Preoperative warming and its impact on unplanned perioperative hypothermia

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Preoperative Warming and the Impact on Unplanned Perioperative Hypothermia

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DEDICATION

This scholarly project is dedicated to my three daughters: Demarie, Laura, and Elizabeth. Your support, encouragement, patience, and understanding during the past three years have made this possible. Without you this could not have been accomplished. I love you all dearly.
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CHAPTER I

Introduction

Unplanned perioperative hypothermia, which is defined as a core temperature of less than 36°C during the perioperative period as a result of surgery by the American Society of PeriAnesthesia Nurses (2002), is a potentially dangerous complication of surgery affecting as many as 85% of all surgical patients (Ensminger and Moss, 1999; Stewart, Lujan, and Ruff, 1987; Vogelsang, 1991). Almost all surgical patients undergoing regional or general anesthesia have been identified as being at risk for developing hypothermia (Sessler, 1997). Currently there are a variety of treatment methods utilized to prevent unplanned perioperative hypothermia including prewarmed cotton blankets, warmed intravenous and irrigating fluids, humidified and warmed anesthetic gasses, and convective warming using forced air warming blankets. These warming treatments are utilized by nursing personnel throughout the perioperative period with some success. However, the most effective and efficient treatment for unplanned perioperative hypothermia has not been identified.

Chapter I will provide background information regarding unplanned perioperative hypothermia including a statement of the problem, statement of the purpose of the project, and the research questions. Definitions and normal body thermoregulatory control will be discussed. Information on the incidence, causes, potential complications, and current treatments of perioperative hypothermia will be reviewed. The Comfort Theory, a theoretical framework developed by Katharine Kolcaba, will be introduced followed by the significance of this study to current nursing practice.
Background Information and problem statement

The American Society of PeriAnesthesia Nurses (ASPAN) have taken a leading role in recognizing the problem of unplanned perioperative hypothermia. They have released clinical practice guidelines for the prevention of unplanned perioperative hypothermia (ASPAN, 2002) which include generally accepted definitions for normothermia, hypothermia, and core body temperature. Defining these terms helps the practitioner to use a consistent data base when communicating about unplanned perioperative hypothermia and its potential causes, complications, and treatments.

Normothermia and hypothermia were defined by a Consensus Conference on Perioperative Thermoregulation hosted by the ASPAN in 1998 (ASPAN, 2002). Normothermia is defined as a core temperature range from 36°C to 38°C (96.8°F to 100.4°F), and hypothermia is defined as a core temperature less than 36°C (96.8°F). Hypothermia may also be present anytime the patient states that they are cold or present with signs and symptoms of hypothermia such as piloerection, shivering, or peripheral vasoconstriction.

Core temperature as described by Sessler (2000) is a measurement of the well-perfused tissues of the head and trunk within which body temperature remains relatively constant, rarely differing by more than a few tenths of a degree centigrade. This compartment makes up approximately 50% to 60% of the total body mass. In contrast, the peripheral compartment consists of the extremities and the skin, contributing 40% to 50% of the total body mass. In a warm environment the core and the peripheral compartment temperatures will remain equal; with exposure to moderate environmental cooling, the peripheral compartment temperature may vary 2°C to 4°C less than the core temperature and in more extreme situations this difference may increase (Sessler, 2000; Marieb, 1992). The core temperature can be measured in the pulmonary
artery, distal esophagus, nasopharynx, and the tympanic membrane, and can be accurately estimated using the oral, axillary, and bladder sites (ASPAN, 2002).

The hypothalamus is the primary regulator of body temperature, receiving afferent input from peripheral receptors located in the skin, and core input from afferent receptors sensitive to the temperature of blood in the abdominal and thoracic cavities, and the skull including the anterior portion of the hypothalamus. Both behavioral and autonomic responses are closely regulated by the hypothalamus in order to maintain normothermia. Behavioral responses to a decrease in either peripheral or core temperature are designed to preserve heat, such as changing posture to reduce exposure to cold, increasing muscular activity, adding extra clothing, or ingesting hot fluids. Autonomic responses to increase heat production include the contraction or “shivering” of the skeletal muscles which produces heat by increasing the body’s metabolic rate 2 to 5 times; vasoconstriction of cutaneous blood vessels to decrease heat conduction through the skin; and nonshivering thermogenesis which increases the metabolic rate and heat production by releasing increased levels of thyroxine and epinephrine (Sessler, 1997).

In order to have a greater understanding of the several potential methods of heat loss during the perioperative period, it is helpful to review the basic mechanisms of heat flow from the body to the environment. These mechanisms include radiation, conduction, convection, and evaporation/respiration. Radiation is defined as the transfer of heat in the form of infrared waves. In this form of heat loss, the flow of heat is always from warmer to cooler, via photons, and is the primary method of heat loss from the body, accounting for approximately 50% of all body heat loss (Sessler, 2000; Marieb, 1992). Conduction is the direct transfer of heat from one object in direct contact with another requiring molecule to molecule contact. Similarly, convection is the transfer of heat from the body to the surrounding air. Because warm air rises,
the air around the body is constantly being replaced with cooler air. Conduction and convection together result in 15% to 20% of body heat loss to the environment (Marieb, 1992, Burns, 2001). Evaporation and respiration involve water droplets moving heat away from the body through the lungs, skin and mucosa of the mouth, and is termed insensible heat loss. Normally 10% of body heat production is lost to evaporation and respiration (Sessler, 2000; Marieb, 1992).

*Causes of unplanned perioperative hypothermia*

There are many aspects of the surgical experience that enhance the reduction of normal body temperature. Both general and regional anesthesias have been identified as the primary cause of unplanned perioperative hypothermia through inhibition of the bodies’ thermoregulatory ability in the hypothalamus (Sessler, 1997). Normally, there is a minimal temperature variation between the periphery and the core areas of the body with the core being slightly higher; in moderate environments the peripheral compartment may be 2-4°C less than the core (Sessler, 2000). Anesthesia affects the vasomotor ability of the body to maintain this temperature gradient which is warmest in the core, and coolest in the periphery, resulting in a cooling of the core area. Sessler, D. I. & Sessler, A. M. (1998), demonstrated that 81% of the 1.6°C heat loss experienced during the first hour of general anesthesia was due to the redistribution of body heat from the core of the body to the peripheral tissues, causing the core temperature to decrease. Frank, El-Rahmany, Cattaneo, and Barnes, (2000) also demonstrated this phenomena with spinal anesthesia, finding that the higher the spinal blockade, the higher the decrease in core temperature. Anesthetic agents including the inhalation gasses, sedatives, and induction agents also contribute to unplanned perioperative hypothermia by causing vasodilatation which increases heat loss through conduction and radiation (Toyota, Sakura, Saito, Ozasa, and Uchida, 2004; Arndt, 1999).
The operating room environment itself contributes to the unplanned decrease in body temperature that the surgical patient may experience. The cool room and exposure of the patient’s skin to the ambient air and surgical skin prep solutions often cause an initial decrease in peripheral temperature due to convection and conduction. Evaporation from large surgical incisions may also be a causative element in perioperative heat loss (Sessler, 1997). Additional factors that affect the development of hypothermia for the surgical patient include anxiety, duration of surgery, age of the patient, body size, and fluid administration or loss (Frank, et al, 2000, Sessler, 2000, Kongsayreepong et al, 2003).

The development of unplanned perioperative hypothermia may also have a role in the recovery of the surgical patient. Unplanned perioperative hypothermia, according to ASPAN (2002), has been implicated in several serious postoperative complications affecting patient comfort, length of hospitalization, increased healthcare costs, and patient mortality. Multiple studies have implicated unplanned perioperative hypothermia as contributing to discomfort and shivering (Kurz, et al., 1995; Vogelsang, 1994), prolonged endotracheal intubation and delayed recovery from anesthesia (Vanni, Braz, Modolo, Amorim, and Rodrigues, 2003), cardiac morbidity (Busch et al., 1995; Elmore, Franklin, Youkey, Oren, and Frey, 1998; Frank et al., 1997), adrenergic stimulation with an increase in serum catecholamine levels (Frank et al., 1997), increased susceptibility to wound infection (Beilin et al., 1998; Flores-Maldonado, Medina-Escobedo, Rios-Rodriguez, and Fernandes-Dominguez, 2001; Kurz, Sessler, & Lenhardt, 1996), delayed wound healing (Kurz et al., 1996), pressure ulcer development (Scott, Leaper, Clark, and Kelly, 2001), and possible clotting disorders (Schmied, Kurz, Sessler, Kozek, and Reiter, 1996). Due to the serious nature of these potential complications, knowledge of the
most effective and efficient treatment for unplanned perioperative hypothermia needs ongoing evaluation.

Statement of Purpose

The purpose of this study was to compare the preoperative use of the forced-air warming blanket versus routine thermal care on the incidence and duration of unplanned perioperative hypothermia in the postanesthesia care unit. The research questions are:

1. Is there a difference in unplanned perioperative hypothermia in the postanesthesia care unit with the preoperative use of the forced-air warming blanket for 30 minutes compared to routine thermal care measures, for patients undergoing total knee arthroplasty, total hip arthroplasty, exploratory laparotomy, abdominal hysterectomy, or open cholecystectomy procedures?

2. Is there a difference in the time required for surgical patients to return to normothermia postoperatively for subjects who use the forced-air warming blanket for 30 minutes preoperatively compared to patients who are given routine thermal care preoperatively undergoing elective surgical procedures lasting over one hour including total knee arthroplasty, total hip arthroplasty, exploratory laparotomy, abdominal hysterectomy, or open cholecystectomy?

Theoretical framework

The Comfort Theory, a mid-range theory of nursing developed by Katharine Kolcaba (1994, 2003), focuses on holistic comfort and is directly applicable to the recognition, treatment, and possible prevention of perioperative hypothermia. She defines comfort for health care providers as the satisfaction of the basic needs for relief, ease, or transcendence arising from stressful health care situations (Kolcaba, 1994). According to Kolcaba (2003), there are three
types of comfort: Relief, which is the absence of specific previous discomforts, such as unplanned perioperative hypothermia; Ease, which is a state of contentment; and Transcendence, which is the state in which one is able to rise or transcend one’s problems or pain. When using the Comfort Theory, all comfort measures, or nursing interventions, are aimed to enhance comfort which include therapies to maintain normothermia in the perioperative area such as applying warmed cotton blankets and forced-air warming blankets. The experience of thermal comfort and the use of thermal comfort interventions can enhance Relief, whether initiated in the preoperative, intraoperative, or postoperative area, and have a beneficial effect on patient satisfaction, levels of anxiety, and positive patient outcomes.

Significance

The goal of this research project is to increase knowledge regarding the effectiveness of nursing interventions initiated in the preoperative area to prevent unplanned perioperative hypothermia in the postanesthesia care unit, and to evaluate whether those actions affect the length of the postoperative recovery time. Knowledge of that effectiveness can be utilized to guide future nursing practice regarding optimal prevention of unplanned perioperative hypothermia, and can also be used to promote positive patient outcomes in the perioperative area.

Summary

Unplanned perioperative hypothermia is a significant problem affecting up to 85% of all surgical patients. It is primarily caused by regional or general anesthesia resulting in redistribution hypothermia, but other factors such as the cool operating room environment, the exposure of the patient to cool skin prep solutions, and the health status of the patient also contribute to its occurrence. The development of unplanned perioperative hypothermia may also
potentiate several serious postoperative complications including discomfort and shivering, prolonged endotracheal intubation and delayed recovery from anesthesia, cardiac arrhythmias, delayed wound healing, increased incidence of wound infection, pressure ulcer development, and possible clotting disorders. The purpose of this study is to evaluate the effectiveness of using the forced-air warming blanket for 30 minutes preoperatively compared to routine thermal care measures, on the incidence of unplanned perioperative hypothermia postoperatively, and whether that use shortens the return to normothermia postoperatively when compared to routine thermal care measures. The conceptual framework for this study will be the Comfort Theory, developed by Katharine Kolcaba, with results adding to the knowledge base of nursing.
CHAPTER II
REVIEW OF LITERATURE

This chapter is divided into two sections. The first section includes a discussion of the theoretical framework of this study. The second section consists of a review of the relevant literature examining unplanned perioperative hypothermia treatment interventions, and the use of those interventions in the preoperative, intraoperative, and postoperative areas. Chapter II concludes with a summary of its contents.

Conceptual Framework

The Comfort Theory, a mid-range theory of nursing developed by Katharine Kolcaba, is built around the concept of comfort, or of the experience of having the needs for relief (having a specific comfort need met), ease (a state of calmness), and transcendence (rising above one’s problems) met within four contexts of human experience: physical, psychospiritual, environmental, and sociocultural (Kolcaba, 2003). It is a holistic theory that provides direction for the practice of nursing and for nursing research because its outcomes are measurable, holistic, positive and nurse-sensitive (Kolcaba, 1994). She defines comfort for health care providers as the satisfaction of the basic needs for relief, ease or transcendence arising from stressful health care situations (Kolcaba, 1994). According to Kolcaba (2003), comfort is a patient focused, essential outcome of all health care. It is complex and holistic, and all aspects are interrelated with the ultimate goal of healthcare being the improvement of comfort compared to a previous level. Enhanced comfort is the goal of all nursing interventions. Enhanced comfort also strengthens patients for health seeking behaviors, either internal or external, which are necessary for their well-being (Kolcaba, 2003). The positive flow between nursing interventions and enhanced comfort is illustrated in Figure 1.
Figure 1

Theoretical framework for perioperative hypothermia adapted from Kolcaba & Wilson 2002.

Identification of Health Care Needs Related to Thermal Comfort:
Temperature <36°C, shivering, verbalization of feeling cold

Thermal Comfort Interventions:
Routine thermal care activities, Forced Air Warming Blanket

Enhanced Thermal Comfort:
Normothermia

Intervening Variables:
Age, Body Mass, Gender, Health Status, Type of Surgery,

Intervening Variables:
Fluid Intake, Length of Surgery, Use of Warming Interventions

Internal Health Seeking Behaviors:
Homeostasis on a subconscious organ and cellular level, decreased incidence of perioperative hypothermia

External Health Seeking Behaviors:
Homeostasis on a conscious level, improved functional status, return to self care activities

Promotion of Health Seeking Behaviors
Enhanced comfort strengthens patients to either consciously or subconsciously behave in ways that move them toward a state of well-being. Kolcaba (1994, 2003) has developed propositions for the Comfort Theory illustrated in Figure 1 which are as follows:

1. Health care needs are the comfort needs identified by the patient and/or the health care team that have not been met by current interventions. Health care needs related to thermal comfort include temperature assessment to identify hypothermia, observation of shivering, and verbalization of discomfort due to feeling cold. If the patient is incapable of conscious thought, then nursing interventions must be alert to signs of hypothermic discomfort i.e. shivering, piloerection, and a decrease in core body temperature.

2. Nursing Interventions are those actions, or comfort measures, that are designed to meet those needs. Nurses must deliver the appropriate interventions in a caring manner. Activities include routine thermal care interventions such as application of warmed blankets, warmed intravenous fluids, or the use of the forced air warming blanket.

3. Intervening variables must be considered when designing those interventions in order to determine their effectiveness. Intervening variables that may affect postoperative hypothermia include age, body mass, current health status, gender, type and length of surgery, fluid intake, and use of warming interventions intraoperatively such as warming irrigation fluids or intravenous fluids.

4. If the comfort measures were appropriate, the patient experiences improved comfort by a rapid return to or the maintenance of normothermia.

5. Enhanced comfort leads to Health Seeking Behaviors, which may be internal or external and function to move the patient toward well-being. Internal Health Seeking Behaviors are homeostatic behaviors occurring on a subconscious cellular and organ level and include
thermoregulatory system, immune system, circulatory system, and wound healing mechanisms of the body. External Health Seeking Behaviors are related to the outer world of the patient occurring at the conscious level and include functional status and self care activities (Kolcaba, 1994). Health seeking behaviors may also include those behaviors leading toward a peaceful death.

The conceptual definition of physical comfort refers to body sensations and homeostatic mechanisms and includes the need for thermoregulation. Application of the forced-air warming blanket preoperatively is a comfort measure that is used to maintain the patient’s physical well-being and enhance thermal comfort by preventing the occurrence of unplanned perioperative hypothermia and its possible complications. By addressing the physical need for thermoregulation, health care providers enhance comfort and promote positive health seeking behaviors.

The forced-air warming blanket is an effective method of patient warming consisting of a disposable blanket attached to a heating unit that circulates warm air through the blanket, and transfers the warmth to the patient via convection and conduction, through holes in the blanket. This blanket therefore assists the patient in maintaining thermal comfort.

Evaluation of thermal comfort interventions will be based on measurement of the postoperative patient’s core body temperature and length of postoperative recovery time. The measurement of core body temperature assesses the internal (unconscious) health seeking behavior of the patient in maintaining normothermia, and will be measured by a tympanic thermometer preoperatively, on admission to the post anesthesia care unit (PACU) and upon PACU discharge.

Postoperative recovery time is the length of time it takes for a surgical patient after receiving general or regional anesthesia, to attain specified baseline discharge criteria from the
PACU including stable vital signs, adequate pain control and absence of active bleeding, minimal nausea and vomiting, and ideally a core temperature of at least 36°C. Often, however, stable patients are discharged from the PACU with a temperature of less than 36°C to return to normothermia on the nursing unit. During this time, the nurse provides a supportive and protective environment for the patient recovering from the surgical experience. Evaluating the length of recovery time compares the effectiveness of the comfort measures used to prevent hypothermia and whether the patient has experienced enhanced thermal comfort which may shorten the time required to recover from anesthesia.

Review of the literature

The literature on unplanned perioperative hypothermia focused on the effectiveness of various prevention and treatment therapies. The literature review is organized to compare interventions to prevent and treat perioperative hypothermia initiated in either the preoperative, intraoperative, or postoperative period.

There is general agreement that warming a patient prior to surgery with a forced-air warming blanket may have a significant effect in preventing hypothermia postoperatively (Fossum, Hays, and Henson, 2001, Bock et al., 1998, and Horn, et al., 2002). These studies found that patients warmed with the forced air warming blanket preoperatively arrived in the PACU significantly warmer than those who were not treated with the forced air warming blanket. In a related study using different treatment interventions, Simmons, Phillips, Doctor, and Liehr (1992) prewarmed patients using either a heat retaining surgical cover or warmed cotton blankets, finding no statistical difference between the two groups; however the preoperatively warmed patients arrived in the PACU with core temperatures greater than 36°C.
In the study conducted by Fossum, Hays, and Henson (2001), 100 outpatients undergoing gynecological, orthopedic, or urological surgical procedures receiving general anesthesia lasting over one hour were randomly selected to receive either warmed cotton blankets (control group) or a forced air warming blanket (treatment group) for a minimum of 45 minutes preoperatively. Core temperatures using a tympanic thermometer were recorded every 15 minutes while in the preoperative area, and every 15 minutes while in the PACU. The patient’s subjective responses to feelings of thermal comfort were also recorded as well as the incidence of postoperative shivering, nausea, and vomiting. Their findings supported the use of the forced air warming blanket to warm patients prior to surgery. They found that patients prewarmed with the forced air warming blanket were significantly warmer in the preoperative area (\(4.5^\circ \pm 0.38\)) compared to the control group (\(1.7^\circ \pm 0.51\)) and were able to maintain a significantly higher mean temperature on arrival to the PACU (\(35.97^\circ \pm 0.52\)) than did patients in the control group (\(35.54^\circ \pm 0.50\)), (\(t = -4.15, p = .00\)).

Another important finding of this study was that patients in the treatment group maintained higher core temperatures throughout the perioperative period when compared to those in the control group. Those warmed with the forced air warming blanket preoperatively changed \(0.067^\circ (\pm .52)\) compared to a decrease of \(2.2^\circ (\pm .48)\) for patients prewarmed with cotton blankets. Reports of thermal comfort were significantly higher in the treatment group (\(\chi^2 = .369, p = .00\)) but there were no statistical differences in complaints of shivering or postoperative nausea and/or vomiting. (Fossum et al. 2001) also found an inverse relationship between age and the initial temperature on arrival to the PACU. Patients in both the control and treatment groups over the age of 60 (\(N = 13\)) had an average temperature of \(35.6^\circ (r = -.21, p = .00)\), thereby placing the geriatric patient at a slightly higher risk for developing hypothermia.
Based on the results of their study, Fossum et al. (2001) recommend the use of the forced air warming blanket on all surgical patients, feeling that the geriatric population would especially benefit from its use. A statistically significant decrease in the incidence of postoperative hypothermia was found, along with reports of positive thermal comfort. Study limitations in patient population, anesthesia time, and type of surgical procedure performed prevent the results of this study from being generalized to all situations.

In a similar study, Bock et al., (1998) found a statistically significant difference in maintenance of core temperature and a decrease in the length of stay in the PACU in those patients treated with the forced-air warming blanket for 30 minutes preoperatively compared to those who were prewarmed with two layers of blankets. This study included 40 patients undergoing major abdominal surgery to be randomly assigned to either a treatment group prewarmed with a forced air warming blanket, or a control group warmed with routine measures including circulating warm water mattresses, blankets, and fluid warming devices. In contrast to Fossum et al. (2001), these warming interventions continued throughout the preoperative and operative phase of the surgical experience. Core temperature was measured at 15 minute intervals throughout surgery with a tympanic membrane thermocouple and at 30 minute intervals during the time in PACU using a tympanic membrane thermometer. Bock et al., (1998) found no significant difference in the core body temperature preoperatively, however the core temperature remained higher in the prewarmed group \( p < .01 \) beginning 15 minutes after intubation and continuing into the PACU. At the end of surgery the change in core temperature was significantly less in the prewarmed patients; \( M = .05 ^\circ C \ (SD = 0.8) \) versus \( M = 1.5 ^\circ C \ (SD = 0.8); \ p < .01 \) for the control group. Length of recovery time in the PACU was found to be statistically shorter comparing the actively warmed group with the control group; \( M = 94 \) minutes \( (SD = 42) \) versus 217 minutes \( (SD = 169); \ p < .01 \). An indirect benefit of this shortened time in the
PACU, according to the authors of this study, is a reduction of hospitalization costs even with the added expense of the forced-air warming blanket.

In a study investigating temperature trends of the mother and newborn infant during elective Cesarean deliveries, Horn et al., (2002) applied 15 minutes of forced air warming combined with intraoperative warming to test whether maternal hypothermia and shivering were prevented. They also investigated whether maternal normothermia increased newborn temperature, umbilical vein pH, and Apgar scores. Fetal temperature is directly related to maternal temperature; therefore maternal hypothermia is directly related to newborn hypothermia. Their sample consisted of 30 randomly selected preoperative elective cesarean section patients receiving epidural anesthesia, 15 of whom were assigned to receive the forced air warming blanket (treatment), and the other 15 to receive a single cotton blanket (control). Core temperatures were measured at the tympanic membrane with thermocouples; peripheral skin temperatures were also recorded. Core temperatures in the mother were found to be greater in those warmed with the forced air warming blanket after 2 hours of anesthesia ($M = 37.1^\circ C$, $SD = 0.4^\circ C$) than in those warmed with the single cotton blanket ($M = 36.0^\circ C$, $SD = 0.5^\circ C$); $p <.01$. Shivering was observed in 2 of 15 (13%) warmed mothers and in 9 of 15 (60%) unwarmed mothers ($p <.05$). The babies of the prewarmed mothers had statistically warmer core temperatures measured rectally ($M = 37.1^\circ C$, $SD = 0.5^\circ C$ versus $M = 36.2^\circ C$, $SD = 0.6^\circ C$) and umbilical vein pH ($M = 7.32$, $SD = 0.07$ versus $M = 7.24$, $SD = .07$). Apgar scores were measured and found to be similar in both groups. The researchers concluded that the 15 minutes of preoperative warming prior to the induction of anesthesia prevented maternal and fetal hypothermia by prevention of redistribution hypothermia through warming of the maternal peripheral tissues. This had the effect of reducing maternal shivering, promoting comfort, and improving the newborn infant’s umbilical vein pH.
Camus, Delva, Sessler, and Lienhart (1995) also prewarmed patients in the preoperative area for 30 minutes, then measured the core temperature while in the operating room, finding that those prewarmed with the forced-air warming blanket experienced a temperature decline more slowly than those who were prewarmed with cotton blankets. A total of 16 patients undergoing laparoscopic cholecystectomy surgery under general anesthesia were randomly selected to receive either the forced air warming blanket for 30 minutes preoperatively (treatment group), or a wool blanket placed during the same time period preoperatively (control group). Tympanic and skin temperatures were measured at 15 minute intervals throughout the preoperative period, and continuously by tympanic membrane thermocouple during surgery. Active warming measures were not continued during the surgical procedure, and patients were actively warmed while in the PACU. Comparison of data between the two groups demonstrated that preoperatively the skin temperature of the prewarmed group increased ($M = 34.0^\circ C$, $SD = 0.1$, to $M = 37.0^\circ C$, $SD = 0.2$), while the control group remained unchanged ($M = 34.7^\circ C$, $SD = 0.3$). Core temperature did not differ significantly in either group during the preoperative period. After the induction of anesthesia, the core temperature decreased more rapidly per hour in the control group than in the treatment group ($M = 1.1^\circ C/hr$, $SD = 0.1$, versus $M = 0.6^\circ C/hr$, $SD = 0.1$), $p < .05$. During surgery there was a greater core temperature decrease in the control group ($M = 37.1^\circ C$, $SD = 0.1$, to $M = 36.0^\circ C$, $SD = 0.1^\circ$) when compared to the prewarmed group ($M = 37.1^\circ C$, $SD = 0.1$, to $M = 36.6^\circ C$, $SD = 0.1$), $p < .05$. Core temperatures at the completion of surgery for the control group were also lower when compared to the treatment group with the control group temperature ($M = 35.7^\circ C$, $SD = 0.2$) cooler than the treatment group ($M = 36.1^\circ C$, $SD = 0.1$). The authors conclude that one hour of prewarming prior to induction of anesthesia helps to minimize redistribution hypothermia and that those prewarmed cooled at approximately
one half the rate of the control patients, and remained significantly warmer for approximately 2 hours after the initiation of the prewarming.

An earlier but related study was conducted by Simmons, Phillips, Doctor, and Liehr (1992) in order to determine a method of preventing perioperative hypothermia initiating the warming in the preoperative area. They studied 117 randomly selected patients having hand, wrist, or elbow surgery, undergoing either general or regional anesthesia. This type of orthopedic patient was selected to control for the effects of an open body cavity on the core temperature. These patients received either a heat retaining cover (Thermadrape) or cotton blankets in the preoperative setting continuing throughout the perioperative period. Core temperature was monitored using a tympanic thermometer in the preoperative area, on admission to the PACU, and on PACU discharge. There was no significant difference in temperature throughout the perioperative period between those covered with the heat retaining cover or the blankets ($F = 1.00; p = .37$). However, admitting temperatures into the PACU for both groups were normothermic on average with the group receiving cotton blankets and general anesthesia at 36.5 ± .63°C, and at 36.7 ± .55°C for those covered with the heat retaining cover. Although not an objective of this study, this clearly supports the application of preoperative warming to aid in the maintenance of normothermia during the perioperative period. The authors also conclude that this study was limited by the generally short duration of surgical procedures, and the limited type of surgeries studied.

The preoperative warming measures studied by Fossum et al., (2001), Bock et al., (1998), Horn et al. (2002), and Cames et al., (1995) demonstrate the effectiveness of the forced air warming blanket to maintain normothermia during the perioperative period. Length of preoperative warming times varied between the cited studies. Horn et al. (2002) prewarmed
patients for 15 minutes prior to the induction of epidural anesthesia. Fossum et al., (2001) prewarmed patients for 45 minutes prior to transport into the operating room. Bock et al., (1998) prewarmed patients for 30 minutes, and Camus et al., (1995) prewarmed for one hour. Camus et al., (1995) however, did not continue the warming measures into the operating room, but compared the rate of developing hypothermia in the operating room between those warmed with the forced air warming blanket and those warmed with a blanket and found that the patients prewarmed with the forced-air warming blanket were able to slow their temperature decline. According to the research reviewed, a 15 to 60 minute period of prewarming appears adequate, but further research is needed to suggest the ideal time that is appropriate to prewarm perioperative patients.

Intraoperative interventions were undertaken in several studies to prevent hypothermia in the operating room, finding that the forced-air warming blanket to be helpful in preventing intraoperative or postoperative hypothermia. Lindwall, Svensson, Söderström, and Blomqvist (1998), Defina and Lincoln (1998), and Frank et al., (1997) used the forced-air warming blanket intraoperatively with success to achieve normothermia postoperatively.

In the Swedish study conducted by Lindwall et al., (1998), 25 patients were randomly selected to receive either a forced air warming blanket intraoperatively along with usual passive measures of fluid warming and blankets ($n = 12$), or to receive only the usual passive measures ($n = 13$). Core temperature was measured using a tympanic thermometer in the preoperative area, and at 30 minutes; and at one, two, and three hour intervals after anesthesia induction. PACU temperatures were recorded on arrival, and at one, two, four, and eight hours. The researchers found that the prewarmed patients were significantly warmer throughout the operative and PACU period. The prewarmed group temperatures ranged from a mean of 36.8°C ($SD = 0.7$) initially to 36.9°C ($SD = 0.8$) after 3 hours. Patients who received only the passive measures
experienced a drop in mean temperature from 36.8°C (SD 0.6), to 35.1°C (SD 0.5) after three hours of anesthesia and surgery (p<.001).

A descriptive, quality assurance study was undertaken by Defina and Lincoln (1998) in order to determine the incidence of unplanned postoperative hypothermia at their institution, and which warming technique was the most effective. This was a large study, with data collected on 502 surgical patients. Data collected included pre- and postoperative temperature trends using a tympanic thermometer; several types of warming interventions were utilized including the forced-air warming blanket; type of surgery; and operative times. Their findings suggested that patients treated intraoperatively with the forced-air warming blanket, (n = 50), 20 (40%) arrived in the PACU with a temperature less than 36°C. Of the remaining 452 patients, 304 (60%) arrived in the PACU with hypothermia. The forced-air warming blanket appeared in this study to be the most effective method of preventing unplanned postoperative hypothermia when compared to warm blankets, warm water circulating blankets, warmed intravenous and irrigating fluids, thermal wraps, and an increase in ambient room temperature.

Frank et al., (1997) in a related study, was able to demonstrate a reduction in cardiac morbidity in patients with known or were high risk for coronary artery disease. A total of 270 cardiac patients were randomly assigned to receive either routine thermal care intraoperatively, or to receive routine thermal care along with a forced air warming blanket. Frank et al., (1997) found that the mean core temperature after surgery was lower in the group that received routine thermal care (M = 35.4°C, SD = 0.1) than in the group that received the forced-air warming blanket intraoperatively (M = 36.7°C, SD = 0.1), p < .001. Cardiac morbidity was significantly lower in the group treated with the forced air warming blanket than those given only routine
thermal care (1.4% versus 6.3%; \( p = .02 \)). Their study indicated that this was a 55% reduction in cardiac morbidity risk when normothermia was maintained.

Warming interventions in the PACU have demonstrated applicability in the clinical setting, however it is generally felt that prevention of hypothermia is preferable to treatment. Several comparative studies have been conducted in the PACU utilizing different types of warming interventions in order to identify the most effective. Giuffre, Finnie, Lynam, and Smith (1991) compared the use of forced warm air blankets, warm cotton blankets, and radiant heat lamps to rewarm patients, finding that the forced air warming blankets rewarmed patients faster when compared to other methods, and that those patients were discharged from the PACU sooner. Although the researchers found that the patients receiving the forced warm air blankets took less time to reach 36°C than the other two groups, this difference did not quite achieve statistical significance (\( p = .06 \)), possibly due to large patient variability. They also found that nonshivering patients who had received the forced air warming blanket were ready for discharge from the PACU an average of 33.6 minutes sooner than those treated with blankets and 21.6 minutes sooner than those treated with the radiant heat lamps.

Stevens, Johnson, and Langdon, (2000), utilizing a quasi-experimental research design, compared the use of the forced air warming blanket with warmed cotton blankets in the immediate postoperative period to rewarm patients who were mildly hypothermic (temperatures 34 to 35.9°C). A total sample of 120 patients were randomly assigned to one of two groups with inclusion criteria of having undergone general, orthopedic, urological, vascular or gynecological surgery; the procedure being of greater than a 20 minute duration, and having general, regional, spinal, or epidural anesthesia. Core temperature was measured by a tympanic thermometer every 15 minutes. Data was collected on 110 participants with 10 having incomplete data collection.
When orthopedic cases were excluded, statistically significant differences were found in the mean rewarming rates of the group warmed with the forced air warming blanket compared with the group warmed with the cotton blankets ($t = 2.15, df = 92, p = .03$). The researchers found the exclusion of the orthopedic patients serendipitously, and could only speculate on its significance.

Hershey, Valenciano, and Bookbinder (1997) rewarmed patients with blankets, reflective blankets, and reflective head coverings, finding no statistically significant difference in rewarming rates among the treatment groups. The researchers did find however that a Pearson’s Product Moment Correlation revealed a significant inverse relationship between the patient’s admission temperature in the PACU and the time required to reach normothermia ($r = -.54, p = .001$). Obviously, the more hypothermic a patient is, the longer it takes to return to normothermia. Reflective blankets, as evidenced in the preoperative studies by Simmons et al., (1992) and Hershey et al., (1997) demonstrated no superiority over warmed cotton blankets for rewarming postoperative hypothermic patients, and the researchers often felt that the warm cotton blankets were more comforting to the patient even though no research was found to support this hypothesis. Future investigation could determine cost and comfort benefit to the patient using the reflective coverings as compared to the warmed cotton blankets. It has been demonstrated however, that the use of the forced-air warming blanket is an effective method of rewarming hypothermic postoperative patients, assisting the return to normothermia faster than cotton blankets or radiant heat lamps.

**Summary**

Unplanned perioperative hypothermia continues to be a potentially serious problem affecting the patient undergoing surgery. This chapter discussed Kolcaba’s Comfort Care Theory which provides the framework and the focus for this project. The relevant literature was
reviewed, discussing the various interventions utilized in treating unplanned postoperative hypothermia and the use of those interventions in the preoperative, intraoperative, and postoperative settings. In most studies, only a portion of the perioperative experience was examined, with some of the research investigating the efficacy of a treatment only after hypothermia was established. Interventions undertaken to maintain normothermia initiated in the preoperative area address this problem, with the goal of normothermia and the prevention of possible untoward complications.

The forced-air warming blanket has been shown to be an effective method of maintaining normothermia throughout the perioperative period, with the literature indicating an optimal duration of preoperative warming ranging between 15 and 60 minutes. Further research is necessary in order to determine a more specific application time and to further evaluate if continuing the warming measures in the intraoperative and postoperative area is necessary. It has been shown that maintenance of normothermia has the additional benefit of reducing healthcare costs by helping to prevent complications and reducing the length of time spent in the PACU. Patient comfort is also an important consideration, as those who are kept warm report feeling of increased satisfaction with their surgical experience. The application of the forced-air warming blanket is a comfort measure that provides comfort in the three general types of comfort: it aids in the maintenance of thermal homeostasis; it relieves anxiety and provides reassurance; and its application helps the patient feel cared for and strengthened (Kolcaba & Wilson, 2002).

The overall goal of this research project was to increase nursing knowledge regarding perioperative hypothermia. The application of the forced-air warming blanket for 30 minutes preoperatively was studied for its impact on postoperative hypothermia, along with its impact on
the surgical patients return to normothermia. The perioperative nurse will therefore have an increased awareness of the problems associated with unplanned postoperative hypothermia, along with the most efficient and effective methods for its prevention and treatment.
CHAPTER III

METHOD

The purpose of this study was to compare the effect of a forced-air warming blanket applied for 30 minutes preoperatively versus routine thermal care measures on the incidence of postoperative hypothermia and the time for return to normothermia. This chapter begins with an examination of the design selected for this project. The setting for the project and the sample are described. The materials used in designing the project and the methods of data collection and analysis are examined. The chapter concludes with a summary of its contents.

Design

This was a non-experimental study with a repeated measures design using a retrospective chart review. A repeated measures design, according to Green and Salkind (2003) is utilized when determining whether participants changed significantly across conditions, or interventions. In this study, the comparison group received the intervention of the forced-air warming blanket for a minimum of 30 minutes preoperatively, while the control group received routine thermal care preoperatively. Selection of this design was to facilitate examination of the effect that the preoperative use of the forced-air warming blanket has on temperature postoperatively compared with the use of standard thermal measures.

The approach to analysis consisted of a comparison of the pre- and post intervention temperature measurements of the actively warmed groups and those that received routine thermal care. The core temperature recorded on both groups preoperatively, postoperatively on admission to the PACU and on PACU discharge was examined. The length of time in minutes from PACU admission to patient core temperature reaching normothermia, or 36°C as determined by ASPAN
(2002) was calculated for both groups from the documentation in the patient records and compared.

**Setting/Subjects**

Chart review was conducted in the Health Information Management Department of a medium sized midwestern academic health center. Inclusion criteria for the subjects included (a) adults over the age of 18 years, (b) undergoing surgery lasting over one hour, (c) returning to a regular inpatient room postoperatively, and (d) the surgery was a total knee arthroplasty, total hip arthroplasty, exploratory laparotomy, abdominal hysterectomy, or open cholecystectomy procedure.

A retrospective review of 86 medical records was done using the above criteria, for the period of January 2003 through December 2003. Data from a convenience sample of 53 subjects meeting the above criteria was used for analysis.

**Material**

Data was collected and coded using the Hypothermia Data Collection Tool included in Appendix A, which is a tool designed to facilitate data collection of temperature patterns. This tool collects and codes information on age, height, weight, length of surgery, intraoperative fluid intake, preoperative and PACU temperature on admission, PACU discharge temperature, and time from PACU admission to patient temperature reaching 36°C. Data was collected regarding the surgical procedure, method of temperature taken, and use and area of use of warming interventions. From the information collected on this tool, descriptive statistics were evaluated regarding age, body size, type of surgery, and use of warming interventions, as well as temperature.
Data Collection

The Internal Review Board (IRB) of the medium-sized midwestern academic health center gave approval for this project to be conducted (see Appendix B). The Health Information Management Department then generated a listing of the patients undergoing total knee arthroplasty, total hip arthroplasty, exploratory laparotomy, abdominal hysterectomy, and open cholecystectomy procedures from January 1, 2003 through December 31, 2003. All patients meeting the inclusion criteria were selected until a total of 86 records were obtained, and all patients meeting the inclusion criteria and receiving the forced air warming blanket preoperatively were selected, for a total of 53 subjects.

Confidentiality was insured by using no patient identifiers on the collected data. The collected data was then coded and entered into a SPSS database file, and the patient listing was then destroyed. The forced-air warming blanket is an effective method of patient warming manufactured by Augustine Medical Inc., Eden Prairie, MN, and is routinely used in many operative and PACU areas to warm hypothermic patients. A disposable blanket is placed directly on the patient and is attached to a heating unit that circulates warm air, transferring warmth to the patient through holes in the blanket. Its use in the preoperative area to warm patients prior to surgery was trialed at the hospital involved in this study for approximately a two week period in the spring of 2003.

Core temperature was obtained by tympanic thermometer at specified intervals throughout the perioperative period and recorded in degrees Centigrade. The forced-air warming blanket was utilized in the preoperative area prior to surgery and applied by the preoperative nurse and documented in the patient care record.
Assumptions and Limitations

A major assumption of this study was that thermoregulation is a physical comfort need of patients, and that patients prefer to feel warm rather than cold. Nursing interventions that promote thermal comfort, such as the application of the forced-air warming blanket, promote comfort and assist in the maintenance of normothermia. Enhanced comfort leads to the promotion of positive health seeking behaviors both internal and external, and is the goal of all nursing interventions.

The primary limitation of this study was that it was a retrospective medical record review with no control over the use of the treatment intervention of the warming blanket, instrumentation used to record patient’s core temperature, or of the documentation of the data. Operator variation in the use of the tympanic thermometer or the use of other methods such as oral or axillary sites to measure body temperature could also threaten internal validity. Another limitation to this study involved inconsistent or variations in documentation by health care providers while recording core temperatures or the use of warming interventions.

Data Analysis

The purpose of this study was to describe the effect of the forced air warming blanket on the incidence of unplanned perioperative hypothermia and the length of time it takes to return to normothermia postoperatively in minutes. The primary dependent variable data collected by the Hypothermia Data Collection Tool was at the interval/ratio level of measurement, including temperature recordings and length of time in minutes to return to normothermia, or 36°C.

The research questions were as follows:
1. Is there a difference in unplanned perioperative hypothermia in the postanesthesia care unit with the preoperative use of the forced-air warming blanket for 30 minutes compared to standard thermal care measures, for patients undergoing total knee arthroplasty, total hip arthroplasty, exploratory laparotomy, abdominal hysterectomy, or open cholecystectomy procedures?

2. Is there a difference in the time required for surgical patients to return to normothermia postoperatively for subjects who use the forced-air warming blanket for 30 minutes preoperatively compared to patients who are given standard thermal care preoperatively undergoing elective surgical procedures lasting over one hour including total knee arthroplasty, total hip arthroplasty, exploratory laparotomy, abdominal hysterectomy, or open cholecystectomy?

Research questions 1 and 2 have one independent and one dependent variable. The independent variable is the forced-air warming blanket in research questions 1 and 2. In question 1, the dependent variable is patient temperature, and in question 2 it is time required to return to normothermia. For the first and the second research questions, a repeated measures analysis of variance (ANOVA) was the primary analysis used to examine the differences between the group receiving routine thermal care preoperatively and the group actively warmed with the forced-air warming blanket. There is one between subjects factor (warmed and unwarmed) and one within subjects factor (temperature) with three occasions of measurement. Descriptive statistics were done to compare characteristics of both the treatment and the control groups.

A power analysis was performed in order to determine an appropriate sample size. With the alpha at .05, and the power at 80%, 44 total subjects were needed (22 subjects per group). However, only 15 prewarmed subjects meeting the inclusion criteria were identified.
Summary

This chapter contained an examination of the design selected for this study, which was a non-experimental study with a repeated measures design using a retrospective chart review. A medium-sized midwestern academic health center perioperative area was the setting and the chart review was conducted in the Health Information and Management Department once IRB approval was obtained. A description of the inclusion criteria was provided, along with a discussion of the Hypothermia Data Collection Tool and the variables collected. Protection of human subjects was addressed through no collection of patient identifiers and the destruction of the patient list of those meeting the inclusion criteria. Assumptions and limitations of the retrospective study were described. The chapter ended with a description of the data analysis and the statistical techniques utilized in the study.
CHAPTER IV
RESULTS

Introduction

The purpose of this study was to determine if using the forced-air warming blanket for a minimum of 30 minutes preoperatively had an effect on the incidence and duration of unplanned postoperative hypothermia. The study sample included those patients over the age of 18 years undergoing total hip arthroplasty, total knee arthroplasty, exploratory laparotomy, abdominal hysterectomy, or open cholecystectomy. The sample population is described using descriptive statistics. Project findings are presented and described. The chapter concludes with a summary of its contents.

Setting/Target Population

The retrospective chart review for this project was performed at a medium-sized midwestern academic health center. A convenience sample of 53 charts of patients meeting the project inclusion criteria were selected from the charts of all persons undergoing surgery during a 12 month period. Ages of the patients ranged from 22 to 84 years, with a mean age of 55.25 years ($SD = 13.87$). Height ranged from 56 to 77 centimeters, with a mean height of 65.7 centimeters ($SD = 4.25$). Weight varied between 44 to 156 kilograms, with a mean of 93.52 kilograms ($SD = 24.93$). A total of 15 males (28.3%) and 38 females (71.7%) participated. There were 34 orthopedic surgical procedures (64.2%) and 19 abdominal procedures (35.8%) performed. Table 1 is a frequency table of the surgical procedure by type.
Table 1

*Frequency of Surgical Procedure by Type*

<table>
<thead>
<tr>
<th>Surgical Procedure</th>
<th>N (53)</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Orthopedic</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total Knee Arthroplasty</td>
<td>26</td>
<td>49.1</td>
</tr>
<tr>
<td>Total Hip Arthroplasty</td>
<td>8</td>
<td>15.1</td>
</tr>
<tr>
<td>Orthopedic Total</td>
<td>34</td>
<td>64.2</td>
</tr>
<tr>
<td>Abdominal</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Exploratory Laparotomy</td>
<td>2</td>
<td>3.8</td>
</tr>
<tr>
<td>Abdominal Hysterectomy</td>
<td>15</td>
<td>28.3</td>
</tr>
<tr>
<td>Open Cholecystectomy</td>
<td>2</td>
<td>3.8</td>
</tr>
<tr>
<td>Abdominal Total</td>
<td>19</td>
<td>35.9</td>
</tr>
</tbody>
</table>

The majority of the procedures performed were orthopedic ($n = 34, 64.2\%$). Total Knee Arthroplasty ($n = 26$) and Abdominal Hysterectomy ($n = 15$) procedures were those most frequently performed and included in this project.

Length of surgery ranged between 74 to 305 minutes, with a mean of 165 minutes ($SD = 46$). Intraoperative fluid intake varied from 1400 to 6500 milliliters with a mean of 2969 ($SD = 1034$).

The preoperative, PACU admission and PACU discharge temperatures were obtained. Table 2 lists the temperature data obtained for each operative phase.
Table 2

Mean Temperature Data for Each Operative Phase

<table>
<thead>
<tr>
<th>Temperature (°C)</th>
<th>$M$</th>
<th>$SD$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preoperative ($N=51$)</td>
<td>36.6</td>
<td>.52</td>
</tr>
<tr>
<td>PACU admission temperature ($N=53$)</td>
<td>35.75</td>
<td>.73</td>
</tr>
<tr>
<td>PACU discharge temperature ($N=52$)</td>
<td>36.26</td>
<td>.68</td>
</tr>
</tbody>
</table>

Preoperative temperatures ($N=51$) ranged between 35.4 to 37.8°C with a mean of 36.6°C ($SD = .52$). PACU admission temperatures ($N=53$) ranged between 34.06 to 37.2°C with a mean of 35.75°C ($SD = .73$). PACU discharge temperature ($N=52$) ranged between 34.61 to 37.78°C with a mean temperature of 36.26°C ($SD = .68$).

The time from PACU admission to the patient temperature reaching normothermia or 36°C ranged between zero minutes for those patients arriving in the PACU at 36°C or higher to 295 minutes, with a mean time of 75 minutes ($SD = 80$).

Routine thermal care activities in the perioperative area at this midwestern hospital include the use of layered cotton blankets, warmed cotton blankets, warmed irrigating fluids, warmed intravenous (IV) or blood products, and thermal head coverings. Currently, the forced-air warming blanket is also used routinely in the operating room at the discretion of the anesthesia personnel as well as nursing personnel in the PACU. Previously the use of the forced-air warming blanket on patients in the preoperative area was an additional thermal care activity not routinely used in that area. There were no other warming interventions documented in the
patient care records that were reviewed. Table 3 lists the warming interventions for each operative phase.

Table 3

_Warming Interventions Utilized For Each Operative Phase_

<table>
<thead>
<tr>
<th>Perioperative Area</th>
<th>N</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Preoperative (N = 53)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Warmed with Forced-Air Warming Blanket</td>
<td>15</td>
<td>28.3</td>
</tr>
<tr>
<td>Routine Thermal Care</td>
<td>38</td>
<td>71.7</td>
</tr>
<tr>
<td><strong>Intraoperative (N = 53)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Warmed with Forced-Air Warming Blanket + Routine Thermal Care</td>
<td>31</td>
<td>58.5</td>
</tr>
<tr>
<td>Routine Thermal Care</td>
<td>22</td>
<td>41.5</td>
</tr>
<tr>
<td><strong>Postoperative (N = 53)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Forced Air-Warming Blanket</td>
<td>11</td>
<td>20.8</td>
</tr>
<tr>
<td>Routine Thermal Care</td>
<td>42</td>
<td>79.3</td>
</tr>
</tbody>
</table>

A total of 15 patients (28.3%) used the forced-air warming blanket preoperatively. There were 38 (71.7%) patients who received routine thermal care measures preoperatively including one who received an additional warm cotton blanket.

Intraoperatively, 31 patients (58.5%) received the forced-air warming blanket while in surgery. Included in this group were those who received routine thermal care measures
including warmed IV or blood products along with the forced-air warming blanket. There were 22 patients (41.5%) who received routine thermal care measures but no forced-air warming blanket.

Postoperatively the majority of the patients, 42 (79.3%), received routine thermal care measures including an additional warm cotton blanket. There were 11 patients (20.8%) who used the forced air warming blanket while in the PACU.

The original purpose of this study was to compare postoperative temperatures and time to normothermia between two groups who were reasonably equivalent excepting the use of preoperative warming. However, this study used a retrospective design which did not allow for any control over the use of specific warming interventions during the intraoperative or postoperative period. It was found that nearly all of the patients who received the forced-air warming blanket preoperatively also received it intraoperatively. This group was considered the warmed group ($N = 14$), while those that had no forced air warming blanket either preoperatively or intraoperatively were considered to be the unwarmed group ($N = 20$). Table 4 gives a comparison of the temperature data per area of the warmed versus the unwarmed groups.
Table 4

*Temperature Comparison of Warmed versus Unwarmed Groups per Area*

<table>
<thead>
<tr>
<th>Comparison Group</th>
<th>Warmed</th>
<th>N</th>
<th>M</th>
<th>SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preoperative Temperature (°C)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Warmed</td>
<td>14</td>
<td>36.78</td>
<td>.54</td>
<td></td>
</tr>
<tr>
<td>Not Warmed</td>
<td>19</td>
<td>36.48</td>
<td>.49</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>33</td>
<td>36.61</td>
<td>.53</td>
<td></td>
</tr>
<tr>
<td>PACU Admitting Temperature (°C)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Warmed</td>
<td>14</td>
<td>35.86</td>
<td>.71</td>
<td></td>
</tr>
<tr>
<td>Not Warmed</td>
<td>19</td>
<td>35.72</td>
<td>.81</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>33</td>
<td>35.78</td>
<td>.76</td>
<td></td>
</tr>
<tr>
<td>PACU Discharge Temperature (°C)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Warmed</td>
<td>13</td>
<td>36.23</td>
<td>.67</td>
<td></td>
</tr>
<tr>
<td>Not Warmed</td>
<td>20</td>
<td>36.23</td>
<td>.72</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>32</td>
<td>38.18</td>
<td>10.83</td>
<td></td>
</tr>
</tbody>
</table>

The total sample of warmed versus unwarmed patients consisted of 34 subjects. There were 3 warmed male patients (21.4%) and 11 warmed female patients (78.6%). The not warmed group by gender was comprised of 7 male patients (34%) and 13 female patients (65%). Orthopedic procedures constituted the majority of the surgical procedures performed with a total of 23 (67.65%), while abdominal surgeries totaled 11 (32%). There were 9 warmed orthopedic patients (39%) and 14 not warmed (61%). Of the abdominal surgery group, 5 were warmed (457%) and 6 were not warmed (55%). It was interesting to note that in the PACU 6 patients in the warmed group received the forced-air warming blanket (42.9%) while 8 in the warmed group did not (57.1%). A total of 3 patients in the not warmed group received the forced-air warming
blanket while in the PACU (15%) while 17 in the not warmed group received routine thermal care measures (85%).

Comparisons were also made on age, height, weight, length of surgery, and intraoperative fluid intake between the warmed and unwarmed groups and included in Table 5.

Table 5

Descriptive Data of Warmed Group versus Not Warmed Group

<table>
<thead>
<tr>
<th>Descriptive Data</th>
<th>Warmed Group</th>
<th>Not Warmed Group</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Valid</td>
<td>M</td>
</tr>
<tr>
<td>Age (years)</td>
<td>14</td>
<td>54.43</td>
</tr>
<tr>
<td>Height (inches)</td>
<td>14</td>
<td>65.64</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>14</td>
<td>95.64</td>
</tr>
<tr>
<td>Length of Surgery in Minutes</td>
<td>14</td>
<td>173.14</td>
</tr>
<tr>
<td>Intraoperative Fluid Intake (ml)</td>
<td>14</td>
<td>3346.43</td>
</tr>
</tbody>
</table>

The descriptive data highlights similarities among the warmed versus the unwarmed groups. The average age was slightly higher in the not warmed group (58.25 years, $SD = 13.91$) than in the warmed group (54.43 years, $SD = 15.13$). Height and weight were also very similar in both groups with the warmed group averaging 65.64 inches ($SD = 3.56$) in height and weighing an average of 95.64 kg ($SD = 24.18$), while the not warmed group had an average height of 66.40 inches ($SD = 5.0$) and an average weight of 95.34 kg ($SD = 27.14$). The average length of surgery in the warmed group was longer than the unwarmed group by approximately
20 minutes. The warmed group averaged 173.14 minutes ($SD = 30.86$) while the unwarmed group averaged 149.68 minutes ($SD = 40.55$). Intraoperative fluid intake was increased in the warmed group, possibly related to the increased length of surgery. The warmed group averaged 3346.43 ml ($SD = 892.81$) of intraoperative IV fluid while the unwarmed group averaged 2794.12 ml ($SD = 1196.59$) of intraoperative IV fluid.

**Findings**

The first research questions asked whether there was a difference in the incidence of unplanned postoperative hypothermia for those patients undergoing total knee arthroplasty, total hip arthroplasty, exploratory laparotomy, abdominal hysterectomy, or open cholecystectomy procedures who received the forced-air warming blanket preoperatively. The overall incidence of hypothermia per perioperative phase for all subjects is included in Table 6.

### Table 6

*Incidence of Hypothermia per Perioperative Phase*

<table>
<thead>
<tr>
<th>Perioperative Phase</th>
<th>N (53)</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preoperative</td>
<td>6</td>
<td>11</td>
</tr>
<tr>
<td>PACU Admission</td>
<td>31</td>
<td>58</td>
</tr>
<tr>
<td>PACU Discharge</td>
<td>13</td>
<td>25</td>
</tr>
</tbody>
</table>

In the preoperative area, 5 patients (9%) were hypothermic with a temperature less than 36°C. There were 2 patients who did not have a preoperative temperature recorded. Upon PACU admission, 31 patients (58%) were hypothermic, while 13 (25%) were hypothermic upon PACU discharge. One patient in the PACU did not have a discharge temperature recorded. It is
interesting to note that the majority of the patients (58%) arrived in the PACU hypothermic with a temperature less than 36°C, and 25% were discharged from the PACU with temperatures less than 36°C.

The first research question was, “Is there a difference in unplanned perioperative hypothermia in the postanesthesia care unit with the preoperative use of the forced-air warming blanket for 30 minutes compared to routine thermal care measures for patients undergoing total knee arthroplasty, total hip arthroplasty, exploratory laparotomy, abdominal hysterectomy, or open cholecystectomy procedures?” A two-way within-subjects analysis of variance was conducted to evaluate the effect of preoperative warming with the forced-air warming blanket on the incidence of unplanned perioperative hypothermia. The dependent variable was patient temperature in degrees Centigrade. The within-subjects factor was temperature measured three times: preoperatively, upon PACU admission and PACU discharge. The between subjects factor was warming with two levels: warmed pre- and intraoperatively and not warmed pre- or intraoperatively. The temperature x group interaction effect was tested using the multivariate criterion of Wilks’ lambda (Λ). The temperature x group interaction was not significant, Λ = 91, F (2, 29) = 1.46, p = .25. The temperature main effect was significant (Λ = .42, F (2, 29) = 19.67, p = .00). A graph of the temperatures by intervention is presented in Figure 2.
Figure 2

Mean Temperature by Intervention

Three paired samples t-tests were conducted to follow up the temperature main effect significant interaction using the Bonferroni approach. Differences in mean temperatures during the perioperative period were found to be statistically significant between preoperative temperature ($M = 36.61, SD = .53$) and PACU admission temperature ($M = 35.78, SD = .76$), $[t$
(32) = 5.44, \( p = .00 \)], preoperative temperature \((M = 36.63, SD = .51)\) and PACU discharge temperature \((M = 36.27, SD = .66)\), \([t (31) = 2.71, \ p = .01]\), and PACU admission temperature \((M = 35.73, SD = .74)\) and PACU discharge temperature \([t (32) = -3.40, \ p = .002]\).

In summary, analysis of the mean temperature of both the warmed and the unwarmed groups demonstrates a significant change between the preoperative and PACU admission temperature, the preoperative and PACU discharge temperature, and the PACU admission and PACU discharge temperature. However, there was no statistically significant difference in temperature between the warmed and unwarmed groups. These results indicate that while temperatures throughout the perioperative experience differ, these differences were not statistically significant between the warmed and unwarmed groups.

The second research question asked “Is there a difference in the time required for surgical patients to return to normothermia postoperatively for subjects who use the forced-air warming blanket for 30 minutes preoperatively compared to patients who are given routine thermal care preoperatively undergoing elective surgical procedures lasting over one hour including total knee arthroplasty, total hip arthroplasty, exploratory laparotomy, abdominal hysterectomy, or open cholecystectomy?” The time in minutes to return to normothermia for the warmed and unwarmed groups is shown in Table 7.
Table 7

| Time to Normothermia for Warmed, Unwarmed, and Total Sample Groups in the PACU |
|---------------------------------|-----|-----|-----|
| Time in Minutes                | Warmed | Not Warmed | Total Sample |
| Normalerhic at PACU Admission  | N (14)  | N (20) | N (53) |
| 7                               | 50%   | 40%   | 41.5% |
| 1 to 60                         | 14.3% | 15%   | 11.3% |
| 61 to 120                       | 14.3% | 15%   | 19%   |
| 121 to 180                      | 21.4% | 15%   | 19%   |
| 181 to 300                      | 0     | 15%   | 9%    |

The largest percentage of the patients who arrived in the PACU with a temperature of 36°C or higher (normothermic) had been warmed with the forced-air warming blanket pre- and intraoperatively (n = 7, 50%). There were 8 patients (40%) in the unwarmed group and 22 patients (41.5%) in the total sample group who arrived normothermic in the PACU. No patient in the warmed group took over 180 minutes to return to normothermia postoperatively, while 3 patients (15%) in the unwarmed group and 5 patients (9%) in the total sample took from 181 to 300 minutes to return to normothermia.

An independent samples t test was conducted to evaluate whether the time to return to normothermia was affected by the preoperative and intraoperative use of the forced-air warming blanket for the warmed and unwarmed groups. The test approached statistical significance (t(32) = -1.265, p = .10). Time from PACU admission to the temperature reaching 36°C in minutes in
the warmed group \((n = 14)\) averaged 45.71 minutes \((SD = 55.85)\) while it averaged 82.4 minutes \((SD = 97.59)\) in the unwarmed group \((n = 20)\).

**Summary**

Chapter IV contained a description of the study setting and a statistical description of the target population. Due to the retrospective design of the study, it was found that nearly all of the patients who had received the forced-air warming blanket preoperatively also received it intraoperatively. This group then became the warmed group, and those that had not received the forced-air warming blanket either pre- or intraoperatively became the unwarmed group. Descriptive data was then provided on these groups. Findings were discussed describing a significant difference in the temperature change between the preoperative and postoperative periods for both the warmed and unwarmed groups. This temperature change however was not statistically significant between the warmed and unwarmed groups. Analysis of whether the time to return to normothermia was affected by the preoperative use of the forced-air warming blanket was also described, and found to be not statistically significant. The chapter ended with a brief summary of its contents.
CHAPTER V
DISCUSSION

Introduction

The purpose of this research project was to examine the preoperative use of the forced-air warming blanket versus routine thermal care on the incidence and duration of unplanned perioperative hypothermia in the postanesthesia care unit. This chapter will discuss the findings of this research study and discuss them in context of the literature review using Kolcaba’s Comfort Theory of Nursing. Conclusions are drawn from this research project and project limitations are stated. The implications for nursing practice that can be identified as a result of this project are discussed, and recommendations for further research are examined. The chapter concludes with a summary of its contents.

Findings

Analysis of the temperature patterns in this study found that 58% of the patients included in the initial sample arrived in the PACU hypothermic (N = 53). These findings support the relevant literature which found the rate of unplanned perioperative hypothermia to range from 52% to as high as 85% in all surgical patients studied receiving routine thermal care methods (Ensminger & Moss, 1999; Stewart, Lujan, & Ruff, 1987; Vogelsang, 1991).

Research Question 1 asked: Is there a difference in unplanned perioperative hypothermia in the postanesthesia care unit with the preoperative use of the forced-air warming blanket for 30 minutes compared to routine thermal care measures for patients undergoing total knee arthroplasty, total hip arthroplasty, exploratory laparotomy, abdominal hysterectomy, or open cholecystectomy procedures?”
Analysis of the mean temperature using three paired samples t-tests of the warmed and unwarmed groups demonstrated a significant difference between preoperative and PACU admission temperature \((p = .00)\); the preoperative and PACU discharge temperature \((p = .01)\); and the PACU admission and PACU discharge temperature \((p = .002)\). Although analysis of the mean temperature of both the warmed and unwarmed groups demonstrated a significant temperature change between the preoperative and PACU admission temperature, preoperative and PACU discharge temperature, and PACU admission and PACU discharge temperatures, there was no significant difference between the warmed and unwarmed groups \((p = .25)\). This finding is in contrast to the relevant literature reviewed. Fossum et al., (2001) prewarmed patients with a forced-air warming blanket for a minimum of 45 minutes prior to transport to the operating room and found patients significantly warmer on arrival to the PACU when compared to patients receiving only warmed cotton blankets \((p = .000)\). Fossum et al., (2001) was able to improve study control however by excluding those who received the forced-air warming blanket intraoperatively. Due to the retrospective design used in this study however, it was not possible to identify two equivalent groups excepting the use of the forced-air warming blanket preoperatively. In addition, the total sample size for this analysis was small further affecting study outcomes.

Research Question 2 asked: Is there a difference in the time required for surgical patients to return to normothermia postoperatively for subjects who use the forced-air warming blanket for 30 minutes preoperatively compared to patients who are given routine thermal care preoperatively undergoing elective surgical procedures lasting over one hour including total knee arthroplasty, total hip arthroplasty, exploratory laparotomy, abdominal hysterectomy, or open cholecystectomy?
An independent samples t-test was performed to evaluate whether the time to return to normothermia was affected by the use of the forced-air warming blanket. Although not statistically significant ($p = .10$), the mean time from PACU admission to the temperature reaching $36^\circ$C was more rapid in the warmed group (45.71 minutes, $SD = 55.85$) than in the unwarmed group (82.4 minutes, $SD = 97.59$). The lack of statistical significance makes it impossible to infer that the rate of rewarming was faster in the warmed group due to the use of the forced-air warming blanket, but it appears that the trend may be in that direction. In a similar study by Bock et al. (1998), patients were warmed with the forced-air warming blanket preoperatively and intraoperatively, finding that patients who were warmed reached normothermia faster in the PACU than those who were not warmed ($p \leq .01$). Again, total sample size and unequal numbers in the warmed and unwarmed groups might have affected the study outcomes.

The findings of this study and the assessment and treatment of unplanned perioperative hypothermia work well with the Comfort Theory developed by Katharine Kolcaba (1994). Relief has been identified as one of the three types of comfort when enhanced moves a patient toward a state of improved strength or well-being. Specifically, relief relates to the state of having a specific discomfort relieved, which in the perioperative setting included relief from feelings of coldness or hypothermia (Kolcaba & Wilson, 2004). In this study the majority of patients ($N = 53, 58\%$) arrived in the PACU hypothermic, which is consistent with the rates of perioperative hypothermia cited in previous studies. Promotion of optimal thermoregulation requires ongoing assessment of the patient and providing positive thermal comfort interventions thereby decreasing the rate of unplanned perioperative hypothermia and its potential untoward consequences.
Conclusions

This study found a significant change in temperature between the preoperative and PACU temperatures of the subjects, but did not find a statistically significant difference in temperature between those who were prewarmed preoperatively versus those who received routine thermal care. Therefore, it is inconclusive as to whether the forced-air warming blanket had a beneficial effect on perioperative hypothermia.

A major limitation of this study was the retrospective design of the project which afforded no control over any of the study variables, including instrumentation, other warming interventions utilized, or complete documentation of the care provided. A convenience sample was also used which limits the application of the results to the general population. An additional limitation was the small sample size and limitation of the type of patient who received the forced-air warming blanket preoperatively. A secondary analysis of the data, further reducing the sample size, was performed due to the finding that nearly all of the patients who received the forced-air warming blanket preoperatively also received it intraoperatively. This group then became the warmed group ($N = 14$), while those that received only routine thermal care became the unwarmed group ($N = 20$).

An important aspect of thermoregulation that was not evaluated in this study was the patient’s perception of thermal comfort. Feelings of cold, piloerection, and shivering contribute to patient discomfort and add to the negative impact of surgery. It is suggested that future studies attempt to incorporate the patient’s perception of thermal comfort into their research protocol.
Implications for Nursing Practice, Education, Administration, Research, and Theory

The primary implication for nursing practice is to increase awareness of the possible complications of postoperative hypothermia and to become more aggressive in its identification and treatment. ASPAN has taken a leading role in developing a useful guideline for identification and treatment of the surgical patient at risk for developing perioperative hypothermia which could be utilized in any perioperative setting. The intent of the guideline is to provide clinicians with a practical standardized approach to the prevention, care, and management of the adult surgical patient with unplanned perioperative hypothermia (ASPAN, 2002).

The Advanced Practice Nurse has an opportunity to take a leading role in providing optimal patient care and education that reduces morbidity and mortality and is also cost effective. The literature suggests that promotion of perioperative normothermia may decrease health care cost by reducing possible untoward complications and decreasing PACU time. With fewer adverse outcomes and faster recovery times, increased health care costs could be significantly prevented or decreased. The APN can promote positive patient outcomes through continued involvement in current research and nursing practices.

Recommendations for future research include further study of preoperative warming using the forced-air warming blanket. This is a low cost, low risk warming intervention that is currently utilized in the operative and PACU setting, and could be easily used in the preoperative setting. Possibly only those patients with the highest risk for developing perioperative hypothermia would benefit from prewarming, such as the elderly, the young, or those that are debilitated, but further research is needed to clarify the best utilization of the forced-air warming blanket in these situations. Suggestions for further research also include investigation of the
cost/benefit of the forced-air warming blanket; patient satisfaction using the forced-air warming blanket; complication rate using the forced-air warming blanket; and the development and use of consistent standards of practice used to treat perioperative hypothermia.

Kolcaba’s Comfort Theory (1994, 2003) provides the foundation for this study. Nurses who utilize the Comfort Theory in the perioperative setting are aided in the identification of thermal comfort needs, and the application of thermal comfort measures. These measures lead to enhanced comfort, or normothermia which promotes patient internal and external well-being. Patient comfort is a positive outcome of the perioperative experience, and according to Kolcaba and Wilson (2004), an important indicator to measure for perianesthesia care and further research.

Summary

The purpose of this project was to determine if using the forced air warming blanket for a minimum of 30 minutes preoperatively had an affect on the incidence and duration of unplanned perioperative hypothermia. There was a significant change in core temperature between the preoperative and the PACU temperatures, but no significant differences between the warmed and the unwarmed group in temperature or time to return to normothermia.

This study was limited by its retrospective design which allowed for no control over study variables, and small sample size. It was found that most patients who received the forced-air warming blanket preoperatively also received it intraoperatively, involving a secondary analysis of the data further reducing the sample size.

The results of this study, although not statistically significant, offer several implications for nursing practice. Early identification and treatment of perioperative hypothermia may prevent patient discomfort and possible untoward postoperative complications which increase
health care costs. Further education and research is needed in order to standardize treatment of perioperative hypothermia and to hopefully prevent its occurrence.


Preoperative Warming and its Impact on Unplanned Perioperative Hypothermia
Frances Jane Ford

ABSTRACT

The purpose of this study was to compare the preoperative use of the forced air warming blanket versus routine thermal care on the incidence and duration of unplanned perioperative hypothermia in the postanesthesia care unit. The theoretical framework for this study was Kolcaba’s Comfort Theory. A non-experimental study with a repeated measures design using a retrospective chart review was used to evaluate routine thermal care versus the preoperative use of the forced air warming blanket on core temperature measured in the PACU, and the time to return to normothermia. Analysis of the mean temperatures of both the warmed and the unwarmed groups demonstrated a significant temperature change between the preoperative and PACU admission and discharge temperatures. However, there was no statistical significance between the groups on either temperature or duration of perioperative hypothermia.
Appendix A

Hypothermia Data Collection Tool

Age: _____ yrs  Height: _____ inches  Weight: _____ lbs

Gender: ① Male ② Female

Procedure: ① total knee arthroplasty ② total hip arthroplasty ③ exploratory laparotomy ④ abdominal hysterectomy ⑤ open cholecystectomy

Length of Surgery ______ min  Intra-op Fluid Intake _______ cc

<table>
<thead>
<tr>
<th></th>
<th>Pre-op</th>
<th>PACU Admission</th>
<th>PACU Discharge</th>
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<tbody>
<tr>
<td><strong>Temperature (°C)</strong></td>
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<td><strong>Time taken</strong></td>
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<td>How taken</td>
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Time from PACU admission to patient temperature reaching 36° C: _______ min

Use of Warming interventions: ① warm blankets ② layering of blankets ③ head wraps ④ forced air warming ⑤ warmed IV or blood products ⑥ warmed irrigating solutions ⑦ Other: _______

① ② ③ ④ ⑤ ⑥ ⑦

APPROVED BY MEDICAL UNIVERSITY OF OHIO AT TOLEDO IRB
Appendix B

TO:        Katherine Kleiner, Ph.D., R.N.
           MUOT School of Nursing

FROM:     Eric Schaub, M.D., M.P.H., Chair Designee
           Connie Roth-Sautter, Ph.D., R.N., Vice Chair
           MUOT Institutional Review Board

DATE:     May 13, 2005

SUBJECT:  IRB # 104973 - Preoperative Warming and its Impact on Unplanned Perioperative Hypothermia

The above project was reviewed and approved by the Chair Designee of the Institutional Review Board as an expedited review (category #5). The requirement to obtain a signed consent/authorization for use and disclosure of protected health information form has been waived at this research is determined to be minimal risk and a signed consent/authorization document would be the only record linking the subject to the data. It was determined that this waiver for signed consent/authorization for use and disclosure of protected health information form will not adversely affect the rights or welfare of the participants. The Principal Investigator must insure that a copy of the cover letter is provided to all participants prior to participation. The full board will review it at its meeting on 05/16/2005.

APPROVAL DATE:  5/13/2005

EXPIRATION DATE:  5/12/2006

It is the Principal Investigator's (P.I.'s) responsibility to:

1. Abide by all federal, state, and local laws and regulations; the MUOT federal assurance and institutional policies for human subject research and protection of individually identifiable health information including those related to record keeping and be sure that all members of your research team have completed the required education in these areas.

2. Ensure that all subjects, or their legally authorized representatives, are provided a copy of the Cover Letter prior to choosing to participate in this research.

3. Comply with the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule Privacy Rule (45 CFR 164) and institutional policy regarding the accounting and tracking of uses and disclosures of protected health information.

4. Promptly notify the MUOT IRB at (419) 383-6796 of any untoward incidents or unanticipated adverse reactions that develop in the course of your research on human subjects. Please complete and submit RGA Form 317 for ALL SUCH REPORTS for this protocol. The Principal Investigator is also responsible for submitting to the MUOT IRB reports of adverse events that occur at other sites conducting this study and for maintaining an up-to-date cumulative table of adverse events (RGA Form 316) and submitting it to the MUOT IRB for each research project. The Principal Investigator is responsible for reporting adverse events to the appropriate federal agencies and the sponsor (when one exists).

5. Report promptly to the MUOT IRB any deviations, violations or participant non-compliance from the MUOT IRB approved protocol in accordance with the procedures outlined in RGA Form 309. In your report include the protocol number and title, the subject’s initials and study I.D. number, date of the event, a brief description of the occurrence and a description of any corrective actions taken. The Principal Investigator is responsible for reporting deviations, violations and participant non-compliance to the appropriate federal agencies and the sponsor (when one exists) in accordance with federal regulations, institutional policy and any other legal agreements with these organizations.

6. Obtain prior MUOT IRB review and approval for changes in procedures, inclusion/exclusion criteria, study personnel, source of participants, new or additional advertising materials, modifications to subject payments, and for any and all changes to the cover letter and survey tool.
7. Report **promptly** to the MUOT IRB, sponsor (if this research is sponsored) and all other required federal and state agencies all new information affecting the risk/benefit ratio and obtain **prior MUOT IRB approval** for any changes in the study documents that may be required by the new information.

8. Obtain **prior MUOT IRB review and approval** for all modified and/or added incentives going to the P.I., study coordinator, other study personnel, and/or the institution. These incentives may be in the form of money or other items of value, including, but not limited to, equipment, such as computers, and intangibles, such as frequent flyer miles.

9. **Promptly** notify the MUOT IRB; other required MUOT committees, departments or individuals; the sponsor (if this research is sponsored); and all other required federal and state agencies of all potential conflicts of interest before beginning this research and, during the course of this research report to these committees, individuals and agencies any changes that may affect conflict of interest for any of the study personnel. **Prior MUOT IRB approval** must be obtained for any changes in the study documents that may be required by information related to conflict of interest or any changes in this information during the course of the research.

10. **Promptly** notify the MUOT IRB of any changes in contracts, budgets, grants or other agreements with sponsors, agencies or individuals regarding the conduct of this research before initiating these changes. The IRB reserves the right to review these study related documents and changes to them to verify accuracy and consistency with regard to the research protocol in order to protect the rights and welfare of the study subjects. Changes in these documents that have the potential to affect the rights, welfare or willingness of the study subjects to participate in or continue to participate in this research and changes in subject documents (such as informed consent, assent or authorization for use and disclosure of protected health information forms, etc.) that are a result of these changes must be reviewed and approved by the MUOT IRB prior to being instituted.

**Additional Information:**

- **Other Required Review(s) or Approval(s)**
  - Review or approval by the MUOT Institutional Review Board does **not** take the place of any other Review or approval required by the Medical University of Ohio at Toledo, non-MUOT performance sites, the government and/or the study sponsor.

- **Required Procedure to Request Review and Approval for Changes/Updates to MUOT IRB Approved Research**
  - Please complete and submit the **Request for Amendment/Changes/Updates** (RGA Form 314 found at [http://www.mco.edu/research/rga_firms/rga314.doc](http://www.mco.edu/research/rga_firms/rga314.doc)) with a copy of all materials relevant to the requested change (including consent/assent/authorization for use and disclosure of protected health information forms if applicable) with the changes **underlined**. If you are requesting review and approval of consent/assent/authorization for use and disclosure of protected health information forms, please attach a clean copy of the revised forms for the MUOT IRB to stamp. Please remember that all changes and correspondence submitted to the MUOT IRB (regardless if they are generated by a sponsor, the P.I. or requested by the MUOT IRB) must be in writing, signed and dated by the Principal Investigator.

- **Federally Mandated Continuing Review**
  - MUOT IRB protocols must be reviewed and reapproved **not less than once per year**. The Institutional Review Board will try to remind you when reapproval is due. However, it is the responsibility of the Principal Investigator to have his/her own reminder system in place to initiate the re-approval process at least a month prior to the expiration date shown above. Please note that Federal Regulations prohibit the extension of this expiration date. Please see the Application for Continuing Review (RGA Form 319 found at [http://www.mco.edu/research/rga_firms/rga319.doc](http://www.mco.edu/research/rga_firms/rga319.doc)) for items required for continuing review.

- **Required Final Report Upon Termination of Research**
  - When you decide to stop this research, you are responsible for completing and submitting a **Final Report** (RGA Form 320 found at [http://www.mco.edu/research/rga_firms/rga320.doc](http://www.mco.edu/research/rga_firms/rga320.doc)) to the MUOT IRB for review.