally, undergoing anesthesia eliminates the patient's ability to autoregulate many normal bodily functions, especially temperature control (Torossian et al., 2015). The use of hypnotic drugs, volatile anesthetic gases, neuraxial anesthesia, and induction drugs like Propofol all inhibit the body's thermoregulation centers in the brain (Rauch et al., 2021). All of these factors and more can contribute to the development of IPH in patients undergoing TJA.

Relevance to Anesthesia

Hypothermia Related to Anesthesia

As a Certified Registered Nurse Anesthetist (CRNA), management of patient vital signs during surgery is part of the job responsibility. The vital signs include heart rate, blood pressure, pulse oximeter, and temperature, with temperature being of least and last concern in most situations (Bindu et al., 2017). "The American Society of Anesthesiology (ASA) standards require every patient receiving anesthesia to have temperature monitoring when clinically significant changes in body temperature are intended, anticipated, or suspected" (Bindu et al., 2017, p. 5). However, these standards leave temperature monitoring up to the provider's discretion as no specific recommendations are given to defining where and when to monitor and for what duration of surgery requires monitoring; this leads to an inconsistency in patient care (Hart et al., 2011). A patient's temperature can be continuously monitored in many different sites, such as the esophagus, bladder, rectum, nares, or external skin (Simegn et al., 2021). Temperature monitoring sites are determined based on accessibility during the case and vary between patient to patient.

During the patient’s operative course their temperature is measured before, during, and after surgery. Patients at any point in the surgical process are vulnerable to hypothermia, so early detection and intervention can be vital. The impairment that anesthesia presents on normal human physiology is one of the main reasons for IPH to occur (Association of Surgical Technologists, 2019). The most significant drop in patient temperature happens in the first 40 to 60 minutes after induction of anesthesia due to the major vasodilating effects from the medications used to induce anesthesia (Association of Surgical Technologists, 2019). This drop in temperature can be 0.5 to 1.5 °C in the first hour in a healthy patient and can be more exaggerated in a higher-risk patient such as patients over the age of 60, malnourished, or preexisting disease processes that alter thermoregulation (Hart et al., 2011). Factors that can influence how severe the drop in body temperature is post-induction include body habitus, patient hemodynamics, pre-induction temperature especially in the periphery; the lesser the gradient of temperature from core to periphery pre-induction will reduce the chance of severe hypothermia post-induction (Rauch et al., 2021). After the initial post-induction temperature drop, the patient's temperature continues to slowly decrease in a linear fashion throughout the rest of the surgical procedure, mainly due to heat loss to the environment via convection and radiation (Association of Surgical Technologists, 2019).

Apart of the CRNA's responsibilities is identifying patients at high risk for hypothermia. The CRNA must be proactive and reactive to treating and maintaining normal body temperature while the patient is under their care. Patients most at risk include those who have undergone trauma, burn patients, sepsis, complex invasive cases, spinal surgeries, malnutrition, and hypothyroidism (Association of Surgical Technologists, 2019). Even shorter surgeries can lead to patients acquiring IPH. Current practice standards do not have a max length of surgery that would not require continuous temperature monitoring. Allowing IPH to go unnoticed for a longer time, letting the risk of complications and adverse effects grow. Due to this lack of standard, the anesthesia provider must determine the appropriate temperature monitoring plan for each patient undergoing anesthesia regardless of the length of surgical intervention.

Complications and Impact of Hypothermia

Since surgery and anesthesia disrupt the body's normal homeostasis, this can increase the complication risk for the patient. Side effects of hypothermia can range from insignificant to life-threatening and can range in severity based on the drop in core body temperature. When a patient is hypothermic, the body does not metabolize and excrete drugs as fast as would be expected when the patient is normothermic (Kim, 2019). The decreased metabolism and excretion of drugs can lead to slowed awakening from anesthesia, requiring longer stays in the operating room or post-anesthesia care unit (PACU). The most common induction agent, Propofol is metabolized in the liver; when a patient is hypothermic blood flow to the liver is reduced which will lead to a higher plasma volume of the Propofol and intensify the effects of the drug (Rauch et al., 2021). The volatile inhalational agents used to maintain anesthesia require a lower minimum alveolar concentration (MAC) by 5% per 1 °C drop in core temperature, decreasing the overall potency (Rauch et al., 2021). Neuromuscular blocking agents, which paralyze a patient, can have a duration of action that is nearly doubled by a two-degree Celsius drop in temperature (Rauch et al., 2021). Severely hypothermic patients may require prolonged respiratory ventilation requiring an Intensive Care Unit (ICU) bed if drugs cannot be appropriately metabolized and excreted in the routine manner (Rauch et al., 2021). Medication administration from the CRNA may need to be altered due to this response to hypothermia as many commonly used medications are affected by hypothermia (Kim, 2019).

One of the body's responses to low body temperature is shivering; Shivering increases the body's oxygen and metabolic demand substantially (Lopez, 2018). Shivering can be detrimental to a patient with poor cardiac function and a fragile coronary system. Shivering can result in overworking the heart and cause cardiac dysrhythmias, which can be lethal. The occurrence of shivering typically happens in the postanesthetic period in up to 40% of patients (Bindu et al., 2017). "The three major common complaints of patients recovering from surgery and anesthesia are surgical site pain, nausea and vomiting due to various medications (anesthetics, opioids, antibiotics, etc.), and shivering due to hypothermia" (Kim, 2019, p. 1). Due to the complications that can arise from shivering due to hypothermia, interventions should be taken to avoid if possible.

Other complications when a patient develops IPH include delayed wound healing and/or an increased risk of surgical site infection (Simegn et al., 2021). In a state of hypothermia, the body will shunt blood to central organs to protect their function and divert blood away from the periphery. This can lead to minimal blood flow to areas on the skin where surgical incisions are made, which desperately need good circulation to heal properly. When the body is hypothermic, the blood coagulation pathways do not work effectively and can slow down the rate at which a clot can form (Simegn et al., 2021). This can lead to more blood loss than expected and slow down healing and necessary clotting of a surgical wound bed (Bindu et al., 2017).

Many circumstances that can occur in the immediate and even distant postoperative time can cause increased length of stay for a patient, whether in the PACU or an unintended hospital admission. Upon arrival to the PACU, a hypothermic patient must stay longer in the recovery area to achieve an optimal core body temperature with the use of active warming devices (Laxton et al., 2019). Ideally the patient’s temperature should be 36°C or greater before discharge from the PACU either to the inpatient floor or to home (Laxton et al., 2019). The duration of recovery time in the PACU for hypothermic patients can be up to 90 minutes longer than a patient who is normothermia postoperatively (Rauch et al., 2021). If the hypothermia cannot be resolved, the patient may not be able to be discharged home on time as planned and may have to be admitted to the hospital longer than anticipated accruing more costs to the patient (Rauch et al., 2021). Furthermore, when patients suffer from hypothermia complications, their overall recovery is delayed, which presents the need for more intensive care, recovery time, and nursing care, which in turn costs more for the patient and healthcare systems (Bindu et al., 2017). In addition, patients may battle with long-term issues with slowed wound healing and necessitate repeat doctor and therapy appointments or additional hospital admissions (Rauch et al., 2021). Due to the wide variety of complications and obstacles that can originate from hypothermia, it is no surprise that the finical impact associated can be considerable.

Overall, the CRNA is responsible for patient monitoring, including temperature, and must respond appropriately to avoid any of the above complications. Most of the time, the CRNA can prevent or correct hypothermia more easily than correcting any potential complications associated with hypothermia. Therefore, reducing the length of stay postoperatively, the cost to the patient and hospital, and any potential adverse complications. The attentiveness to monitoring and maintaining patient body temperature is an essential but an easily forgone responsibility of the CRNA.

Project Objectives

Currently, there are various methods medical staff use to avoid and treat hypothermia in surgical patients (Bindu et al., 2017). However, there is no universal standardized practice policy to make preventing and managing hypothermia routine, especially in patients undergoing total joint arthroplasties. This population of surgical patients have many risk factors that put them at a high chance of experiencing hypothermia in the perioperative setting and the associated complications, such as older age, large body surface exposure during surgery, and moderate expected blood loss during surgery (Akers et al., 2019). The goal of this DNP project is to use best practice recommendations supported by the current evidence-based literature to create and implement guidelines for a standardized practice policy to keep patients undergoing total joint arthroplasties normothermic, outline the methods to maintain normothermia, and treat hypothermia when necessary. In addition, this project will compare how maintaining normothermia versus acquiring hypothermia will affect the postoperative length of stay in patients undergoing total joint arthroplasties.

The objectives for this project include the following:

1. Develop evidence-based guidelines for temperature management and maintenance of patients undergoing total joint arthroplasties in the perioperative setting.
2. Develop a comprehensive plan to implement the above guidelines in the perioperative setting.
3. Develop a comprehensive plan for monitoring and measuring the guidelines' effectiveness.
4. Develop a comprehensive plan to adjust the temperature management and maintenance guidelines if the outcomes, such as decreased length of stay postoperatively and decreased complications associated with hypothermia, are less than desirable.

Literature Review

PICO Question

By reviewing available literature, patients undergoing total joint replacement surgery, such as hip or knee, are patients at high risk of acquiring hypothermia in the perioperative setting. This project will address the following PICO question: In adult patients undergoing inpatient total joint arthroplasties (**P**), how does maintaining normothermia (**I**) compared to acquiring hypothermia (**C**) perioperatively affect the length of hospitalization postoperatively (**O**)?

Perioperative hypothermia is a common inadvertent occurrence in most surgical patients (Matos et al., 2018). Currently, many different interventions are used to combat hypothermia and maintain normothermia for surgical patients throughout the perioperative settings. With severe and prolonged hypothermia, adverse effects can occur that affect the patient's surgical outcome and length of stay postoperatively (Rauch et al., 2021). Patients undergoing total joint arthroplasties have a higher chance of experiencing perioperative hypothermia, presenting them with a higher risk of complications related to hypothermia (Scholten et al., 2018). Evidence-based literature can be utilized to form best practice guidelines for preventing hypothermia and maintaining normothermia.

Databases

This literature review was conducted via Otterbein University's OneSearch through the Courtright Memorial Library. OneSearch conducts literature searches using keywords, Boolean operators, and search filters through databases such as Cumulative Index to Nursing and Allied Health Literature (CINAHL), PUBMED, and Cochrane Library. A literature search was performed and analyzed to find the most current evidence of inadvertent hypothermia in patients undergoing total joint arthroplasties and recommendations for implementation into practice.

Search Terms

The initial search terms and Boolean operators for this literature review include the search terms "inadvertent AND hypothermia AND perioperative AND complications AND total joint replacements". Next, a filter was applied to include only articles published in the last five years (2017-now), and a total of 2,419 results were given. Additional filters of available full text online and peer-reviewed scholarly articles were applied, then yielding 133 results. Finally, the additional search terms of "AND guidelines AND adult" was added, narrowing down the results and producing 80 results.

Of the 80 total results, seven articles were excluded due to pertaining to other surgical procedures such as thoracic, cardiac, or laparoscopic and not total joint arthroplasties. Nine results did not pertain to hypothermia at all, therefore not pertinent to this project. Two articles were about pediatrics, seven results were eposters, 26 results were meeting abstracts, and four results were written in another language other than English, therefore, being excluded. After reviewing all the available results, 15 articles were chosen that met the inclusion criteria and were applicable to this project. The literature review table can be found in Appendix B.

Literature Analysis

Incidence of Hypothermia in Total Joint Arthroplasties

Total joint arthroplasties (hip or knee) are one of the most common inpatient surgeries performed each year, therefore, making it imperative that complications and hospital length of stay postoperatively are kept at a minimum (Matos et al., 2018). According to Matos et al. (2018), 72.6% of a sample population of patients undergoing total hip or knee replacements experienced hypothermia at one or more of the ten points of temperature measurement throughout the study. In this research, 20.6% of the patients were hypothermic for over one hour, and 47.1% of the patients were hypothermic in the time following surgery (Matos et al., 2018). Matos et al. (2018), identified risk factors that lead to hypothermia as female gender, increased age, administration of spinal or regional anesthesia, increased fluid administration, lower preoperative temperature, and cooler operating room temperature. Other research, such as that from Scholten et al. (2018), found similar risk factors in acquiring hypothermia, such as female gender and spinal anesthesia.

In the prospective observational cohort study of 2600 patients by Scholten et al. (2018), the total incidence of mild hypothermia (35 to 36 °C) in patients undergoing a total hip arthroplasty (THA) or a total knee arthroplasty (TKA) was 11.7%. This incidence rate was reduced from 26.3% in a previous study conducted in 2013 with the implementation of active warming interventions and overall education and awareness of IPH for the perioperative staff (Scholten et al., 2018). In a cross-sectional study of 286 patients undergoing total knee replacements, 26.6% of the patients became hypothermic during surgery, and 13.3% of patients were hypothermic postoperatively (Ukrani et al., 2021). As evident in the literature this patient population has a high risk of experiencing hypothermia at some point in time during the perioperative setting.

Patients undergoing total joint arthroplasties (TJA) such as hip and knee replacements are found to be at higher risk of becoming hypothermic. Many of these patients are older, which is usually related to more comorbidities and the loss of thermoregulation ability due to age and other disease processes (Matos et al., 2018). Patients over the age of 60 with preexisting diseases such as diabetes or hypothyroidism, which impairs thermoregulation, are at an exceptionally high risk of acquiring IPH (Torossian et al., 2016). In addition, many patients undergoing these surgeries benefit from spinal anesthesia, either with or without the combination of general anesthesia, but this causes systemic vasodilation which also alters and decreases the body's ability to effectively thermoregulate (Matos et al., 2018). Other risk factors leading to IPH include low body weight, poor nutritional status, hypothermia in the preoperative setting, surgery lasting longer than two hours, and an ASA classification greater than two, increasing the risk the higher classification reached (Torossian et al., 2016).

Complications of Perioperative Hypothermia

As outlined in the Relevance to Anesthesia section above, hypothermia can lead to many complications and be detrimental to the patient's recovery. Perioperative hypothermia can result in increased blood loss due to disrupted coagulation pathways, surgical site infections, impaired drug metabolism, delayed emergence from anesthesia and/or delayed wound healing (Matos et al., 2018). Scholten et al., 2018, noted that a decrease in core body temperature of 1.9 degrees Celsius can nearly triple the likelihood of a surgical site infection and increased length of stay postoperatively. During the first hour of anesthesia body temperature can drop as much as 1.6° C (Nordgren et al., 2020). Anesthesia in all forms decreases the body's protective and automatic thermoregulation abilities controlled by the hypothalamus (Horosz et al., 2021). Peripheral dilation occurs with the administration of intravenous or inhaled anesthetic induction agents and/or from the administration of local anesthetics from regional anesthesia techniques resulting in a rapid decrease in body temperature (Horosz et al., 2021).

Perioperative Warming

Evidence shows that maintaining normothermia during the perioperative setting effectively shortens a patient's length of stay postoperatively (Matos et al., 2018). There are multiple passive and active warming interventions that can be utilized in combination or alone to maintain normothermia or correct hypothermia. Passive warming methods include warm blankets and surgical drapes (Link, 2020). Active warming methods include forced-air warming devices, fluid warmers, and electric warming blankets (Link, 2020).

Prewarming before the patient undergoes surgery can be effective in combating and preventing hypothermia (Torossian et al., 2016; Nordgren et al., 2020). Prewarming with the use of active warming such as forced air warmers (FAW) should be performed for 10 to 30 minutes before the administration of spinal, epidural, or general anesthesia (Torossian et al., 2016). Intraoperatively, patients who will have surgery lasting over an hour should continue to be actively warmed during the surgical case using a FAW (Torossian et al., 2016). Warm blankets can be used in supplementation. Any fluids or blood given intravenously or as irrigation should be warmed to prevent significant shifts in intravascular temperature resulting in hypothermia quicker (Torossian et al., 2016).

A study of 120 patients undergoing either a total hip or knee replacement was performed by Nordgren et al. (2020), comparing four different warming interventions. The four interventions were: convection warming with prewarming (patient-controlled temperature settings), conductive warming with prewarming (active self-warming blanket and FAW in all phases of care), reflective and convective warming without prewarming (head and leg covering intraoperative), and convection warming only (cotton blanket preoperative and in PACU only with use of upper body FAW intraoperative) (Nordgren et al., 2020). The group that was prewarmed with a full body warming blanket, continued to use an upper body FAW in the operating room, and then a full body warming blanket again in the PACU experienced the smallest drops in body temperature and the least amount of complications such as blood loss compared to the other three study groups that did not receive continued active warming methods in all phases of perioperative care (Nordgren et al., 2020).

Clinical Guidelines

The literature supports the need for the implementation of effective clinical evidence-based guidelines to maintain normothermia and prevent hypothermia in the surgical patient, especially those at higher risk, such as patients undergoing total joint arthroplasties. The Association of periOperative Registered Nurses (AORN) released guidelines for hypothermia prevention in surgical patients, most recently revised in 2020. The AORN's guidelines are broken down into different ratings: Regulatory Requirement, Recommendation, Conditional Recommendation, and No Recommendations (Link, 2020). Regulatory requirements are recommendations that *must* be implemented for all patients every time; recommendations are guidelines that *should* be implemented unless contraindicated or an alternate approach is available; conditional recommendations are those that may be implemented based on a benefit versus harm analysis specific to the individual patient; and finally, no recommendations are those that are not supported anywhere in the available literature (Link, 2020). The 2020 revised guidelines include only recommendations and conditional recommendations based on the support of current evidence-based literature. These guidelines are broken down into body temperature measurement, prevention methods, and passive and active forms of warming (Link, 2020). Appendix C outlines the recommendation set forth by the AORN for a quick reference guide in the clinical setting.

Body temperature measurement is recommended for all surgical patients during each part of the perioperative setting: preoperative, intraoperative, and postoperative (Link, 2020). The recommendations include collaborating with the perioperative staff to determine the best site of temperature measurement for the individual and consistently using this site throughout the entire time to get the most accurate and consistent temperature readings. The time in between temperature measurement is also up for consideration for the perioperative staff to decide for individual patients based on factors such as "factors specific to the procedure (invasiveness, accessibility of body sites), the anesthesia type and delivery method, and factors specific to the patient (age, body surface or weight, preexisting medical conditions)" (Link, 2020).

The AORN recommends that all surgical patients receive any method of warming necessary to treat or prevent hypothermia during all perioperative care phases (Link, 2020). Performing preoperative assessments on patients to identify patients with increased risk factors of developing hypothermia is crucial to determining what methods will need to be utilized to maintain normothermia (Link, 2020). Evidence shows that going into surgery with a higher body temperature leads to a lesser drop in temperature during surgery and less chance of hypothermia postoperatively (Link, 2020). In addition, high-quality evidence outlined by the AORN guidelines shows that prewarming at least 10 minutes preoperatively is effective (Link, 2020).

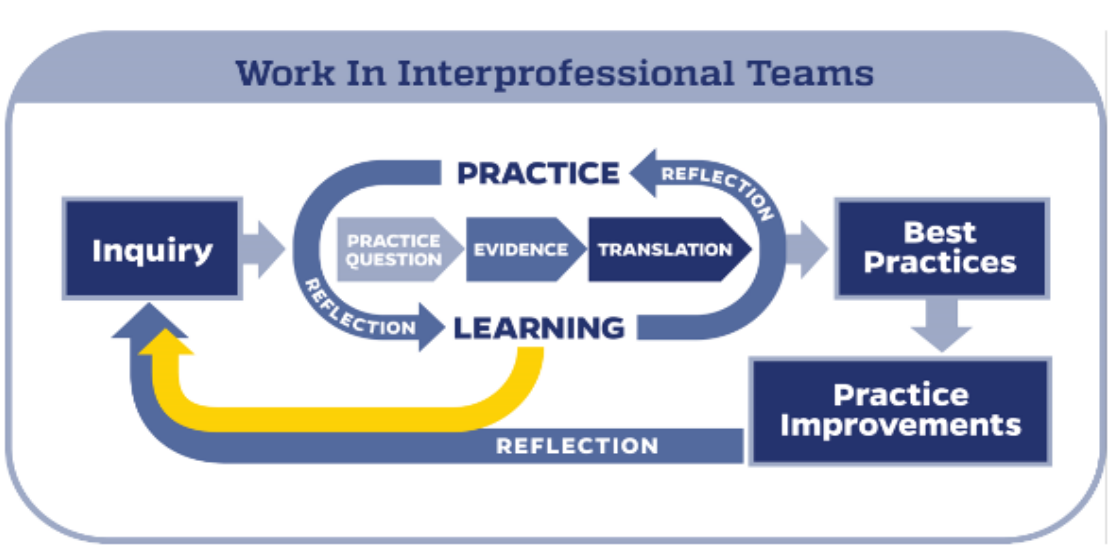
The AORN recommends that any surgical facility perform a gap analysis for their patient population to determine the need to implement hypothermia prevention guidelines and identify the lack of compliance with current policy (Link, 2020). The AORN also has resources, tools, and guidelines for implementation available to make the transition and implementation smooth (Link, 2020).

Evidence Based Practice Model: The Johns Hopkins Evidence-Based Practice for Nurses and Healthcare Professionals Model

The Johns Hopkins Evidence-Based Practice for Nurses and Healthcare Professionals Model (JHEBP) is a problem-solving tool for healthcare professionals to utilize to make clinical decisions and changes with the use of evidence-based practice (EBP) with a focus on the "interprofessional activity to enhance team collaboration and care coordination" (Dang et al., 2022, p. 1). This author obtained permission to use The Johns Hopkins Evidence-Based Practice Model for this project via the online Copywrite permission form on July 7, 2022, and can be found in Appendix A. This model uses a clinical inquiry to form a question, followed by evidence-based research and translation into best practice guidelines to yield improvements and continual learning and reflection throughout the process (Dang et al., 2022). The JHEBP model offers a series of tools to guide the process of completing this project. Figure 1 below shows the most recently revised 2022 version of The Johns Hopkins Model.

Figure 1

Revised JHEBP 2022 Edition



(Dang et al., 2022)

The JHEBP model was originally created to streamline the process of taking new evidence-based knowledge and translating and implementing the knowledge into clinical practice in a timely and standardized linear fashion that can be utilized by any nurse or healthcare professional (Melnyk & Fineout-Overholt, 2019). This evidence-based practice model begins with a clinical inquiry and curiosity about defining best practices related to a particular dilemma or gap in care (Dang et al., 2022). This inquiry begins the PET process of forming a *practice* *question*, researching the *evidence*, and *translating* the evidence into clinically appropriate guidelines (Dang et al., 2022). The JHEBP model allows the initial clinical inquiry to be addressed and may trigger new clinical questions (Melnyk & Fineout-Overholt, 2019).

Practice Question

The first stage of the JHEBP model includes defining a practice question from a clinical problem, forming an interprofessional team, and identifying key stakeholders (Dang et al., 2022). The clinical problem identified for this project is a need for adequate guidelines regarding temperature maintenance and monitoring for patients undergoing total joint arthroplasties such as knee or hip replacements. This problem is reflected in the following PICO question: In adult patients undergoing an inpatient total joint arthroplasty (P), how does maintaining normothermia (I) compared to acquiring hypothermia (C) perioperatively affect the length of hospitalization postoperatively (O)?). The interprofessional team for this project includes this graduate student and a nurse anesthesia program director who serves as an advisor. The key stakeholders involved in making this implementation of the EBP guidelines include the nursing staff in the preoperative unit, PACU, and the operating room, surgeons, anesthesia providers, surgical assistants, education staff such as clinical nurse educators, and the patients undergoing total joint arthroplasties at the proposed facility of implementation.

Evidence

The next phase of the PET process is evidence. This stage includes conducting a literature search of evidence selected based on inclusion and exclusion criteria, evaluating the level of evidence for the literature, summarizing, and synthesizing the evidence, and finally developing recommendations and clinical guidelines based on the best evidence-based research available for implementation into practice (Dang et al., 2022). A systemic literature review was performed using multiple databases to establish best practice guidelines for temperature management in patients undergoing total hip arthroplasties. The level of evidence and quality of each article is evaluated and used for consideration while creating the clinical guidelines. A literature review table can be found in Appendix B.

Translation

The final phase of the PET process is translation. The evidence-based recommendations will be translated into an action plan and implemented as new guidelines in clinical practice. The Action Planning tool will be utilized to help implement the new guidelines into the theoretical facility and used to assess the facility's acceptability, feasibility, and functionality (Dang et al., 2022). Outcome metrics will be defined and utilized to determine the success of the implementation process. Strengths and weaknesses will be identified from the pre-implementation and post-implementation to allow changes to be made to the plan to yield the best results (Dang et al., 2022). This model is ideal for an evidence-based implementation project because the continual cycle can be modified and adjusted indefinitely to meet the needs and requirement for specific facilities.

Methodology & Project Design

The JHNEBP Model is used to form the PICO question. Based on the literature review and synthesis, evidence shows that the use of passive and active warming mechanisms in each perioperative setting yield the least incidence of hypothermia in TJA patients. Based on an extensive literature review, it is evident that TJA patients have a high incidence rate of IPH. Therefore, it is imperative that clinical practice guidelines to reduce IPH should be implemented to help decreases rate, decrease length of stay, and other associated complications. This project will use a mix of quantitative and qualitative data to implement the CPG for treating hypothermia and maintaining normothermia in TJA patients and to analyze the implementation of the new clinical guidelines.

Qualitative Data

Qualitative data is information that cannot be expressed with numbers but is expressed as descriptive language that can be used to identify patterns and themes. Qualitative data is important when implementing a project such as this to receive descriptive feedback about the implementation and the new processes rolled out to help make changes and adjustments that can lead to the best possible outcomes. Using qualitative and quantitative data will yield the most comprehensive data and give the strongest results from the implementation of the CPG.

Qualitative data will be collected before and after implementation in several different ways through the implementation process. Before implementation, qualitative data collection will include the facility's gap analysis before implementing the new clinical practice guidelines (CPG). This gap analysis can be found in Appendix D; it will survey and analyze the current environment and the use of guidelines and policy for IPH management and treatment at the facility of interest. This will allow for the gaps in practice to be identified and areas of improvement to be addressed.

After implementation the qualitative data is collected via the post implementation employee survey, using a Likert scale to assess overall compliance and adaptation into practice. This survey, found in Appendix E, will ask the staff to rate the new guidelines and their implementation into daily clinical practice by rating statements on a Likert scale of strongly disagree to strongly agree. This information will allow staff perspective to be taken into consideration for future changes or adjustments to the CPG that may not have been evident before implementation.

Quantitative Data

Quantitative data will include any information collected with a measured or counted numerical value. These data points can be used to assess and analyze important values before and after implementing the evidence-based developed CPG. Quantitative data will include data collected from the electronic health records of the patients undergoing total joint arthroplasties at the facility of interest. Data collection pre-implementation will include the number of TJA surgeries, the incidence of IPH of the number of TJA performed, and the actual length of stay (LOS) postoperatively from the previous year before implementation of the new CPG. Data collection after implementation will be collecting these same data points but also will include estimated LOS compared to actual LOS. All these data points can be analyzed statistically to show whether there was an improvement in the overall incidence of IPH and a decrease in LOS postoperatively or if the CPG failed to achieve these outcomes.

Implementation Plan

Phase 1

For the implementation of this project there will be three different phases, with different data collection tools used for each phase of implementation. The first phase is having the facility of implementation perform a gap analysis of the current policy in place for the management and prevention of hypothermia in total joint arthroplasty patients or the lack of compliance or overall policy. The gap analysis adapted from the AORN can be found in Appendix D. This tool will give baseline information for where the facility is starting and help identify areas for growth and improvement. The second part to phase one will be collecting data from charts on patients in the previous year who have undergone a total joint arthroplasty (hip or knee arthroplasty) and calculating the overall incidence of IPH, as well as the average length of stay (LOS) postoperatively for those patients. This information will be the baseline data and will be used for comparison in the postimplementation phase to assess the overall outcome of the project's implementation. Finally, a chi squared test will be used to analyze the correlation of the incidence of IPH and the LOS postoperatively to the post implementation incidence of IPH and LOS. The chi square test tests whether the expected outcomes versus the observed outcomes are what was hypothesized or not.

Phase 2

The second phase includes implementing the new clinical guidelines into practice by first providing an in-service education class of approximately one hour for all staff in the perioperative settings. This in-service will provide the staff with knowledge about IPH, such as complications associated with hypothermia, populations at risk, different tools and equipment to maintain normothermia or treat hypothermia, different temperature monitoring devices, and an explanation of the CPG. Staff will have an opportunity for a hands-on experience with new equipment and tools such as fluid warmers, forced air warmers, underbody warming devices, or temperature measurement tools, that the facility currently needs to have to streamline the rollout of the CPG and use new or unfamiliar warming devices. The clinical practice guidelines can be found in Appendix E, which be used at the hospital of implementation.

Once this education is complete and the new guidelines are live, data collection from patients' charts will take place at the one-month, three months, and six months points. The following will be collected and analyzed at each chart review: consistent temperature monitoring and charting, anticipated versus actual length of stay (LOS) postoperatively, and the overall incidence of IPH for TJA. These data collection points will be used to compare the pre-implementation numbers and assess for the effectiveness of the CPG.

Phase 3

Finally, a post implementation survey of the staff will be performed based on a Likert scale survey. This post implementation survey can be found in Appendix F. Employees will choose from a scale of strongly disagree to strongly agree on a series of seven questions, with extra room to elaborate or leave additional feedback at the end of the survey. This survey will allow all staff affected by this change in practice guidelines to express their experiences and feedback about the implementation period of the new CPG. The feedback collected from this survey and the chart reviews of patients will allow for any changes to make the CPG work more efficiently and identify any weaknesses or challenges faced with implementation. After collecting the surveys, a staff meeting with representation from each area of the perioperative setting and department will be held to discuss the results and explore opportunities for change and/or improvement.

Data Collection and Outcome Analysis

Data collection at one, three, and six months after implementation will be collected via the patient's electronic medical records. The information needed will include the incidence of IPH in the patients undergoing TJA during those time intervals, the estimated LOS before surgery, and then the actual LOS postoperatively. The anticipated results will show a decrease in the trend of IPH and LOS following the implementation and use of the new CPG, with at least a 25% drop from pre-implementation data by the end of month six. Therefore, if by the sixth-month post implementation, the overall incidence of IPH and the LOS is decreased by 25% or more from the starting data collected, no changes will be needed. However, if by this time, there was not a decrease in IPH incidence and decreased LOS or there is dissatisfaction from the staff with the guidelines, changes will be necessary. Then changes will be instituted based on the employee feedback from the survey performed at the six-month point and on the data collected from each checkpoint compared to pre-implementation data. This information will highlight the weaknesses or gaps in the CPGs that can be amended for that facility.

Sample Setting

This project will take place in a small rural hospital in the Mid-West that has no current guidelines in place or lacks compliance with current guidelines for the prevention and management of hypothermia in TJA patients. The implementation of this project would include all perioperative nursing staff, all anesthesia providers, surgeons, nurse educators, finance departments, and supply management. The CPG would be implemented on all inpatient TJA patients.

Timeline

The timeline for this project would take approximately eight months. The first step includes allowing the facility to perform a gap analysis of its current practice and policy regarding hypothermia prevention and management in TJA patients. This analysis would take approximately one to two weeks to complete. During this time, an inventory of current equipment that the facility has regarding warming methods and temperature measuring would be collected. Following this analysis and inventory, any equipment necessary that is not currently available in the perioperative settings would need to be acquired. Having all the proper warming and temperature monitoring devices will yield the best patient outcome.

Once the facility has collected inventory and filled out the gap analysis, then baseline data of TJA IPH incidence will need to be collected and LOS. This data collection must be completed before the rollout of the CPG in practice. An in-service education and training session of one hour for all staff in the perioperative settings, including nurses, techs, anesthesia providers, ancillary OR staff, and surgeons. Depending on the staff schedules and availability, this may take one to two weeks to complete. All appropriate staff must be educated before the rollout so that all patients receive the proper care and that all staff understands the CPG. Once training is complete, a rollout date will be set up for when the CPG will become live. During this period, chart audits will happen at the one, three, and six-month milestones. The number of patient charts audited will depend on how many TJA are performed during these time frames with a goal of at least 100 patients total. By the end of the sixth month, all data will be collected and statistically analyzed to determine whether adjustments and amendments to the CPGs are necessary.

By the time the data has been collected and analyzed, and the necessary changes have been made, the facility will then decide the future of these CPG in their daily policy and protocol. The refinement and adjustment of the CPGs may take different amounts of time based on the facility, and the feedback received. The goal is that within a month following the sixth-month data collection and employee survey, all the changes will have been made, and the CPG will be ready for finalization at the facility.

Budget & Financial Considerations

The budget for this project would differ significantly based on the facility of implementation. Since this project is theoretical, all possible options for budgeting will be outlined. Specific budget requirements would be based on the specific facility, including the size, the number of operating rooms available, and the current equipment in use and available for staff. Research has shown that using multiple passive and active warming methods yields the best patient outcomes. Therefore, the facility should have options including but not limited to warm blankets and warming devices, fluid warmers and tubing sets, over-body forced air warmers and disposable blankets, and under-body warmers. These devices should be available in each setting of the perioperative units.

Another finical consideration includes paying the staff for the required in-service if it cannot work into a previously scheduled mandatory staff meetings and/or training. Finally, signage with important tips and tricks related to the CPG for quick reference will need to be printed to post in high-traffic areas in each preop, operating rooms, and PACU to be available for staff. Below in Figure 2 is a theoretical budget breakdown for a small hospital based on popular warming devices and average salaries.

Figure 2

Example Budget

Product	Cost	Amount
Bair Hugger unit (FAW)	$1,500 per unit	X1 per OR
Disposable Bair Hugger blanket	$10.50 per blanket	Approx X70 per month
Fluid warmer unit (3M Ranger)	$1,000 per unit	X1 per OR
Disposable tubing for warmer	$41.99 per tubing set	Approx Xy70 per month
Underbody warmer (hot dog device)	$279 per month per OR	X1 per OR
Blanket Warmer	$5,000	X3 (preop, OR, PACU)
Lander for one Blanket	$1 per blanket	
Nurse Hourly Salary	$34 per Hour	X50 perioperative Staff nurses
CRNA Hourly Salary	$105 per hour	X10 Staff CRNAs
Printing of signage	$10.50 per poster	X10 posters

Project Limitations

The limitations of this project may include obtaining all the necessary equipment and tools that would be used for warming and temperature monitoring. This can be a financial limitation based on the facility. However, most facilities own or rent many of these devices, and the project could be helpful even without every single device outlined above. Secondly, this project only pertains to patients undergoing total joint arthroplasties, which is a small population of surgical patients but could be used to build guidelines for IPH in the general surgical population. Overall, this project should be easily adapted and implemented in any size or level facility.

Conclusion

Hypothermia is a drop in core body temperature below 36 degrees Celsius (Horosz et al., 2021). Hypothermia is not only uncomfortable for the patient, but also linked to adverse effects such as surgical site infection, increased blood, impaired drug metabolism, myocardial events, coagulation impairment, delayed wound healing, and potential death (Nordgren et al., 2020). All these adverse effects can be associated with increased length of stay postoperatively, whether in the PACU or as an expected or unexpected inpatient hospital stay. Surgical patients risk acquiring hypothermia at any stage of their perioperative time, especially those receiving total joint arthroplasties. Risk factors such as length of surgery, amount of body surface exposure, type of surgery, age, gender, use of spinal anesthesia, and preexisting health conditions play a role in the patient's overall risk of hypothermia (Bindu et al., 2017).

Patients undergoing TJA have many identifiable risk factors that increase the risk of hypothermia, along with factors related to the surgical process that increases the risk. Since TJA are very common surgical procedures, any facility that performs these surgeries should perform a gap analysis to assess the need for improved perioperative guidelines for hypothermia prevention and normothermia maintenance as outlined above. Although hypothermia is a common occurrence in TJA patients, the frequency can be reduced with the proper utilization of warming methods and prompt intervention (Nordgren et al., 2020).

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Appendix A

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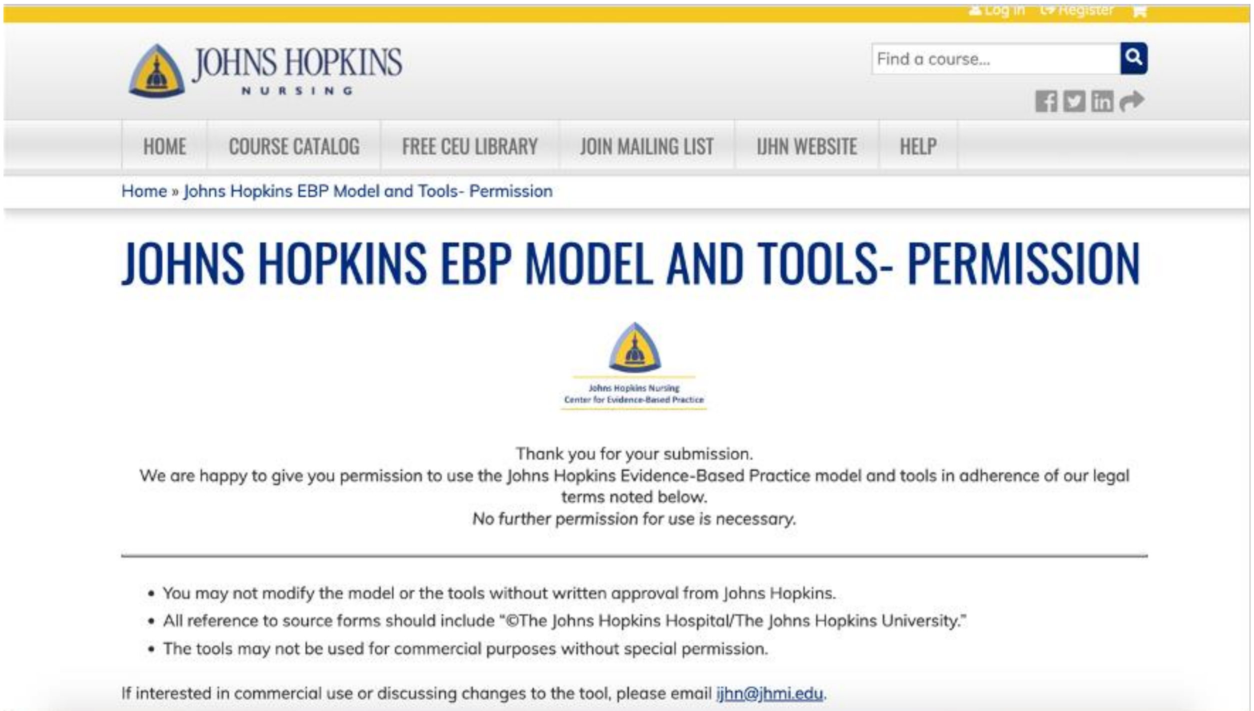

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Appendix B

Literature Synthesis Table

Citation (Author, Year, Title)	Design/ Method	Sample/ Setting (Number, Characteristics, Exclusions, Criteria, Attrition, etc.)	Major Variables; definitions (Independent variables; dependent variables)	Outcome Measurement (What scales used- reliability information)	Data Analysis (What stats used?)	Findings	Level of Evidence	Quality of Evidence Strengths Limits Risks Feasibility
Article 1: What is the incidence of inadvertent hypothermia in elderly hip fracture patients and is this associated with increased readmissions and mortality?								
Williams, M., Ng, M., & Ashworth, M. (2018). What is the incidence of inadvertent hypothermia in elderly hip fracture patients and is this associated with increased	A single center retrospective study	929 hip fracture surgical patients from July 2015 to July 2017 Exclusion- under 65 years old without temperature data	Independent- age, preop temperature, type of anesthesia Devices, type of surgical repair, presence of active warming devices Dependent- temperature postop	Primary outcome measurement was overall incidence of hypothermia below 36 degrees C. Secondary outcomes 30-day mortality rate, LOS, readmission rates, and secondary diagnosis	Data collected include type of anesthetic, operative time, presence of active warming devices. A chi-squared analysis was used for comparison analysis and a t-test was used. Statistically relevant data	Overall rate of hypothermia was 10% in hip fracture surgical patients. There was a strong correlation of preoperative temperature to incidence of hypothermia postoperatively. Many of the patient who experienced hypothermia were considered older mainly in their 80's. Patients who were hypothermic preop were 40 times likely to be hypothermic entering into recovery. Higher 30 day mortality trend was seen in hypothermic patients. 3% of patients were readmitted within 30 days	II	This study is a strong level of evidence. Although only conducted at one location, the findings correlate with findings from other studies that hypothermia is an issue in patients undergoing joint arthroplasties and that active warming is important to decrease the incidence.

readmissions and mortality?. *Journal of orthopaedics*, *15*(2), 624–629. https://doi.org/10.1016/j.jor.2018.05.020					with p< 0.001	postop.		
Article 2: Inadvertent Perioperative Hypothermia Risks and Postoperative Complications: A Retrospective Study								
Akers, J. L., Dupnick, A. C., Hillman, E. L., Bauer, A. G., Kinker, L. M., & Hagedorn Wonder, A. (2019). Inadvertent Perioperative Hypothermia Risks and Postoperative Complicatio	Retrospective comparative study at a large academic hospital in the Midwest	298 surgical patients Inclusion- patients 18 years of age and older who underwent a hysterectomy, laparoscopic cholecystectomy, colectomy, hernia repair, total knee arthroplasty, or total hip	Independent- age, gender, length of surgery, postop complications, type of anesthesia Dependent- temperature postop	Aim is to describe the major risk factors and outcomes associated with IPH. The purpose of this study to help support that there is a need for a more structured perioperative process for promoting better patient outcomes	We analyzed the data using SAS (Version 9.4) and used descriptive statistics for demographic and surgery-related factors. We summarized the categorical variables by frequency and percentage of patients who	This study found 7 patients with documented hypothermia and those patients experienced more complications such as a need for postop blood transfusions. The study noted that patients >60 years old are at highest risk of experiencing IPH. "The study showed that for patients with an intra operative temperature between 34.2° C (93.5° F) and 36.9° C (98.4° F), each one-degree centigrade increase in temperature resulted in 31% less time in the intensive care	III	This study shows the risk factors and the compilations that can arise from IPH but it does not only assess the TJA population. It does include other surgical populations, but this does not discredit the importance of hypothermia complication and is still relevant to the foundation of this project. This study recommends nurses having appropriate tools to assess for at risk patients, and the implementation of guidelines for temperature measurements and monitoring in the perioperative setting which is the objective of this project. "Nurses and perioperative

ns: A Retrospective Study. AORN Journal, 109(6), 741–747. https://doi.org/10.1002/aorn.12696		arthroplasty in 2017 during a 3 month time period This study used Donabedian's QI framework		related to IPH	experienced either hypothermia or normothermia, and summarized the continuous variables by mean, standard deviation, median, minimum, and maximum. We tested for differences in means and proportions between hypothermic and normothermic groups using the Wilcoxon rank sum test and Fisher exact test. We set significance at $P < .05$.	unit."		leaders should understand the risk factors and complications associated with perioperative hypothermia to collaboratively develop and test evidence-based initiatives, improve care, and promote optimal patient outcomes.
Article 3: Inadvertent hypothermia in hip and knee total joint arthroplasty								

Williams, M., & El-Houdiri, Y. (2018). Inadvertent hypothermia in hip and knee total joint arthroplasty. *Journal of orthopaedics*, *15*(1), 151–158. https://doi.org/10.1016/j.jor.2018.01.035	Retrospective cohort study .	2431 total joint arthroplasty patients from March 2013 to December 2016 Exclusion- all patients had to have baseline core temp of >36 degrees C before entering OR.	Independent- age, implant type, gender, ASA grade, BMI, anesthetic type, operating time, presence of warming devices Dependent- postoperative temperature and complications	Total incidence of IPH in TJA patients with temp < 36 degree C and postoperative complications. Secondary outcomes measured are LOS, 31 day readmission rates, and 31 day complication events (infection and thrombotic).	"Nominal and ordinal data is presented as case numbers and pro-portions with comparison used chi-square analysis. Continuous data is presented as mean and standard deviation with comparison using t-test. Statistical significance is set at the 95% confidence interval. SPSS was used for analysis."	Incidence of IPH ranged from 3.9% to 13.2% in the different surgeries analyzed. Overall rate of IPH was 11.7%. Lower BMI undergoing total hip arthroplasties were the group with the highest incidence of IPH. IPH was associated with higher risk of hematoma and infection rates postoperatively. Protective steps to maintain normothermia are necessary in this population.	II	This article is a high level of evidence and statically relevant for this DNP project. The incidence of IPH in TJA is recognized as well of risk factors associated with IPH in this population. The risk factor of lower BMI is evident in this study. No bias is present and serves as a good foundation for the problem identified in this project. The limitation for this study includes not being able to include certain patients due to no documentation of warming devices, this could have demonstrated a higher IPH rate.
Article 4: Forced-Air Warmers and Surgical Site Infections in Patients Undergoing Knee or Hip Arthroplasty								
Austin, P. N. (2017). Forced-Air	Annual review/Editorial	N/A	N/A	The aim of this article is to outline the use	N/A	Maintaining normothermia is important in patients undergoing TJA. FAW have been shown to help maintain	4	This article helps give background knowledge to IPH and defines many of the key concepts. Although not

Warmers and Surgical Site Infections in Patients Undergoing Knee or Hip Arthroplasty. *Annual Review of Nursing Research*, *35*(1), 179–199. https://doi.org/10.1891/0739-6686.35.179				of FAW in TJA patients for warming and maintaining normothermia. There is little evidence that suggest that the use of FAW is linked to surgical site infection		normothermia and there is no evidence that they can increase chance of surgical site infection.		the highest level of evidence it still helps to describe and outline the issue of hypothermia in TJA patients.
Article 5: Temperature management under general anesthesia: Compulsion or option								
Bindu, B., Bindra, A., & Rath, G. (2017). Temperature management under general anesthesia: Compulsion or option.	Systemic Literature review of "the physiology of thermoregulation, temperature monitoring sites, and inadvertent	Reviewed multiple different proposed guidelines for IPH management	N/A	The overall goal is find the most effective guidelines to prevent IPH and what warming methods work the best.	N/A	Body temperature should be kept above 36 degree C, temperature monitoring should be performed in any surgery over 30 mins and continuously while under general anesthesia	II	This article is without Bias and is a strong level of evidence therefore useful for this DNP project as it compares different guideline recommendations for hypothermia management in the perioperative setting

Journal of anaesthesiology, clinical pharmacology, *33*(3), 306–316. https://doi.org/10.4103/joacp.JOACP_334_16	intraoperative hypothermia and focuses on the current thermoregulation guidelines and practical aspects of intraoperative temperature management” Editorial							
Article 6: Guidelines of the Polish Society of Anaesthesiology and Intensive Therapy regarding prevention of inadvertent intraoperative hypothermia								
Horosz, B., Adamiec, A., Malec-Milewska, M., & Misiołek, H. (2021). Guidelines of the Polish Society of Anaesthesiology and Intensive Therapy regarding prevention of inadvertent intraoperative	Literature review of all meta and systemic analysis identifying the most updated and relevant guidelines for inadvertent perioperative hypothermia.	This article included 11 meta-analysis and systemic reviews regarding the issue of intraoperative hypothermia	The articles that contained recommendations by government institutions or national scientific societies were highly sought after.	Each article used in this article is given a level of evidence and the strength of the recommendation to use the guidelines in practice.	N/A	This article outlines guidelines for each stage of the perioperative setting **Preoperative period** Attention should be paid to possible benefits of informing the patient about possible exposure to hypothermia during the perioperative period. It is recommended to measure core temperature before anaesthesia in each case. In the case of measurements from locations other than those recommended for core	I	This article is a great refence as it is the highest level of evidence and has combined many of the most current evidence-based recommendations to form guidelines pertaining to IPH.

hypothermia. *Anaesthesiology Intensive Therapy*, *53*(5), 376–385. https://doi.org/10.5114/ait.2021.111871						temperature measurements, it should be remembered to properly compare the reading with core temperature, except for the use of devices in which such reading changes are made automatically. 4. The preoperative assessment should identify relevant risk factors for intraoperative hypothermia and its possible consequences for an individual patient: • ASA ≥3; • preoperative body temperature < 36°C; • BMI; • the extent of the procedure*/the procedure over 1 hour; • planned combination of general and block anaesthesia; • anticipated blood loss above 500 mL. **Intraoperative period** 1. Continuous core temperature measurements or at least every 30 minutes are recommended during anaesthesia; the continuous measurement is preferable.		

						2. It is recommended to use active warming since the induction of anaesthesia, e.g. forced air warming systems or electric heating mattresses and blankets, when the anticipated duration of the procedure exceeds 60 minutes. 3. It is recommended to maintain core body temperature within the range of values accepted for normothermia. 4. The time when a significant part of the body sur- face of the anesthetized patient is not covered in the period preceding draping should be kept to a minimum. 5. The operating theatre temperature should not be lower than 21°C until the active warming systems have been activated. 6. If it is planned to transfuse more than 1000 mL of infusion fluids, they should be warmed to 37°C using the devices designed for this purpose. 7. Warming of whole blood, red blood cell concentrate, and other blood preparations to 37° C is indicated in transfusions with a rate above 50 mL min^{-1}		

						and only with the devices designed for this purpose. 8. It is advisable to warm the fluids used for intra- operative rinsing of body cavities (irrigation) to 37–40°C. **Postoperative period** 1. Postoperative monitoring of body temperature, which is one of the main vital signs, is recommended. 2. During the patient's stay in the recovery room and in the postoperative ward, forced-air warming should be provided to maintain core body temperature above 36.5°C.		
Article 7: Guidelines in Practice: Hypothermia Prevention								
Link, T. (2020). Guidelines in Practice: Hypothermia Prevention. *AORN JOURNAL*, *111*(6), 653–666. https://doi.org/10.1002/aorn.13038	Systemic literature review- Guidelines	The AORN gives different level of recommendation for certain guidelines supported by the literature and if and when it should be	N/A	Objectives: Explain the recommendation rating levels in AORN guidelines for perioperative practice. Discuss recommendations specific to	N/A	This article has combined all recommendations and literature to form updated hypothermia management and prevention guidelines for the perioperative settings.	I	This article From AORN is the framework for the guidelines for this project. It is the most recently updated guidelines by AORN and have been combined with all other relevant literature to form the CPGs.

		implemented into practice.		the AORN "Guideline for prevention of hypothermia." Identify tools that can assist with implementing guide- line recommendations.				
Article 8: Examination of intra-operative core temperature in joint arthroplasty: a single-institution prospective observational study								
Matos, J. R., McSwain, J. R., Wolf, B. J., Doty, J. W., & Wilson, S. H. (2018). Examination of intra-operative core temperature in joint arthroplasty: a single-institution prospective observationa	Prospective observational study	120 patients undergoing knee or hip arthroplasty "Inclusion criteria included English-speaking patients who were at least 18 years of age and able to provide informed consent. Four orthopedic	Independent- gender, preop temp, OR temp, type of anesthesia, BMI, presence of warming device Dependent- intraop and postop temp All temperature were taken temporally and at the same timed intervals for each patient	"Evaluation of the association between ever being hypothermic and categorical variables was conducted using chi- square or Fisher's exact tests. The thermometers are precise up to 0.1 °C and the	"Each temporal measurement was taken and recorded three times for accuracy and the mean value utilized for data analysis at each time point. Temperatures were measured upon (1)	72.6% of patients experienced hypothermia (<36 degrees C), 20.6% were hypothermic for over an hour, 47.1% were hypothermia after surgery in the recovery area. Risk factors associated with hypothermia were female gender, neuraxial anesthesia, low preop temp, and low OR temp	I	This study is statically strong and significant. This study assessed both hip and knee arthroplasties and have identified the high incidence of IPH in the population. This is a strong study and shows the need for improved guidelines for managing temperature.

l study. *International Orthopaedics*, *42*(11), 2513–2519. https://doi.org/10.1007/s00264-018-3967-y		surgeons per-formed all surgical procedure”		standard deviation of patient temperature was expected to be approximately 0.5 °C. A minimum sample size of 97 subjects produced a two-sided 95% confidence interval with a distance from the mean temperature (or change in temperature) equal to 0.1 °C assuming the standard deviation of 0.5 °C. The sample size was increased to 120 subjects to account for patients that declined to participate on the day of surgery. “	leaving holding area; (2) operating room (OR) arrival; (3) after anesthetic induction; (4) upper body forced air warmer initiation (used for all patients); (5) incision; (6–8) every 30 minutes after incision; (9) leaving the OR; and (10) arrival to PACU. “ OR temps were measured on arrival into the room			

Article 9: The Effectiveness of Four Intervention Methods for Preventing Inadvertent Perioperative Hypothermia During Total Knee or Total Hip Arthroplasty								
Nordgren, M., Hernborg, O., Hamberg, Å., Sandström, E., Larsson, G., & Söderström, L. (2020). The Effectiveness of Four Intervention Methods for Preventing Inadvertent Perioperative Hypothermia During Total Knee or Total Hip Arthroplasty. *AORN Journal*, *111*(3), 303–312. https://doi.org/10.1002/aorn.12961	A study based on a comparison group design to investigate whether the incidence of IPH in patients undergoing primary elective unilateral TKA or THA differed and if the occurrence of IPH could be reduced by any of the four groups of interventions.	Inclusion criteria: patients undergoing primary elective unilateral TKA or THA between January and June 2013 at Östersund Hospital, Region Jämtland Härjedalen, Sweden, Exclusion criteria: none was listed	Independent variables: type of warming device used The interventions included convective warming (ie, FAW) with prewarming (group 1), conductive warming with prewarming (group 2), reflective and convective warming without prewarming (group 3), and convective warming only (group 4) Dependent variables: Temperature of the OR, patient core temperature measurement time intervals, anesthesia	This study was assessing which study group experienced IPH. The use of different warming and prewarming methods were used on four different groups of 30 patients.	Tested all variables using Pearson's chi-square analysis, analyzed quantitative variables using the Kruskal-Wallis test. The relationship between the interventions and the average number of episodes of IPH using a generalized linear model with a Poisson assumption.	At the beginning of surgery, the mean temperature fell below the hypothermic limit for all patients in groups 2, 3, and 4. During surgery, we observed an increase in core temperature for all interventions. Overall, prewarming patients before going to the OR showed better outcomes and less incidence of IPH.	3	Although this study was not completely blinded, it compared four different interventions in controlled environments. Keeping the testing environments, the same and the anesthesia technique yielded more precise results. The results of this study show that risk factor identification and warming methods need to be assessed and implemented for TKA patients, therefore relevant to this DNP project.

			technique/providers, operating room,					
Article 10: The incidence of mild hypothermia after total knee or hip arthroplasty: A study of 2600 patients.								
Scholten, R., Leijtens, B., Kremers, K., Snoeck, M., & Koëter, S. (2018). The incidence of mild hypothermia after total knee or hip arthroplasty: A study of 2600 patients. *Journal of Orthopaedics*, *15*(2), 408–411. https://doi.org/10.1016/j.jor.2018.03.014	Prospective observational cohort study	2600 patients having THA or TKA from January 2011-December 2014 Exclusion-patients undergoing bilateral or revision surgery	Independent-use of FAW on all patients, core temperature measurement before and after surgery, use of warm blankets pre and postop, room temperature b/t 18-21 degrees Dependent-hypothermia, infection in joint, type of surgery, type of anesthesia, gender, age, BMI	Primary outcome is the incidence of hypothermia. Secondary outcome is the correlation of hypothermia with joint infection rates.	A chi-square test showed a significant difference between the incidences of hypothermia between the years 2011 and 2012 ($p = 0.000$), 2012 and 2013($p = 0.042$). A linear regression analysis shows a negative linear relationship between gender and core temperature ($p = 0.000$) and type of anesthesia	Overall incidence of hypothermia was 11.7%, 46 patients had a joint infection. This study shows that IPH can be reduced from increased awareness combined with the standardized use of warming protocols on all joint patients. From an earlier study the incidence of hypothermia was 26.7% which decreased to 11.7% in this study. Risk factors such as gender, BMI, and type of anesthesia can all predispose a patient to a higher chance of acquiring hypothermia,	II	This study is significant to this project because it shows that implementing change in the awareness and protocol around temperature management and monitoring in the perioperative setting can decrease the incidence of hypothermia associated with TJA. This study also notes that the use of combination use oof active nd passive warming methods are the most effective way to prevent and treat hypothermia.

					and core temperature(p = 0.033). A positive linear relationship was shown between core temperature and BMI (p = 0.000), female gender (p = 0.000) and the date of surgery (p = 0.000).			
Article 11: Guideline implementation and raising awareness for unintended perioperative hypothermia: Single-group 'before and after' study								
Şenkal, S., & Kara, U. (2020). Guideline implementati on and raising awareness for unintended perioperative hypothermia : Single-group 'before and after'	A prospective quality improvement study	We measured and compared the perioperative hypothermia incidence before the implementati on (November 24th, 2015 – January 15th, 2016) and after the implementati	Three phases of the study- before implementation, the during the development and implementation of new guidelines, and finally the postimplementa tion period. During each phase temperature	The primary outcome was the incidence of unintentional perioperative hypothermia in the pre and post-implementation groups. Temperature was measured on each patient in the temporal region with the same thermometer each time.	A sample size of at least 600 patients was needed to be a significant sample size. The distribution of the categorical variables in the groups was	Statistically significance of 35% incidence of IPH before implementation and then 23.8% incidence post implementation. This study shows that with implementation of EBP recommendations, the incidence of IPH can be decreased	II	This study compares their findings to many other similar studies to confirm that the overall incidence of IPH is high in many cases. "Our primary recommendation is the standardization of the core body temperature monitorization in the perioperative period and the incidence of UPH and indirectly related perioperative complications can be significantly decreased" This goal correlates to the outcomes of this DNP project.

study. Turkish journal of trauma & emergency surgery : TJTES, 26(5), 719–727. https://doi.org/10.14744/tjtes.2020.55237		on (April 6th, 2016 – July 21st, 2017) Inclusion- Patients, who were older than 18 years, scheduled for elective surgery by the departments of general surgery, urology, orthopedics, and thoracic surgery with an expected duration of surgery longer than 30 minutes, had ASA scores of I, II, and III; and accepted to participate with a verbal and written informed patient consent	measurement Is the dependent variable and the warming methods and guidelines changed in each [hase.		analyzed with Pearson's Chi-Square test. The normal distribution was checked using the Kolmogorov-Smirnov test. The distribution of the variables that do not match parametric assumptions (age, BMI, and PACU length of stay) was investigated with the Mann-Whitney U test in both groups.			

		A total of 669 patients were included						
Article 12: Prevention and management of perioperative hypothermia in adult elective surgical patients: A systematic review.								
Simegn, G. D., Bayable, S. D., & Fetene, M. B. (2021). Prevention and management of perioperative hypothermia in adult elective surgical patients: A systematic review. *Annals of Medicine and Surgery (2012)*, *72*, 103059. https://doi.org/10.1016/j.amsu.2021.103059	Systemic literature review	Inclusion criteria- “studies presented as original articles, Meta analysis, systematic review, RCT and comparative studies on perioperative hypothermia management for adult elective surgical patients, inadvertent perioperative hypothermia, complication of hypothermia incidence and	N/A	The aim of this review is to develop clinical protocols for prevention and management of IPH for elective surgical patients	Systematic review of multiple data bases, taking into consideration the level of evidence and degree of recommendations of each study analyzed.	From the literature reviewed, hypothermia was noted to be one of the least monitored complications from surgery and can result in many adverse effects such as “cardiac abnormalities, impaired wound healing, increased surgical site infections, shivering and delayed postoperative recovery, and coagulopathies”	I	Although this population is elective surgical patients, this study is a high level of evidence and the methods of preventing and treating IPH is very similar no matter the surgical case so this information can be applicable to this project’s population of TJA patients.

		management studies written in English”						
Article 13: Preventing inadvertent perioperative hypothermia								
Torossian, A., Bräuer, A., Höcker, J., Bein, B., Wulf, H., & Horn, E. P. (2016). Preventing inadvertent perioperative hypothermia. *Deutsches Arzteblatt International*, *112*(10), 166-172. https://doi.org/10.3238/arztebl.2015.0166	Systematic literature review from November 2021 to August 2014.	All national guidelines were reviewed, and multiple literature reviews with filters were performed to find the most current and relevant literature and the strength of each article was considered.	Five key clinical questions to answer- ● What is the normal core body temperature of a surgical patient; when and where should it be reliably measured in the perioperative period? ●What are the risk factors for the occurrence of perioperative hypothermia? ●What are the consequences of perioperative hypothermia? ●What warming techniques exist to reduce peri -	How to prevent IPH	Recommendations are developed and agreed upon by 14 expert representatives from 5 medical specialty societies	The general conclusions of these guidelines is that hypothermia is preventable and actions should be taken to prevent and treat hypothermia as it can cause adverse effects during and after surgery. Guidelines- “The patient’s core temperature should be measured 1–2 hours before the start of anesthesia, and either continuously or every 15 minutes during surgery. Depending on the nature of the operation, the site of temperature measurement should be oral, naso/oropharyngeal, esophageal, vesical, or tympanic (direct). The patient should be actively prewarmed 20–30 minutes before surgery to counteract the decline in temperature. Prewarmed patients must be actively warmed intraoperatively as well if the planned duration of anesthesia is longer than 60 minutes (without prewarming,	I	These guidelines collected from a large systematic review are significant to this project because they are supported by research and large medical societies. Strong recommendations like these will help develop the guidelines proposed by this project.

			operative hypothermia? ●How should the guideline be implemented?			30 minutes). The ambient temperature in the operating room should be at least 21°C for adult patients and at least 24°C for children. Infusions and blood transfusions that are given at rates of >500 mL/h should be warmed first. Perioperatively, the largest possible area of the body surface should be thermally insulated. Emergence from general anesthesia should take place at normal body temperature. Postoperative hypothermia, if present, should be treated by the administration of convective or conductive heat until normothermia is achieved. Shivering can be treated with medications"		
Article 14: Intraoperative hypothermia in patients undergoing Total knee arthroplasty: a cross-sectional study from a developing country								
Ukrani, R. D., Arif, A., Sadruddin, A., Hasan, O., & Noordin, S. (2021). Intraoperativ e hypothermia	Retrospective cross-sectional study of patients who underwent total knee arthroplasty at the Aga Khan University Hospital	Nonprobabilit y consecutive sampling was used for all patients fulfilling the inclusion criteria which was adults ⩾18 years	Independent variables: age, past medical history, gender, ASA status, length of surgery, Dependent variables:	"IBM SPSS (Statistical Package for Social Sciences) Ver- sion 23.0 was used for all statistical analysis. Continuous data	Primary outcome is the incidence of IPH in TKA patients	The results of this study highlight that age, bilateral procedure, ASA level and postoperative hypothermia were significantly associated with intraoperative hypothermia. The incidence of intraoperative hypothermia reported in our study was 26.6%.	III	This study helps to identify many of the same risk factors that lead to the incidence of hypothermia in joint patients. This articles also show a need for methods to reduce the incidence of hypothermia as it effects a large amount of the surgical population.

in patients undergoing Total knee arthroplasty: a cross-sectional study from a developing country. *BMC Musculoskeletal Disorders*, *22*(1), 1–6. https://doi.org/10.1186/s12891-021-04390-7	(AKUH) between the period January 2016 to December 2017	under- going TKA at the University Hospital.	operating room temperature, TKA procedure	is presented as mean ± standard deviation with comparison using independent sample t-test. Nominal and ordinal data is presented as N (%) with percentages compared using Chi-Square test. A p-value of < 0.05 was considered significant for all analyses"				

Appendix C

AORN Guidelines

Sidebar 1. Guideline for Prevention of Hypothermia Recommendations Addressed in This Article

Body Temperature Measurement

1.1 *Measure and monitor the patient's temperature during all phases of perioperative care.* [Recommendation][1(p331)]

1.2 *Select the temperature measurement site and method in collaboration with the perioperative team based on the requirements of the procedure, anesthesia type, anesthesia delivery method, accessibility of the body site for measurement, and invasiveness of the method.* [Recommendation][1(p331)]

1.3 *Use the same site and method of temperature measurement throughout the perioperative phases when clinically feasible.* [Recommendation][1(p334)]

1.4 *Determine the frequency of patient temperature measurement based on the individual patient assessment and the health care organization's policies and procedures.* [Conditional Recommendation][1(p334)]

Prevention Methods

2.1 *Implement methods for preventing or treating hypothermia for all patients during all phases of perioperative care.* [Recommendation][1(p334)]

2.2 *Select the method for preventing hypothermia (ie, active warming, passive insulation, a combination of methods) preoperatively in collaboration with the perioperative team members (eg, perioperative registered nurse, anesthesia professional, surgeon, scrub person) based on the following criteria:*

- *patient-specific factors:*
  - *age (eg, premature and other low-birth-weight infants, older than 65 years),*
  - *sex (ie, female),*
  - *low body-surface area or weight,*
  - *congestive heart failure,*
  - *cardiac vessel disease,*
  - *previous cardiac surgery,*
  - *preexisting medical conditions (eg, hypothyroidism, hypoglycemia; malnourishment, burns, trauma, infantile neuronal ceroid lipofuscinosis, neurologic disorders),*
  - *hypotension, and*
  - *history of organ transplantation;*
- *type and duration of the surgical procedure;*
- *type and duration of the planned anesthesia;*
- *patient positioning;*
- *use of a pneumatic tourniquet;*
- *use of an intermittent pneumatic compression device;*
- *warming equipment constraints (eg, access to the surgical site, skin surface area contact, device size); and*
- *potential for adverse events associated with the use of warming equipment.* [Recommendation][1(p335)]

2.3 *A combination of active warming methods or active and passive insulation methods may be used.* [Conditional Recommendation][1(p335)]

2.4 *When active warming is indicated, prewarm the patient with the selected method.* [Recommendation][1(p336)]

REFERENCE

1. Guideline for prevention of hypothermia. In: *Guidelines for Perioperative Practice*. Denver, CO: AORN, Inc; 2020:327-356.

Appendix D

Gap Analysis

Hypothermia Prevention and Management Gap Analysis			
	Meets Recommendations?		Additional Comments/Actions
	Yes	No	
Body Temperature Management			
Is there a policy and procedure in place that specifies:			
1. the patient's body temperature will be measured and monitored in all phases of perioperative care?			
2. The temperature measurement site and method will be selected in collaboration with the perioperative team?			
3. The temperature measurement site and method will be selected on the following: -anesthesia type -invasiveness of procedure -accessibility of the site -requirements of the procedure			
4. The frequency of the temperature and value to be documented in the patient's chart during all phases of perioperative care?			
Are consistent temperature monitoring devices available that can be used during each phase of perioperative care? If not, are the devices available comparable with results?			
Method Selection			
Is there a policy and procedure in place that specifies:			
1. The method of prevention hypothermia (active warming, passive warming, or a combination) will be determined preoperatively in collaboration with the perioperative staff?			
2. The minimum amount of time for prewarming the patient anesthesia induction?			
3. Interventions to normalize the patient's core body temperature if the patient is hypothermic before transferring to the OR?			

Adapted from AORN (Link, 2020)

Appendix E

Clinical Guidelines for Inadvertent Perioperative Hypothermia in Total Joint Arthroplasty

Inadvertent Perioperative Hypothermia Management and Monitoring in Total Joint Arthroplasties Guidelines and Policy- 2022	
Developed Date: 10/10/2022	**Effective Date:**
Developed By: Courtney Morris, SRNA	**Reviewed Date:**
Reviewed By: Dr. Kacy Ballard	**Approved By:** Dr. Kacy Ballard

STATEMENT OF PURPOSE:

The purpose of this guideline is to provide evidence-based practice recommendations regarding temperature measurement, monitoring, and management in surgical patients undergoing total joint arthroplasties (hip or knee). Inadvertent perioperative hypothermia (IPH) is a common complication of surgery and can result many times from receiving anesthesia. IPH exposes the patient to many adverse effects that can complicate the course of surgery and postoperative length of stay and recovery. The use of multiple passive and active warming methods with frequent and consistent temperature measurements reduces the overall incidence of IPH in total joint arthroplasty patients.

DEFINITIONS:

- Hypothermia- core body temperature below 36 degrees Celsius or 96.8 degrees Fahrenheit.
- Inadvertent Perioperative Hypothermia- hypothermia below 36 degrees Celsius in a surgical patient, usually related to anesthesia.

POLICY:

These guidelines are for all perioperative nursing and anesthesia staff caring for patient undergoing anesthesia for a total joint arthroplasty. This policy gives the minimum required standards of care for these patients in the perioperative care setting. Clinical judgement should always be considered, and additional monitoring or management should be obtained and performed when necessary.

GUIDELINES:

Body Temperature Measurement:

1. All patients must have a baseline temperature documented on arrival and risk assessment for hypothermia in the preoperative area.
2. All patients will have core body temperature measured and monitored during all phases of perioperative care
3. The temperature measurement site should be collaboratively decided on by the team based on the procedure, patient conditions, and accessibility to measurement site. Examples of temperature measurement sites include external skin, nasal, bladder, rectal, or esophageal
4. The same temperature measurement site should be utilized during each phase of care for the most accurate temperature monitoring trends.
5. The frequency of the temperature measurement should be decided in collaboration with the team and according to ASA guidelines and continued throughout all phases of perioperative care. (Minimum of every 15 minutes while under general anesthesia)

Warming Devices and Prevention

1. Hypothermia prevention should begin in the preoperative setting and maintained during the entire perioperative course, taking any actions to maintain normothermia.
2. Active prewarming should take place for each patient for at least 10 minutes in the preoperative setting.
3. Selecting the warming methods (active, passive, or combination) should be a collaborative decision with the whole team, individualized for the patient's needs and utilized during each phase of care. Considers for choosing warming methods include the following:
    a. Type and duration of surgery
    b. Patient positioning
    c. Type of anesthesia and required monitoring devices
    d. Patient specific factors such as: gender, weight, medical history, age, hemodynamic profile
4. Options for warming devices and methods include but are not limited to:
    a. Forced air warming device with disposable blankets or gown
    b. Underbody heating pads
    c. Fluid warmer device and/or warm fluids
    d. Warm blankets
    e. Increase in Operating room temperature if indicated
5. The patient must have a minimum of a core body temperature of 97 degrees to leave the recovery area, either to inpatient or discharge.

Adapted from AORN (Link, 2020)

Appendix F

Staff Post Implementation Survey

Post Implementation Evaluation

Ratings	1 = Strongly Disagree	2 = Disagree	3 = Neutral/ N/A	4 = Agree	5 = Strongly Agree
I measure every patient's temperature when under my care at appropriate frequencies.	☐	☐	☐	☐	☐
The same site of temperature measurement is used for an individual patient during their time in perioperative care consistently.	☐	☐	☐	☐	☐
The guidelines were easy to understand and to implement into my personal routine of care.	☐	☐	☐	☐	☐
Education for this policy was efficient and effective.	☐	☐	☐	☐	☐
I referred to posted signage for tips or when questions arose about the guidelines.	☐	☐	☐	☐	☐
The equipment was user friendly and easily accessible when needed for patient use.	☐	☐	☐	☐	☐
Overall, I would keep these guidelines in place and recommend them for other facilities.	☐	☐	☐	☐	☐

Please leave any additional comments/concerns below

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Appendix G

IRB Exemption

Otterbein University
IRB Exemption Statement
Conversation between IRB Chair, Dr. Noam Shpancer and Dr. John Chovan, Department of Nursing Chair.

From: Shpancer, Noam <nshpancer@otterbein.edu>
Sent: Wednesday, October 13, 2021 9:44 AM
To: Chovan, John <jchovan@otterbein.edu>
Subject: Re: IRB and DNP Projects

John: The way I see it, a project is not subject to IRB review unless and until it collects data from human participants. So, I agree with you that these projects will not need IRB approval until someone decides to implement them for data collection, at which point that person may apply for IRB approval.
Thanks, Noam.
From: Chovan, John <jchovan@otterbein.edu>
Sent: Wednesday, October 13, 2021 9:10 AM
To: Shpancer, Noam <nshpancer@otterbein.edu>
Subject: IRB and DNP Projects

Good morning, Noam,
I could use some advice--maybe a conversation– about the Doctor of Nursing Practice final scholarly projects and submitting for IRB approval. The projects parameters from our accreditors for some of the projects have changed. The list of acceptable projects now includes the option of writing a plan for a project that is not implemented. So, it can effectively stop at the proposal stage, and then these projects can be available for a future student to implement if someone has that interest. I have at least two questions.
1.The IRB Guidelines states "Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge." Most of these projects are not intended to develop or contribute to generalizable knowledge. They are clinical change projects that are intended to eventually change a clinical practice of health care professionals (humans) in one identified setting. They have the possibility of contributing to generalizable knowledge in that each would be an instance of a clinical change that, if implemented in other places by others, could eventually be generalized. But that is not the primary intent of the projects. Would they be considered research? I think they would not.
2.If indeed they are considered research and should be submitted for review by the IRB, at what point in the process should IRB approval be obtained? I would think that although implementation is not part of the initial project, review by IRB would be helpful to the original team in shaping their project plan. Yet if this proposal is not going to be implemented, then the approval to move forward would be moot. But if a second team eventually reads the proposal and wants to implement it, would they be the ones seeking IRB approval? If you would prefer that we talk in real time, I am open to that. Or perhaps you could visit one of our faculty meetings for a discussion?
Thank you.
Best,

John
John D. Chovan, PhD, DNP, RN, CNP, CNS, PMHNP