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Protocol Development for Preventing Inadvertent Perioperative Hypothermia in Outpatient

Surgical Patients

James A. Lower, BSN, RN

Doctor of Nursing Practice Final Scholarly Project

In Partial Fulfillment of the Requirements for the Degree Doctor of Nursing Practice

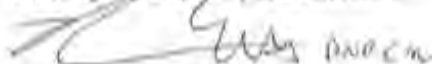
Otterbein University

2022


DNP Final Scholarly Project Team



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Abstract

Hypothermia changes normal physiology resulting in altered clotting, metabolism, immune function, and healing processes which increases patient's risk for adverse outcomes. During the perioperative period anesthesia is recognized as a main cause of inadvertent perioperative hypothermia (IPH). As a result several organizations have developed clinical practice guidelines (CPG) to prevent IPH. There is an inconsistent utilization of warming devices and a lack of policy and procedure directing the effective maintenance of normothermia for surgical patients at a medium sized academic level one trauma hospital in the Midwest. Having no established standard practice protocol within this institution places the patients at an increased risk for the development of hypothermia during outpatient elective surgeries, which may lead to adverse patient outcomes. The Rosswurm and Larrabee (1999) model for Change to Evidence-Based Practice will frame this project and a CPG will be evaluated by key stakeholders using the Appraisal of Guidelines for Research and Evaluation II. The AGREE II tool evaluations scaled domain scores ranged from 82-93%. Overall quality of the CPG was evaluated at 89% and 80% would recommend the CPG for implementation. The Rosswurm and Larrabee (1999) model for Change to Evidence-Based Practice framed this project and the 2016 AORN CPG was evaluated by key stakeholders using the Appraisal of Guidelines for Research and Evaluation II. The AGREE II tool evaluations were scored using AGREE II set scoring. The CPG was found to be of high quality and a recommendation was made to the facility to form a protocol based on the CPG.

Introduction

A current clinical problem in surgical patients is the development of hypothermia, defined as a core temperature less than 36 degrees Celsius (Akers et. al, 2019; Beedle et. al., 2017; Berríos-Torres et. al, 2017; Diaz & Newman, 2015). Hypothermia developed during the perioperative period is termed inadvertent perioperative hypothermia or IPH (Madrid et. al, 2016). IPH results in adverse patient outcomes including poor wound healing, increased length of stay in the hospital, and increased health care costs (Diaz & Newman, 2015). Maintaining normothermia during the perioperative period is a category 1A recommendation with moderate to strong evidence by the Centers for Disease Control (CDC) 2017 Guideline for Prevention of Surgical Site Infections (Berríos-Torres et al., 2017). Nurses and anesthesia providers are essential in monitoring patient body temperature throughout the perioperative period. Early detection of hypothermia enables providers to intervene, leading to decreased adverse patient outcomes such as longer hospital stays, increased blood loss, wound infections, and increased hospital costs (O'Hare, Thom & Preas, 2018).

Preventing IPH is an active problem in outpatient elective surgical procedures where the Continuous Process Improvement Team (CPIT) identified 38 cases of surgical site infections over a 14-month surveillance period (Personal Communication, 2020). The CPIT committee reviewed all 38 cases of surgical site infections and found that current facility policies to prevent surgical site infections were followed; however, the CPIT committee found that all 38 cases were hypothermic during the intraoperative period (Personal Communication, 2020). While hypothermia may not be the only cause of these surgical site infections, several organizations such as the American College of Surgeons, the Association of perioperative Registered Nurses (AORN), the Centers for Disease Control (CDC), and the American Society of Perianesthesia

Nurses (ASPAN) all recommend maintaining normothermia during the perioperative period to prevent surgical site infections (Clinical guideline for the prevention of unplanned perioperative hypothermia, 2001; Guideline Summary: Prevention of Unplanned Patient Hypothermia, 2016; Ban et al., 2017; Berríos-Torres et al., 2017). Prevention of inadvertent perioperative hypothermia is one area of improvement to prevent surgical site infections at a medium sized academic level one trauma hospital in the Midwest.

Utilizing a needs assessment to discover a solution to inadvertent perioperative hypothermia (IPH), the first step is to identify a current policy, standard of care, or guideline that provides direction on preventing IPH. The American Society of Anesthesiologist (ASA) and the American Association of Nurse Anesthetist (AANA) both have regulations stating temperature must be monitored during anesthesia care but there is no direction on how to maintain normothermia (American Association of Nurse Anesthetist, 2019; American Society of Anesthesiologist, 2015). A comprehensive review of current hospital policy, as well as, Quality Department facilitated interviews with key stakeholders and anesthesia providers were conducted at a medium sized academic level one trauma hospital in the Midwest, all of which revealed a lack of institutional policy on maintaining normothermia during the perioperative period. There are current clinical practice guidelines at a national level that provide recommendations on strategies to maintain normothermia (Clinical Guideline for the Prevention of Unplanned Perioperative Hypothermia, 2001; Guideline Summary: Prevention of Unplanned Patient Hypothermia, 2016). In summary, there is a lack of local facility policy on the best practice to maintain normothermia during the perioperative period to prevent IPH. As a result, patients at a medium sized academic level one trauma hospital in the Midwest continue to suffer the consequences of IPH and inconsistent ways of symptom treatment.

Literature Review

Consequences of Hypothermia

Normal core temperature in humans is approximately 37°C or 98.6°F and is controlled by the hypothalamus through a negative feedback mechanism producing physiologic changes such as shivering and vasoconstriction as a means to maintain normothermia (Sessler, 2016; Sessler 2001). A core temperature less than 95.9°F or 36°C is considered hypothermic and inadvertent perioperative hypothermia (IPH) has several negative consequences including increased bleeding, immune system impairment, and poor wound healing (O'Hara, et al., 2018). Many processes in the human body require temperature-dependent enzymes and proteins for normal functioning and are inactivated as the core body temperature drops below 35.5 °C (Akers et al., 2019; Ruetzler & Kurz, 2018; Sessler, 2016).

Coagulopathy

The most common adverse event related to inadvertent perioperative hypothermia (IPH) is coagulopathy which results from direct inhibition of enzymes in the coagulation cascade (Akers et al., 2019; Sessler, 2016). The most common impairment is the reversible inhibition of thromboxane A3 which forms the initial platelet plug (Akers et al., 2019; Sessler, 2016). Coagulopathy during the perioperative period leads to greater blood loss and increased need for blood transfusion. These conclusions are supported by the Yi et al. (2019) randomized controlled trial in which the maintenance of normothermia during the intraoperative period resulted in a decreased blood loss.

Immune System Impairment

Core temperature below 35.5°C impairs immune system defenses and slows wound healing, increasing the risk of postoperative infection. Hypothermia inhibits tissue healing

leading to increased incidence of wound dehiscence and longer healing times (Ruetzler & Kurz, 2018; Sessler, 2016). Surgical site infections are the third most common cause of hospital-acquired infections and account for 14-16% of nosocomial infections (Ruetzler & Kurz, 2018). Mild hypothermia produces vasoconstriction, reduces systemic immune activation, and limits the mobility of immune cells and T cell-mediated antibody production (Ruetzler & Kurz, 2018; Sessler, 2016; Sessler, 2001). Each of these events weakens immune defenses against bacterial infection and increases susceptibility to surgical site infections that increase hospital length of stay 5-20 days (Sessler, 2001).

Pharmacodynamics

Hypothermia prolongs the duration of action of many medications through decreased metabolism. This phenomenon is particularly evident with common anesthetic drugs such as sedatives and muscle relaxants. For example, the duration of action for the muscle relaxant vecuronium doubles with a two-degree Celsius drop in core temperature (Ruetzler & Kurz, 2018). Hypothermia increases the solubility of volatile anesthetics resulting in longer circulation times and decreased minimum alveolar concentration (MAC) dose of the anesthetic gas (Ruetzler & Kurz, 2018).

Circulating endogenous norepinephrine levels increase during hypothermia through a stress response manifested as hypertension and tachycardia (Sessler, 2016). While hypertension and tachycardia increase the risk for myocardial injury, shivering induced from a cool body temperature increases oxygen consumption (Sessler, 2016). As a result, myocardial ischemia or infarction and hypoxemia risks increase (Sessler, 2016).

Length of stay and mortality

Patients who are hypothermic experience longer stays in the postanesthesia recovery unit (PACU) or require unplanned hospital admissions resulting in higher medical care costs (Ruetzler & Kurz, 2018). IPH results in a higher 30-day mortality rate and a higher readmission rate compared to normothermic patients (Williams & Ashworth, 2018).

Causes of Perioperative Hypothermia

Inadvertent perioperative hypothermia typically occurs during the intraoperative phase due to anesthesia medications and skin exposure requirements for surgery (Akers et al., 2019; Sessler, 2016; Sessler 2001). Another cause of IPH is impairment of normal thermoregulation in the hypothalamus due to anesthesia induction drugs such as volatile and intravenous anesthetics (Ruetzler & Kurz, 2018; Sessler, 2016; Sessler, 2001). Induction medications decrease brain functioning and alter normal regulatory control to maintain normothermia.

The peak incidence of hypothermia occurs 60 minutes after induction of anesthesia and is the result of systemic vasodilation from induction agents and heat loss to the environment (Akers et al., 2019; Sessler, 2016). Systemic vasodilation eliminates the temperature gradient between the core and periphery causing warmer core blood to mix with cooler blood in the periphery, decreasing overall body temperature (Akers et al., 2019; Sessler, 2016). Sessler (2001) further explains the decline in core temperature as a result of heat loss through radiation and convection from surgical skin exposure. Both radiation and convection heat losses are most significant in infants, children, and the elderly (Beedle et al., 2017).

Inadvertent Perioperative Hypothermia Prevention Strategies

Recent research suggests IPH is entirely preventable and focuses on strategies to prevent the incidence of hypothermia during the perioperative period (Watson, 2018). Currently,

warming strategies are implemented after the induction of anesthesia. However, recent research indicates prewarming patients in the preoperative area significantly reduces the core to periphery temperature gradient reducing the incidence of IPH (Ruetzler & Kurz, 2018; Sessler, 2016; Sessler, 2001). During prewarming, vasodilation is promoted, eliminating the temperature gradient of blood and significantly reducing the initial hypothermia after induction of anesthesia.

Types of Warming

There are two types of warming: active warming (AW) with an external heat source or passive warming (PW) using cotton blankets. The most common type of active warming is the application of a forced-air warmer (FAW) that uses a unique blanket connected to an external heater to circulate warmed air over the patient (Yi et al., 2018). FAWs come in a variety of sizes such as full body, upper body, or lower body blankets that can be placed on top of or underneath the patient depending on the surgical procedure (Yi et al., 2018). The FAW temperature can be titrated to the patient's need and comfort. In the RCT by Yi et al. (2018), the intraoperative FAW group had a zero percent incidence of hypothermia whereas the intraoperative PW group had a hypothermic rate of 37.5%. High-level research including multiple systematic reviews and meta-analyses support AW as a superior method for preventing IPH, increasing thermal comfort, and decreasing time to hypothermia when compared to PW (Alderson et al., 2014; Nieh & Su, 2016; Warttig et al., 2014).

Preoperative Warming

One strategy to decrease IPH is prewarming patients in the preoperative unit before anesthesia induction and surgery. A randomized controlled trial by Torossian et al. (2016) compared intraoperative hypothermia rates in prewarmed patients with FAW versus no prewarming. Results found statistically significant higher temperatures in FAW prewarmed,

decreasing IPH incidence to 38% in the FAW group as compared to a 60% incidence of IPH in the no prewarming group. This trend continued in the post-anesthesia care unit (PACU) where 24% of FAW prewarmed patients experienced IPH compared to 49% of the non-prewarmed group.

Best practice evidence suggests that optimal prewarming is initiated upon admission to the preoperative area; however, prewarming for even 15 minutes before anesthesia induction is effective in preventing IPH. A 2019 observational study of 140 patients undergoing spinal anesthesia found a statistically significant decrease in hypothermia rates by prewarming patients prior to spinal anesthesia. The results demonstrated a 96% incidence in hypothermia in non-prewarmed patients compared to a 71% incidence in hypothermia in patients actively prewarmed for 15 minutes and a 75% incidence in hypothermia in patients actively prewarmed for 30 minutes (Becerra et al., 2019). Another non-randomized controlled trial suggests combined active prewarming for 10 minutes and continued intraoperative active warming reduces hypothermia by 70% (Alfonsi et al., 2019).

Clinical Practice Guidelines (CPG)

Clinical practice guidelines were first described and developed by the institute of medicine in the early 1990s (Field et al., 1990). Clinical Practice Guidelines are “systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances” (Field et al., 1990). The National Institute of Health (NIH) summarizes CPGs as evidence-based practice recommendations developed from systematic review and synthesis of published medical literature to provide recommended interventions to consider while providing health care. During the mid 1990s there were several research studies and publications about perioperative hypothermia that led to the first clinical practice guideline

to prevent inadvertent perioperative hypothermia (IPH) in 2001 by American Society of PeriAnesthesia Nurses (ASPAN). This CPG provided evidence-based practice interventions for preoperative, intraoperative and postoperative patient management. Since this time CPGs have been updated and other national organizations have provided updated recommendations for the prevention of IPH as a strategy to decrease surgical site infections.

The most recent and up-to-date clinical practice guideline for preventing IPH was published by the Association of periOperative Registered Nurses (AORN) in 2016. The AORN provides a strong stance on maintaining normothermia by stating “All perioperative patients are at risk for developing hypothermia” (Guideline Summary: Prevention of Unplanned Patient Hypothermia, 2016). In summary the AORN recommends the perioperative Registered Nurse (RN) should perform a preoperative nursing assessment to determine the presence of factors that could contribute to IPH, the patient’s temperature should be measured and monitored in all phases of perioperative care, the perioperative RN should develop an individualized plan of care and implement the interventions chosen for prevention of IPH, and a quality-improvement management program should be in place to identify and respond to opportunities for improvement related to unplanned perioperative hypothermia (Guideline Summary: Prevention of Unplanned Patient Hypothermia, 2016).

A large focus of this CPG is the individualized plan of care and warming method selection. Patient specific risk factors such as age, sex, low-body surface area or weight, heart failure, preexisting diseases, hypotension, and history of organ transplantation place patients at increased risk of becoming hypothermic (Guideline Summary: Prevention of Unplanned Patient Hypothermia, 2016). Other factors include type and duration of surgical procedure, type and duration of planned anesthesia, patient positioning, use of pneumatic tourniquet, and warming

equipment constraints affect incidence of IPH (Guideline Summary: Prevention of Unplanned Patient Hypothermia, 2016). These risk factors are assessed and warming strategies of active or active and passive warming are indicated. This CPG does note that when active warming is indicated, patients should be prewarmed with the selected method for a minimum of 10 minutes prior to transporting to the operating room (Guideline Summary: Prevention of Unplanned Patient Hypothermia, 2016). The AORN cites several international CPGs from England, Toronto, and Germany as well as CPGs from ASPAN and the Enhanced Recovery After Surgery (ERAS) Society that recommend prewarming patients as an intervention for preventing unplanned hypothermia.

Summary

A core temperature below 95.9°F or 36°C is considered hypothermic. The CDC and American College of Surgeons strongly recommend maintaining normothermia, with moderate to strong supporting evidence, as a strategy to prevent surgical site infections (Ban et al., 2017; Berrios-Torres et al., 2017). The highest incidence of hypothermia occurs 60 minutes after induction of anesthesia and is caused by the physiologic changes produced by anesthetic medications and skin exposure for surgery (Ruetzler & Kurz, 2018; Sessler, 2016; Sessler, 2001). FAW is demonstrated as the superior method for maintaining normothermia and is currently utilized during the intraoperative period (Alderson et al., 2014; Nieh & Su, 2016; Warttig et al., 2014). Newer research indicates FAW during the preoperative period for 10-30 minutes prior to anesthesia induction is a successful method in decreasing the incidence of hypothermia after induction of anesthesia (Alfonsi et al., 2019; Becerra et al., 2019; Torossian et al., 2016). Finally, preoperative FAW is shown to reduce surgical site infections and post-surgical complications while increasing patient comfort and satisfaction scores (Madrid et al., 2016). Progress in the

understanding patient temperature management led to the creation of clinical practice guidelines. Recent clinical practice guidelines recommend a multidisciplinary team approach to patient temperature management.

Methods and Materials

Evidence-Based Practice Framework

This DNP project utilizes the *Model for Change to Evidence-Based Practice* [EBP] theory (Rosswurm & Larrabee, 1999). The utilization of this EBP practice change model provides the scaffolding to implement this DNP project in a clinical institution. Rosswurm & Larrabee (1999) describe the six steps for implementing the EBP change model as 1) Assess the need for practice change, 2) Determine the connection between the problem, interventions, and outcomes, 3) Review and critique current literature, 4) Develop a practice change by identifying resources, constructing an implementation plan, and defining outcomes, 5) Implement and evaluate the change through a trial period and making adjustments to the practice change, 6) Incorporate and maintain practice change through communication with staff and key stakeholders. This EBP framework provides a step-by-step plan for the development of a facility policy based review and critique of a current clinical practice guideline.

Project Purpose

There was inconsistent utilization of warming devices and a lack of facility policy to direct the effective maintenance of normothermia for surgical patients at a medium sized academic level one trauma hospital in the Midwest. The absence of standard practice policy within this institution placed patients at an increased risk for the development of hypothermia during outpatient elective surgeries, which may lead to adverse patient outcomes. Therefore, the overall goal of this project was to improve the quality of patient care in the perioperative period

by meeting the objectives: 1) standardizing perioperative temperature management strategies in elective surgical patients, and 2) development of an evidence-based practice institutional clinical protocol to maintain normothermia during the perioperative period.

General Procedure

Problem Identification

The evidence-based practice and quality improvement project took place in a medium sized academic level one trauma hospital in the Midwest and follows the Rosswurm & Larrabee, 1999 EBP change model. The first step in the EBP practice change model was to assess the need for practice change. The Continuous Process Improvement Team (CPIT) found that over a 14-month period, there were 38 cases of surgical site infections in elective outpatient surgeries where all current policies to prevent surgical site infections were followed, but patients were hypothermic during the intraoperative period (Personal Communication, 2020). Next, the connection between the problem, interventions and outcomes were assessed. While hypothermia may not be the only cause of these surgical site infections several organizations such as the American College of Surgeons, the Association of Perioperative Registered Nurses (AORN), the Centers for Disease Control (CDC), and the American Society of Perianesthesia Nurses (ASPAN) all recommend maintaining normothermia during the perioperative period to prevent surgical site infections (Clinical guideline for the prevention of unplanned perioperative hypothermia, 2001; Guideline Summary: Prevention of Unplanned Patient Hypothermia, 2016; Ban et al., 2017; Berríos-Torres et al., 2017). Prevention of inadvertent perioperative hypothermia was one identified area of improvement to prevent surgical site infections at a medium sized academic level one trauma hospital in the Midwest. The second step was to form a connection between the lack of practice standard or facility policy to direct the maintenance of

normothermia during the perioperative period, and the solution with clinical practice guidelines. There are clinical practice guidelines with recommended strategies to maintain normothermia. Since there was a lack of practice standard or facility policy for the maintenance of normothermia during the perioperative period, a clinical practice guideline was evaluated using the Appraisal of Guidelines for Research and Evaluation II (AGREE) tool.

CPG Evaluation

The third step in the EBP change model was to synthesize the best evidence. The most recent 2016 CPG from the Association of Perioperative Registered Nurses (AORN) was evaluated by key stakeholders using the AGREE II tool. Key stakeholders included facility staff members from the anesthesia department, quality department, and perioperative nursing.

Appraisal of Guidelines for Research and Evaluation II (AGREE) Tool

The AGREE II tool assesses the practice guideline methodology and transparency, and can be used to evaluate an established practice guideline for facility implementation. Assessment of the CPG through the AGREE II tool, an open-source instrument, provides feedback on CPG structure, content, and quality (AGREE II, 2017). The AGREE II tool meets validity and reliability standards and is accepted nationally and internationally as a CPG evaluation instrument (AGREE II, 2017). The AGREE II demonstrates adequate reliability and internal validity, which has been reported as acceptable to good internal consistency with Cronbach's alpha coefficients ranging from 0.64 to 0.89 (Brouwers, et al., 2010). Since this project involves CPG evaluation, the use of a nationally and internally accepted instrument with preferred reliability and validity made the AGREE II tool an appropriate fit for this project in meeting the objectives. The AGREE II tool can be referenced in appendix C.

The AGREE II tool is a 23-item tool used by multiple independent appraisers to assess six domains: 1) scope and purpose, 2) stakeholder involvement, 3) rigor of development, 4) clarity of presentation, 5) applicability, and 6) editorial independence (AGREE II, 2017). Each domain item is scored on a Likert scale from 1 (strongly disagree) to 7 (strongly agree) and each appraiser evaluated the CPG based on how well they felt each item was adequately addressed. The items in each domain were added and the domain score of each appraiser represented the percentage of the maximum possible score (see data collection for more scoring details). The information provided feedback on the CPG structure, content, and quality.

Practice Change

The fourth step in the EBP model was to design practice change. After evaluation of the AORN Guideline for Prevention of Unplanned Patient Hypothermia, 2016 the results of the AGREE II tool were evaluated using preset AGREE II tool standards. If the established CPG was found to be good quality, a facility protocol that reflects the CPG would be developed and a plan to implement the protocol into practice would follow as step five of the EBP change model. If the CPG was found to be of poor quality, then evidence from a synthesis of literature would be gathered to determine best practices and from the literature a protocol would be formed by key stakeholders. After formation the protocol would be presented to the Continuous Process Improvement Team for review. The final step of the EBP change model would be to integrate and maintain practice change. This step was beyond the scope of this DNP project and will need to be completed by the facility after implementation of protocol.

Methods Summary

This Doctor of Nursing Practice Scholarly Project took place at a medium sized academic level one trauma hospital in the Midwest. The Rosswurm and Larrabee (1999) Model for change

to evidence-based practice outlined the framework for this project. The first step was to assess the need for change establishing an absence of practice standard or policy regarding normothermia but current CPGs are present to guide warming strategies. The second step was to summarize the relationship between hypothermia, warming strategies, and the decrease in IPH. Then literature and CPG were reviewed and critiqued in step three with the AGREE II tool. Next, a plan to change practice was developed based on the results of CPG evaluation with the AGREE II tool. Step five (implement and evaluate) would follow the formation of a facility protocol and step six (incorporate and maintain practice change through communication with key stakeholders) was beyond the scope of this DNP project and would need to be completed by the facility in the future.

Subject/Participant Population

Key Stakeholders

The population for the CPG evaluation was composed of clinicians and persons experienced in the perioperative period. There were five team members (N=5) one person from the anesthesiology department, a member from the quality department, a preoperative Registered Nurse (RN), intraoperative RN, and Post-anesthesia Care Unit RN. Team members were requested on a volunteer basis with requests made to anesthesia administrators, Quality department professionals with experience in the perioperative period, a preoperative Registered Nurse (RN), intraoperative RN, and Post-anesthesia Care Unit RN champion. Excluded were any professionals not involved in the areas of anesthesia, quality or perioperative nursing.

Informed Consent

Stakeholders were requested on a volunteer basis. No personal data was collected as only quantitative raw data from the AGREE II tool forms was collected and entered into a password

protected Microsoft Excel spreadsheet. There was minimal to no risk to stakeholders for participating and as such informed consent was obtained through the completion of the AGREE II tool.

Risks

The project involved completing self-report AGREE II form questionnaires regarding the AORN 2016 CPG. Therefore, the risk to participants was minimal to no risk. Justification for risk included participants are routinely asked questions such as their demographic data, perceptions concerning feasibility and utility of CPGs, policies, procedures, and education programs.

Data Collection and Analysis Plan

Data Collection Instruments

The DNP project used the AGREE II tool to critique and evaluate a CPG. The AGREE II tool has been utilized nationally and internationally in the development of clinical practice guidelines (AGREE, 2017; Antoniou et al., 2020; Romeo et al., 2019; Shallwani et al., 2019). The AGREE II tool assessed the clinical practice guideline methodology and transparency. Assessment of CPG through the AGREE II tool, an open-source instrument, provided feedback on CPG structure, content, and quality (AGREE II, 2017). The AGREE II tool meets validity and reliability standards and is accepted nationally and internationally as a CPG evaluation instrument. Internal consistency or Cronbach's alpha score for AGREE II ranges from 0.64 to 0.89 (Brouwers, et al., 2010).

The AGREE II tool is a 23-item tool to be used by multiple independent appraisers which assesses six domains: 1) scope and purpose, 2) stakeholder involvement, 3) rigor of development, 4) clarity of presentation, 5) applicability, and 6) editorial independence (AGREE

II, 2017). Each domain item is scored on a Likert scale from 1 (strongly disagree) to 7 (strongly agree) and each appraiser evaluated the CPG based on how well they felt each item was adequately addressed. The items in each domain were added and the domain score of each appraiser was represented as a percentage of the maximum possible score. This information provided feedback on the CPG structure, content, and quality.

Protection and Security of Data and Identifying Information

A member of the project team reviewed the completed AGREE II feedback responses obtained from all applicable project participants in a designated private and secure office space. The names of the participants were not extracted from the original AGREE II forms. Only the participants de-identified AGREE II responses were extracted, placed into an excel spreadsheet, and analyzed. Original AGREE II forms were immediately temporarily stored in a password protected computer and participant electronic data was deleted after the project was completed.

Disposition of Data and Identifying Information at Project Completion

Once the data collection process was completed, only de-identified information was kept by the principal and associative investigator (PI/AI). De-identified data was saved on an encrypted password-protected device and will be stored for a minimum of three years per institutional guidelines.

Data Analysis

No data analysis of the AGREE II tool was conducted, as this would have compromised the reliability of the AGREE II tool. AGREE II set standards were adhered to in the evaluation of the CPG. The AGREE II Consortium describes that each of the six AGREE II domains are independent and cannot be aggregated into a single quality score (Brouwers et al., 2010). The AGREE II was scored based on appraiser score per domain i.e. for Domain 1 (scope and

purpose) there are three items, each item had a maximum potential score of seven (strongly agree) and a minimum score of 1 (strongly disagree) (Brouwers et al., 2010). Having five appraisers the maximum possible score was 105 (7 points x 3 domain questions x 5 appraisers) while the minimum score was 15 (1 point x 3 domain questions x 5 appraisers) (Brouwers et al., 2010). The scaled domain score was then calculated as the obtained score minus minimum possible score divided by maximum possible score minus the minimum possible score (Brouwers et al., 2010). Domain scores were useful for comparing guidelines and informed the quality of the guideline but the Consortium did not set a minimum domain score to distinguish between high quality and low quality guidelines (Brouwers et al., 2010).

Project Evaluation

The success of the DNP project was directly linked to patient outcomes. The overall goal of this project was to improve the quality of patient care in the perioperative period. Goal achievement would be measured by decreased adverse events related to perioperative hypothermia and increased patient satisfaction during the perioperative period. The objectives were measured by the standardization of perioperative temperature management strategies in elective outpatient surgical procedures, and the development of an evidence-based practice institutional clinical protocol to maintain normothermia during the perioperative period.

Gender and Ethnicity

The key stakeholders that participated in this project are expected to represent the gender and ethnic demographic characteristics of the professional anesthesia department, Quality department, and perioperative registered nurses in this facility.

Facilitators

The major facilitators were the key stakeholders. Key stakeholders understood the value of developing a protocol and held positions to aid in the evaluation of the protocol. Other important facilitators were academic advisors, project manager, facility Nursing Evidence-Based Practice Review Committee members, and professors that provided insight into DNP project.

Ethical Considerations/Protection of Human Subjects

The project was approved by the facility Nursing Evidence-Based Practice Review Committee, and the academic Institutional Review Board (IRB) determined the project did not meet criteria for full IRB review (See appendices F and G). As previously mention, no names or unique patient/staff identifiers were requested, collected or stored. No PHI was collected. All collected information was fully de-identified prior to storage into a password-protected, secured spreadsheet as previously described. Only de-identified aggregate data was shared outside of the hospital with academic Nursing Department Faculty and Students as part of the dissemination of the DNP Final Scholarly Project Report Presentation (in Partial Fulfillment of the Requirements for the Degree: Doctor of Nursing Practice at Otterbein University).

Results

Five faculty members evaluated the CPG using the AGREE II tool to determine if the CPG met standards on content, structure and quality. Faculty included one member from each of the following areas anesthesia, quality, pre-operative nursing, intra-operative nursing, and post-operative recovery nursing. The raw scores from the AGREE II tool results were converted to scaled domain using the AGREE II conversion rules (Brouwers et al., 2010). Scaled domain scores ranged from 82-93%. The highest scores were in stakeholder involvement (93%) and Editorial Independence (93%). The lowest score was in clarity of presentation (82%). Overall

quality of the CPG was evaluated at 89% and 80% would recommend the CPG for implementation.

Discussion

Faculty scaled domain and overall quality scores support the utilization of the AORN Guideline for Prevention of Unplanned Patient Hypothermia, 2016 CPG. Utilizing this CPG to maintain normothermia during the perioperative period supports the overall goal (to improve quality of patient care) and objectives (to develop a standardized perioperative temperature management strategy and allow the creation of an evidence-based practice institutional protocol) of this DNP project. Based on the data from the AGREE II tool this CPG should be used as a framework to create a facility guideline for implementation. Creation and implementation of this facility guideline would be carried out by the implementation facility.

Limitations and Barriers

There were limitations and barriers experienced during this DNP project. One major barrier was evaluating a guideline that all stakeholders felt was sufficient. Another limitation was the inability to conduct in-person meetings due to COVID-19. As such many meetings took place individually via phone or virtual interactions which limited the efficiency of the project requiring additional time.

Project Timeline.

The DNP project was completed from May 2020 to April 2022. A detailed description of timeline is outlined in appendix B. Starting in July 2020 the project proposal was completed and approval of the project to move forward is expected. During the Fall of 2020, the proposed project was approved by a facility Nursing Evidence-Based Practice Review Committee and an academic Internal Review Board (IRB). After receiving the final approval from the EBP NRC

and IRB, the project started. From January- March 2021 key stakeholders were gathered, educated on clinical practice guidelines and how to use the AGREE II tool with resources for support. March-June 2021 AGREE II evaluations were collected and data was synthesized. Fall 2021 final project was written up, a poster was formed for a DNP project dissemination, and recommendations were made to the facility.

Conclusion

Hypothermia changes normal physiology resulting in altered clotting, metabolism, immune function, and healing processes which increases patient's risk for adverse outcomes. During the perioperative period anesthesia was recognized as a main cause of inadvertent perioperative hypothermia (IPH). As a result, several organizations have developed clinical practice guidelines (CPG) to prevent IPH. There was inconsistent utilization of warming devices and a lack of policy and procedure directing the effective maintenance of normothermia for surgical patients at a medium sized academic level one trauma hospital in the Midwest. The lack of an established standard practice protocol within this institution placed patients at an increased risk for the development of hypothermia during outpatient elective surgeries, which may lead to adverse patient outcomes. The Rosswurm and Larrabee (1999) model for Change to Evidence-Based Practice framed this project and the 2016 AORN CPG was evaluated by key stakeholders using the Appraisal of Guidelines for Research and Evaluation II. The AGREE II tool evaluations were scored using AGREE II set scoring. The CPG was found to be of high quality and a recommendation was made to the facility to form a protocol based on the CPG.

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Appendix A

Table 1. Synthesis Review Table

Author, Year	Study Objective	Design/ Intervention	Sample (N)	Outcomes Studied	Results/ Recommendation	Limitations	Level of Evidence
Akers et al., 2019	Identify risk factors for IPH and postoperative complications	Retrospective cohort analysis	N= 298 Included: adults . 18 years old w/ hysterectomy, laparoscopic cholecystectomy, colectomy, hernia repair, total knee arthroplasty or total hip arthroplasty during 2017	Hypothermia risk factors and postoperative complications	Hypothermic patients require more transfusions, have higher sepsis rates, and higher mortality.	Sample size only included one hospital, lack of validation on data collection	IVa
Alderson et al., 2014	Evaluate thermal insulation role in preventing IPH.	SR	N=22 trials Inclusion: RCT of thermal insulation compared to normal practice standard	How does type of insulation affect rates of IPH	No benefit of extra thermal insulation. FAW maintains core temperature better than extra thermal insulation by 0.5-1°C higher.	Most evidence included was graded as low quality.	Ib
Alfonsi et al., 2019	Evaluate the prevalence of IPH and use of FAW during	Observational prospective multicenter study.	N= 893 Inclusion: >45 years old, non-cardiac, non-	Prevalence of hypothermia in perioperative patients.	Combined pre and intraop warming significantly reduces IPH.	Nonrandomized study	IIIa

	perioperative period.		outpatient surgery lasting >30 minutes in 52 centers.		Prewarm for 10 minutes halves the incidence of hypothermia on arrival to PACU.		
Becerra et al., 2019	Study the effectiveness of prewarming on IPH in surgical patients with spinal anesthesia	Prospective observational study	N=140 Exclusion: female, active infection, antipyretics within 24 hours of surgery, neuropathy, thyroid disorders, PVD, skin lesions, or Hx of skin hypersensitivity.	AW prewarming vs. no prewarming incidence of IPH. Varying lengths of prewarming.	56 patients did not receive prewarming- 96% developed hypothermia. Prewarm 15 minutes hypothermic rate of 73%, Prewarm for 30 minutes hypothermic rate of 75%. PACU LOS shorter in Prewarm 15 and prewarm 30.	Nonrandomized study and excluded females.	IVb
Beedle et al., 2017	Prevent unplanned IPH in children	Quasiexperimental	N= 1,190 patients Exclusion: >9 years 11 months old, females who reached menarche, did not go to PACU, active infection.	Incidence of IPH	IPH 1.34% with new CPG compared to 16.3% with old CPG. Low body temperature at beginning indicator for risk of developing hypothermia.	Restricted age and large range of time under anesthesia.	IIIb
Berrios-Torres et al., 2017	2017 CDC guideline for prevention of surgical site infections	SR of RCT	N=170	Evaluating the level of supporting evidence for SSI prevention measures	Maintaining perioperative Normothermia Category IA- strong recommendation, high	No discussion on how to maintain normothermia.	IA

					to moderate quality evidence. SSI cost range from \$10,000-25,000		
Madrid et al., 2016	Determine AW prevents complications by IPH in adults	SR	N=67 Included: RCTs compared FAW and normothermia in perioperative period.	FAW vs. PW and complications in perioperative period.	FAW had lower complications, improved patient comfort, use in preop does not pose significant risk.	Did not evaluate how temperature was recorded.	Ia
Nieh & Su, 2016	Perform a meta-analysis of effectiveness of FAW for preventing IPH.	MA	N=29	Core temperature based on warming types.	FAW superior to PW in preventing IPH. No difference in using top or bottom half warming blanket only. FAW offered thermal comfort superior to other methods.	Non-blinded meta-analysis	Ia
O'Hara et al., 2016	Strategies for implementing CDC guidelines for prevention of Surgical site infections.	SR of RCTs Practice recommendation	N=5000	Factors affecting SSI	Maintain normothermia (>35.5 °C). Hypothermia increase SSI by impairing neutrophils and increases blood loss.	Lacks guidance on how to maintain normothermia	IA
Sessler, 2016	Discuss thermoregulation connections with anesthesia and heat loss	SR	N= 102 Contain robust methodology, large sample size, and importance	Anesthesia effects thermoregulation and heat loss. Complications of hypothermia	Complications include: coagulopathy, reduced immune function, wound healing.	Poorly described selection of articles for inclusion	I Ib

					Passive layers decrease heat loss by 30% but additional layers do not decrease heat loss		
Ruetzler & Kurz, 2018	Provide a discussion of consequences of perioperative hypothermia.	Textbook Chapter	-	What occurs as a result of hypothermia in the body? What are strategies to avoid hypothermia?	Hypothermia impairs pharmacodynamics, increases SSI, increased blood loss, coagulopathy, shivering, cardiac complications, delayed discharge.	No description of data analysis	IIIa
Sessler, 2001	Provide discussion on complications and treatment of mild hypothermia	Review	-	What are hypothermia induced complications? Strategies to minimize hypothermia perioperatively.	<p>Hypothermia increases SSI (6% vs. 19%), LOS (12.1 vs. 14.7 days), intraop blood loss (1.7L vs. 2.2L), cardiac events (1% vs. 6%), plasma NE, Thermal discomfort (50 vs. 18).</p> <p>Hypothermia alters pharmacokinetics and dynamics.</p> <p>Prewarming decreases normal core to periphery temperature gradient by provoking vasodilation.</p>	No discussion on how articles were evaluated for reliability.	IIIc

Torossian et al., 2016	Evaluate how AW vs. PW compare thermal warming	Multinational, multicenter RCT	<p>N=246</p> <p>Inclusion: elective orthopedic, gynecologic, or ENT; duration 30-120 minutes; ASA 1-3.</p>	<p>Does warming strategy affect temperature?</p> <p>Is there a difference in thermal comfort, patient satisfaction and adverse outcomes?</p>	<p>Core temperature higher in AW group with preop hypothermia 43% vs. 68% in PW.</p> <p>Intraop hypothermia AW: 24% vs. 60% in PW.</p> <p>Thermal comfort statistically significant higher in AW.</p> <p>No difference in adverse events, LOS, or overall hospital satisfaction.</p>	Only included short procedures and tympanic temperatures.	Ia
Warttig et al., 2014	Develop interventions for treating IPH	MA of RCT	<p>N=11 n=699 patients</p> <p>Inclusion: RCT of post-op warming interventions.</p>	Interventions to treat postoperative hypothermia	FAW reduces mean time to achieve normothermia.	Small sample size.	Ia
Watson, 2018	Evaluate IPH prevention with PW vs. AW	SR	<p>N= 17</p> <p>Exclusion: Age <18 years, non-clinical or non-human studies, studies of neurocritical</p>	Type of warming and incidence of hypothermia.	<p>IPH completely preventable.</p> <p>AW more effective than passive.</p>	<p>Small sample size.</p> <p>No discussion on measure of reliability.</p>	Ib

			patients, local anesthesia				
Williams et al., 2018	Determine the incidence of IPH in elderly hip fractures	Quasiexperimental single center retrospective study from June 2015-July 2017	N=929 Inclusion: Hip fracture managed intraoperatively. Excluded: <65 years old, missing temperature data	Incidence of IPH in elderly hip fracture patients. Identify risk factors and outcomes in patients with IPH.	Hypothermia rate of 10%. Patients who were hypothermic preop were 40 times more likely to be hypothermic entering PACU. Hypothermia resulted in higher 30-day mortality. 9.8% readmission rate in hypothermic patients compared to 2.3% readmission rate in normothermic.	Single center study	IIIa
Yi et al., 2018	Evaluate the effect of normothermia on blood loss	Prospective, parallel two arm RCT	N=62 Large Beijing hospital. Inclusion: age >18, ASA 1-3, open thoracic operations or initial unilateral total hip replacement.	Incidence of hypothermia in PW vs AW. What are rates of intraop blood loss, SSI, CV events, and LOS	AW 0% incidence of hypothermia, PW 71% incidence of hypothermia. Blood loss statistically significant less in AW: 464mL vs. 682mL. LOS statistically significantly shorter in AW at 28.7 minutes vs. PW 35.4 minutes.	Small sample size. Only performed at one medical center	IIb

Appendix B

Table 2. Project Timeline

Month(s)	Task
July 2020	Project proposal
October- December 2020	Submission to OHNRC and Otterbein IRB
January- February 2021	Key stakeholders gathered
March- April 2021	AGREE II evaluations completed
April-June 2021	Results from evaluations analyzed
Fall 2021	Final write-up and results presented to local providers
December 2021	Project presentation

Appendix C

Figure 1. AGREE II Tool

Domain 1: Scope and Purpose (1-3) (For each question below, please circle the your choice).

1. The overall objective(s) of the CPG is specifically described.
 Strongly Disagree 1 2 3 4 5 6 7 Strongly Agree

Comments:

2. The health question(s) covered by the CPG is specifically described.
 Strongly Disagree 1 2 3 4 5 6 7 Strongly Agree

Comments:

3. The population to whom the CPG is meant to apply is specifically described.
 Strongly Disagree 1 2 3 4 5 6 7 Strongly Agree

Comments:

Domain 2: Stakeholder Involvement (4-6)

4. The guideline development group includes individuals from all relevant professional groups.
 Strongly Disagree 1 2 3 4 5 6 7 Strongly Agree

Comments:

5. The views and preferences of the target population and stakeholders have been sought.
 Strongly Disagree 1 2 3 4 5 6 7 Strongly Agree

Comments:

6. The target users of the guideline are clearly defined.
 Strongly Disagree 1 2 3 4 5 6 7 Strongly Agree

Comments:

Domain 3: Rigor of Development (7-14)

7. Systematic methods were used to search for evidence.

Strongly Disagree	1	2	3	4	5	6	7	Strongly Agree
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Comments:

8. The criteria for selecting the evidence are clearly described.

Strongly Disagree	1	2	3	4	5	6	7	Strongly Agree
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Comments:

9. The strengths and limitations of the body of evidence are clearly described.

Strongly Disagree	1	2	3	4	5	6	7	Strongly Agree
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Comments:

10. The methods for formulating the recommendations are clearly described.

Strongly Disagree	1	2	3	4	5	6	7	Strongly Agree
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Comments:

11. The health benefits, side effects, and risks have been considered in formulating the recommendations.

Strongly Disagree	1	2	3	4	5	6	7	Strongly Agree
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Comments:

12. There is an explicit link between the recommendations and the supporting evidence.

Strongly Disagree	1	2	3	4	5	6	7	Strongly Agree
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Comments:

13. The guideline has been externally reviewed by experts prior to its publication

Strongly Disagree	1	2	3	4	5	6	7	Strongly Agree
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Comments:

14. A procedure for updating the guideline is provided.

Strongly Disagree	1	2	3	4	5	6	7	Strongly Agree
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Comments:

Domain 4: Clarity of Presentation (15-17)

15. The recommendations are specific and unambiguous.

Strongly Disagree 1 2 3 4 5 6 7 Strongly Agree

Comments:

16. The different options for management of the condition or health issue are clearly presented.

Strongly Disagree 1 2 3 4 5 6 7 Strongly Agree

Comments:

17. Key recommendations are easily identifiable.

Strongly Disagree 1 2 3 4 5 6 7 Strongly Agree

Comments:

Domain 5: Applicability (18-21)

18. The guideline describes facilitators and barriers to its application.

Strongly Disagree 1 2 3 4 5 6 7 Strongly Agree

Comments:

19. The guideline provides advice and/or tools on how the recommendations can be put into practice.

Strongly Disagree 1 2 3 4 5 6 7 Strongly Agree

Comments:

20. The potential resource implications of applying the recommendations have been considered.

Strongly Disagree. 1 2 3 4 5 6 7 Strongly Agree

Comments:

21. The guideline presents monitoring and/or auditing criteria.

Strongly Disagree 1 2 3 4 5 6 7 Strongly Agree

Comments:

Domain 6: Editorial Independence (22-23)

22. The views of the funding body have not influenced the content of the guideline.

Strongly Disagree 1 2 3 4 5 6 7 Strongly Agree

Comments:

23. Competing interests of guideline development group members have been recorded and addressed.

Strongly Disagree 1 2 3 4 5 6 7 Strongly Agree

Comments:

Overall Assessment

For each question, please choose the response which best characterizes the guideline addressed:

1. Rate the overall quality of this guideline.

Lowest possible quality 1 2 3 4 5 6 7 Highest possible quality

2. I would recommend this guideline for use:

Yes.

Yes, with modifications

No

Notes:

Appendix D

Table 3. AGREE II Raw Data

	Evaluator					
	1	2 €	3	4	5	Total score
Domain 1 Scope and Purpose						
1	7	7	6	6	5	31
2	7	7	6	6	5	31
3	7	7	6	7	5	32
Domain 2 Stakeholder Involvement						
4	7	7	7	7	4	32
5	7	7	6	6	6	32
6	7	7	6	7	7	34
Domain 3 Rigor of Development						
7	7	7	6	6	7	33
8	7	7	6	7	6	33
9	7	7	6	7	7	34
10	7	7	5	7	4	30
11	7	7	6	6	6	32
12	7	7	6	6	4	30
13	7	7	6	6	7	33
14	7	7	6	5	4	29
Domain 4 Clarity of Presentation						
15	7	7	6	7	2	29
16	7	7	6	7	3	30
17	7	7	6	7	3	30
Domain 5 Applicability						
18	7	6	6	6	5	30
19	7	7	6	6	5	31
20	7	7	6	6	5	31
21	7	7	6	5	4	29
Domain 6 Editorial Independence						
22	7	7	6	6	7	33
23	7	7	6	6	7	33
Overall Quality	7	7	6	6	5	31
Would recommend	Y	Y	Y	Y	N	

Appendix E

Table 4. Domain Overall and Scaled Scores

	Overall	Scaled
Domain 1 Scope and Purpose	90%	88%
Domain 2 Stakeholder Involvement	93%	92%
Domain 3 Rigor of Development	90%	89%
Domain 4 Clarity of Presentation	84%	82%
Domain 5 Applicability	86%	84%
Domain 6 Editorial Independence	94%	93%
Overall Quality	89%	
Would recommend	80%	

Appendix F

Figure 2. NEBPRC Letter



James A. Lower
Otterbein University

December 3, 2020

RE: Protocol Development for Preventing Inadvertent Perioperative Hypothermia in Preoperative Outpatient Surgical Patients

Dear Mr. Lower:

The Nursing Evidence-Based Practice Review Committee (NEBPRC) has reviewed the proposal referenced above. Clear evidence was submitted to justify both the need for the practice change and that evidence supports the proposed plan. You have adequately addressed all concerns from the pre-review and the revisions are accepted.

The NEBPRC has determine that the project proposal you submitted does not meet the Federal definition of research as cited in CFR 45-46:102. According to the Federal Code, research is defined as:

(1) *Research* means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes.

You have permission to move forward with the protocol development as described in your proposal. The proposed protocol must be evaluated and approved through CPIT as stated in the proposal. Upon completion of the project and before dissemination (poster or manuscript), you must submit the results so that the OhioHealth can review the presentation to ensure Health Insurance Portability and Accountability Act (HIPAA) compliance.

Congratulations on your progress towards this worthy endeavor.

Teresa Wood PhD, RN, NEA-BC

Teresa Wood PhD, RN NEA-BC
Program Manager, Nursing Research

Appendix G

Figure 3. IRB Letter


OTTERBEIN
 UNIVERSITY

INSTITUTIONAL REVIEW BOARD

Dear Dr. Ballard,

With regard to the employment of human subjects in the proposed research:

Ballard, Lower, & Sribanditmongkol: Protocol development for preventing inadvertent...

THE INSTITUTIONAL REVIEW BOARD HAS TAKEN THE FOLLOWING ACTION:

The IRB has made the determination that this project is not human subjects research, as the researchers are not interacting with participants, nor are they obtaining, using, generating, or analyzing any identifiable private information or biospecimens. As such 45 CFR part 46 does not apply, and IRB review is not required for this project.

☐ Original Review
☐ Continuing Review
☐ Amendment

Date: 10 December 2020

Signed: Meredith C. Frey
Chairperson

(Revised January 2019)