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Inadvertent Perioperative Hypothermia: A Retrospective Chart Review

Kailee Petro

Inadvertent Perioperative Hypothermia: A Retrospective Chart Review

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Abstract

Background: Inadvertent perioperative hypothermia (IPH), defined as recorded temperature at or below 36°C (96.8°F), is a common adverse effect that can occur during any surgical procedure, leading to increased postoperative morbidity and mortality. The data was analyzed for statistical significance and plotted on a graph to show the mean and median temperatures, along with the highest and lowest during each phase of care.

Purpose: The purpose of this project is to examine core temperatures in total knee arthroplasty (TKA) patients at four different phases of care: preoperatively, procedure start time, procedure stop time, and postoperatively.

Methods: A retrospective chart review will be completed to collect temperatures for using the 3M Spot-On core temperature monitoring device on 38 patients undergoing TKA procedures.

Implementation: The data will be analyzed plotted on a graph to show the mean temperatures, along with the highest and lowest temperatures during each phase of care.

Conclusion: Patients were found to be hypothermic at the beginning and end of the procedure. On average, patients were 95.5°F at the start of the procedure and 96°F at the end. Preoperatively, patients were 98°F and 97.3°F in the recovery room.

Keywords: hypothermia, total knee arthroplasty, inadvertent perioperative hypothermia

Inadvertent Perioperative Hypothermia: A Retrospective Chart Review

Introduction

Inadvertent perioperative hypothermia (IPH), defined as recorded temperature at or below 36°C (96.8°F), can facilitate many unfavorable physiological side effects including bleeding, surgical site infections (SSIs), altered pharmacodynamics, and increased postoperative length of stay (Joanna Briggs Institute [JBI], 2010). Total knee arthroplasty (TKA) patients are at risk of IPH due to heat loss from radiation and massive vasodilation from neuraxial anesthesia (Diaz & Becker, 2010). A SSI in a TKA patient can have detrimental effects on the patient's health and recovery; therefore, preventing IPH is essential in this population.

Background

IPH affects roughly 70% of surgical patients leading to increased morbidity and mortality (Giuliano & Hendricks, 2017). Although hypothermia can be cerebral and cardioprotective in the absence of shivering due to decreased oxygen requirements, it can have detrimental physiologic effects in the perioperative period. Unfavorable outcomes of hypothermia include cardiac arrythmias, coagulopathy, delayed drug metabolism, and impaired wound healing (Butterworth IV, Mackey, & Wasnick, 2018).

"When there is no attempt to actively warm an anesthetized patient, core temperature usually decreases 1°C to 2°C during the first hour of general anesthesia…" (Butterworth IV et al., 2018, p. 1214). TKAs are typically performed under spinal anesthesia and sedation unless contraindications or complications are encountered. Initially, IPH occurs due to redistribution of heat through the mixing of warmer central core blood with peripherally cooler blood (Terkawi, n.d.). Neuraxial anesthesia intensifies this phenomena due to the extreme vasodilation of the

peripheral vasculature. Heat loss to the environment is minimal and equilibrates due to metabolic heat production during the surgical procedure (Butterworth IV et al., 2018).

The theory behind preoperative forced-air warming encompasses the heating of periphery blood so when redistribution occurs upon induction, the mixing of warm core blood now mixes with warmer periphery blood, diminishing the central-peripheral temperature gradient (Butterworth IV et al., 2018). Maintaining normothermia leads to improved patient outcomes, better healing, quicker recovery.

TKA is a reportable surgical procedure, meaning hospitals must publicly report adverse events that occur during or after the procedure including wound complications and SSIs. “There are significant benefits associated with forced-air warming in terms of better outcomes such as higher core temperatures, reduced incidence of shivering and morbid cardiac events, increased thermal comfort, reduced blood loss, reduced surgical site infections and shorter length of hospital stay” (Joanna Briggs Institute [JBI], 2010, p. 2).

Problem Statement

TKA procedures are typically elective; therefore, an adverse event such as a SSI, can be catastrophic for the patient and surgeon. All adverse outcomes are reported to specific agencies that track and compile the data into publicly available records. It reflects directly upon the performance of the facility and surgeon. Identification of IPH occurrences and at what specific time intervals in the perioperative period it transpires, will help support the implementation of pre-operative warming within Eskenazi Health. The formulated problem question is as follows: In total knee arthroplasty patients, what is the incidence of documented core temperatures less than 36° C throughout the perioperative phases of care?

Organizational "Gap" Analysis of Project Site

Eskenazi Health's perioperative department has identified that surgical patients are hypothermic during the perioperative period. The data had the potential to be skewed due multiple different temperatures sources, so the 3M Spot-On monitoring device was implemented. Literature supports the use of preoperative warming devices to decrease the incidence if IPH during the intraoperative phase by warming the peripheral blood before redistribution of central blood occurs during general or neuraxial anesthesia. According to a study published in the American Journal of Infection Control, the implementation of a TKA checklist that included preoperative warming 30 minutes before and during the surgery using the Bair Hugger system resulted in zero SSIs over a seven-month period (Hogenmiller et al., 2011). The facility currently does not have any policy in place regarding surgical warming and temperature tracking which has been identified as a gap in practice.

Review of Literature

Search Strategy

A focused review was completed using the Cumulative Index Nursing and Allied Health Literature (CINAHL) and PubMed database through the Marian Library. The keywords searched alone and in conjunction with each other included "perioperative", "preoperative", "hypothermia", "warming", "forced-air", and "inadvertent". The period searched was January 2013- April 2020. A total of 22 studies were first identified discussing different aspects of maintaining normothermia or IPH prevention. 7 of the articles were then further reviewed and appraised. Exclusion of studies occurred if it did not pertain specifically to IPH or preoperative

warming, was consider low on the level of evidence, or contained vulnerable populations. Of the 7 articles identified, 3 are systematic reviews of literature, 1 randomized control trial (RCT), 1 case-control study, 1 clinical practice guideline (CPG), and 1 retrospective study. Appraised studies were I or III level of evidence sources.

Incidence of Hypothermia

Identification of hypothermia occurred in a wide range of ages, procedures, length of case, and types of anesthesia. The systematic reviews came to the same conclusion where 80% or more of their articles recommended pre-operative warming at 38°C for a minimum of 30 minutes before surgery (Broback, Skutle, Dysvik, & Eskeland, 2018). Hypothermia is known to be a problem in the operating room affecting approximately 70% of patients, especially during the first hour of surgery (Li, Liang, & Feng, 2020). Torossian et al. suggests a up to 90% of patients suffer from hypothermia especially if they are over the age of 60 or suffer from pre-existing diseases, such as diabetes mellitus, that affect thermoregulation. Differences in temperature measurements (temporal, esophageal, nasopharyngeal, skin, and oral) and inaccuracy by not using core temperatures were common elements listed as a limitation in many studies (Broback et al., 2018; Connelly et al., 2017; Roberson, Dieckmann, Rodriguez, & Austin, 2013; Rosenkilde, Vamosi, Lauridsen, & Hasfeldt, 2017).

Causes of Hypothermia

IPH is a result of many factors, one being related to the mixing of warm core blood with peripheral cool blood during induction of anesthesia or vasodilation from neuraxial anesthesia (Broback et al., 2018). Radiation, which is the loss of heat to the environment by exposed areas, accounts for 50-70% of heat loss resulting in IPH (Torossian et al., 2015). Cold intravenous

fluids, cooler ambient room temperatures, and inhibition of thermoregulation are additional contributing factors to IPH in the operating room (Roberson, Dieckmann, Rodriguez, & Austin, 2013).

Pre-Operative Warming and It's Benefits

A case-control study regarding the use of a prewarming device identified IPH in 13% of patients being prewarmed and 43% in patients in the control group (Rosenkilde et al., 2017). A RCT conducted on patients undergoing gynecological surgery receiving prewarming during epidural placement identified a 0.34 °C drop in prewarmed patients and a 0.9 °C drop in the control group using the 3M Spot-On temperature monitoring device (Kaufner et al., 2019). All of the appraised studies discussed the common adverse effects from IPH including increased oxygen demand, bleeding dysfunction, increased risk of infection, decreased wound healing, and discomfort to the patient (Broback et al., 2018; Connelly et al., 2017; Kaufner et al., 2019; Li et al., 2020; Roberson, Dieckmann, Rodriguez, & Austin, 2013; Rosenkilde, Vamosi, Lauridsen, & Hasfeldt, 2017; Torossian et al., 2015). Additional benefits included decreased shivering resulting in decreased oxygen consumption, decreased blood loss, and thermal conform for the patient increasing patient satisfaction (Roberson et al., 2013). Preoperative warming times varied from 30 minutes to 120 minutes along with temperature settings from 38°C to 46 °C (Broback et al., 2018; Connelly et al., 2017; Kaufner et al., 2019; Li et al., 2020; Roberson, Dieckmann, Rodriguez, & Austin, 2013; Rosenkilde, Vamosi, Lauridsen, & Hasfeldt, 2017; Torossian et al., 2015).

Total Knee Arthroplasty and Hypothermia

TKA patients are at higher risk of complications from SSIs and decreased wound healing due to the nature of the procedure and implantation of a medical device. TKA procedures are typically performed under neuraxial/spinal anesthesia which further accentuates the mixing of peripheral and core blood due to extreme vasodilation. The goal is to get TKA patients mobilized as soon as possible; however, hypothermia delays the metabolism of anesthetic drugs leading to an increased length of stay in the post anesthesia care unit (PACU) and longer time until mobilization.

The body's ability to respond to hypothermia is altered by anesthesia agents mixed with environmental heat loss leads to an initial drop in a patient core temperature of 1-1.5 °C (Rosenkilde et al., 2017). Naturally there is a 5-8 °C temperature difference between peripheral and core blood. CPGs recommend actively prewarming the patient for 10-30 minutes and ideally before and during placement of a spinal or epidural. This decreases the temperature gradient allowing for a decreased drop in temperature upon redistribution (Torossian et al., 2015). Hypothermia in the post-operative phase can lead to shivering which increases oxygen consumption, causes release of catecholamines, and could potentially cause myocardial ischemia. By preventing these adverse effects, patients' length of stay is shortened thus decreasing the patients' hospital costs (Roberson, Dieckmann, Rodriguez, & Austin, 2013).

Evidence Based Practice: Verification of Chosen Option

Based on the review of literature and CPGs analyzed, temperatures will be evaluated at different phases of care to identify periods of IPH and at what time intervals it occurs. The goal is to help guide Eskenazi Health in their decision to implement pre-operative warming based on the incidence of IPH.

Evidence Based Practice Model

The Johns Hopkins Nursing Evidence-Based Practice Model (JHNEBP Model) helps nurses evaluate EBP research and translate the findings into their nursing practice and patient care (White et al., 2016). This model incorporates all three aspects of nursing: practice, education, and research. The JHNEBP follows the 3 phases of practice question, evidence, and translation, with each phase being broken down into individual steps. IPH is an exceptionally relevant clinical practice problem affecting most surgical patients. This project will utilize the practice question and evidence phases, leading to translation once IPH has been identified. The JHNEBP model utilizes the PICOT method for forming the practice problem question, evaluation of evidence, and translation into practice to improve processes. A diagram of the JHNEBP is included in the appendix below (Figure 1.1)

Goals, Objectives, and Expected Outcomes

The goal of this project is to identify periods of IPH and at what phases of care it occurs in patients undergoing TKA procedures. Identification will assist the facility to obtain in assistance in implementation of pre-operative warming and purchasing warming devices for all preoperative patient rooms. The objectives of this projected are listed below:

1. To obtain core temperatures using the 3M Spot-On Temperature Monitoring system on approximately 35 TKA patients by March 2020.
2. Temperatures collected will be analyzed for periods of IPH, temperature < 36°C, at specific time intervals: preoperative, procedure start, procedure stop, and first recorded temperature in the PACU.

3. Analyzed temperatures will be plotted on a graph showing mean, highest, and lowest temperatures for each time interval.

The expected outcome is identification of IPH within the first hour of surgery in patients that have not been warmed in the pre-operative period leading to the need for implementation of preoperative active forced air warming.

Project Design

Using an integrative review with presentation quality improvement project design, a retrospective chart review of the electronic medical record (EMR) will be performed. Quantitative data will be collected, analyzed, and plotted on a graph to determine the periods of IPH during specific time intervals within the perioperative period. The data will then be presented to the facility to help determine when interventions should take place to prevent IPH.

Project Site and Population

This project will take place at Eskenazi Health in the perioperative departments. The facility is a non-for-profit public hospital located in Indianapolis, Indiana. They serve a diverse patient population, stemming from different socioeconomic statuses, ethnic backgrounds, and education levels. The population being utilized for this study will consist of patients from all ages, excluding minors, undergoing TKAs being performed by two different orthopedic surgeons. The inclusion criteria include all patients undergoing a TKA January 2020 to March 2020. The exclusion criteria include currently admitted inpatients, minors, emergency room admissions, trauma patients, and any patient with missing documented temperatures.

Stakeholders and Barriers

Originally, this project was supposed to be implementation of preoperative warming. However, due to changes within the facility, implementation was delayed until precise temperatures could be analyzed. Implementation of the 3M monitoring device was to help prevent skewed data and all for more reliable tracking of perioperative temperatures; hence the project change to temperature tracking at specific time intervals. Indiana University Health (IUH) and Eskenazi Health Institutional Review Board (IRB) approval was delayed due to the coronavirus pandemic shifting working responsibilities and prohibiting students from entering the facilities.

Stakeholders included employees from IUH and Eskenazi Health. Dr. Michael Sanford, MD assisted the project investigator with identification of the problem and current strategies being investigated. Hayden Joubert, RN, MSN, perioperative manger, is a co-project investigator that assisted with data collection, project guidelines, and communication within the hospital. Dr. Jennifer Embree, RN, DNP, a facility member at Indiana University School of Nursing and employee of Eskenazi Health, is also a co- project investigator and assisted with facility and IRB approval, project formatting, implementation strategies, and final project formulation.

Methods

Starting in January 2020, all reportable patients undergoing surgery will utilize the 3M Spot-On Temperature Monitoring device until a total of 150 patients have been documented. This device is applied to the patient's temple, however, monitors a core temperature throughout all phases of care. All perioperative personnel, including the nurses, patient care techs, and anesthesia providers will be educated on the proper use of the device and how to appropriately document temperatures in the EMR. Temperatures are electronically pulled from the device

monitor; however, must be verified by the documenting provider. The data will be extracted from the EMR for only the TKA patients and complied into a data collection tool on a password protected, secured server at Eskenazi Hospital.

Measurement Instruments & Data Collection Procedure

An excel spreadsheet will be developed, omitting identifiable information with the following data categories: preoperative, procedure start time, procedure stop time, and the first recorded temperature in the PACU. Data will be collected by Hayden Joubert, perioperative manager, and then dispersed to project investigator for analysis. Identifiable information, such as names and medical record number, will be removed from the data prior to disbursement to limit any chances of patient data breaches.

Data Analysis

The data will be analyzed and the mean, highest, and lowest temperatures will be calculated and plotted on a graph. The collected data will be presented to the facility with the goal of identifying periods of IPH and recommending interventions or practice changes to prevent IPH. This will allow for trending and identification of IPH during different periods of perioperative care. Identification is important to know where interventions need to be implemented regarding warming patients.

Results

Data was collected on 38 TKA patients and 4 were removed due to exclusion criteria. The average temperature for the 34 TKA patients in the preoperative phase of care was 98.0 °F, the highest temperature documented was 98.8°F, and the lowest temperature documented was 97.3°F. Temperatures documented at the start of the procedure averaged to 95.5°F, which is

below the hypothermia threshold of 96.5°F. The highest temperature documented was 99.3°F and the lowest temperature was 91.7 °F. Temperatures documented at the end of the procedure averaged to 96.0°F, with the highest documented temperature 98.6°F and the lowest was 89.9°F. Temperatures documented in the PACU averaged to 97.4°F, with the highest documented temperature 98.5°F and the lowest was 93.3°F. The average temperature dropped a total of 2.5°F between the preoperative phase and start of the procedure. See Figure 1.6 in the Appendix for the chart and graph of patient temperaures.

Interpretation/Discussion

Using the temperature of 96.5°F as the benchmark for hypothermia, it is concluded that on average patients are hypothermic at the start and end of the procedure. Further studies are needed to study the effects of preoperative warming on intraoperative temperatures. Devices and blankets must be used to insulate the patient while traveling in between the phases of care; otherwise, the heat is quickly lost. Most of the patient's heat is lost during the first hour of surgery because once a patient is induced their blankets are immediately removed, and they are bathed in cold prep solutions. It is imperative for anesthesia providers to keep warm blankets on the patient and minimize skin exposure (Diaz & Newman, 2015). According to the Association of Operating Room Nurses (AORN), the ambient temperature in the OR should be between 20 and 25°C (68-77°F) (Diaz & Newman, 2015).

There were many limitations to this study which may have altered the data collected. The 3M device was originally supposed to be utilized on each of these patients; however, it was only used for approximately the first 10 patients leading to multiple methods for collecting temperatures. Other limitations included documentation by different anesthesia providers,

missing data, misuse of the thermometers, inaccurate documentation, and the inability to decipher if intraoperative warming was initiated and what mechanism was used.

Cost-Benefit Analysis

There was no cost or budget for this particular project as it is a retrospective chart review; however, the goal of the project is to illustration the periods of IPH and the need for preoperative forced air warming implementation. Decreasing patient stays due to less adverse events will have a greater effect than the cost of purchasing forced-air warmers for each preoperative patient room.

Timeline

Approval from all necessary committees, facilitators, review boards was required before this project could be implemented. Approval of this project was granted in October 2019; however, the project was changed to temperature analysis rather than pre-operative warming in December 2019. Data collection began in January 2020 by the perioperative manager, Hayden Joubert. Prior to submitting for IUH and Eskenazi Health IRB approval, the project investigator had to present the project to the unit and hospital wide shared governance committees. Once their approval was obtained, the project investigator along with co-project investigators, Dr. Jennifer Embree, RN, DNP and Hayden Joubert, RN, MSN submitted for IUH IRB approval. Once it was obtained, it was then also submitted to Eskenazi Health IRB for approval. Once all approval was obtained, data previously collected could be analyzed. The Covid Pandemic delayed the ability to obtain the collected data from the facility until September 2020. See Appendix Figure 1.2 for Gantt chart and detailed project timeline.

Ethical Considerations

Marian University (MU) IRB approval was obtained prior to initiating the Doctor of Nursing Practice (DNP) Project with an exempt status (Appendix Figure 1.3). IRB approval was also obtained from IUH and Eskenazi Health, both with exempt status prior to initiation of the DNP project (Appendix Figure 1.4 and 1.5). All patients were protected by the Health Insurance Portability and Accountable Act of 1996 (HIPAA), which guarantees the protection of patients' privacy and confidentially regarding their health information ("HIPAA," 2019). Patient identifiers were removed from all collected data as part of the evaluation process. Informed consents were not required as there was no risk to the patient beyond the risk identified regarding the surgical procedure. Patient confidentially was assured by removing any patient identifiers and storing the data collected on an Eskenazi password protected secured server. At the conclusion of this project, all data will be deleted and destroyed.

Conclusion

IPH remains a problem in many institutions due to the rapid loss of patient heat during surgical procedures performed in the operating room. IPH can lead to many detrimental side effects including bleeding, infection, and increased tissue oxygen consumption. There are many warming devices, blankets, and tasks that can be implemented to help decrease the amount of heat loss; however, these cost money and require data to explain the need for the device. IPH was identified during intraoperative phases of care, despise patients being above they hypothermic threshold preoperatively and in the recovery room. Further studies are needed to identify which methods of preoperative and intraoperative warming are best to prevent IPH.

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Appendix

Figure 1.1: Johns Hopkins Nursing Evidence-Based Practice Model

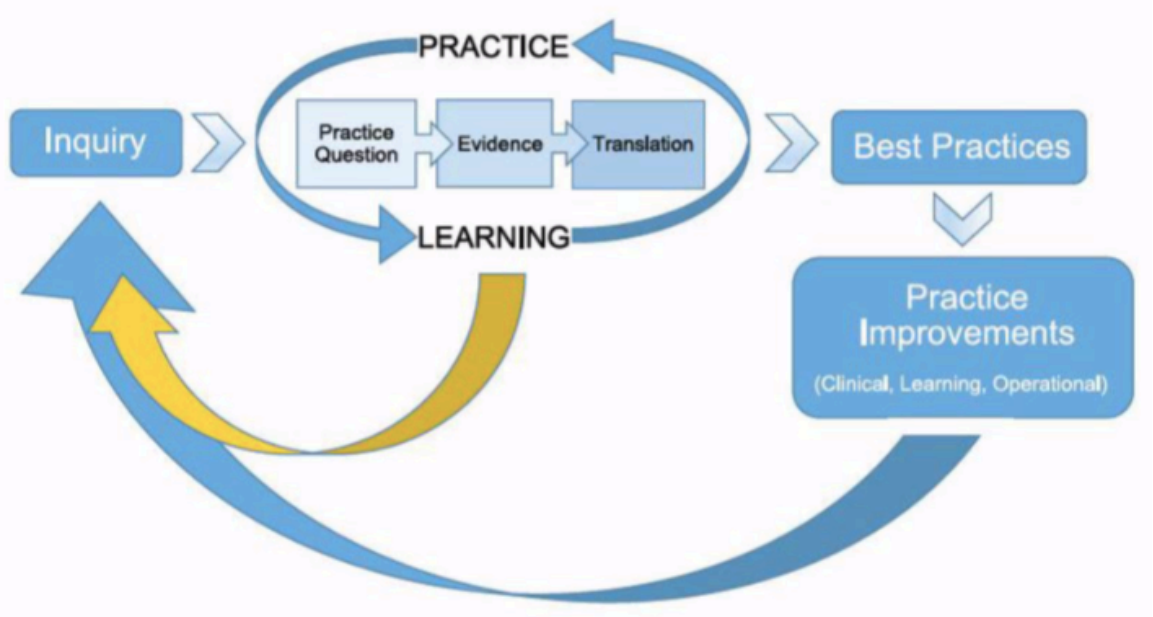


Figure 1.2 Timeline

Task Name	Done	Start Date	End Date	Comments
Topic & Chair				
Practice Question Form	done	08/24/19	09/04/19	
DNP Project Team	done	*	*	Dr. Sanford MD, Hayden Joubert, RN, MSN, Dr. Jennifer Embree, RN, DNP
Faculty Chair	done	08/24/19	09/04/19	Dr. Summerlin-Grady (CRNA) /Dr. Hitt
Final Approved PICOT	done	08/24/19	09/04/19	In total knee arthroplasty patients, what is the incidence of documented core temperatures less than 36° C throughout the perioperative phases of care?
Review of Literature				
Clinical Practice Question	done	09/05/19	10/06/19	
Annotated Bibliography	done	09/05/19	10/17/19	
Literature Matrix	done	09/05/19	10/06/19	
Draft Proposal				
CITI Training	done	08/24/19	10/06/19	
GANTT Chart		10/20/19	12/15/20	continuing
Written Proposal Draft	done	10/21/19	12/13/19	
Framework	done	10/21/19	11/01/19	
SWOT Analysis	done	10/21/19	11/01/19	
IRB Approval				
Marian	done	10/21/19	11/04/19	exempt
IU Health	done	11/04/19	05/08/20	submitted 3/ 2020
Eskenazi	done	11/04/19	06/06/20	submitted 5/ 2020
EPIC access	done	01/15/20	02/15/20	no longer need access however finished all of the modules
Collection of data	done	01/01/20	04/01/20	data collection done per H. Joubert. Unable to obtain data until 9/2020 due to Covid restrictions
Analysis of temperatures	done	09/20/20	10/03/20	
Rough Draft of Final Paper	done	01/01/20	10/08/20	
Complete project report	pending	11/01/20	12/01/20	
Project Presentation	pending	11/01/20	12/15/20	formulate project presentation poster
Send results to facility	pending		12/15/20	

Figure 1.3 Marian University Institutional Review Board Exempt Letter

MARIAN UNIVERSITY
Indianapolis

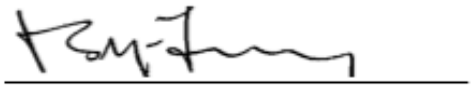
Institutional Review Board

DATE:	11-25-2019
TO:	Kailee Petro
FROM:	Institutional Review Board
RE:	IRB #B19.120
TITLE:	Preoperative Warming with Forced-Air Warming to Prevent Inadvertent Perioperative Hypothermia
SUBMISSION TYPE:	New Project
ACTION:	Determination of Exempt Status
DECISION DATE:	11-25-2019

The Institutional Review Board at Marian University has reviewed your protocol and has determined the procedures proposed are appropriate for exemption under the federal regulations. As such, there will be no further review of your protocol and you are cleared to proceed with your project. The protocol will remain on file with the Marian University IRB as a matter of record. Please be mindful of the importance of reporting only de-identified, HIPAA-compliant information about the patient in any exhibit or publication.

Although researchers for exempt studies are not required to complete online CITI training for research involving human subjects, the IRB **recommends** that they do so, particularly as a learning exercise in the case of student researchers. Information on CITI training can be found on the IRB's website: http://www.marian.edu/academics/institutional-review-board.

It is the responsibility of the PI (and, if applicable, the faculty supervisor) to inform the IRB if the procedures presented in this protocol are to be modified or if problems related to human research participants arise in connection with this project. Any procedural modifications must be evaluated by the IRB before being implemented, as some modifications may change the review status of this project. Please contact me if you are unsure whether your proposed modification requires review. Proposed modifications should be addressed in writing to the IRB. **Please reference the above IRB protocol number in any communication to the IRB regarding this project.**



Bryan Larsen, Ph.D.

Figure 1.4 Indiana University Hospital IRB Exempt Letter

INDIANA UNIVERSITY
OFFICE OF THE VICE PRESIDENT FOR RESEARCH
Office of Research Compliance

NOTICE OF EXEMPTION - NEW PROTOCOL
NOTICE OF EXEMPTION GRANTED

DATE:	May 08, 2020
TO:	Jennifer Embree, Principal Investigator NURSING Hayden Joubert UNIVERSITY LEVEL Kailee Petro UNIVERSITY LEVEL
FROM:	KRONENBERGER, WILLIAM G. Chair - IRB-01
RE:	Protocol #: 2003603373 Protocol Type: Exempt Protocol Title: Inadvertent Perioperative Hypothermia Investigation Funding Source: None

In accordance with 45 CFR 46.101(b) and/or IU HRPP Policy, the above-referenced protocol is granted exemption. Exemption of this submission is based on your agreement to abide by the policies and procedures of the Indiana University Human Research Protection Program (HRPP) and does not replace any other approvals that may be required. Relevant HRPP policies and procedures governing Human Subject Research can be found at: https://research.iu.edu/compliance/human-subjects/guidance/index.html.

Submission and Review Information:

Type of Submission:	Initial Protocol Application
Level of Review:	Exempt
Exempt Category(ies), if applicable:	Category 4: Secondary research for which consent is not required.
Date of Exemption Granted:	May 08, 2020
Authorized IRB Signature:	Kelly M. Anderson Kelly Anderson

Regulatory Determinations:

- Waiver of authorization under 45 CFR 164.512(i)
- The PHI to be used or disclosed is determined to be necessary
- The explanation of how this research involves no more than minimal risk of loss of privacy to the subject is sufficient
- There exists an adequate plan to protect the identifiers from improper use and disclosure
- There exists an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research
- There exist adequate written assurances that the requested information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of the requested information would be permitted by the Privacy Rule

- The explanation of how this research could not be practicably conducted without waiver of authorization is adequate
- The explanation of how this research could not be practicably conducted without access to and use of the individually identifiable health information is appropriate
- PHI to be used or disclosed:
  - For collection and use: Procedure Type of Anesthesia Was a nerve block completed? If so, where was the procedure performed? Preoperative temperature procedure start time temperature procedure stop time temperature 1st Postanesthesia care unit temperature Any intra-operative warming initiated?

Documents Approved with this Submission (for Amendments and Renewals, documents appearing in bold were either added or replaced with the submission):

Attachment Type - Document Version #
Protocol - IRB Protocol-Embree, Petro, Joubert Data Collection Instrument - Data Collection Sheet

NOTE: If you submitted and/or are required to provide subjects with an informed consent document, please ensure you are using the most recent version of the document to consent subjects.

The following key personnel are approved to participate in the above titled research activities:

Investigator Name	Role	Training
Jennifer Embree	Principal Investigator	Yes
Hayden Joubert	Co-PI Student/Fellow/Resident	Yes
Kailee Petro	Co-PI Student/Fellow/Resident	Yes

Organizations:

Organization
SYDNEY & LOIS ESKENAZI HOSPITAL

You should retain a copy of this letter and all associated approved study documents for your records. Please refer to the assigned study number and exact study title in future correspondence with our office. Additional information is available on our website at https://research.iu.edu/compliance/human-subjects/guidance/index.html.

If you have any questions or require further information, please contact the HSO via email at irb@iu.edu or via phone at (317)274-8289.

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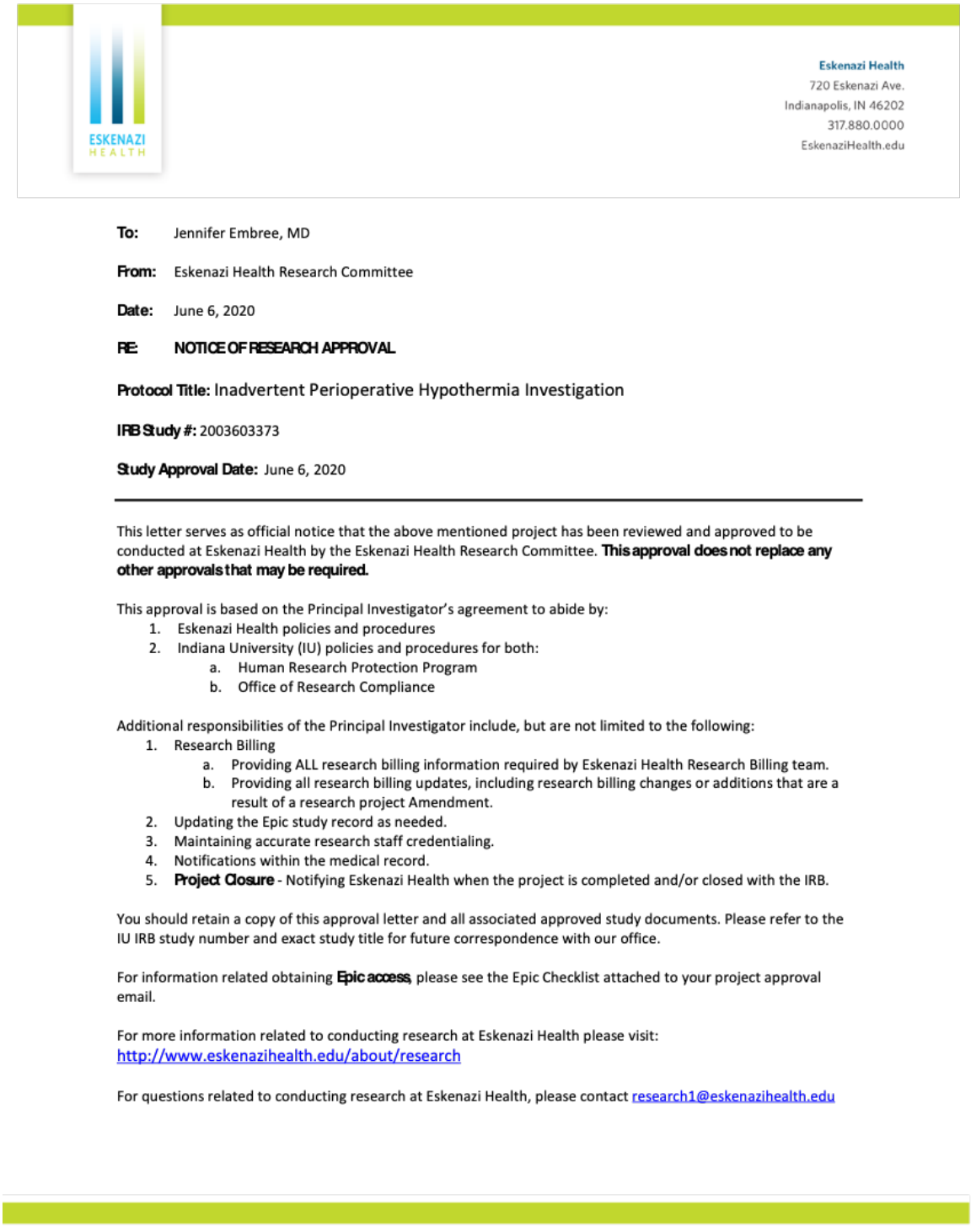
Figure 1.5 Eskenazi Health IRB Exempt Letter



ESKENAZI HEALTH

Eskenazi Health
720 Eskenazi Ave.
Indianapolis, IN 46202
317.880.0000
EskenaziHealth.edu

To: Jennifer Embree, MD

From: Eskenazi Health Research Committee

Date: June 6, 2020

RE: **NOTICE OF RESEARCH APPROVAL**

Protocol Title: Inadvertent Perioperative Hypothermia Investigation

IRB Study #: 2003603373

Study Approval Date: June 6, 2020

This letter serves as official notice that the above mentioned project has been reviewed and approved to be conducted at Eskenazi Health by the Eskenazi Health Research Committee. **This approval does not replace any other approvals that may be required.**

This approval is based on the Principal Investigator's agreement to abide by:

1. Eskenazi Health policies and procedures
2. Indiana University (IU) policies and procedures for both:
    a. Human Research Protection Program
    b. Office of Research Compliance

Additional responsibilities of the Principal Investigator include, but are not limited to the following:

1. Research Billing
    a. Providing ALL research billing information required by Eskenazi Health Research Billing team.
    b. Providing all research billing updates, including research billing changes or additions that are a result of a research project Amendment.
2. Updating the Epic study record as needed.
3. Maintaining accurate research staff credentialing.
4. Notifications within the medical record.
5. **Project Closure** - Notifying Eskenazi Health when the project is completed and/or closed with the IRB.

You should retain a copy of this approval letter and all associated approved study documents. Please refer to the IU IRB study number and exact study title for future correspondence with our office.

For information related obtaining **Epic access**, please see the Epic Checklist attached to your project approval email.

For more information related to conducting research at Eskenazi Health please visit:
http://www.eskenazihealth.edu/about/research

For questions related to conducting research at Eskenazi Health, please contact research1@eskenazihealth.edu

Figure 1.6 Data Chart and Graph

Perioperative Temperatures in °F

	Preoperative	Procedure Start	Procedure Stop	PACU
Mean	98.0	95.5	96.0	97.4
Highest	98.8	99.3	98.6	98.5
Lowest	97.3	91.7	89.9	96.5