TRANSWARMER® MATTRESS PROJECT (TeMP) AT DELIVERY: A PROSPECTIVE, RANDOMIZED CONTROL TRIAL OF THE TRANSWARMER MATTRESS TO REDUCE ADMISSION HYPOTHERMIA OF LOW BIRTH WEIGHT INFANTS

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Dedication

This research is dedicated to all the premature infants, including my children, which I have cared for in my career and my commitment to them to continually improve the care, provided to all premature infants in the future.
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ABSTRACT

Background/Significance
Low birth weight infants are at particularly high risk for altered thermoregulation. Factors such as the absence or low amounts of brown fat in the preterm infant do not allow for non-shivering thermogenesis. Despite research of hypothermia in low birth weight infants it remains a common problem today. (1-3)

Hypothesis
Standardized use of the TransWarmer® mattress will reduce the incidence of admission hypothermia.

Sample
Low birth weight infants, between 30 - 35 weeks gestation, born at Kapi‘olani Medical Center for Women and Children, Honolulu, HI, admitted to the neonatal intensive care unit.

Research Design
Prospective, experimental randomized control trial.

Instrument
TransWarmer® mattress, CooperSurgical, Trumbull, CT

Procedure
Patients were randomized into a control group or an experimental group. Infants in the control group underwent routine care provided by the medical team attending the delivery. Participants in the experimental group followed a scripted protocol of the use of the TransWarmer® mattress with the infant through delivery and admission into the NICU for a total time period of two hours.

Data
53 infants recruited into the study. Thirteen participants were removed from the study due to delivery after 35 weeks gestation. Data was obtained from a sample of 40 infants.

Results
The results revealed that the occurrence of hypothermia on admission was significantly lower in the TransWarmer® mattress group.
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LIST OF ABBREVIATIONS

Delivery Room (DR)
Extremely Low Birth Weight (ELBW)
Grams (gm)
Low Birth Weight (LBW)
Neonatal Intensive Care Unit (NICU)
Operating Room (OR)
Randomized Control Trials (RCT)
Very Low Birth Weight (VLBW)
BACKGROUND AND SIGNIFICANCE

Low birth weight infants are at particularly high risk for altered thermoregulation. Factors such as the absence of, or low volumes of brown fat in the preterm infant do not allow for non-shivering thermogenesis. This and other immature physiologic systems of the premature infant cause them to act as poikilotherms. (4) Thermoregulation of low birth weight infants has been evaluated over many years because of instability of these processes. (5-7)

Physiologic concerns associated with hypothermia effect infants of all ages. Decreased temperatures can lead to disruptions in metabolic processes such as vasoconstriction, increased blood viscosity and ischemic cellular injury. Despite current research findings on hypothermia in low birth weight infants it remains a common problem today. (1-3) Hypothermia in the newborn is defined as a temperature less than 36.5°C or 97.7°F. (8)

Despite advances in modern technology, hypothermia on admission to neonatal intensive care units remains a common problem throughout the world (8) (9, 10). The incidence of hypothermia ranges from 40% (9) to as high as 84%. (11) Complications related to hypothermia for the preterm infant include, but are not limited to, hypoglycemia, poor perfusion, increased oxygen requirements, and increases in metabolic rate that may lead to further long term effects (12).

Several devices designed to prevent heat loss in newborn infants have been used over the years (5, 13-18). Among the studies, the sample subjects ranged from very low birth weight infants (less than 1500 grams) to full term infants. Earlier studies done before 1997 examined the use of assisted heating devices primarily in term infants (5, 13, 19-21) while studies spanning the last thirteen years have focused on the very low birth weight infant (16, 18, 22-24).

Randomized Controls (RCT) in VLBW infants

In review, there were three RCT studies that evaluated the use of a device to assist in maintaining temperature of the very low birth weight infant less than 29 weeks gestation and consisted of a total of 167 subjects (16, 18, 22). The first study by Brennan (16) in 1996 (a master’s thesis) looked at the efficacy of the
TransWarmer® mattress, made by CooperSurgical, using a randomized prospective study of the TransWarmer® vs. no TransWarmer®. The author looked at twenty-four infants less than 1,500 grams admitted to the neonatal intensive care unit. Her results indicate that use of the heat gel mattress improved the admission temperature. Her analysis included 12 infants in each arm of the study. Control and experimental groups were compared with descriptive statistics and showed no significant difference between the groups. Randomization was through selected sealed envelopes at study entry. Statistical analyses using two sample t-tests were performed. Results revealed a mean admission temp of 35°C in the control group and 36.6°C in the experimental group (p = 0.0009)(16), concluding that infants admitted on the TransWarmer® mattress had a statistically significant higher axillary temperature. Limitations of this study were lack of documentation of maternal temperature at delivery and the temperature of the delivery room. These may have affected the temperature of the infant on admission. As noted in a study by Carmichael (25) the maximum temperature of the sodium acetate mattress is dependent on the ambient temperature at which it is activated, therefore delivery room temperature would be an important variable that should have been collected. Informed consent did not state the possibility of burns to the skin of the premature infants. By current internal review board (IRB) standards, this consent would be considered inadequate.

The second RCT evaluated was by done by Vohra, et.al (18) in 2004. This study evaluated the use of polyethylene wrap, 20cmx50cm (Eastern Paper; Division of EPC Industries Ltd) instead of conventional drying of the VLBW infant at delivery. The sample included 55 extremely low birth weight infants (28 in the experimental group and 27 in the control), with two deaths in the delivery room. The control group received standard practice of drying and applying hat while the experimental group only had the head dried, hat applied and placed in the polyethylene wrap. Their results indicate that infants in the polyethylene group had better admission temperatures. Wrapped infants had a higher mean rectal admission temperature, 36.5°C (SD, 0.8°C), compared with 35.6°C (SD, 1.3°C)
in control infants ($P = .002$). Secondary outcome revealed a positive correlation between birth weight and admission temperature in both groups. The regression model suggested that the mean rectal temperature on admission to the NICU increased by $0.21^\circ C$ (95% CI, 0.04 to 0.4) with each 100-g increase in birth weight (18). Mean temperature increase of the wrapped group remained unchanged after multiple linear regression was performed using such variables as early rupture of membranes, delivery route, sex, gestational age and birth weight (18). Limitations of this study included no mention of adjustment for maternal fever that may affect the admission temperature of the neonate. Upon further review the study by Vohra, ET. al. (18) states that infants were “carried to the NICU” then placed in a heated isolette. The practice of carrying the infant from the delivery room to the NICU has not been documented as a standard practice. The study also made note that there was no informed consent signed by parents “as there wouldn’t be enough time”. This practice, in a highly vulnerable population, is not current with today’s standards of protection of human subjects.

The third RCT done by Knobel, et. al (22) 2005 evaluated the use of a polyethylene bag. Eighty-eight subjects were enrolled into this trial. There were 41 infants in the control group and 47 in the experimental group. This study described the delivery room temperatures and the attempts to maintain a warmer temperature in the delivery room for the delivery of infants less than 29 weeks gestation. Delivery rooms were kept at 26$^\circ C$. Control group infants were dried, hat applied and covered with warm blankets, per NRP guidelines(26) and transported without being placed in polyurethane bags. Experimental group were placed in polyurethane bags up to their necks immediately after delivery before being dried with head sticking out for airway management. They were resuscitated per NRP guidelines, covered with warm blankets, and transported to the NICU, where the bags were removed and rectal temperatures were recorded. Knobel, et. al (22) found that infants in the bags had higher admission temperatures. Intervention patients were less likely than control patients to have temperature $< 36.4^\circ C$ on admission, 44 vs. 70% ($p<0.01$) and the intervention
group had a higher mean admission temperature, 36.5°C vs. 36.0°C (p<0.003). This association remained significant (p<0.0001) when the analysis was controlled for delivery room temperature. A secondary outcome revealed that a higher delivery room temperature was associated with higher admission temperatures in both intervention and control infants. A limitation to the study may be the association of the delivery room temperature and the bag starting temperature. The polyethylene bag used for this investigation may be affected by the ambient temperature in a way that is similar to the description provided by Carmichael et. al (25). It was not stated in the study if the polyethylene bag used was stored in the delivery room prior to use or if was brought to the delivery by the neonatal team.

Review of four other RCTs evaluated the use of a device at delivery to prevent hypothermia in groups of infants ranging from 31 weeks to term. A study done by Baum and Scopes in 1968 (20) evaluated one of the earliest hypothermia prevention devices, a silver swaddling, similar to material used by astronauts. The device is a blanket made with a layer of polyester with aluminum layer on top. Twenty-one term infants were randomized into the study before they entered the delivery room. How randomization was achieved was unclear. No infant requiring intubation was included. The infant’s were temperatures measured at 5 minutes of age and again at one hour. Statistical analyses were done evaluating the differences from the 5 minute and one hour temperatures. The groups were compared using student t-tests. Results were significant with infants in the experimental group having less of a temperature drop than those infants in the control group (control decrease of 2.35°F vs. 1.19°F in experimental). Limitations of the trial included lack of randomization and small sample size (10 in control and 11 in experimental). There was also insufficient information to clarify if more than one mother in the study had a temperature at delivery.

In a study done by Besch, et. al (13) examining use of a plastic bubble wrap, the same that used in packaging materials, in conjunction with radiant heat. Bags were made out of the bubble wrap by using a hand-held heat sealer.
that made the bubble wrap into bags 43 - 48cm long and 30cm wide. The study examined a total of 85 infants each weighing over 2,000 grams. Groups included, 26 infants, that were placed under radiant heat; 6 placed feet first in bubble plastic wrap, with head exposed; 25 infants put in bubble plastic bag with head covered; 11 infants in bubble plastic with head exposed placed under radiant heat; 17 infants in bubble plastic with head covered, under radiant heat. The infants had temperatures taken starting at five minutes and every five minutes until 40 minutes of age. The results suggested that infants in the wrap, hat and radiant warmer group had the least amount of temperature decrease after delivery. The results were described using a linear graph but statistical analysis was not provided. The authors did describe that prewarming the plastic bag was not associated with a significant difference in the temperatures obtained. A decrease of 0.63 ± 0.22°C (SD) was similar to the fall in temperature of infants placed in room temperature bags, 0.63 ± 0.30°C (SD). Limitations were related to the lack of statistical information in to confirm the conclusions made by the authors. No definition or description of the gestational ages of the infants was provided. Were they small for gestational age but gestationally more mature? The reader is unable to illicit the information from the publication.

Horn, et. al (19), tested the hypothesis that 15 min of forced-air pre-warming, combined with intraoperative warming, prevents hypothermia and shivering in patients undergoing elective cesarean delivery. They simultaneously tested the hypothesis that maintaining maternal normothermia increases newborn temperature. The sample consisted of 30 scheduled cesarean sections with computerized randomization for study groups. Infants ranged from 35.3 to 37.6 weeks gestation. Forced hot air heater was started 15 minutes before insertion of epidural catheter; OR temperature set at 24°C/ 75.2°F for both groups. The forced-air cover (Bair Hugger; Augustine Medical, Eden Prairie, MN) was positioned over the upper body of the mother 15 minutes before insertion of the epidural catheter, the warmer was set to “high” (43°C). The intraoperative ambient temperature was maintained near 24°C. As a result, babies born to mothers who were actively warmed remained a full degree
centigrade warmer than those born to unwarmed mothers. Though further evaluation of the statistical information makes the clinical importance of this difference unclear. Limitations in the study included the examination of infant temperatures as a secondary outcome and a stated statistically significant difference in both groups. The passive warming group infants’ age ranged from 35.3-37.1 weeks and the active warming group 36.3-37.6. Previous studies have suggested a positive correlation with admission temperature and gestation age, providing a possible explanation of the infant temperatures. The study did not describe birth weights, which has also been shown to correlate with admission temperatures.

Dahm and James (5) historical study in 1972 was done to evaluate if initial heat loss after delivery was due to evaporation. The infants were of gestation ages from 38-39 weeks with one being 31 weeks. The subjects were placed into five different groups. Group one was delivered and placed on a dry sheet at room temperature (m=25°C/77°F), group two same as one but dried thoroughly, group three infants were wrapped in a warm blanket with only face exposed, group four placed on a radiant heater without drying, group five was also placed on a radiant heater but was dried thoroughly. The infants ranged from vigorous at birth to depressed infants requiring resuscitation and intubation. Results reported by Dahm and James indicate drying and wrapping infant immediately after birth is just as effective as using the radiant warmer. The disadvantage is that with the infant wrapped constant observation is not possible; therefore, use of a servo-controlled radiant warmer is an effective method of reducing heat loss immediately after delivery while allowing for constant access and observation to the infant. Limiting factors in Dahm’s study were a small sample size leading to inability to achieve statistical significance. There were 10 subjects in each arm of the group and a lack of descriptive statistics to show that the groups were comparable. Another limitation was lack of logistic regression to control for multiple variables within the sample groups.
Convenience Sample Studies

Studies by Guthrie (21), Kent and Williams (23), and Almeida, et. al (24) were reviewed. A total of 353 infants were evaluated for temperatures using either the TransWarmer® mattress [19],(24), or polyethylene wrap (23) in the delivery room. Almeida, et. al. and Kent, et. al. both examined VLBW infants while Guthrie examined late preterm to term infants.

Kent and Williams (23) used both increased operating room temperatures and polyethylene wrap of cesarean section infants less than 31 weeks gestation. This was a retrospective review of three groups of infants over a five-year span from 2000-2005. The first group evaluated was from 2000-2002, this group was delivered in an OR set at 20°C/ 68°F, placed on a heated radiant warmer, dried and wrapped in blankets (total of 73 infants), group 2 data was collected after a formal educational in-service of increasing OR temperatures to prevent hypothermia. The OR temps were raised to 26–28°C (78.8-82.4°F) for deliveries <27 weeks and 25°C (77°F) for deliveries ≥28–35 weeks gestation (35 infants). A third group of data was collected after 2004 with the introduction of polyethylene wrap in addition to the increase OR temps (total of 48 infants). The statistical analysis included correlations between birth weight and admission temperature done with Pearson correlations, Kruskal-Wallis test done for differences between admission temperatures across three groups; Chi-square done for comparisons of sample groups. Results revealed that the smaller gestation infants (24-27 weeks) had the larger temperature improvement (p <0.0001) and in the larger gestation 28-31 weeks (p 0.005). There was no difference in days on ventilator, NEC, Grade 3 or 4 intraventricular hemorrhages, or survival. A limitation of the study was that the design only evaluated infants delivered by cesarean section. Forty-eight percent of the preterm infants delivered in that institution were delivered vaginally in labor rooms.
This intervention should be applicable to both groups of infants. Another limitation not described by the authors is the healthcare teams’ response to the warmed temperatures in the OR. This warm temperature in the OR may cause overheating of the staff that is dressed in sterile attire to perform their duties safely.

Two other convenience studies looked at the use of the TransWarmer® mattress. This product was originally designed for preventing heat loss during transport of infants (28). Its’ expanded use for low birth weight infants has been common practice but with limited peer reviewed publications used to evaluate its’ use.

In 1996 Guthrie (21) evaluated the use of the TransWarmer® mattress on all cesarean section infants born in a Santa Rosa, Texas hospital with gestational ages 34- 41 weeks. Assignment to the mattress was by one-month rotation, one month only standard of care with drying at delivery and the second month all c/s infants placed on mattress and then proceeded with standard drying procedures and resuscitation. According to Guthrie, 100% of infants admitted on the mattress had temperatures above 36.5°C/ 97.8°F rectal and below 37.3°C/ 99.2°F. The study had multiple limitations including lack of randomized controls, no documented temperatures, and no descriptive statistics of the groups were provided.

A published study of the TransWarmer® mattress from Almeida et. al (24) revealed that the mattress was an effective tool in reducing admission hypothermia (52.5% vs. 77.3% using a definition of hypothermia as body temperature less than 97.4°F, P < .01). It was done using a retrospective quasi-experimental design. The sample included 40 in the experimental group and 75 in the control group. Descriptive statistics revealed that the groups were not statistically similar but that the higher risk group with the use of the mattress was admitted with less hypothermia, lower mean age (26 vs. 28.5 wk, P < .001), a lower birth weight (876 vs. 1091 g, P < .004), and a higher proportion of Apgar scores of less than 5 at 5 minutes (13.2% vs. 6.4%, P< .29) compared with controls. A linear regression model adjusted for birth weight and gender.
In addition, gestational age demonstrated that the use of the heated gel mattress raised body temperatures by a mean of 0.7°F per infant (P < .001). Limitations of this study were the lack of randomized controls and a retrospective design.

When reviewing the literature there is a common trend in the use of additional heat sources used at delivery for infants less than 28 weeks gestation to assure thermo s neutral thermal environment but this was not true for those greater than 28 weeks. Standardization of how additional heat sources are used may improve admission temperatures of all premature infants, less than 35 weeks. This may assist in lowering the overall incidence of admission hypothermia in premature infants. Also, of the interventional studies reviewed none looked at long-term outcomes related to admission hypothermia as a primary outcome. A retrospective, observational study by Laptook, et. al (27) revealed no association with admission temperature and NEC, severe IVH, or duration on ventilator. These investigators did find association between admission temperature, late onset sepsis and in hospital mortality. On adjusted analyses, admission temperature was inversely related to mortality (28% increase per 1°C decrease). This trend is similar with adults, with non-induced hypothermia being associated with morbidity and an independent predictor of morbid cardiac events, that may occur as a result of unintended postoperative hypothermia(29).
PURPOSE AND SPECIFIC AIMS

This study's purpose is to reduce the incidence of hypothermia on admission of the low birth weight infant using the TransWarmer® mattress from delivery through admission to the NICU.

Specific Aims:

- To compare standardized use of the TransWarmer® mattress to general practice from initial stabilization at delivery to admission to the NICU.
- To describe the TransWarmer® mattress as a safe heat source for preterm infants <35 weeks gestation.
- To explore the use of the TransWarmer® mattress to reduce the incidence of complications associated with hypothermia in the preterm infant.
HYPOTHESIS

Standardized use of the TransWarmer® mattress will reduce the incidence of hypothermia on admission to the NICU.
SAMPLE
Infants 30 - 35 weeks gestation born at Kapiʻolani Medical Center for Women and Children, Honolulu, HI from October 2012 through October 2013 and admitted to the neonatal intensive care unit.
METHODS

Design
Prospective, experimental randomized control clinical trial.

Instruments
- Welch Allyn® SureTemp® Thermometer used to obtain all temperatures just after birth and on arrival to the neonatal intensive care unit. The thermometer has a pediatric axillary time of ten seconds to obtain temperature. Reliability test done indicates newborn data axillary temperatures ranged from 35.88° C to 37.38° C. The total number of data sets was twenty. Subjects ranged from 1 hour to 3 days old. The average error was 0.044° C with a standard deviation of 0.199° C. (30) The thermometers were calibrated quarterly for accuracy.
- TransWarmer® Infant Transport mattress, CooperSurgical, Trumbull, CT; The TransWarmer® Infant Transport mattress reaches a 40°C/104°F peak temperature (dependent on a 24°C/75°F start temperature). The TransWarmer® is made with non-toxic, food-grade materials (sodium acetate) and is PVC and latex free. 10” x 16” TransWarmer® provides warmth for up to 2 hours (depending on ambient temperature). Figure 2.
- Liquid Crystal Forehead Thermometer®, BV Medical, Barrington, IL; to monitor temperature of the mattress. They have a 15 second readout and are FDA approved. An temperature accuracy of one degree is reported by BV Medical. The thermometer was applied with adhesive to the surface of the Transwarmer® mattresses and forehead for constant monitoring of the surface temperature. Figure 3.
Procedures

Informed consent was obtained from pregnant women that were <35 weeks gestation admitted to the Kapi‘olani Medical Center for Women & Children antepartum floor. Permission to meet with the pregnant women was obtained by discussions with the primary nurse. There were several occasions that nurses recommended patients not be approached due to maternal physical or emotional distress. Women who were non-English speaking and unable to read English were excluded, due to the lack of a consent form offered in their language. Once study consent was obtained a computer based randomization program (31) was used to assign participants to each arm of the study. Infants were randomized to either a general practice group or the TransWarmer® mattress group.

In preparation for the start of the study a total of sixteen in-services were held with the nursing staff of the NICU. In-services occurred on day shift, night shift, and weekends in order to obtain the highest attendance possible. Nurses were given a 20 minute presentation including the recruitment criteria, and the procedures to follow for all infants enrolled in the study. Nursing staff from the labor and delivery and the neonatal intensive care unit received the in-service. Educational fliers about the study and an algorithm of the study were placed in the nursing staff lounges, bathrooms and on a large television screen used daily for institutional updates. An algorithm for this study is provided in Appendix A.

The resuscitation nurse in the NICU that must attend all high risk deliveries was given study note sheets that provided prompts for information that had to be gathered in the delivery room in Appendix B The note sheets included date of delivery, time of delivery, measure of maternal temperature <1 hour prior to delivery, delivery room number, and delivery room temperature. If the mattress was used, the temperature of mattress, infant temperature prior to transport and temperature of the transport incubator were measured. Upon completion of the delivery, the resuscitation nurse brought the infant and the note sheet back to the NICU. On arrival to the NICU the resuscitation nurse gave the delivery note data to the admitting nurse. The admission nurse had a second note sheet that requested the following information (Date, time of admission, weight, temperature
on admission, mattress used, mattress temperature on admission, blankets used, 15, 30, 45 minute temperatures of infant and mattress, vital signs, glucose, labs, respiratory support). Weekly updates with the nursing and medical staff were held after the study began. Identification of mothers consented for the study was done using the NICU status board and having the label "TeMP" by each room. In the mother's room at delivery the neonatal team would read the label secured to mother's chart to determine which arm of the study the infant was to be enrolled in.

Strict protocol was followed due to the nature of vulnerable subjects of high risk pregnant women and the vulnerability of the preterm infants. Research personnel all completed required CITI training (Protection of Human Subjects Course and Good Clinical Practice)(32). The study received WIRB approval and FDA notification. Families were required to sign the IRB approved consent form prior to any study procedures being performed.

The control group was titled "General Practice" and received care according to the Newborn Resuscitation Program as currently provided by the Kapiʻolani NICU Team. The current process is for the resuscitation team leader to decide whether a TransWarmer® mattress would be used or not. If the mattress is not used infants would be placed on a radiant warmer, dried with warm blankets, hat applied and then wrapped in blanket. If there was a mattress used by the team leader it would normally be covered by several blankets, the infant would be placed on the blankets, the infant would be dried and then the wet blankets removed. There would be at least one to two blankets covering the TransWarmer® mattress. The infant would then be placed on the blankets on the mattress and hat applied. Temperatures were obtained for the infants prior to placement into the incubator for transport. The NICU nurse also documented the temperature of mother that was obtained within one hour prior to delivery, temperature of the delivery room and temperature of any TransWarmer® mattresses that may have been used. The infant was then placed in heated transport incubator with a blanket covering the infant and taken to the NICU. Upon arrival to the NICU the infant would be removed from the blankets and
weighed, and the admission process would begin. Often if a TransWarmer® mattress was used upon admission to the NICU the mattress would be disposed of and the infant would be placed on the radiant warmer and the admission process begun. Am admission axillary temperature was obtained of the infant on arrival to the NICU using a Welch Allyn® SureTemp® thermometer.

The experimental group (TransWarmer® mattress) had a gel mattress activated and placed on radiant warmer at the delivery. A "Liquid Crystal Forehead Thermometer", BV Medical, Barrington, IL, was secured in the upper right quadrant of each mattress to the patient surface side and indicated the mattress surface temperature. The infant was placed directly on the soft, paper side of the mattress and dried, hat applied and routine stabilization occurred. Stabilization may have included intubation or full resuscitation. There was no blanket between the infant and the mattress surface; a blanket was then wrapped over infant when placed into incubator. The axillary temperature of infant was recorded just prior to placement into the incubator for transport, as well as the temperature of the mattress, temperature of the mother within one hour prior to delivery, and the temperature of the delivery room. Upon arrival to the NICU the infant was gently lifted in incubator and held by care provider, mattress was removed from incubator, placed on scale and weighed. Using the tare mode mattress was measured then infant was placed on mattress and weight obtained (to prevent infant from coming in contact with any cold surface). Once the infant’s weight was obtained, both the infant and mattress were placed onto radiant warmer. Admission temperatures were obtained of infant and from mattress adhesive thermometer. Any infant with a temperature greater than 37.8°C (100°F) was removed from the mattress. Infants on the mattresses had skin observation (including rotation of body to assess the posterior side that is in contact with mattress) and the axillary temperatures were assessed every 15 minutes for the first hour. Temperatures of the adhesive thermometer were also obtained. At two hours of life the heat gel mattress was removed and infant was settled on the radiant warmer. The two hours use of the mattress is the recommended of the manufacturer.
Data Collection

Data was collected from electronic medical records of both mother and baby. Data collected included:

- ethnicity
- maternal diagnosis
- date and time of rupture of membranes
- maternal diagnosis of chorioamnionitis
- maternal steroids
- delivery room or operating room number
- maternal temperature < one hour prior to delivery
- temperature of infant in delivery room
- temperature of transport incubator
- temperature of mattress in delivery room
- gestational age
- birth weight
- date of birth
- time of birth
- birth presentation
- singleton or multiple
- one minute Apgar
- 5 minute Apgar
- intubation
- surfactant administration in delivery room
- time of admission
- temperature of infant on admission
- temperature of mattress on admission
- 15 minutes temperatures
- 30 minute temperatures
- 45 minute temperatures
- blankets covering mattress
• admission diagnosis
• admission glucose
• highest documented Fi02 in first 12 hours of age
• medications administered within first 12 hours to infant
• first blood gas, death

Data safety management was controlled by placing all data in a password protected hard drive that only the investigators had access to.
STATISTICAL ANALYSIS

Statistical analysis was done using SAS 9.2 (SAS Institute, Inc., software). The initial analyses were descriptive, examining means and frequencies of the study variables. Subsequent analyses examined differences in outcome variables by the arm of the study. The statistical significance for continuous outcomes such as admission and delivery room temperature were assessed with t-tests. The statistical significance for categorical variables such as hypothermia on admission were assessed with chi-square tests, or alternatively, with Fisher’s exact tests when cell numbers were small. Final models included multiple predictor variables using multiple linear regression for continuous outcomes and logistic regression for binary outcomes.
RESULTS

Thirteen participants were eliminated from the study due to reaching a gestational age ≥35 weeks. One infant in the study was removed from the mattress on admission due to having an admission temperature >37.8°C/100°F. This infant's mother also had an elevated temperature of 38.1°C/100.5°F prior to delivery. There were no other adverse events during the study.

The control group consisted of 14 participants, while there were 26 in the intervention group. The control group's mean birth weight was 1906gm (+ 526) and the intervention group's weight was 1989 gm (+ 626) p=0.65. Gestational age was 32 weeks +1.3 for the control and 32 weeks + 0.91 for the intervention group with no statistically significant difference. Apgar scores of less than 5 at 5 minutes were not significantly different (p=0.35) and type of birth was also not significant. Maternal temperature prior to delivery was not statistically significant in the two groups (p=0.3). This value was evaluated due to the possible association of maternal temperature prior to delivery on infant temperature on admission.(33) A description of the study groups can be found in Table 1. There were no participants with major congenital anomalies.

Design of the study allowed neonatal resuscitation team leaders to determine the course of treatment in the control group. This meant they did not have to use a heated gel mattress if this was not their usual practice. Evaluation of the two groups revealed a significant difference in the use of the mattress between the two groups. It was found that often in the control group a heated gel mattress was not common practice for infants greater than 32 weeks gestation, therefore causing the control group to have a smaller number of mattresses used.

Comparison of the control and experimental groups revealed that infants in the experimental group had higher admission temperatures by 0.73°C (1.0°F) compared to controls, See Table 2. There was statistical significance of p=0.005 using a t-test. These results exceed a previous study done by Almeida, et. al., where there was an increase in the temperature of experimental group compared to the control by 0.39°C (0.7°F). Examination of other co-morbidities was
explored. Linear regression was used to describe co-morbidities that might be associated with hypothermia on admission.

The study attempted to examine a relationship between hypothermia and hypoglycemia, need for respiratory support and hypotension. Results indicated that hypoglycemia was an associated finding when controlled for hypothermia on admission, with a p value of 0.06, See Table 3. Other comorbidities such as need for respiratory support (nasal cpap, nasal cannula, ventilator, bipap) or hypotension (documented by the administration of boluses or an inotropic agent within the first twelve hours of life) were assessed. There was no association of hypothermia with respiratory support or hypotension. There was a negative correlation with length of stay and gestational age, similar to the study done by Laptook, et. al (27). Use of logistic regression revealed no difference in the length of stay adjusting for hypothermia and then for arm of the study. The mean length of stay was 19 days for the two groups (p=0.27). Lastly, there was an attempt to evaluate for a relationship between maternal temperature prior to delivery and delivery room temperature prior to delivery with admission temperature. Due to small sample size and missing data points this analysis could not be done at this time. The current plan is to continue this evaluation when a larger sample is obtained that would provide scientific significance.
DISCUSSION

One reason proposed for the persistence of hypothermia is that the definition of low birth weight infants has continued to change as smaller infants are resuscitated. As the science of neonatology has evolved over the past forty years the weights of low birth weight infants has decreased three fold from an average of 1500 grams to approximately 500 grams currently. Despite this change in size, the equipment and procedures we use in the delivery of these infants has only changed in small proportions. Radiant heat has been the cornerstone of thermal resuscitation of the low birth weight infant. (5) This device proved effective when used with term infants, but without additional equipment, preventing hypothermia of admission temperatures of preterm infants remains a constant problem. The studies of additional devices used in conjunction with the radiant warmer have shown the ability to improve VLBW infant temperatures (16, 18, 22, 24).

Several trends appeared in the review of the previous research. Throughout the studies maternal temperature at the time of delivery, delivery room temperatures and infants from 29-35 weeks gestation were deficient. As noted previously, the mother’s temperature prior to delivery would have a direct effect on the temperature of the infant at birth (19). An infant may be born hyperthermic and eventually cool to a normothermic range. Lack of documentation of the temperature of the delivery room is an important variable not described in the majority of the studies. As described by Kent (23), increasing the temperature of the room was associated with an increase in newborn temperatures on admission. Therefore, knowing the temperature in the delivery room becomes an important variable for evaluation in future research. Lastly, there is lack of scientific evidence in the improvement of admission temperatures of preterm infants greater than 28 weeks (34).

Eleven of the 14 participants in the general practice group (control) did not have a mattress used. This may reveal a belief with within the resuscitation team that the mattress was not necessary for this particular gestational age group during the resuscitation process. This study shows that the group of
gestational age infants from 30 through 35 weeks gestation can and should benefit from the use of the TransWarmer® mattress to protect them from hypothermia on admission to the NICU.
LIMITATIONS

In the development phase of the protocol a power analysis was done to obtain a 25% reduction in hypothermia, it revealed the need for a sample size of 335 based on the results from a previous study done by Almeida, et. al. This large sample was established to describe and evaluate a safe standardized use of the TransWarmer® mattress to prevent hypothermia of premature infants from 23 through 35 weeks gestation. Due to financial and time constraints initial data obtained was evaluated after twelve months. During the initial statistical analysis it was found that statistical significance in the reduction of hypothermia had been obtained for infants from 30-35 weeks gestation. The current plan and IRB approval is to continue the study to obtain larger sample size to evaluate the safe standardized use of the TransWarmer® mattress with all preterm infant less than 35 weeks.

There appeared to be bias by the healthcare teams regarding when use of the TransWarmer® mattress was needed, which in turn, was associated with the number of infants in the control group that did receive a mattress. Also, due to the low number of participants compared to the number of admissions, nurses often did not remember the study protocol causing missing data points. Lastly, use of the heat gel mattress is not routinely documented in the electronic chart making it difficult to find use of the mattress for a delivery, this required interviews with the staff that participated in the delivery to confirm if a mattress was used during resuscitation.
RECOMMENDATIONS FOR FUTURE RESEARCH

A review of the studies evaluating the Transwarmer® mattress, specific instructions for safe use with premature infants have not previously been described. Description of mattress use protocol is warranted to provide the evidence that the mattresses will not cause harm when the extremely low birth weight infant is placed directly onto the mattress. Data collection throughout the next year will continue to provide the sample size needed to evaluate the safety of the mattress. Renewed IRB approval has been received and is valid through October 2014. Other research to be done would include the use of previously used plastic wraps in conjunction with the heated gel mattresses. This combination would address all the mechanisms of heat transfer that could be protected with the use of the additional products at delivery. Standardized descriptive studies to guide healthcare teams in the use of these products would prove helpful to dispel concerns of safety for this vulnerable population. With the use of these additional products, cost analysis should also be evaluated to define the cost effectiveness of implementing these procedures and products.

As rising healthcare costs continue further evaluation regarding admission hypothermia and its association with long term morbidities needs to be further evaluated. Admission hypothermia has been previously associated with late onset sepsis and with hospital morbidity.
CONCLUSION

Standardized use of the TransWarmer® Mattress at delivery and through transfer to the neonatal intensive care unit reduced the incidence of hypothermia on admission of low birth weight infants between 30-35 weeks gestation.
### TABLE 1. DETAILS OF PARTICIPANTS

<table>
<thead>
<tr>
<th>Details of Participants</th>
<th>TransWarmer Mattress</th>
<th>Control (General Practice)</th>
<th>P = &lt;0.05</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of infants</td>
<td>26</td>
<td>14</td>
<td></td>
</tr>
<tr>
<td>Birth weight</td>
<td>1906 ± 526</td>
<td>1989 ± 626</td>
<td>0.65</td>
</tr>
<tr>
<td>Gestational age (weeks)</td>
<td>32 ± 1.3</td>
<td>32 ± 0.91</td>
<td>0.49</td>
</tr>
<tr>
<td>Apgar score &lt;5 at 5 min. (%)</td>
<td>0 (0%)</td>
<td>1 (7%)</td>
<td>0.35</td>
</tr>
<tr>
<td>Vaginal birth</td>
<td>13 (50%)</td>
<td>13 (57%)</td>
<td>0.66</td>
</tr>
<tr>
<td>Maternal temp</td>
<td>36.8 ± 0.35°C</td>
<td>36.6 ± 0.12</td>
<td>0.3</td>
</tr>
</tbody>
</table>
### TABLE 2. ADMISSION TEMPERATURES

<table>
<thead>
<tr>
<th></th>
<th>Admission Temperature</th>
<th>N</th>
<th>Mean</th>
<th>Std Dev</th>
<th>Std Err</th>
<th>Minimum</th>
<th>Maximum</th>
</tr>
</thead>
<tbody>
<tr>
<td>TransWarmer Mattress</td>
<td></td>
<td>26</td>
<td>36.6</td>
<td>0.6600</td>
<td>0.1294</td>
<td>35.1</td>
<td>38.5</td>
</tr>
<tr>
<td>Control</td>
<td></td>
<td>14</td>
<td>35.9</td>
<td>0.8934</td>
<td>0.2388</td>
<td>34.2</td>
<td>36.9</td>
</tr>
<tr>
<td>Diff (1-2)</td>
<td></td>
<td></td>
<td>0.7295</td>
<td>0.7481</td>
<td>0.2480</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hypothermia on Admission (&lt;36.5°C)</td>
<td>Fisher’s Exact</td>
<td>P</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>-----------------------------------</td>
<td>---------------</td>
<td>-------</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>N</td>
<td>N%</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>hypoglycemia</td>
<td>5, 71.4%</td>
<td>0.06</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Respiratory support</td>
<td>4, 28.5%</td>
<td>NS=0.29</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hypotension</td>
<td>0</td>
<td>-</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
**TABLE 4. Length of Stay**

<table>
<thead>
<tr>
<th></th>
<th>LOS (length of Stay)</th>
<th>Mattress</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control</td>
<td>N = 13</td>
<td>N = 25</td>
<td></td>
</tr>
<tr>
<td>Days in NICU</td>
<td>19 ± 13.0</td>
<td>19 ± 8.9</td>
<td>p = 0.27</td>
</tr>
</tbody>
</table>
APPENDIX A

TeMP Study

1. Activate mattress, if plan on drying baby place one blanket on mattress for drying.
2. Once infant dried remove blanket and place infant in direct contact with paper side of mattress. Proceed with resus.
3. Obtain temps. of baby, mom, room and transport bed before leaving.
4. Wrap a blanket around baby and mattress for transport.

General Practice (GP)

1. Perform routine practice that may include using a mattress or not and you may use the mattress however you like (with blankets on top)
2. Obtain temps. of baby, mom, room, and transport bed before leaving.
3. Please note on cheat sheet how many blankets used, etc.

Mattress Group (Matt)

1. Upon admission to the NICU infant does not go on scale but infant is lifted while someone else places mattress on scale. Scale zeroed and then infant placed on mattress for weight.
2. Infant then placed on warmer ON Mattress during the next two hours. After the two hours are up mattress to be removed and discarded.

What about babies not in study?... You may use or not use a mattress but do not use TeMP mattresses that have the pink seal on them.

Place cheat sheets in TeMP box at front desk and sign your names so you may be entered in the raffle.
APPENDIX B

DR/OR Sheet

TeMP Study DATA
Patient Name:
TIME: DATE:
LDR / OR # __________
Room temp:________
Mom temp._______ (< 1 hour prior to delivery)
Baby temp:_______ mattress = Y / N
Mattress temp_______ (before placed in isolette)
blankets covering mattress = Y / N

NICU Admission Sheet

NSCU ADMISSION DATA
DATE:___________ TIME:______________
(place pt. sticker on back of form)
WEIGHT: _______lb(s)_______oz
TEMP:________ mattress = Y / N mattress temp
blankets covering mattress = Y / N
15min. temp._______ mattress temp_______
30min. temp_______ mattress temp_______
45min. temp_______ mattress temp_______

HR:
RR:
SPO2:
BP: / ( ) L LEG R LEG L ARM R ARM
HC:
ABD:
LENGTH:
PCX:
LABS:
XRAY:
IV: RATE:
VIT K:
RA HF CPAP SIPAP INTUBAT
FIGURE 1.
ADMISSION TEMPERATURES
MATTRESS VS. CONTROL

Admission Temperature (Celsius)

Mattress  Control
FIGURE 2.

Infant Warming Mattress

TransWarmer®
Only nature builds a better nest

Features & Benefits
Minimizes the risk of cold stress

- Patented Warming® mattress
  - Nests infant, absorbing vibration during transport
- Consistent, uniform heat distribution
  - Prevents the complications of cold stress
- Heats in less than 60 seconds
  - Provides rapid thermal support
- Easy to activate
  - Simple, no inner bag to rupture

Transwarmer: It’s not just for transport anymore

Neonatal Products

@opersurgical
Keeping you at the forefront of women’s health care
FIGURE 3.

Liquid Crystal
Forehead
Thermometer
REFERENCES


