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The Effect of Warmed Humidified Oxygen on the Temperature of Depressed Newborns

Earlene Scharping

Abstract

THE EFFECT OF WARMED HUMIDIFIED OXYGEN ON THE TEMPERATURE OF DEPRESSED NEWBORNS

By Earlene Scharping

The purpose of this study was to evaluate the effect of warmed humidified oxygen on the body temperature of depressed newborns and compare it to the effect of unwarmed unhumidified oxygen administered under similar circumstances. The sample group consisted of a total of ten infants (five control and five experimental) with birth weights > 2000 gms who had an Apgar score of less than seven at birth and who required the administration of oxygen. The control group received oxygen in the routine delivery room manner (unwarmed and unhumidified). The experimental group received oxygen which had been warmed to a temperature of 32-34°C and humidified to a level of 80-100 per cent relative humidity. The data were analyzed using an analysis of covariance and partial correlation. The results of the study revealed no statistical ($p = <0.05$) difference in the body temperature of infants in the experimental group as compared to infants in the control group immediately following resuscitation. One factor which appeared to contribute to those results was the fact that the "unwarmed" oxygen administered to the control group was in fact warmed by using the oxygen resuscitation equipment under a radiant warmer. It was concluded that the use of a radiant warmer in the care of depressed newborns in the delivery room may provide adequate warming of the oxygen.

LOMA LINDA UNIVERSITY

Graduate School

THE EFFECT OF WARMED HUMIDIFIED OXYGEN ON THE TEMPERATURE OF DEPRESSED NEWBORNS

by

Earlene Scharping

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Each person whose signature appears below certifies that this thesis in his/her opinion is adequate, in scope and quality, as a thesis for the degree Master of Science.

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TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

Chapter 1

THE PROBLEM

The fact that the administration of unwarmed unhumidified oxygen to the newborn infant may contribute to hypothermia is significant in that hypothermia of the newborn is associated with an increased incidence of serious complications. Yet, the use of unwarmed, unhumidified oxygen continues to be an accepted standard of practice in the delivery rooms of many hospitals. Because of the possibility that even the brief use of an unwarmed unhumidified gas might result in hypothermia of the newborn infant this study was undertaken to examine the effects of warmed, humidified oxygen on the body temperature of depressed newborn infants.

BACKGROUND AND NEED

During the past two decades there has been a significant amount of literature which has contributed to our understanding of temperature regulation in the newborn infant. In spite of the knowledge gained from the literature, however, the principles underlying thermal regulation of the newborn have at times been unknowingly violated, with the result that newborns are unintentionally subjected to thermal insult.

In the process of conducting courses on neonatal nursing care it was brought to the attention of the investigator that one such possible violation of the principles of thermoregulation occurs in the delivery room. Although considerable emphasis is placed on the importance of warming and humidifying oxygen before its administration to sick newborns,

unwarmed unhumidified oxygen is routinely administered to depressed newborns in the delivery room at the University of California Irvine Medical Center. Investigation revealed that it is a common practice, and unwarmed unhumidified oxygen is administered to newborns in the delivery rooms of many perinatal centers and community hospitals (Cha, 1977; Huxtable, 1977).

The temperature of the fetus has been found to be approximately 0.5°C higher than that of the mother, or about 37.6°C (Adamson and Towell, 1965, p. 536). However, the temperature has been noted to drop readily when birth occurs under certain delivery room circumstances. Miller and Oliver (1966, p. 965) stated that the temperature of the newborn infants in their study dropped three degrees centigrade within the first 45 minutes of postnatal life. Gandy and others (1964, p. 751) found the average drop in skin temperature of the newborn to be nearly four degrees centigrade within the first 15 minutes after birth, and Stern (1968) has stated that skin temperature of newborns under normal delivery room conditions falls at the rate of 0.3°C per minute. Tahti and others (1972, p. 161) demonstrated in normal term infants that the first breath was accompanied by an instantaneous drop in skin temperature of the area on the anterior thoracic cage. Thus, it was felt that even infants greater than 2000gm may be at risk for cold stress under certain delivery room conditions, as well as preterm or low birth weight infants.

Thermoregulation is an important area for consideration because hypothermia in the newborn infant produces undesirable effects. One of those effects is an increase in oxygen needs. Oxygen consumption for a

normal term infant has been found to be less than 6ml/kg/minute, but that amount is increased significantly for the infant who is cold stressed. Stern and others (1965, p. 369) found that oxygen consumption increased an average of 48 per cent in infants exposed to reduced environmental temperatures. Hey (1969, p. 589) substantiated those findings and concluded that " . . . the newborn baby responds to a cool environment with considerable immediate increase in heat production . . ." which results in increased oxygen needs.

Brück (1961, p. 111) laid the groundwork for understanding the effect of the compensatory thermal mechanism on oxygen consumption with his study which revealed that at birth the full term infant was able to increase his metabolic rate by 100 per cent in response to cold stress. Other investigators have confirmed this and have noted that this increase was not correlated to physical movement but rather was the result of chemical thermogenesis (Silverman and Sinclair, 1966, p. 92; Stern and others, 1965, p. 367; Hey, 1969, p. 589).

The problem of hypothermia is compounded for infants who are depressed at birth, for hypoxia is already significant and to increase oxygen needs by allowing hypothermia intensifies the problem. To administer unwarmed and unhumidified oxygen is to add a further stress factor for an infant already at risk. Stern (1968, p. 20) has stated that "the administration of cold, unhumidified oxygen . . . may be an important and often unrecognized source of cold stress to the infant." Mestyán and others (1964, p. 253) have demonstrated that a cold stimulus to the face will increase oxygen consumption even though the body

temperature remains normal. Other investigators (Rashad and Benson, 1967, p. 716) have demonstrated the value of administering humidified gas to the infant as a means of increasing body temperature.

It therefore seemed reasonable that the use of warmed, humidified oxygen in the resuscitation of depressed newborns would decrease the incidence of hypothermia which is associated with an increase of oxygen consumption. Increasing oxygen needs places the infant at risk for acidosis, hypoglycemia, and hyperbilirubinemia (Stern, 1968), as well as coagulation defects (Chad and Gray, 1972, p. 821). It is, therefore, generally accepted that hypothermia should be avoided whenever possible.

PROBLEM STATEMENT

The prevailing medical opinion seems to be that since oxygen is given for such a brief period of time in the delivery room that the effects of administering unwarmed unhumidified oxygen to the depressed newborn are inconsequential. The literature, however, indicated that this may not be so, and the administration of an unwarmed unhumidified gas may be subjecting the newborns to cold stress unnecessarily. The bulk of current literature on thermoregulation of the newborn deals with the low birth weight infant; therefore, it was concluded that investigation was indicated for the effects of warmed humidified oxygen on the body temperature of depressed newborns in the delivery room who weighed 2000gm or more.

PURPOSE

This study was undertaken to explore the possibility that warming and humidifying oxygen given in the delivery room might affect the temperature of the infant who is depressed at birth and requires resuscitation.

Whereas maintaining the temperature of a newborn at the point of thermal neutrality (where the least amount of oxygen is consumed) is a nursing responsibility (Williams and Lancaster, 1976, p. 355; Nalepkia, 1976, p. 17), this study was undertaken to identify a possible method of nursing intervention which would decrease the potential for hypothermia in depressed newborns.

HYPOTHESIS

The hypothesis was a directional hypothesis which stated that warm, humidified oxygen given to depressed newborns who weigh >2000gms would result in significantly ($p = <0.05$) less hypothermia of the resuscitated infant, as compared to oxygen which had not been warmed or humidified.

DEFINITION OF TERMS

For the purpose of this study a "depressed newborn" was a newborn with a one-minute Apgar score of six or less who weighed 2000 gm or greater. Other terms as used throughout this study are as follows.

Warmed Oxygen

Oxygen at 32-34°C at the face.

Humidified Oxygen

Oxygen with a relative humidity of 80-100 per cent.

Hypothermia

Rectal temperature less than 37°C.

Thermal Neutral Environment

Ambient temperature of 32-34°C.

Thermal Neutrality

The body temperature at which oxygen consumption is minimum.

ASSUMPTIONS

The hypothesis is based on the assumption that violation of the principles of thermoregulation when providing care to the depressed newborn was important regardless of the time period involved. It was further assumed that strict adherence to a method of care which follows those principles is necessary at all times. It was also assumed that oxygen is a medication and, therefore, must be administered in the correct manner to minimize side effects which are a potential result of its use.

APPLICATION AND LIMITATION

It was expected that results of the study would have application in terms of warming and humidifying oxygen administered to all newborns

in the delivery room. However, experience has shown that not all oxygen warmers are equally successful in providing warmed, humidified oxygen; and so application of these results are contingent upon use of equipment designed to deliver oxygen at 32-34°C and 80-100 per cent humidified at the level of the face.

It should be noted that the degree of expected hypothermia was related to several factors. These factors included the size of the infant, the length of oxygen administration time, whether or not the infant was dried immediately, use of the radiant warmer, and cross currents in the delivery room. These variables must be controlled; therefore, study results are applicable to infants greater than 2000gm who receive oxygen for a period not to exceed nine minutes. The infants must be dried immediately and placed under a radiant warmer. Delivery room temperature should be in the range of 23-25°C.

THEORETICAL DEVELOPMENT

The review of the literature indicates that infants who receive unwarmed, unhumidified oxygen in the delivery room are at increased risk for hypothermia because, (1) unhumidified gases remove moisture from the tracheobronchial tree causing heat loss by evaporation (Brück, 1962, p. 880); (2) the administration of an unwarmed gas to the trigeminal region of the face produces increased oxygen consumption regardless of the ambient temperature (Přiblová, 1968, p. 13; Mestyán and others, 1964, p. 250); (3) the administration of unwarmed unhumidified gases causes an increased caloric expenditure for the newborn infant (Stern and others,

1965, p. 369). This study attempted to show that the administration of warmed humidified oxygen to the depressed newborn in the delivery room would decrease the incidence of hypothermia.

Chapter 2

REVIEW OF RELATED LITERATURE

Williams and Lancaster (1976, p. 355) have stated that "a growing number of babies continue to be subjected to 'cold stress' by their caretakers. This may be due in part to a lack of understanding of the basic principles of thermoregulation or a failure to apply these principles maximally in neonatal care." Thus, it seems appropriate to begin the review of the literature with a review of the basic principles of thermoregulation, to be followed by a discussion of complications of hypothermia, the effects of warmed oxygen, and the effects of humidified oxygen.

PRINCIPLES OF THERMOREGULATION

The human fetus in utero has a temperature approximately 0.5°C higher than its environment as created by the maternal organs (Adamsons and Towell, 1965, p. 546; Silverman and Sinclair, 1966, p. 92). When delivered the fetus has a mean temperature of 37.65°C according to some authors (Adamson and Towell, 1965, p. 536) and 37.0-37.8°C according to (Williams and Lancaster, 1976, p. 358). However, under certain delivery room conditions the temperature quickly drops. Temperature drop has been noted even in the presence of environmental temperatures of 35-36°C (Scopes and Amed, 1966, p. 418), and Evans (1974, p. 204) found that in a delivery room of 21-24°C (70-76°F) the skin temperature of the newborn infant dropped to 35°C within 2-4 minutes after delivery. McClure and Caton (1955, p. 583) found that the newborn's temperature dropped 1-3°C

during the first 45 minutes postpartum. Hill and Rahimtulla (1965, p. 247) demonstrated that the body temperature of term infants under "normal" conditions falls 1-3°C immediately after birth. Adamson (1966, p. 605) has stated that the skin temperature drops at the rate of 0.3°C/minute while core temperature drops at a rate of 0.1°C/minute.

It is thought that the sudden drop in temperature contributes to initiation of the first extrauterine breath which the newborn takes, but it may also have less desirable effects. As a basis for understanding the undesirable effects of cold stress, it is necessary to understand the physiologic response of the newborn infant to a cold environment. At one time it was considered that the newborn was poikilothermic and its body temperature was dictated by the environment, as is true of some reptiles. However, a study (Brück, 1961, p. 65) revealed that the newborn demonstrated constriction of peripheral blood vessels in response to cold, and that when challenged by cold could increase the rate of heat production. There appeared to be no relationship between heat production and physical activity. Therefore, Brück proposed that nonmuscular (or chemical) thermogenesis was responsible for the increase in temperature. Since that time, this has been substantiated by other investigators and the newborn infant is now known to be an imperfect homeotherm (Hill and Rahimtulla, 1965, p. 246).

Stern (1968, p. 8) has stated that the newborn infant responds to cold with increased oxygen consumption and metabolic activity. Hill and Rahimtulla (1965, p. 243) found oxygen consumption to be increased when the environmental temperature was less than 32°C. Hey (1969, p. 589)

found the increase to occur in temperaturess less than 33°C. He stated that O_2 consumption was less than 6ml/kg/min in the first 12 hours of life, but that this increased by a mean of 0.56ml/kg for each 1°C fall of environmental temperature. He further noted that this response was linear and inversely related to the environmental temperature in the range of 28-33°C. However, this increase in heat production was insufficient to keep the infant's temperature from falling. Adamson and other (1965, p. 495) found that oxygen consumption in the normal term infant was a function of the difference in temperature of the skin and the environment. When that temperature gradient was less than 1.5°C, oxygen consumption was minimal if the infant was in a neutral thermal environment. In 1965 Stern and others (p. 367) noted that "the existence of an environmental neutral zone for newborn infants is now well recognized." They went on to define that neutral zone as the environmental temperature at which metabolism (as reflected by oxygen consumption) is minimal and sufficient to maintain body temperature. They quoted the range for adults as 25-30°C and for newborns as 32-34°C (p. 367). Their study showed that oxygen consumption was increased by 48 per cent, or an average of 3.6ml/kg/min, for infants in a cool environment, and in each instance there was a significant increase in noradrenalin excretion. They, therefore, contended that the major thermogenic agent in the newborn infant was norepinephrine. Epinephrine was also found to contribute but not as significantly. The reverse is true in the adult.

Stern (1968, p. 8) described the action of norepinephrine as an activator of adipose tissue lipase which triggers the metabolism of brown fat. The metabolism of brown adipose tissue has been proven to be the

basis of heat production in the newborn infant (Aherne and Hull, 1966, p. 223). Rylander (1972, p. 597) demonstrated comparatively high skin temperatures at the nape and interscapular region (the areas of brown fat disposition) during cold exposure. This occurred as the result of cold stimulated metabolism of subcutaneous brown adipose tissue. Brown fat is initially deposited around 26-30 weeks gestation and continues until 3-5 weeks postnatal (Sinclair, 1970, p. 154). Brown fat constitutes 2-6 per cent of the infant's total body weight at birth, but atrophies after about three months of age (Doniech, 1975, pp. 160-161). More recently Doniach has indicated that the thyroid stimulating hormone as well as norepinephrine may also be an important factor in the regulation of brown fat.

COMPLICATIONS OF HYPOTHERMIA

When cold stress is greater than can be compensated, hypothermia ensues. Hypothermia has been associated with various complications in the newborn. Brunberg and others (1974, pp. 60-68) have stated that with deep hypothermia cerebral metabolism is altered and neurological defects may result. Chad and Gray (1972, p. 821) found a "marked deleterious effect" of cold on the coagulation status of the newborn. Dole (1957, p. 50) noted that hypoglycemia associated with hypothermia was the result of elevation of nonesterfied fatty acids which was accompanied by a fall in blood glucose. Thus, neurologic deficit, coagulation defects and hypoglycemia have all been associated with hypothermia of the newborn infant.

Depressed newborns develop a pronounced metabolic acidosis when in a cold environment (Gandy and others, 1964, p. 757). In 1968 Stern (p. 16) indicated that increased oxygen needs may be the final precipitating event in the onset of respiratory failure, and the role of acidosis as a precipitating factor in Respiratory Distress Syndrome (RDS) is now well accepted (Williams and Lancaster, 1976, p. 357). Acidosis has also been demonstrated to interfere with the capacity of albumin to bind bilirubin and thus increases the affinity of the brain mitochondria for it (Odell, 1959, p. 268). Therefore, hypothermia with subsequent acidosis places the infant at risk for hyperbilirubinemia and knericterus.

In view of the deleterious effects of hypothermia of the newborn infant, the goal of nursing care should be prevention rather than "remedy finding" (Williams and Lancaster, 1976, p. 358). Sinclair (1970, p. 155) has stated that "with special measures to reduce heat loss certain biochemical improvements may be expected." Miller and Oliver (1966, p. 967) declared that if there is to be prevention of a large fall in body temperature after birth the environment must be modified.

EFFECTS OF WARMED OXYGEN

The use of radiant warmers in the delivery room has aided in the prevention of heat loss (Motil and others, 1975, p. 546); however, hypothermia remains a potential problem for depressed newborns. Asphyxia has been noted to cause lower newborn temperatures and hypothermia was thought to be ". . . a natural consequence of anoxia in the baby" (Burnard and Cross, 1958, p. 1199). One wonders how much hypothermia could be avoided by warming the oxygen administered to the asphyxiated infant.

Přiblová (1968, p. 13) has stated that in ". . . the human being, metabolic changes may be provoked by changes of the facial skin temperature." He found that the inhalation of cold air increased oxygen consumption even though the environmental temperature remained constant. Mestyán and others (1964, pp. 250-253) found the facial skin of the human neonate to be an important thermoreceptive region in eliciting thermoregulatory responses and noted that cooling of the face alone could induce an increase in oxygen consumption. Stern (1968, p. 20) has stated that "even if the thermal environment is otherwise adequate, the application of a cold stimulant to the forehead and trigeminal area of the face will trigger the obligatory increase in oxygen consumption." He further states that cold unhumidified oxygen may be an important but unrecognized source of cold stress to the infant.

There have been numerous animal and human adult studies regarding the beneficial effect of the inhalation of warmed gas in rewarming hypothermic adults (Hayward and Steinman, 1975, p. 1236; Lloyd, 1973, p. 41; Wessel and other, 1966, p. 1403). This effect has been shown to be the result of the heat transfer ability of the upper respiratory tract, for the temperature of the upper respiratory mucosa is affected by heat transfer via turbulent convection and evaporation (Beran and others, 1975, p. 340). It therefore appears that the administration of warmed oxygen should make an important contribution to the preservation of thermal homeostasis in the depressed newborn.

EFFECTS OE HUMIDIFIED OXYGEN

In addition to warming inhaled gases there is considerable evidence in the literature to support the concept of humidification as an equally important method of conditioning gases prior to administration (Shanks and Sara, 1972, p. 1351). Boys and Howell (1972, p. 881) have stated that humidification of gases prior to administration prevents tracheal inflammation, ciliary paralysis and micro atelectasis. It is also useful in decreasing evaporative heat loss from the lung. There has been demonstrated to be 350 Kcal of heat loss in the expired air of the adult male in a single day (Walker and Wells, 1961, p. 259). Rashad and Benson (1967, p. 713) found that for every gram of water vaporized in expiration, 580 calories must be supplied by the infant. Therefore, infants have a three-fold increase in caloric needs in order to warm and humidify gases which have not been warmed or humidified prior to administration (Rashad and Benson, 1967, p. 716). Silverman and Blanc (1957, p. 481) demonstrated that even though the environmental temperature remained constant there was a difference in body temperature of infants cared for in a relative humidity of 80-90 per cent versus a relative humidity of 30-60 per cent. The effects of humidification are related to the concept that evaporative heat loss occurs in the upper respiratory tract and at the alveolar capillary interface (Wessel and others, 1966, p. 1403). It therefore appears that humidification of gases prior to administration is important in promoting thermoregulation of the newborn infant.

Chapter 3

METHODOLOGY

This was an experimental study of the effects of warmed, humidified oxygen on the body temperature of depressed newborns. It was conducted in the delivery rooms of the University of California Irvine Medical Center (UCIMC). UCIMC (formerly Orange County Medical Center) is a 493-bed teaching hospital located in central Orange County, California. It serves a high risk obstetrical population and, at the time of the study, averaged 260 deliveries per month. Each newborn infant delivered at UCIMC during the data collection period was a potential candidate for the study. The actual sample consisted of those infants born during that period who met the criteria for the study whose birth occurred when the investigator was present.

CRITERIA FOR SELECTION

The criteria for selection were as follows:

1. The subject was considered depressed on the basis of an Apgar score of less than seven at one minute after delivery.
2. The subject's birthweight was 2000gm or greater.
3. The subject was free from major congenital anomalies.
4. The subject received oxygen.

"Major congenital anomalies" for the purpose of this study included anomalies which involved an abnormal heat loss or abnormal temperature control. Therefore, infants presenting with gastroschesis,

omphalocele, myelomeningocele, hydrocephalus, or anancephalus were omitted from the study. The criteria for selection was based on the definition of a depressed newborn as any infant with an Apgar score less than 7 (Apgar, 1962, p. 421). This included moderately depressed infants with a score between four and six and severely depressed infants with a score of 0-3. These infants were chosen for the study because according to the UCIMC protocol for resuscitation (see Appendix A) these infants would be likely to receive oxygen. The newborn infant's response to cold varies if birth weight is less than 2-2.5kg (Scopes and Ahmed, 1966, p. 419; Hey and Katz, 1970, p. 671). Therefore, only infants whose birth weight was estimated to be greater than 2000gm were included in the study. Birth weight was verified after the infant was weighed and data for infants whose actual weight was found to be less than 2000gm were excluded from the study. Randomization of subjects was achieved in the following manner: each potential subject was assigned a numeral from 1 to 40 by using a table of random digits (Runyon and Haber, 1972, p. 319). Row 0044 was arbitrarily selected and 40 numerals were assigned to the 40 potential subjects. The numerals of 1 to 20 were then assigned to the control group and the numerals of 21 to 40 to the experimental group.

CONTROL GROUP

Immediately following delivery and after the cord was cut, infants were placed under a radiant warmer by the delivering physician. Temperature of the warmer was manually preset to maintain maximum heat

output. The infants were dried, evaluated, and assigned a one-minute Apgar score by the physician. Resuscitation measures were initiated by the staff as per the UCIMC protocol for resuscitation (Appendix A). Oxygen used for resuscitation was, as is customary, unwarmed and unhumidified. Oxygen temperature was monitored and recorded before and after resusctiation (see Appendix B, Data Collection Instructions). While resuscitation was performed by the delivery room staff, a surface temperature thermistor (YSI series 409) was attached to the anterior abdominal wall of the infant and a general purpose thermistor (YSI series 401) was inserted 2-2.5 cm into the infant's rectum and taped in place by the investigator. The abdominal thermistor was protected from the heat of the overhead radiant warmer by a foil-shielded foam pad to assure accurate recording. The thermistors were attached to a Yellow Springs telethermometer and the temperatures recorded by the investigator. The Yellow Springs instrument was selected because of its reputation for dependability and accuracy in the field of scientific investigation (Stern and other, 1965, p. 367; Miller and Oliver, 1966, p. 965; Dahm and James, 1972, p. 508).

When in the opinion of the physician infants were considered stable and ready for transfer they were transferred via a warmed transport incubator to the designated area (term nursery or neonatal intensive care unit, depending on the infant's condition). Just prior to transfer final temperatures (skin and rectal) were noted and recorded. Thermistors were then removed by the investigator. Other data recorded included Apgar scores, gestational age, sex, race, delivery room

temperature, oxygen temperature, and oxygen administration time. Note was also made regarding open versus closed delivery room doors, bagging, intubation, blanket change and total time in the delivery room (see Appendix C, Data Collection Sheet).

EXPERIMENTAL GROUP

The experimental group was handled in exactly the same manner as the control group except that oxygen used for resuscitation was warmed and humidified via an Aqua Therm cartridge humidifier. The temperature control knob of the warmer was set at 3.0-3.25 and the mean oxygen temperature was 34.2°C at the point of inhalation. The humidity of the inspired oxygen varied from 80-100 per cent relative humidity.

When, in the opinion of the physician, infants were considered stable and ready for transfer they were transferred via a warmed transport incubator to the designated area (term nursery or neonatal intensive care unit, depending on the infant's condition). Just prior to transfer final temperatures (skin and rectal) were noted and recorded. Thermistors were then removed by the investigator. Other data recorded included Apgar scores, gestational age, sex, race, delivery room temperature, oxygen temperature, and oxygen administration time. Note was also made regarding open versus closed delivery room doors, bagging, intubation, blanket change and total time in the delivery room. Oxygen humidity was not measured in the delivery room as it was not feasible to do so and laboratory trials assured the investigator of the dependability of the equipment to routinely deliver oxygen humidified at 80-100 per cent.

Informed consent was not requested from the parents of infants participating in this study. It was agreed by the Loma Linda University School of Nursing Ethics in Nursing Research Committee and the Human Subjects Committee of UCIMC that in view of the non-invasive and routine nature of the treatment of the experimental group, the accepted method of warming and humidifying the oxygen and the potential maternal emotional trauma associated with asking each mother admitted for delivery for consent in the event her infant was depressed negated the need for informed consent.

VARIABLES

The dependent variable of this study was the rectal temperature of the infant immediately following resuscitation. The independent variable was the temperature and humidity of the oxygen administered to the infant. Other factors not controlled which could affect the results were (1) the initial temperature of the infant, (2) the one-minute Apgar score, (3) the gestational age of the infant, (4) the environmental temperature of the delivery room, and (5) the length of time required for administration of the oxygen. These factors therefore were considered as co-variants and data analysis was conducted accordingly.

DATA ANALYSIS

The hypothesis stated that warmed humidified oxygen administered to depressed newborns who weigh more than 2000gm would result in significantly ($p = <0.05$) less hypothermia of the resuscitated infant, as

compared to oxygen which had not been warmed or humidified. To determine if support was established for the hypothesis the data was analyzed as follows. Data from the design variables (i.e., group, sex and race) were compiled and analyzed using an analysis of covariance procedure. This procedure is a specific form of a general linear model test (Dixon, 1969, p. 543). Whereas a T test would have been the simplest valid test of significance it would not have made the necessary adjustments for the variables (Dixon and Massey, 1969, p. 150). The analysis of covariance was chosen because it is considered a more powerful tool and removes bias by adjusting for variables (Yahiku, 1977). An analysis of partial correlation was also performed to determine if there was any correlation between the covariants (i.e., Apgar score, gestational age, oxygen temperature, oxygen administration time, and delivery room temperature).

PILOT STUDY

Prior to conducting a pilot study, the method of data collection was applied to three nondepressed newborns. The purpose was to give the investigator experience in attaching thermistors and manipulating the equipment. This proved to be valuable in determining the most efficient method for securing thermistors and for allowing the investigator to establish the skill for rapid data collection which is necessary in the emergency situation associated with a depressed newborn.

A pilot study was then carried out on a sample of four depressed newborns who required oxygen to determine if there would be any problems regarding the methodology. Three of the samples were in the control group and one was in the experimental group as the result of randomization.

The results indicated that the methodology was workable and no changes were indicated for that procedure. However, it was determined that a different sequence was indicated for the information on the data collection sheet (see Appendix C). The pertinent results of the pilot study are compiled in Table 1. In retrospect it can be observed that the pilot study did give an indication of a nontechnical problem that was encountered in subsequent data collection. The time required for data collection greatly exceeded expectations.

Table 1

PILOT STUDY RESULTS

Subject Number	Group Assigned	One Minute Apgar Score	Gestational Age	Sex	Race	Delivery Room Temp.	Mean Oxygen Temp.	Preresuscitational Rectal Temp.	Post Resuscitational Rectal Temp.	O_2 Time	Weight (gms)
1	Exp.	6	38	M	Cauc.	25	38	36.2	36.5	4 min	2880
2	Cont.	2	42	M	Laotian	28	29	37.5	37.5	8 min	3260
3	Cont.	5	38	M	Black	25	30	37.7	37.0	8 min	2680
4	Cont.	6	40	F	Mexican-American	26	28	37.2	37.0	9 min	4540

Chapter 4

RESULTS, ANALYSIS, CONCLUSIONS AND RECOMMENDATIONS

The study sample consisted of ten infants each with a birth weight of 2000gm or greater who were depressed at birth (Apgar score less than 7) and who received oxygen during resuscitation. There was a total of five infants in the control group (two males and three females) and five in the experimental group (all males). The control group contained three Mexican-Americans, one Laotian and one Black while the experimental group was composed of four Mexican-Americans and one Caucasian.

STUDY RESULTS

The results of the study did not support the hypothesis that warmed humidified oxygen would result in a statistically significant ($p = <0.05$) decrease in the incidence of hypothermia for depressed newborns immediately following resuscitation. The raw data is summarized in Tables 2 and 3 and compared in Table 4.

Two factors were considered as design variables. They were the sex and the ethnic background of the infants. There were three females in the study (all randomly fell into the control group) and seven males (five in the experimental and two in the control groups). Ethnic background was Mexican-American for seven of the subjects (four experimental and three control). The ethnic backgrounds of the non-Mexican-Americans were Oriental, Black and Caucasian (one of each). For purposes of data

Table 2

Raw Data Summary: Experimental

Subject I.D. Number	Sex	Race	One Minute Apgar	Gestational Age	Mean O_2 Temp.	O_2 Time	Weight (gms)	Delivery Room Temp.	Preresus-citation Temp.	Post Resus-citation Temp.
1	M	Caucasian	6	38 wks.	38	4	2880	25	36.2	36.5
6	M	Mexican-American	3	41 wks.	36	6	4950	24	37.0	36.8
7	M	Mexican-American	3	40 wks.	39	6	3655	23	37.5	37.6
8	M	Mexican-American	6	37 wks.	35	3	3150	22	36.5	36.5
10	M	Mexican-American	1	35 wks.	38	7	2100	21	37.0	37.0
Mean Data			4.4	38.4	37.2	5.2	3347	23	36.8	36.9

Table 3

Raw Data Summary: Control

Subject I.D. Number	Sex	Race	One Minute Apgar	Gestational Age	Mean O_2 Temp.	O_2 Time	Weight (gms)	Delivery Room Temp.	Preresus-citation Temp.	Post Resus-citation Temp.
2	M	Laotian	2	42 wks.	29	8	3260	28	37.5	37.5
3	M	Black	5	38 wks.	30	8	3680	25	37.7	37.0
4	F	Mexican-American	6	40 wks.	28	9	4540	26	37.2	37.0
5	F	Mexican-American	5	42 wks.	28	3	3380	25	37.5	37.5
9	F	Mexican-American	2	40 wks.	28	2	5210	23	36.8	37.0
Mean Data			4	40.4	28.6	6	3814	25.4	37.3	37.2

Table 4

Comparison of Raw Data

Group	Mean Apgar	Mean Gestational Age	Mean O_2 Temp.	Mean O_2 Time	Mean Weight (gms)	Mean Delivery Room Temp.	Mean Pre-Temp.	Mean Post Temp.
Experimental	4.4	38.4	37.2	5.2	3347	23.0	36.8	36.9
Control	4.0	40.4	28.6	6.0	3814	25.4	37.3	37.2

computation these were listed as "other" and totaled three (one in the experimental group and two in the control group.

Data from the covariants revealed that experimental group infants were slightly less depressed (Apgar score of 4.4 vs. 4.0) as a whole than the control group infants and received oxygen on an average of two minutes less than the control group. Infants in the experimental group were smaller in weight (3347gm vs. 3814gm) and less mature (38.4 weeks vs. 40.4 weeks) than infants in the control group. The temperature in the delivery room was somewhat cooler for the experimental group than for the control group with a mean temperature of 23°C for the experimental group versus 25.4°C for the control group.

The data also revealed that the infants in the experimental group received oxygen at a warmer temperature, but for a shorter duration than the control group infants. The "warmed" oxygen administered to the experimental group was approximately 8.7°C warmer than the "unwarmed"

oxygen administered to the control group. This will be discussed in detail later. Oxygen was administered to the experimental group for a mean time of 5.2 minutes as compared to 6.0 minutes to the control group. The post resuscitation rectal temperatures for the experimental group averaged 0.1°C higher than the pre-resuscitation rectal temperatures for that same group. Post resuscitation rectal temperatures for the control group averaged 0.1°C lower than the pre-resuscitation rectal temperatures.

Five data items that were compiled proved to be noncontributory as they remained relatively constant for each subject. These items were as follows: (1) It was thought that if the delivery room doors were open during some deliveries and closed during others there would be a potential difference in heat loss via convection. This factor remained relatively constant in that the delivery room doors were open for nine of the ten sample subjects. (2) Another potential variable was the temperature set point for the radiant warmer. This remained constant also in that the radiant warmer was not used with the servo control but was set for manual control and was maintained at maximum heat output during each delivery. (3) Intubation would have bypassed the nasopharynx (a physiologic oxygen warmer and humidifier) and thus increased the potential for hypothermia; however, none of the subjects of this study required intubation. (4) Failure to replace the blanket which had been used to dry the infant with a dry blanket may contribute to hypothermia as the result of evaporate heat loss. However, the blanket was changed in each instance. (5) There is a possibility that ventilating the infant with a resuscitation bag (i.e., bagging) may affect thermoregulation. Bagging was

necessary for an equal number of experimental group and control group infants (i.e., one from each group). Therefore, this data was also considered noncontributory.

ANALYSIS

An analysis of covariance was performed on the design variants (group, sex, and race). It compared the post resuscitation rectal temperature, while adjusting for the pre-resuscitation temperature of the (1) control versus experimental group, (2) males versus females, and (3) Mexican-Americans versus others. There was no significant difference between these groups ($p = > 0.05$).

Next an analysis of partial correlation was performed between the post resuscitation rectal temperature and the covariants of Apgar score, gestational age, oxygen temperature, oxygen administration time, and delivery room temperature. The correlations for those variants were as follows:

Apgar score	=	-0.167
Gestational age	=	0.418
Oxygen temperature	=	0.081
Oxygen time	=	-0.401
Delivery room temperature	=	0.0302

As a correlation factor of 0.559 was necessary to be of significance ($p = < 0.05$), it was concluded that there was no statistically significant correlation between post resuscitation temperatures and any of the design covariants.

Depressed newborns who received warmed and humidified oxygen during resuscitation in the delivery room had immediate post resuscitation body temperatures which were not significantly warmer than the body temperatures of infants who received "unwarmed" unhumidified oxygen ($p = >.05$). Therefore the hypothesis was not supported.

DISCUSSION AND IMPLICATIONS FOR NURSING

Several factors may have contributed to the study results. For example, results may have been affected by the relative short oxygen administration period and may have been different if oxygen had been administered over a longer period of time.

Results may also have been affected by the unanticipated warming of the "unwarmed" oxygen as administered to the control group. Observation before and during the data collection period revealed that the routine placement of the resuscitation bag and oxygen connecting tubings under the radiant warmer prior to resuscitation resulted in an increased temperature of "unwarmed" as well as "warmed" oxygen (see Figure 1).

Therefore the difference in temperature between "unwarmed" and "warmed" oxygen was not as great as expected. The "unwarmed" oxygen was in fact warmed an average of 7-8°C. This must be considered in interpreting the results of this study. It is the opinion of the investigator that study results should not be interpreted as an indication that oxygen given to the newborn in the delivery room need not be warmed. The interpretation may be that the warming of oxygen tubing and resuscitation bag under the radiant warmer prior to resuscitation will warm oxygen

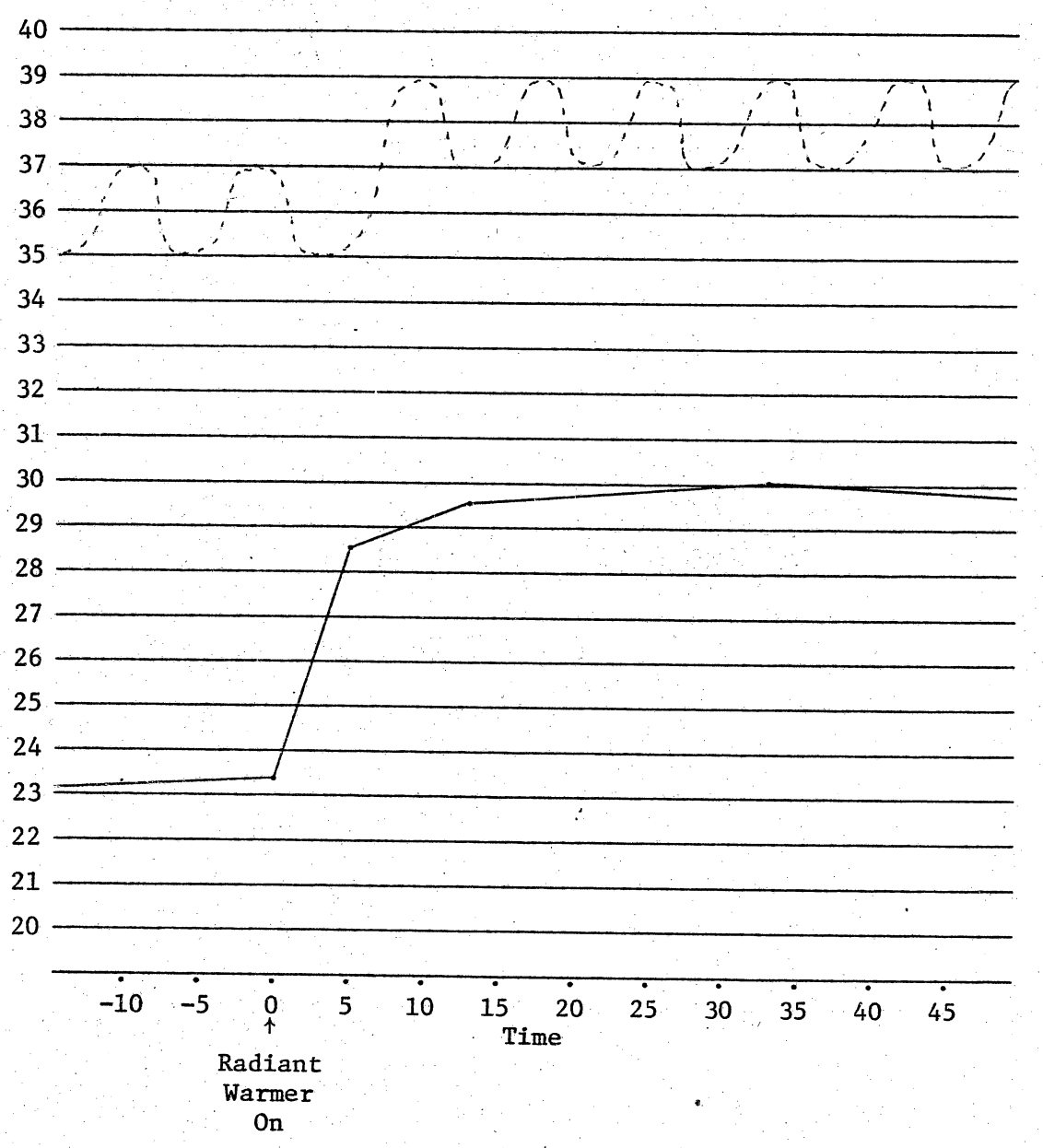

Figure 1

Comparison of Warmed and Unwarmed Oxygen Temperatures

"Unwarmed" Oxygen = ——
Warmed Oxygen = - - - -

sufficiently to maintain thermoneutrality in infants with a birth weight greater than 2000gm.

It should be noted that oxygen temperatures recorded for the experimental group varied from 35-39°C with a mean temperature of 37.2°C. These temperatures were measured distal to the resuscitation bag to avoid interference in the resuscitation process. Oxygen temperature at the patient mask interface was found to be 2.5-3.0°C cooler or approximately 34.4°C.

As demonstrated in Figure 1, there was a fluctuation in the temperature of the warmed oxygen which reflected the variation in heat output of the oxygen warmer. This was not considered to be a problem, however, as it was possible to maintain the temperature of the oxygen approximately within the thermal neutral range of 32-34°C at the point of face contact. The oxygen warmer used in this study was the only one of several tested by the investigator that demonstrated the ability to consistently maintain oxygen temperature within this range at the point of face contact. This consistency was maintained during prolonged intermittent bag compression, indicating that oxygen temperature was not affected by bagging during the resuscitation procedure.

A final factor which may have contributed to the lack of support for the hypothesis was the small size of the sample. It is desirable to have a larger sample for such an investigation, but the time involved in gathering the study sample exceeded expectations and it was necessary to analyze study results with a small sample due to time limitations.

RECOMMENDATIONS

Considering the solid theoretical base which supports the use of warmed humidified oxygen for maintaining thermoneutrality of the newborn infant and in view of the above discussion it is the opinion of the investigator that all oxygen should be warmed prior to administration to depressed newborns regardless of the outcome of this study.

The results of this study suggest several areas for further investigation:

1. Study is indicated in areas where radiant warmers are not in use in the delivery room, to investigate the effect of oxygen which has not been warmed at all. Whereas this situation could not be ethically created, clinical observations indicate that such situations do exist in some community hospitals.

2. Because low birth weight infants are at increased risk for hypothermia it is suggested that this study be repeated using a sample of infants who weigh less than 2000gm.

3. The effects of humidified oxygen have not been examined independently from the effects of warmed oxygen within the context of this study. It is therefore suggested that an investigation could be conducted to examine these components separately to determine if each is equally significant.

4. As previously discussed, it is suggested that this study be repeated with the goal of a larger sample to validate study results.

SUMMARY

This study was conducted to evaluate the effects of warmed humidified oxygen on the temperature of depressed newborns as compared to the effects of oxygen which had not been warmed or humidified. Study results were affected by several factors. A major factor was that the "unwarmed" oxygen administered to the control group was in fact warmed 7-8°C by the overhead radiant warmer under which the resuscitation bag and tubing were kept prior to resuscitation. In view of this and the review of the literature which supports warming oxygen, it was recommended that all oxygen administered to depressed newborns should be warmed and humidified. Suggestions for further study included: (1) a study in cases where oxygen is completely unwarmed; (2) a study using a sample of infants weighing less than 2000gm; and (3) repeating the study with the goal of a larger sample.

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BIBLIOGRAPHY

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APPENDIX A

RESUSCITATION PROTOCOL

University of California Irvine Medical Center--Department of Pediatrics

RESUSCITATION PROTOCOL

Assess the infant's condition--heart rate, respiratory effort, muscle tone, reflex irritability, and color concurrent with drying infant.

Take the following steps based on the one-minute Apgar score.

NOTE: An infant requiring more than routine care (Apgar <7) indicates the necessity of two persons for optimal resuscitation.

APGAR SCORE	BABY'S CONDITION	RESUSCITATIVE MEASURES
4-6 moderately depressed	Heart rate 100 Respiratory effort decreased or absent Decreased muscle tone Poor response Cyanotic	1. Suction oropharynx briefly. 2. Monitor heart rate. 3. If breathing is spontaneous but color is cyanotic, deliver O_2 to the face by mask. 4. If respiratory effort is slow or weak, stimulate respirations with a single brisk slap to the soles of the feet, or by rubbing fingers up and down the spine. 5. If no spontaneous respiration, deliver oxygen by bag and mask at approximately 35cm H_2O pressure and a rate of 30-40 per minute. 6. If improved, continue as for a normal infant. 7. If condition deteriorates, intubate and administer CPR as below.
0-3 severely depressed	Heart rate decreased or absent Flaccid Unresponsive	1. Suction oropharynx briefly 2. Monitor heart rate. 3. Deliver oxygen by bag and mask as above. 4. If condition does not improve, intubate with Cole tube. 5. Bag with 100% oxygen at a pressure of 15-20cm H_2O and a rate of 30-40 per minute (small puffs of short duration to avoid pneumothorax). 6. For heart rate <60 administer cardiac compression. Use thumbs in opposition exerting pressure over midsternum to depth sufficient to produce femoral pulse (2/3 distance

Cyanotic or pale	from sternum to vertebrae). Other fingers surround chest wall and support back. Maintain a compression rate of 90-120 with a ratio of 3 compressions per 1 ventilation.

7. May need:
   - Bicarbonate 2 mEq/kg
   - Epinephrine 0.1ml/kg of 1:10,000 solution
   - 5% Albumin 10ml/kgm
   - 10% glucose in water 2-4ml/kg

NOTE: These medications will only supplement your other resuscitative efforts, not substitute for them. Transfer to area for intensive observation.

If infant is born following particulate or "pea-soup meconium" staining:

a. Do not stimulate to breathe. The obstetrician should not suction the oropharynx unless the infant breathes immediately upon delivery.
b. Insert laryngoscope and suction oropharynx under direct visualization.
c. Visualize the trachea. Intubate with a shoulder endotracheal tube, apply mouth suction directly to the endotracheal tube while withdrawing same.
d. Repeat procedure as necessary and proceed as indicated on preceding chart.

APPENDIX B

DATA COLLECTION INSTRUCTIONS

WARMED HUMIDIFIED OXYGEN STUDY

DATA COLLECTION INSTRUCTIONS

1. Identify potential subjects on basis of expected depressed baby (i.e., meconium stain, late decelerations, loss of variability, caesarean section, or vacuum extraction).

2. Note schedule on side of telethermometer to determine if subject is control or experimental, and proceed as indicated.

3. Control
   Predelivery
   A. Oxygen
      1. Insert gauge into wall outlet
      2. Turn on at 6 liters
   B. Telethermometer
      1. Turn to "Red Line"
      2. Calibrate if necessary
      3. Turn to "On"
   C. Recording: record data collection items marked with an asterisk
      1. Name
      2. Delivery room temperature
      3. Doors open or closed
      4. Oxygen temperature

   Postdelivery
   A. Attach thermistors
      1. Insert rectal probe to depth of 2-3 cm. Secure with tape around thigh. Record time and temperature.
      2. Attach skin thermistor to abdomen. Record time and temperature.
   B. At the completion of resuscitation
      1. Note and record
         a. Oxygen temperature
         b. Rectal temperature
         c. Skin temperature
         d. Oxygen administration time
      2. Remove thermistors
      3. Note and record
         a. Blanket change
         b. Time of transfer from delivery room.

4. Experimental
   Predelivery
   A. Oxygen
      1. Insert gauge into wall outlet
      2. Turn on at 6 liters.

B. Telethermometer
   1. Turn to "Red Line"
   2. Calibrate
   3. Turn to "On"

C. Aquatherm heater
   1. Connect to power
   2. Switch to "on"
   3. Set temperature control knob at 3.0

D. Record on data collection sheet those items marked with an asterisk
   1. Name
   2. Delivery room temperature
   3. Aquatherm set point
   4. Doors open or closed
   5. Oxygen temperature

E. If infant is depressed (i.e., Apgar score less than 7):
   1. Insert rectal probe to a depth of 2-3cm, record time and temperature
   2. Attach skin thermistor to abdomen, record time and temperature

F. At the completion of resuscitation
   1. Note and record oxygen, rectal, and skin temperatures as well as the length of time oxygen was administered
   2. Remove thermistors
   3. Note and record if blanket was changed and time of transfer from the delivery room.

APPENDIX C

DATA COLLECTION SHEET

WARMED HUMIDIFIED OXYGEN STUDY

*NAME_____ PF#_____

DATE_____ STUDY #_____

TIME OF DELIVERY_____ M_____ WEIGHT_____

APGAR SCORE: ONE MINUTE_____ FIVE MINUTES_____

GESTATIONAL AGE _____WEEKS

SEX_____ RACE_____

*D.R. TEMP._____ TIME_____ *DOORS OPEN: YES___ NO___

*RADIANT SET TEMP._____

*AQUA THERM SET POINT_____

*PRE RESUSCITATION TEMPS

OXYGEN_____ TIME_____

RECTAL_____ TIME_____

SKIN_____ TIME_____

*POST RESUSCITATION TEMPS TOTAL O_2 TIME _____ MIN.

OXYGEN_____ TIME_____

RECTAL_____ TIME_____

SKIN_____ TIME_____

INTUBATED: YES_____ NO_____

*BLANKET CHANGE: YES_____ NO_____

*TRANSPORTED @_____

TEMPERATURE UPON ARRIVAL IN UNIT_____

COMMENTS_____

_____

_____

* INVESTIGATOR

APPENDIX D

LETTERS

641 S. Echo St.
Anaheim, CA 92804
April 12, 1977

Evelyn Elwell, M.N.
Chairperson, Ethics Committee
Graduate Nursing
Loma Linda University
Loma Linda, CA 92354

Dear Ms. Elwell:

The attached research proposal is for the consideration of the Ethics Committee at their April 19 meeting. I am requesting that the committee waive the requirement for signed consent for this study.

As you will note on the attached letter from Dr. Robert Huxtable, Director of Neonatology at the University of California Irvine Medical Center (UCIMC), the Human Subjects Review Committee at UCIMC will be asked to approve the study prior to its implementation. When presented it will be accompanied by a request to waive the requirement for informed consent. This will be done for the reasons discussed in Dr. Huxtable's letter (non-invasive treatment, accepted standard of care, etc.) and because a request of the expectant mother for her informed consent in the event her newborn is depressed and requires resuscitation, may produce an emotionally disturbing situation.

Therefore, I am requesting permission of the Ethics Committee to omit that portion of the research proposal. However, in the event that is not possible, the attached proposal does indicate the consent that will be obtained and the method that will be used in obtaining it.

Thank you for your consideration.

Sincerely,

Earlene Scharping

Earlene Scharping, BSN
Graduate Student

ES:pc

LOMA LINDA UNIVERSITY
Graduate Program in Nursing

Approval Date: April 19, 1977

Earlene Scharping
641 South Echo
Anaheim, California 92804

Dear Earlene:

The Ethics in Nursing Research Committee has reviewed the proposal you submitted for a research study to partially fulfill the School of Nursing requirements for a Master of Science degree from Loma Linda University.

The committee has voted that your study is:

__x__ Approved as submitted. - without consent form.

_____ Approved after the attached recommended changes have been made and a memo from your committee chairman to this effect has been received by the committee chairman.

_____ Not approved as submitted to the committee. See the attached comments for recommended changes. Must be resubmitted prior to any data collection.

_____ Deferred to: ___ URACHE ___ Major Advisor ___ Research Chairman

___ Other ___ Advisor

Please see attached comments regarding this action.

Please contact the Chairman of the Ethics in Nursing Research Committee if you have questions related to the decision of the Committee. If any changes are made in the hypothesis, tool, consent form, or the procedure for data collection, this proposal must be resubmitted to this Committee.

We pray that the Lord will continue to bless your endeavors.

Sincerely,

Evelyn L. Elwell

Evelyn L. Elwell, Chairman
Ethics in Nursing Research Committee

ELE:lw

cc: Research Committee Chairman - C. Woodward

641 S. Echo St.
Anaheim, CA 92804
May 2, 1977

Lillian E. Brown
Director of Nursing
University of California Irvine Medical Center
Irvine, CA 92717

Dear Ms. Brown:

As you know, I am currently completing work at Loma Linda University for a Master of Science degree in Maternal-Child Nursing. Class requirements will be completed in June, and I would like to begin data collection for my thesis at that time. The title of my thesis is "The Effect of Warmed Humidified Oxygen on the Body Temperature of Depressed Newborns in the Delivery Room." The proposal was approved by the Ethics Committee of the Graduate Nursing program at Loma Linda on April 19, 1977.

It would be to my advantage (because of distance) to do the study at U.C.I.M.C. Therefore, I am enclosing a copy of my research proposal for your consideration with the request that I be allowed to implement it at U.C.I. Dr. Ragnar Amlie, Assistant Director of Newborn Service at U.C.I. is an ex officio member of my research committee, and will serve as a consultant during the data collection period.

Please feel free to contact me regarding any questions, I am anxiously awaiting your reply.

Thank you for your consideration.

Sincerely,

Earlene Scharping

Earlene Scharping, BSN
Graduate Student

cc: C. Woodward, MSN
R. Amlie, MD
R. Huxtable, MD

Irvine: California College of Medicine
Department of Pediatrics

May 31, 1977

DENNIS L. MING, PHARM.D.
CHAIR
HUMAN SUBJECTS REVIEW COMMITTEE
MEDICAL

The attached proposal is for the consideration of the Human Subjects Review Committee at their June 23, 1977, meeting. I am requesting that the committee waive the requirement for signed consent for this study.

Warming and humidifying oxygen prior to administration to newborns is an accepted standard of care for newborns. In view of the accepted recommendation for such, it is surprising that many perinatal centers do not do so in the delivery room. Because it is a non-invasive procedure and because a request of the expectant mother for her informed consent in the event her newborn is depressed and requires resuscitation, may create an emotionally disturbing situation I am requesting permission of the committee to omit that portion of the research proposal. However, in the event that is not possible, the attached proposal does indicate the consent that will be obtained and method that will be used in attaining it.

Thank you for your consideration.

Earlene Scharping

Earlene Scharping, B.S.N.
Lecturer

ES:pls

UNIVERSITY OF CALIFORNIA, IRVINE
HUMAN SUBJECTS REVIEW COMMITTEE

HSRC APPROVAL NO. HS_____
HSM-77-94

APPROVAL NOTICE

1. INVESTIGATOR/TITLE Earlene Scharping, B.S.N.
2. DEPARTMENT/SCHOOL Pediatrics/Medicine
3. PROJECT TITLE The Effect of Warmed Humidified Oxygen on the Body Temperature of Depressed Newborns in the Delivery Room
4. FUNDING AGENCY/COMPANY -
5. AGENCY AWARD NO. _____ PROJECT PERIOD: 3-months

THE HUMAN SUBJECTS REVIEW COMMITTEE (General Campus ___, Medical X) HAS REVIEWED THE PROPOSED USE OF HUMAN SUBJECTS IN THE PROJECT IDENTIFIED ABOVE AND HAS DETERMINED:

1. X HUMAN SUBJECTS NOT AT RISK. If substantive changes are made in the protocol in the future, the HSRC requires the submission of a new application.
2. ___HUMAN SUBJECTS AT RISK, PROTOCOL APPROVED, INFORMED CONSENT REQUIRED:
   a. ___INFORMED CONSENT FORM APPROVED.
   b. ___MODIFIED CONSENT PROCEDURES APPROVED AS REQUESTED IN APPLICATION.
   c. ___DEBRIEFING PROCEDURES ARE CONSIDERED NECESSARY.
3. CONDUCT OF ACTIVITY IS SUBJECT TO CONTINUING REVIEW AS FOLLOWS: (All projects must be reviewed at least annually *from date of approval.*)

   X ANNUAL REVIEW REQUIRED: Date 6/78

   _____OTHER (Schedule):_____

   TYPE OF REVIEW AND FORM AND CONTENT OF INFORMATION TO BE SUBMITTED AT TIME OF REVIEW:

   PROJECT REPORT _____OTHER_____

THE INVESTIGATOR SHALL REPORT PROMPTLY ANY (1) CHANGES, or (2) UNANTICIPATED PROBLEMS INVOLVING RISK TO SUBJECTS OR OTHERS, INCLUDING ADVERSE REACTIONS TO BIOLOGICALS, DRUGS, RADIOISOTOPE LABELLED DRUGS, OR TO MEDICAL DEVICES:

(1) To HSRC: CHANGES - submit Application requesting review of "MODIFICATIONS."
UNANTICIPATED PROBLEMS - report on Form UCI/HS-5.
(2) To DHEW, IF DHEW SPONSORED - Provide the Contract and Grant Office with documentation of this action.
(3) To FDA, SIGNIFICANT ADVERSE DRUG REACTIONS - report on Form FD-1639.

DATE APPROVED: 6/28/77

Dennis Zapien
CHAIR, HUMAN SUBJECTS REVIEW COMMITTEE

Distribution: Original to Principal Investigator
cc: Coordinator, Human Subjects Committees
HSRC File

UCI/HS-4