1992

A comparative pilot study on the effects of two cleansing agents on premature infants

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DOI: <https://doi.org/10.31979/etd.89pa-6wmp>
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Hensle, Valerie Wilk, M.S.

San Jose State University, 1992

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A COMPARATIVE PILOT STUDY ON THE EFFECTS OF
TWO CLEANSING AGENTS ON PREMATURE INFANTS

A Thesis
Presented to
The Faculty of the Department of Nursing
San Jose State University

In Partial Fulfillment of
the Requirements for the Degree
Master of Science

By
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May, 1992

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ABSTRACT

A COMPARATIVE PILOT STUDY ON THE EFFECTS OF TWO CLEANSING AGENTS ON PREMATURE INFANTS

by Valerie Wilk Hensle

The purpose of this quasi-experimental pilot study was to compare the effects that bathing with either Phisoderm or Cetaphil had on premature infants born at 27 to 32 weeks gestation. Ten infants were randomly assigned immediately after birth into either the Phisoderm or Cetaphil group. The babies remained in the study for 3 weeks and received a total of 6 baths each (2 per week).

The results showed that infants bathed with Cetaphil dropped their axillary temperatures an average of 0.56°C while infants bathed with Phisoderm dropped their axillary temperatures an average of 0.81°C . The difference was not statistically significant. Babies bathed with Cetaphil had slightly better skin condition as measured by a nine point dry skin rating scale. The difference in skin condition was not statistically significant. The amount of bacterial and fungal colonization was about equal among the groups.

ACKNOWLEDGEMENTS

On a professional level, I would like to thank Dr. Al Lane. Without his expertise and assistance, I would never have begun nor completed this project. Secondly, I would like to thank all my nursing readers and advisors. Their help in focusing and refining the thesis idea and printed text was appreciated. On a personal level, I would like to thank my husband. Bob Mensle deserves a huge reward for supporting me throughout the entire thesis process. When I wanted to give up, he said, "No, you don't." Bob also warrants credit for all his time spent at the computer typing and "fixing" my goofs. I would also like to acknowledge my parents who instilled in me the value of higher education.

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Chapter 1

INTRODUCTION

Bathing premature infants with cleansing lotions or soaps is part of routine nursing care. Synthetic soaps are alkaline in nature and are derived from laurel sulfate, a medium chain fatty acid (Morrelli & Weston, 1987).

Phisoderm and Cetaphil are nonsoap cleansing agents as indicated by their package labeling. The purpose of any cleansing agent is to emulsify oils and suspend small solid particles on the skin so that they may be wiped away along with microorganisms (Lyons & O'Brien, 1969; Morelli & Weston, 1987).

Nurses in the intensive care nursery (ICN) may prevent nosocomial infection by providing good skin care. Within the ICN at a large teaching hospital in northern California, nurses often ask one another, "What cleansing agent is best for use in bathing premature infants?" Many nurses offer their personal opinions about this issue. There have been no studies to date which compare various cleansing agents effects on the skin of premature infants.

Professional nurses must make decisions about patient care based on nursing research. In regard to premature infants, the nurse's plan for skin care should be scientifically based. The results of this study will

provide scientific data that support rational for patient care.

Background

Grace (1990) suggests that nurses move away from the medical care model which focuses on treatment of disease to the health care maintenance model which focuses on prevention of disease and promotion of optimal well-being. Prevention of disease is more cost effective than treatment of disease. In the ICN, nurses may assist patients with health care maintenance by providing good skin care.

Premature infants, especially those less than 32 weeks of gestation, have a deficient immunologic system which impairs their resistance to microorganisms (Gotoff, 1974). Skin, usually an effective barrier between an individual and the environment, has been proven to be an ineffective barrier in preterm infants (Harpin & Rutter, 1983). The preterm infant's skin is easily damaged by mild trauma, and damaged skin may be a site of entry of serious infection (Harpin & Rutter, 1983). Gotoff (1974) states that disruption of the skin may predispose one to infection.

In addition to being immunocompromised and having an ineffective skin barrier, newborns hospitalized in intensive care nurseries (ICN) are colonized with bacteria that reflect their exposure to pathogens in the ICN. They are not colonized with normal flora (Goldman, 1988). The skin

of the newborn is a major initial site of bacterial colonization, and any break in the integrity of the protective skin affords an opportunity for infection to develop (American Academy of Pediatrics, 1988).

The nurse may prevent skin breakdown and overgrowth of bacterial colonies by cleansing the skin regularly. But, bathing premature infants is not without risks. Premature infants are susceptible to cold stress (Davis, 1980).

"Bathing can contribute to significant thermal stress, particularly in the low-birth-weight infant" (Streeter, 1985, p. 93). Bathing infants with a cleansing agent that does not require the use of water on the body may decrease the incidence of cold stress during bathing.

There is little evidence in the literature as to which soap or cleansing agent is best for premature infants. In a large teaching hospital in northern California, Phisoderm is most commonly used to bathe infants. Cetaphil lotion is also used, but on a less frequent basis. Phisoderm, with its acidic pH of 5.5, may protect the acid-mantle of the skin. Cetaphil has a pH of 6.8 to 7.2 (Lyons & O'Brien, 1969). This higher pH may alter the bacteriocidal abilities of the acid mantle. Phisoderm requires the use of water for cleansing. Evaporation of water on the skin may lead to cold stress. Cetaphil does not require the use of water. This may decrease cold stress related to bathing. The

difference in the number of bacterial colonies associated with the use of Phisoderm and Cetaphil lotions is unknown. The comparative effects on skin condition such as drying and cracking is also unknown.

This study compared the effects of Phisoderm and Cetaphil lotion on premature infants. Specifically, the type and number of bacterial and fungal colonies on the skin as measured by skin culture were examined. The effects of bathing with either Phisoderm or Cetaphil as they related to cold stress to the infant as measured by axillary temperature and oxygen saturation change were scrutinized. Finally, the infants' subsequent skin condition as measured by a nine point dry skin rating scale was evaluated.

Problem

The problem facing nurses in the ICN is a lack of knowledge needed to make decisions about bathing premature infants. If nurses are going to provide good skin care in the hope of preventing complications associated with poor skin integrity, they must know how to accomplish this task. Nurses can begin the search for information about bathing practices by determining, through nursing research, which soap or cleansing agent is best for premature infants.

Purpose of the Study

The purpose of this study was to compare the effects of two cleansing agents, Phisoderm and Cetaphil, on premature

infants and their skin. The infant's skin condition and bacterial and fungal colonies of the skin were examined. The occurrence of cold stress related to bathing with respect to each product was noted by recording axillary temperature and oxygen saturation change.

Research Question and Hypotheses

The overall research question for this study is, "Which cleansing agent, Phisoderm or Cetaphil, is most beneficial in bathing premature infants?" The hypotheses for this study are as follows:

H₁ Premature infants bathed with Cetaphil lotion twice per week will have better skin condition than premature infants who are bathed with Phisoderm lotion twice per week.

H₂ Premature infants bathed with Cetaphil will experience less cold stress during the bath than premature infants who are bathed with Phisoderm.

H₃ Premature infants bathed with Cetaphil will have less bacterial and fungal skin colonization than premature infants bathed with Phisoderm.

Definition of Terms

For the purpose of this study, the following terms apply:

1. Premature infant is any infant born between 27-32 weeks of gestation as determined by mother's estimated date of confinement or Dubowitz exam (Klaus & Fanaroff, 1977).

2. Skin condition refers to the state of intactness of the skin as it appears to visual observation. Skin condition was assessed and graded using Stanfield, Levy, Kyriakopoulos, and Waldman's (1981) rating scale (see Appendix A).

3. Cold stress is an increase in the need for oxygen and glucose related to decreased body temperature (Streeter, 1985, p. 99). This was assessed by noting decreases in axillary temperature and oxygen saturation. The axillary temperature and oxygen saturation were noted immediately before the bath and 2 minutes after the bath was completed.

4. Bathing refers to the washing or cleansing of the hair and skin with a cleansing agent and the face with clear water.

5. Cleansing agent refers to a substance which is used to emulsify oils and suspend small solid particles on the skin surface which can then be removed from the skin (Morelli & Weston, 1987). Phisoderm and Cetaphil lotion were used in this study (see Appendixes B and C).

Summary

Premature infants have special skin care needs because of the immaturity of their skin. Nurses are faced with making a decision as to which skin care agent is the most appropriate for these infants. However, there is limited information in the literature to help guide neonatal nurses

in their decision and practice. This study was designed to produce information about bathing valuable to those who care for premature babies. Using a nursing conceptual framework, this research attempted to determine which is more beneficial to preterm infants, bathing with Phisoderm or Cetaphil lotion.

Chapter 2

THEORETICAL FRAMEWORK AND REVIEW OF RELATED LITERATURE

Introduction

The theoretical framework used for this research was based on Johnson's (1968) Behavioral Systems Model. Johnson used Florence Nightingale's contention that a nurse's job was to assist individuals in the prevention or recovery from disease or illness (Loveland-Cherry & Wilkerson, 1989). In the development of her model, Johnson also relied on systems theory (Conner, Magers, & Watt, 1989). Johnson believed that within the context of a system, the whole should be considered as the interaction among its parts (Johnson, 1974). The person as a system is bio-psycho-social in nature (Johnson, 1959). The system is divided into eight subsystems which are interlinked (Loveland-Cherry & Wilkerson, 1989). Of particular importance to this study are the aggressive, ingestive, and restorative subsystems. Johnson's model also addresses nursing, health and the environment (see Figure 1).

Basic Considerations of the Model

Nursing

Professional nurses provide a service to the person to whom they are attending (Johnson, 1974). Nursing's goal is seen as the maximization of effective systems operation (Johnson, 1974). The nurse fosters efficient behavioral

**HEALTH = DYNAMIC EQUILIBRIUM
OF THE SUBSYSTEMS**

Figure 1. Conceptual Model of Johnson's Behavioral Systems Model (Hensle, 1991).

functioning (Johnson, 1968). The nurse accomplishes this goal by directing her actions on either the environment (stressors) or the person in order to produce an equilibrated system. The nurse is seen as an external regulatory force. Loveland-Cherry and Wilkerson's (1989) interpretation of Johnson's notion of nursing activity is as follows:

When instability or disequilibrium is evident in the behavioral system, nursing as an external regulatory force acts to assist the person to regain stability or equilibrium by imposing temporary regulatory or control mechanisms, attempting to change structural units in a desirable direction, or by providing resources to assist the person to meet the functional requirements of the subsystem (p. 148).

The nurse acts upon the person by nurturing, protecting, or stimulating the subsystems so that growth is enhanced and stagnation inhibited (Johnson, 1968).

Health

Health is not explicitly defined by Johnson, but it can be interpreted as a moving state of equilibrium in which the interrelationship among the subsystems is harmonious (Johnson, 1968). The state of equilibrium makes possible more effective utilization of available energy, facilitating recovery from illness or promoting health (Johnson, 1959).

Illness occurs when there is a malfunction among the subsystems. Stressors within the environment may cause the system to malfunction. Health is concerned with the person's state of being but is not limited only to the lack of illness (Loveland-Cherry & Wilkerson, 1989). Health is the presence and maintenance of equilibrium among the subsystems.

Environment

The environment is mentioned frequently as something that affects the person and something with which the nurse must contend in order to protect, nurture or stimulate the person (Johnson, 1968). The environment consists of that which is external to the behavioral system (Loveland-Cherry & Wilkerson, 1989). Stressors are contained in the environment, and these stressors can either positively or negatively affect the person (Loveland-Cherry & Wilkerson, 1989). Elements within the environment can produce a change in the balance of the subsystems. For example, when a mother talks to and socializes with her baby, the affiliative subsystem may be positively influenced.

Person

Johnson views the person as a behavioral system (Johnson, 1968). The person is regulated or controlled by

biological, psychological and social factors (Johnson, 1968).

The structural elements of the person are the set, drive, choice, and behavior (Loveland-Cherry & Wilkerson, 1989). The set is the person's background. Drive equals motivation. Together, the set and drive assist the person in making a choice. The choice is then seen as a behavior. These concepts are most easily understood by reviewing an adult situation. For example, a female is a vegetarian (set). She is hungry (drive). She chooses to eat and decides to eat a piece of fruit (choice and behavior).

In infants, the structural elements of the person are not fully developed. Because premature infants have no past experiences, they do not have a developed set. These babies certainly have drive. For example, they get hungry and want to eat. The infants have no choice over what they eat. The nurse makes the choice for them. The nurse also decides how the baby will receive the feeding. In caring for premature infants, nurses provide for the undeveloped aspects of the infant's structural elements.

The functional elements of the person are protection, nurturance, and stimulation (Johnson, 1968). The nurse can enhance subsystem function by assisting the person with protection, nurturance, and stimulation of the subsystems.

The whole system or person is made up of interrelated

parts called subsystems of behaviors (Johnson, 1968). The subsystems are labeled as affiliative, aggression, dependency, achievement, ingestive, eliminative, restorative, and sexual (Loveland-Cherry, 1989). Johnson (1968) states that "the subsystems are linked and open, and a disturbance in one is likely to have an effect on the others" (p. 3). The subsystems are interlinked.

The Aggressive, Ingestive, and Restorative Subsystems

This study was primarily concerned with the aggressive, ingestive, and restorative subsystems. Focusing on these subsystems in no way discounts the importance of linkage with the other subsystems. The aggressive, ingestive, and restorative subsystems are identified as being directly affected by the variable under investigation.

"The aggressive subsystem's function is protection and preservation" (Conner, Magers, & Watt, 1989, p. 312). The ingestive system deals with the behavioral aspects of some biological functions such as nutrition and oxygenation (Loveland-Cherry & Wilkerson, 1989). The relief of fatigue or the redistribution of energy to achieve a state of equilibrium is the job of the restorative subsystem (Loveland-Cherry & Wilkerson, 1989).

The premature infant's subsystems hang in a delicate balance. Equilibrium among the subsystems must exist for growth and development and the maintenance of health. Minor

disturbances in one subsystem can have a major negative impact on another.

For example, if during a bath the infant cries and kicks (aggressive subsystem) in order to stop the activity, oxygen saturation (ingestive subsystem) may decrease. In this case, a disturbance in the aggressive subsystem leads to a negative disturbance in the ingestive subsystem. This disturbance in turn leads to a negative disturbance in the restorative subsystem where the replenishment of resources is unable to take place. The nurse must act on either the patient and/or the environment in order to facilitate the return of the baby to balanced equilibrium.

By evaluating the impact of the cleansing agents on the infant's subsystems as defined by Johnson, this study provides direction to nurses and other health care providers on how to protect and nurture the premature infant.

Review of the Literature

The literature review is organized into five components: (a) the skin of the premature infant, (b) the relationship between infection and hygiene, (c) the risks of bathing premature infants, (d) soaps and cleansing agents, and (e) bathing routine. Each of these components is important when making decisions about bathing premature infants.

The Skin of the Premature Infant

The skin of the newly born premature infant is not like that of a full term infant. Understanding the structure and function of the skin as a protective organ is important when viewing it as a protective barrier against water loss and microbial invasion. "The outer layer of the epidermis, the stratum corneum, gives the skin its barrier properties" (Harpin & Rutter, 1983, p. 422). The stratum corneum does not begin to develop until about the 25th week of gestation, and its development is not complete until near term (Hashimoto, Gross, & Dibella, 1966). Approximately 2 weeks after the birth of the premature infant, however, the stratum corneum shows considerable maturation in terms of thickness and keratin production (Harpin & Rutter, 1988). After 2 weeks of age, the undamaged skin of the premature infant acts as a more effective barrier against water loss and the environment.

The premature infant is most susceptible to problems associated with the skin when he or she is less than 2 weeks old (Harpin & Rutter, 1983). As a boundary organ, the skin is subjected to a variety of physical, chemical and infection influences (Dietel, 1978). Some of these influences may lead to a lowered moisture content in the stratum corneum (Stanfield, Levy, Kyriakopoulos, & Waldman, 1981). The inflexibility of the skin may lead to cracking

and fissuring of the skin (Stanfield, Levy, Kyriakopoulos, & Waldman, 1981).

In assessing skin permeability to drugs, Harpin and Rutter (1983) have shown that the skin of premature infants of 32 weeks gestation or less has increased permeability. After 2 weeks of age, the permeability of preterm infant's skin is similar to that of mature neonates (Harpin & Rutter, 1983). Skin damaged by the removal of adhesive tape on the preterm and full term infant has increased permeability (Rutter, 1983). Immature or damaged skin of the neonate has increased permeability to the environment.

The Relationship Between Infection and Hygiene

"Prematurity, stress, immature immune systems, and complicated medical and surgical problems" increase the premature infant's susceptibility to nosocomial or hospital acquired infection (Bruhn, Jones, O'Donnell, & Merenstein, 1989, p. 346). Nosocomial (hospital acquired) infections increase hospital stay and increase health care costs as well as contribute to mortality (Reinarz, 1978). In a classic study conducted by Hemming, Overall, and Britt (1974), nosocomial infections were discovered to be a major problem in newborn intensive care units. These researchers enrolled 1161 infants into their study. A total of 222 nosocomial infections was detected among 904 infants discharged from their unit. Surface infections such as

cutaneous abscess accounted for 40.1% of the nosocomial infections. There was no mention of hygiene or skin care in the report.

There is scant information in the literature regarding skin care of premature infants, bathing premature infants, and the effect these practices have on skin condition and nosocomial infection. Studying infections in adult hemodialysis patients, Kaplowitz, Comstock, Landerehr, Dalton and Mayhall (1988), found that there was a strong relationship ($p = .002$) between poor hygiene and vascular access-site infection. This may have been attributed to the high concentration of the bacterial infecting agent on the antiseptically cleansed skin of those with poor hygiene (Kaplowitz et al., 1988). These findings support the notion that decreasing the concentration of bacteria on the skin by ensuring good hygiene and preventing skin breakdown in premature infants may decrease nosocomial infection.

The Risks of Bathing Premature Infants

Bathing premature infants is not without risk. The possibility of cold stress occurring with bathing must be considered. In order to maintain body temperature when subjected to a cool environment, infants must increase their basal metabolic rate and metabolize brown adipose tissue (Davis, 1980). Brown adipose cells begin to differentiate in the 26-30th weeks of gestation (Davies, 1980).

Therefore, the premature infant does not have a full complement of brown adipose tissue (Davis, 1980). In addition, the use of brown adipose tissue is metabolically expensive since the requirements for glucose and oxygen are increased during use (Streeter, 1986). "These increased requirements for oxygen and glucose can result in hypoxia, respiratory distress, and hypoglycemia" (Streeter, 1986, p. 99). Therefore, the first bath may be done 6 to 8 hours after birth only if the infant has adjusted to extrauterine life (Streeter, 1985). Temperature and other vital signs must be stable before any bath is given.

Changing the pH of the infant's skin is another unwanted side effect of bathing premature infants. Immediately after birth the mean pH of the skin is 6.34, and then the pH declines to an average of 4.95 after four days of life (Dietel, 1978). "An acid skin surface with a pH lower than 5.0 has bacteriocidal quality" (Kuller, Lund, & Tobin, 1983, p. 200). Bathing with alkaline-based soaps such as Ivory increases the skin pH, the regeneration of which takes longer than an hour in the majority of newborns (Dietel, 1978). The time needed for the premature infant's skin pH to return to an acidotic state after an alkaline bath is even longer (Kuller, Lund, & Tobin, 1983). The acid mantle of the skin may not be functioning as well during this recovery period. Due to the possible risks of changing

the skin pH and inducing cold stress, cleansing agents for this population must be carefully selected.

Soaps and Cleansing Agents

Soaps are cleansing agents and their function is to emulsify oils and suspend small solid particles on the skin surface (Blank, 1969). The skin can then be wiped or rinsed thereby removing unwanted materials. Cleansing of the skin surface also includes the removal of transient and resident microorganisms and superficial soil (Lyons & O'Brien, 1969).

Soaps are thought to be a mild irritant, especially alkaline soaps (Morelli & Weston, 1987). "Extended bathing time is not necessary to achieve cleanliness," nor is it desired since frequent soaping or prolonged contact of soap to the skin leads to irritation of the skin (Morelli & Weston, 1987, p. 635). In a study comparing the mildness of two soaps on infants up to 14 months of age, Ellickson and Jungermann (1967) found no difference in mildness (defined as irritation to the skin) between Ivory and Dial soap. In regard to bathing full term babies and children with sensitive skin or dermatitis, Morelli and Weston (1987) recommend using a soap substitute such as Cetaphil lotion.

Bathing Routines

There is conflicting information in the literature as to how often premature infants should be bathed. Rarely is a type of cleansing agent recommended. William (1985)

states that "...following the admission bath, baths should be given only as needed" (p. 43). Streeter (1986) indicates that the bathing routine is an individual matter for each hospital nursery. The American Academy of Pediatrics (1988) states that skin care is important for infection control in the nursery, but that guidelines regarding the time of the first bath and method of cleansing is a matter for individual nurseries. Kuller, Lund and Tobin (1983) suggest that because of the various properties of the premature infant's skin, infrequent bathing (2 to 3 times per week) should be carried out. They also suggest that less alkaline soaps be used. The bathing routine in the ICN at a large teaching hospital in northern California is twice per week, with Phisoderm or Cetaphil lotion being used as the cleansing agent.

Summary

Much is unknown about the effect bathing has upon premature infants. The literature reveals that premature infants' skin is immature; consequently, they are susceptible to infection and have decreased abilities to handle cold stress. There is disagreement among care givers as to how often premature infants should be bathed. Johnson's model provides a framework to examine the literature and speculate on nursing solutions to the problems associated with the bathing of premature infants.

Chapter 3

METHODOLOGY

Design

A prospective and quasi-experimental design was used to organize the components of this pilot study. A quasi-experimental design was used for examination of causality in this situation in which complete control was not possible. This study compared two groups.

The manipulation or treatment was the bathing of premature infants. In order to maximize the probability of equivalence between groups, the subjects were randomly assigned into either the Phisoderm or the Cetaphil group. Because there was no control group as such but two comparative groups, the design must be labeled as quasi-experimental instead of experimental. The dependent variables (items measured) were cold stress, microbial colonization of the skin, and skin condition.

The assumptions of the study were as follows: (a) nurses value good skin care and hygiene for their patients and therefore want to bath their patients in an efficient manner, (b) newborn premature infants do not tolerate being handled as evidenced by the dropping of their oxygen saturation during the manipulation, (c) premature infants need assistance with thermoregulation and (d) nurses monitor

and regulate the infants' thermal environment on an hourly basis.

Subjects and Setting

Ten premature infants between 27 to 32 weeks of gestational age participated in this study. The criteria for selection included weight between 1,000 grams and 1,500 grams at birth. Infants with birth defects were not considered for the study. The ICN charge nurse notified the principal investigator when infants meeting the criteria were born.

All subjects were born at a large teaching hospital in northern California and admitted to the intensive care nursery there. The site was chosen because it was a referral center for high risk pregnancies. Therefore, a large number of premature infants were born at the facility.

The subjects were recruited from the intensive care nursery at this major hospital. Upon notification of the birth of an infant meeting the criteria for the study, the principal investigator talked with the mother and/or the father of the child so that informed consent could be obtained. Permission to conduct the study within the nursery was granted by the clinical nurse coordinator of the ICN (see Appendix D).

Human Subjects Approval

This study was reviewed and approved by the

Institutional Review Board-Human Subjects at San Jose State University (see Appendix E). Participation in this study was voluntary. Informed consent (see Appendix F) was obtained by the principal investigator or an assistant research nurse from either the mother or father of the child. The parent was shown the two cleansing agents and told that the infants would be bathed per present nursery protocol (twice per week). A copy of the consent form was given to the parent.

The identity of the subjects was protected. Each infant was assigned a code number. Data were kept in a locked file cabinet.

Data Collection and Instruments

So that they would understand their role of identifying potential subjects for the study, the staff nurses in the ICN were prepared through a 15 minute class held twice a day for three days. The classes were held before data collection began. The purpose of the study, namely comparing the effects of bathing premature infants with either Phisoderm or Cetaphil, was reviewed. A brief overview of the research process was also given. The staff nurses were instructed not only to identify potential subjects, but they were also instructed not to bathe the infant. The principal investigator did all the bathing of the babies.

When a potential subject was admitted to the ICN, the staff nurse informed the charge nurse or the principal investigator of the admission. Once the infant was identified as meeting the criteria for entry into the study, the principal investigator or the assistant research nurse obtained informed consent from the parent and enrolled the baby in the study. A copy of the signed consent form was given to the parent.

After the informed consent was obtained, demographic data such as date of birth, weight at birth, gestational age, etc. were recorded by the research nurse onto the Demographic Data Collection Form (see Appendix G). The principal investigator then evaluated the subject's skin by examining the dorsum of one hand, the dorsum of one foot, and the abdomen. This initial skin evaluation was also recorded on the Demographic Data Collection Form. Areas of the skin which had recently been taped were excluded from examination. Future skin evaluations were recorded on the Skin Condition Evaluation Form (see Appendix H).

Next, a swab culture of the area 1 centimeter to the right of the xiphoid process was taken 1 minute before the bath. The size of the cultured area was 1.2cm^2 . This area was stroked five times horizontally and five times vertically with the swab culturette. This same procedure was used to obtain a culture 2 minutes after the bath was

completed. The samples were then taken to the laboratory and plated immediately on the blood, Sabourauds Dextrose (SABS), and SABS with oil agar. Forty-eight hours later, the results of the skin cultures were read and recorded on Culture Results Sheet (see Appendix I).

When beginning the bath, a glass thermometer was placed under the infant's axilla for 2 minutes. After the 2 minute period, the baby's axillary temperature was read by the principal investigator and recorded on the Bedside Vital Sign Data Sheet (see Appendix J). Other vital signs such as heart rate and respiratory rate were taken from the Hewlett-Packard cardio/respiratory monitor and recorded on the Bedside Vital Sign Data Collection Sheet. The baby's oxygen saturation (O_2 Sat) was monitored via pulse oximetry. The pulse oximeter probe was in place on either the hand or the foot. This digital O_2 Sat was also recorded on the Bedside Vital Sign Data Collection Sheet. Vital signs were constantly monitored and values noted every one half minute during and after the bath and recorded on this sheet. The final set of vital signs were recorded immediately after the axillary temperature was noted.

Following the admission bath, the infants were bathed twice per week (Monday and Friday) following the routine in the ICN. The swab cultures of the skin were taken before and after the first, third, and sixth bath. The skin

condition was initially assessed before the first bath. Then it was assessed by a dermatologist twice during the first, second and third week of life after which time the skin was thought to have matured. The dermatologist did not know to which group the infants belonged. The results of these skin evaluations were recorded on the Skin Evaluation Form (see Appendix H). The babies remained in the study for 3 weeks and received a total of 6 baths.

The Cleansing Agents

Phisoderm and Cetaphil lotion were chosen for this study because of their current use in the intensive care nursery at a large teaching hospital in northern California. Both of these cleansers are non-alkaline as indicated by their packaging. Phisoderm has a pH of 5.5. Cetaphil lotion has a pH of 6.8 to 7.2 (Lyons & O'Brien, 1969). Phisoderm must be rinsed with water after application. Cetaphil does not need to be rinsed. It needs to be wiped away with a clean soft cloth. The ICN staff considered both products to be effective cleansers (see Appendixes B and C).

Bathing Method

All babies were lying under a radiant warmer or in a heated isolette. The bathing method was as follows. First, the nurse washed her hands thoroughly with a 4% hexachlorophene cleanser. Then she donned nonsterile gloves. Next, she instructed the assisting nurse to record

heart rate, respiratory rate, oxygen saturation and mean arterial blood pressure from monitors already in place on the subjects. The bathing nurse took the infant's axillary temperature, leaving the thermometer under the arm for 2 minutes, immediately before and immediately after the bath. A glass thermometer was used. The infant's axillary temperature had to be at least 36.8 degrees Celsius before beginning the bath because "the infant whose core temperature has fallen below 36.5 degrees Celsius is losing heat more rapidly than he is producing it" (William, 1985, p. 32). Vital signs were stable before beginning the bath.

The bath water from the tap was 105 degrees Fahrenheit at the start of the bath (Whitner & Thompson, 1970). This temperature was warm to the touch. Both groups of infants had their faces washed with clear water. Each eye of the infant was cleansed using a clean, separate area of the wash cloth moistened with clear water. The face was then cleansed using a disposable wash cloth and clear water. The nurse started at the forehead and cleansed down over the nose, cheeks and external ears. This area was then patted dry with a clean blanket. This wash cloth was then rinsed and 1 ml of Phisoderm or 2 mls of Cetaphil (depending on the group) was applied to the cloth. The hair was then washed. A comb was used to remove debris from the hair if necessary. The hair of both groups was then rinsed and dried.

For infants in the Phisoderm group, the neck creases, upper extremities and chest down to the umbilicus were washed with a clean moistened wash cloth with 1 ml of Phisoderm on it. The area was then rinsed and patted dry. The infant was then turned so that the back could be washed with 0.5 ml of Phisoderm on the cloth, rinsed and patted dry. Next, the lower abdomen and legs were washed with 0.5 ml of Phisoderm, rinsed and patted dry. Lastly the perineal area was washed with the moistened cloth with 0.5 ml of phisoderm on it. The area was then rinsed and dried. The bath with Phisoderm was then completed. A total of 3.5 mls of Phisoderm was used during the bath.

The infants who were bathed with Cetaphil were bathed without water on the body. Instead of a washcloth, 2 mls of Cetaphil was placed into the nurse's gloved hand. This amount of Cetaphil was used to cleanse the neck creases, upper extremities, and chest down to the umbilicus. The Cetaphil lotion was then removed from the skin with a clean dry cloth. Next, using a gloved hand with 1.5 mls Cetaphil on it, the back was cleansed. The excess Cetaphil was wiped from the back using a clean dry cloth. The lower abdomen and legs were cleansed with 1.5 mls of Cetaphil and wiped. Lastly, the perineal area was cleansed with 0.5 ml of Cetaphil and wiped. The bath with Cetaphil was then complete. A total of 8 mls of Cetaphil was used during the

bath. No bath in either group took no longer than 8 minutes.

Data Analysis

Upon completion of the data collection forms, the data were entered into the computer. The Minitab software program was used to run the statistical analysis. Descriptive statistics including means and standard deviations were calculated for all data. Independent pooled t-tests were used to determine if there was a statistically significant difference of the vital signs (O_2 Sat and Ax temp) before and after the bath between the Phisoderm and Cetaphil groups. This same test was used to determine whether or not a statistical difference of the lowest oxygen saturation drop between the groups existed. In essence, these tests determined whether the infants in the Cetaphil group experienced less cold stress than the infants in the Phisoderm group.

Bacterial colonization of the skin and the infants' skin condition were also analyzed. An independent pooled t-test was used to determine whether there was a statistically significant difference in bacterial cultures between the Phisoderm and the Cetaphil groups. An independent t-test was used to determine whether there was a statistically significant difference in skin condition between the Phisoderm and Cetaphil groups. For all statistical tests,

the alpha level was set at .05.

Chapter 4

FINDINGS AND INTERPRETATION

Introduction

The overall research question for the study was, "Which cleansing agent, Phisoderm or Cetaphil, is best for bathing premature infants?" Specifically, the occurrence of cold stress, the amount of bacterial and fungal skin colonization, and the condition of the skin were examined. Ten premature infants were enrolled in the study (see Table 1).

Cold Stress

In assessing cold stress, the infants' axillary temperatures before and after the bath were recorded and analyzed. Infants in both groups dropped their axillary temperatures a minimum of 0.5 degrees Celsius. The temperature drop occurred despite the nurse's attempt to prevent this by increasing the radiant warmer output or by using heat lamps over isolettes. The mean temperature loss for infants in the Phisoderm group was 0.81 degrees Celsius. The mean temperature loss for infants in the Cetaphil group was 0.56 degrees Celsius (see Table 2). There was no statistical significance between the groups ($p > .05$).

Infants in both the Phisoderm and the Cetaphil group experienced a temporary drop in their oxygen saturation

Table 1

Gestational Age of Subjects (N = 10)

	Group 1 (Phisoderm) (<u>n</u> = 5)	Group 2 (Cetaphil) (<u>n</u> = 5)
	32	29
	29	29
	31	31
	27.5	28
	29	31
Mean	29.7	29.6

Note. Gestational age is in weeks.

Table 2

Mean Temperature Loss per Subject by Group (N = 10)

	Group 1 (Phisoderm) (<u>n</u> = 5)	Group 2 (Cetaphil) (<u>n</u> = 5)
	1.04	0.50
	0.73	0.73
	0.45	0.58
	1.06	0.53
	0.80	0.46
Mean	0.81	0.56

Note. Temperature in degrees Celsius.

during the bath. For the Phisoderm group, the mean of the lowest oxygen saturation was 84, and for the Cetaphil group the mean of the lowest oxygen saturation was 87. No significant statistical difference between the two groups was identified.

Although the infants of both groups dropped their temperatures and oxygen saturation during the bath, they did not experience real cold stress. Cold stress in this study is defined as an increased need for oxygen related to axillary temperature drop. The babies in this study did not experience cold stress because the difference between oxygen saturation before and after the bath was negligible. For the infants in the Phisoderm group, the mean change in O_2 Sat before and after the bath was -0.3%. For the Cetaphil group the mean change was +0.7% (see Table 3). The difference between the groups was not statistically significant.

The babies of both the Phisoderm and the Cetaphil groups experienced disequilibrium of their subsystems while being bathed. Frequently, the babies cried during the bath. Many babies in both groups experienced increased heart rates during the bath. Often, the babies dropped their oxygen saturation during the bath, and the nurse was required to give the babies rest periods lasting 15 seconds to 60 seconds so that the O_2 Sat level would return to a minimum

Table 3

Amount of Change in Oxygen Saturation Before and After the
Bath per Subject by Group (N = 10)

	Group 1 (Phisoderm) (<u>n</u> = 5)	Group 2 (Cetaphil) (<u>n</u> = 5)
	-3.00	+0.16
	-1.16	-1.60
	+0.66	+1.80
	-0.33	+0.80
	+2.30	+2.60
Mean	-0.31	+0.75

Note. Normal oxygen saturation is 90% to 100%

of 90%. In many instances, the nurse increased the amount of oxygen the baby was receiving in order to help the baby recover from the oxygen desaturation. In some instances, infants were given intravenous boluses of morphine sulfate prior to or during the bath. This may have altered O₂ Sat results, but the health of the infants had to be maintained.

Although the babies of both groups dropped their temperatures after being bathed, their oxygen saturation after the bath was nearly unchanged. The infants rested and recovered for 2 minutes while their axillary temperature were being taken. It was after these 2 minutes that the final vital signs readings including the O₂ Sat were taken.

In summary, cold stress (as defined in this study) related to bathing did not occur in either the Phisoderm or the Cetaphil group. However, infants in both groups experienced disequilibrium of their subsystems which required intervention from the nurse. These interventions, giving intravenous morphine sulfate or increasing the amount of oxygen to the babies, may have altered the results. Overall, bathing was a stressful experience for these premature infants.

Skin Condition

The infants' skin condition was evaluated by an investigator who did not know to which group the infants

Table 4

Mean Skin Condition per Subject by Group (N = 10)

	Group 1 (Phisoderm) (<u>n</u> = 5)	Group 2 (Cetaphil) (<u>n</u> = 5)
	3.28	1.30
	0.92	0.08
	1.00	1.40
	1.70	1.40
	1.50	--
Mean	1.68	1.05

Note. Skin condition evaluated on a 0-9 point rating scale (Stanfield, Levy, Kyriakopoulos, & Waldman, 1981).

were assigned. The evaluations took place twice during the first, second, and third week of life. The skin condition rating scale in Appendix A was used. The mean skin condition rating for babies in the Phisoderm group was 1.68. The mean skin condition rating for babies in the Cetaphil group was 1.05 (see Table 4). The babies in the Cetaphil group had slightly better skin condition, but the difference between the groups was not statistically significant.

Bacterial and Fungal Colonization

The skin of infants in both the Phisoderm and the Cetaphil groups were predominately colonized with gram positive cocci. The amount of bacterial colonization was calculated based on the cultures taken before the third bath of each infant. The calculated amount of bacterial colonization was reported in log form. The amount of bacterial colonization between the groups was virtually identical with the Phisoderm mean equaling 2.77 and the Cetaphil mean equaling 2.79 (see Table 5). The difference between the groups was not statistically significant.

Fungal colonization was noted as either a positive or negative occurrence. Two of the babies in the Phisoderm group and two of the babies in the Cetaphil group had positive fungal cultures. There was no difference in fungal colonization between the two groups.

Table 5

Amount of Bacterial Colonization Before the Third Bath per
Subject by Group (N = 10)

	Group 1 (Phisoderm) (<u>n</u> = 5)	Group 2 (Cetaphil) (<u>n</u> = 5)
	2.77	2.93
	2.98	2.55
	3.15	2.46
	2.82	2.88
	2.13	3.15
Mean	2.77	2.79

Note. Bacterial colonization in log form.

In summary, no significant statistical difference was noted between the Phisoderm group and the Cetaphil group in the category of axillary temperature change. In the other categories of O₂ Sat change, skin condition and bacterial colonization, no statistically significant difference was noted (see Table 6).

Table 6

Comparison of the Phisoderm Group (n=5) and the Cetaphil Group (n=5) in Terms of Gestational Age, Change in Axillary Temperature and O₂ Sat Before and After the Bath, Skin Condition, and Bacterial Skin Cultures as Assessed by Means of an Independent t-test

variable	<u>PHISODERM GROUP</u>		<u>CETAPHIL GROUP</u>		<u>t</u>	<u>p</u>
	<u>M</u>	<u>SD</u>	<u>M</u>	<u>SD</u>		
Gestational age	29.7	1.79	29.6	1.34	0.10	.92
Temperature change	0.81	0.25	0.56	0.10	2.11	.07
O ₂ Sat change	-0.31	1.98	0.75	1.61	0.93	.38
skin condition	1.68	0.95	1.04	0.64	1.13	.29
bacterial culture	2.77	0.39	2.79	0.28	0.11	.38

Chapter 5

DISCUSSION

Summary of the Study

Premature infants less than 32 weeks gestation have problems associated with the immaturity of their skin (Lane, 1987). There is limited information in the literature as to bathing and its effect on premature infants and their skin. The purpose of this study was to compare the effect bathing with either Phisoderm or Cetaphil had on premature infants born at 27 to 32 weeks of gestation.

For this study, 10 infants were randomly assigned immediately after birth into either the Phisoderm or Cetaphil group. The babies remained in the study for approximately 3 weeks and received a total of 6 baths each, 2 per week. After the admission bath, the babies were bathed on Mondays and Fridays as per the ICN routine.

The results showed that infants bathed with Cetaphil dropped their axillary temperatures an average of 0.56°C while the infants bathed with Phisoderm dropped their axillary temperatures an average of 0.81°C. The difference was not statistically significant. Although not statistically significant, babies bathed with Cetaphil had slightly better skin condition. The amount of bacterial colonization between the groups was nearly equal, and the amount of fungal colonization between the groups was equal.

Although bathing disturbed the infant's subsystems, neither group experienced true cold stress. In addition, this investigator found Cetaphil easier to use because it only needed to be wiped away and not rinsed.

Conclusions

Bathing was a stressful event for the premature infants. The babies often cried and kicked during the bath. This aggressive activity negatively affected the infant's ingestive subsystems as evidenced by the oxygen saturation drop during the bath. As noted in Johnson's Behavioral Systems Model, it was the nurse's job to protect the infants. Johnson's model provided a framework within which the nurse could organize, monitor, and interpret results from the study.

Bathing with Cetaphil was preferable to bathing with Phisoderm because the infants experienced a smaller temperature drop when bathed with Cetaphil. Not only was bathing with Cetaphil more beneficial to the premature infant, it was easier for the nurse to use the Cetaphil because it did not need to be rinsed from the body. Originally, the infants in the Phisoderm group were to have been bathed with 6 mls of Phisoderm. The principal investigator found that she could not effectively rinse that amount of the cleansing agent off the baby. Therefore, the amount of Phisoderm used to bathe the babies was changed to

3.5 mls. Using Cetaphil to bathe the infants was easier for the nurse and more beneficial to the babies.

Scope and Limitations

All the infants in the study were bathed by the same nurse. This aided in the internal validity of the study. Bias in skin assessment was eliminated by having a dermatologist evaluate the infant's skin condition without knowing to which group the infant had been assigned.

The study was limited to premature infants who were born at a large teaching hospital in northern California and whose parents consented to enrolling their babies into the study. Therefore, the results can only be generalized to premature infants born at this hospital. The sample size was small with only 5 subjects in each group. This small sample size decreased the ability of the statistics to detect a significant difference between the groups.

In general, the premature infants did not tolerate being bathed. They cried and experienced oxygen saturation drops during the bath. Many times, especially with the first and second baths, infants needed increased oxygen during the bath. The nurse increased the percentage of oxygen being delivered via the ventilator as needed to keep the O_2 Sat greater than 90%. Sometimes, the infants were given morphine sulfate just prior to or during the bath in order to help them tolerate the procedure. Increasing the

percentage of oxygen delivered to the baby and giving morphine sulfate to the infants may have altered the results. But first and foremost, the infants had to be protected.

Recommendations

Nursing practice should be guided by nursing theory. Johnson's (1968) Behavioral Systems Model provides a framework in which neonatal intensive care nurses can work. When bathing premature infants, the nurse should monitor the infant's subsystems, especially the ingestive, aggressive and restorative subsystems. Specifically, the nurse should check the infant's temperature before the bath and monitor the oxygen saturation during the bath. Continued observation of the infant's skin condition is also recommended. The nurse's goal is to keep the subsystems in a state of equilibrium.

In order to gain statistical significance, a larger number of subjects are needed. All of the infants in the study dropped their axillary temperature after being bathed. Therefore, all babies should have minimum axillary temperatures of 37°C before a bath is begun. Because bathing disrupts the equilibrium among the subsystems of premature infants, spot bathing with Cetaphil is recommended.

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APPENDIX A
Dry Skin Rating Scale

Dry Skin Rating Scale

(Stanfield, Levy, Kyriakopoulos, & Waldman, 1981)

0 = normal	No sign of dry skin.
1,2,3 = mild	Dry skin with fine white, thin scales barely raised along margins. Skin may be slightly rough to touch. No fissures or inflammation.
4,5,6 = moderate	Dry skin with white to tan or light brown scales with definite margins. Skin rough to touch with white appearance. Few fissures may be present but are shallow and not hemorrhagic. There may be faint erythema, not due to extrinsic causes such as excoriations, rubbing, irritants, or other skin disorders.
7,8,9 = severe	Very dry skin with well-demarcated heavy scaling and clearly discernible patches. Skin very rough to touch. Deep fissures may be present, some hemorrhagic to the extreme of eczema craquele. Erythema is usually present.

APPENDIX B
Phisoderm Product Information

pHisoDerm.

SKIN CLEANSER & CONDITIONER

DIRECTIONS:

Wet area to be washed. Apply pHisoDerm with hands, washcloth or sponge. Gently massage. Rinse thoroughly.

CONTAINS: SODIUM OCTOXYNOL-2 ETHANE SULFONATE SOLUTION, WATER, PETROLATUM, OCTOXYNOL-3, MINERAL OIL (WITH LANOLIN ALCOHOL AND OLEYL ALCOHOL), COCAMIDE MEA, IMIDAZOLIDINYL UREA, SODIUM BENZOATE, TETRASODIUM EDTA AND METHYLCELLULOSE

**CONTAINS NO HEXACHLOROPHENE.
FOR EXTERNAL USE ONLY.**

Winthrop Consumer Products
Division of Sterling Drug Inc
New York NY 10016

**CLEANS & SOFTENS
COMBINATION SKIN**

**REGULAR FORMULA
UNSCENTED**

APPENDIX C
Cetaphil Product Information

CETAPHIL® was formulated for dermatologists as a gentle, non-irritating cleanser for sensitive skin. Unlike soap, CETAPHIL is completely non-alkaline, mild enough for all skin types. CETAPHIL soothes and softens as it cleanses, helping the skin retain needed moisture. Use CETAPHIL for face, hands, and the entire body. CETAPHIL is also an excellent cleanser for the delicate skin of babies.

CETAPHIL is easy to use.

Without Water: Apply a liberal amount to the skin and rub gently. The unique, low lathering formula allows gentle, yet thorough cleansing. Remove excess with a soft cloth, leaving a thin film of CETAPHIL on the skin. The emollient quality will leave the skin soft and moist.

With Water: Apply to the skin and rub gently. Rinse.

INGREDIENTS: WATER, CETYL ALCOHOL, PROPYLENE GLYCOL, SODIUM LAURYL SULFATE, STEARYL ALCOHOL, METHYLPARABEN, PROPYLPARABEN, BUTYLPARABEN.

0299-3921-08 0

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APPENDIX D
Site Permission Letter

January 1991

Dear CNC;

I am currently pursuing a Master's Degree in Nursing at San Jose State University. A research component including a thesis is required for the degree. The objective of my thesis is to compare the effects of bathing premature infants with either Phisoderm or Cetaphil lotion. Specifically, skin condition, cold stress due to bathing, and bacterial and fungal cultures of the skin will be examined. The infants will be bathed twice per week as per unit protocol. I will be bathing the infants. Anonymity of the patients will be protected: confidentiality will be maintained by a coding system. Dr. _____ will assist me in obtaining informed consent from the parents. The proposal will be screened by the Committee for the Protection of Human Subjects.

I have been advised that your permission is needed in order to conduct the research in the nursery. If additional information is needed, I will be happy to supply it on your request.

Thank you for your assistance.

Valerie W. Hensle, BSN, RN
4896 Scarletwood Terrace
San Jose, CA 95129

Site permission granted for bathing study.

signature CNC

date

APPENDIX E
Institutional Review Board - Human Subjects
Approval Letter

Office of the Academic Vice President • Associate Academic Vice President • Graduate Studies and Research
One Washington Square • San Jose, California 95192-0025 • 408/924-2480

To: Valerie W. Hensle, Nursing
4896 Scarletwood Terrace
San Jose, CA 95129

From: Charles R. Bolz
Office of Graduate Studies and Research

Date: April 23, 1991

The Human Subjects Institutional Review Board has approved your request to use human subjects in the study entitled:

"Bathing Premature Infants with Either Phisoderm
or Cetaphil: A Comparative Study"

This approval is contingent upon the subjects participating in your research project being appropriately protected from risk. This includes the protection of the anonymity of the subjects' identity when they participate in your research project, and with regard to any and all data that may be collected from the subjects. The Board's approval includes continued monitoring of your research by the Board to assure that the subjects are being adequately and properly protected from such risks. If at any time a subject becomes injured or complains of injury, you must notify Dr. Serena Stanford immediately. Injury includes but is not limited to bodily harm, psychological trauma and release of potentially damaging personal information.

Please also be advised that each subject needs to be fully informed and aware that their participation in your research project is voluntary, and that he or she may withdraw from the project at any time. Further, a subject's participation, refusal to participate or withdrawal will not affect any services the subject is receiving or will receive at the institution in which the research is being conducted.

If you have any questions, please contact Dr. Stanford or me at (408) 924-2480.

cc: Frances Munet-Vilaro, Nursing

APPENDIX F
Informed Consent

**Bathing Premature Infants with Either Phisoderm or Cetaphil:
A Comparative Study**

March 5, 1991

**Alfred T. Lane, M.D.
Valerie W. Hensle, B.S.N., R.N.
Susan Stuart, M.D.**

EXPERIMENTAL SUBJECTS BILL OF RIGHTS

Persons who participate in a medical experiment are entitled to certain rights. These rights include but are not limited to the subject's right to:

- be informed of the nature and purpose of the experiment;
- be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized;
- be given a description of any attendant discomforts and risks reasonably to be expected;
- be given an explanation of any benefits to the subject reasonably to be expected;
- be given a disclosure of any appropriate alternatives, drugs or devices that might be advantageous to the subject, their relative risks and benefits;
- be informed of the avenues of medical treatment, if any available to the subject after the experiment if complications should arise;
- be given an opportunity to ask questions concerning the experiment or the procedures involved;
- be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation without prejudice;
- be given a copy the signed and dated consent form;
- and be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion or undue influence on the subject's decision.

Informed Consent

Your son/daughter is invited to participate in a study involving the bathing of premature infants. We hope to learn which cleansing agent, Phisoderm or Cetaphil, is more beneficial in bathing premature infants. Both methods of bathing are currently used in the neonatal intensive care unit (NICU) at _____. Your child was selected as a possible participant in this study because he/she is premature. The risk for developing adverse effects from

either the Phisoderm or the Cetaphil appear to be very minimal.

If you decide to enroll your child in the study, Valerie Hensle, RN and her associates will bath your baby with either Phisoderm or Cetaphil. In this study, your child will be assigned by chance of one group or the other and will have a 50/50 chance of being placed in a group which will receive the Phisoderm bath or the group that will receive the Cetaphil bath. Baths will be given twice per week as is the practice in the NICU. Your baby will be enrolled in the study for three weeks. After that time, your baby will be bathed by whichever nurse is caring for him/her. The cleansing agent used after the study will be left up to the discretion of the nurse caring for your baby. Your baby's temperature, heart rate, respiration rate, oxygen saturation and blood pressure will be recorded before and after each bath. This will be done in order to establish how well the baby tolerated the bath. A swab culture of the baby's skin will be taken before and after the first, third, and sixth bath. This will be done in order to determine the number and type of germs on the skin. The condition of the baby's skin will be observed and recorded. Pictures may also be taken of your baby. This study could lead to findings which show which cleansing agent is better for premature infants. WE CANNOT AND DO NOT GUARANTEE OR PROMISE THAT YOU WILL RECEIVE ANY BENEFITS FROM THIS STUDY.

Any data or pictures that may be published in scientific journals will not reveal the identity of your child. In the interest of public safety, patient information will be provided to Federal and regulatory agencies as required. The Food and Drug Administration, for example, has the right to inspect research records and, therefore, could learn the identity of your child if your were involved in any study performed under FDA supervision.

No payment will be provided for this project. There will be no additional cost to you for participation in this study. The Pediatric Research Group at _____ is providing financial support for this study.

Your decision whether or not to have your child participate will not prejudice his/her medical care. If you decide to participate, you are free to withdraw your consent and to discontinue participation at any time without prejudice to you or effect on your medical care. If you have questions, we expect you to ask us. If you have any additional questions later, Nurse Valerie Hensle at ____-7176, will be happy to

answer them.

All forms of medical diagnosis and treatment -- whether routine or experimental -- involve some risk of injury. In spite of all precautions, your child might develop medical complications from participating in this study. If such complications arise, the researchers will assist you in obtaining appropriate medical treatment, but this study does not provide financial assistance of additional medical or other costs. You do not waive any liability rights for personal injury by signing this form. For further information, please call (____) ____-5244 or write the Administrative Panel on Human Subjects in Medical Research at Medical School Office Building, _____. In addition, if you are not satisfied with the manner in which this study is being conducted or if you have any questions concerning your rights as a study participant, please contact the Human Subjects Office at the same address and telephone number.

YOUR SIGNATURE INDICATES THAT YOU HAVE READ AND UNDERSTAND THE ABOVE INFORMATION, THAT YOU HAVE DISCUSSED THIS STUDY WITH THE PRINCIPAL INVESTIGATOR AND HER STAFF, THAT YOU HAVE DECIDED TO PARTICIPATE BASED ON THE INFORMATION PROVIDED, AND THAT A COPY OF THIS FORM HAS BEEN GIVEN TO YOU.

Child's Name

Signature of Parent

Date

Signature of Investigator or Witness

APPENDIX G
Demographic Data Collection Form

BASIC DATA COLLECTION SHEET

BACKGROUND

Name/ID # _____

Group: Phisoderm/Cetaphil

Sex: male/female

Date of Birth _____

Gestational Age at Birth _____

Birth Weight _____

Skin Condition Before 1st Bath _____

ANTIBIOTICS

Name	Started	Disc.	BC results
------	---------	-------	------------

1.

2.

3.

MEDICAL PROBLEMS

1.

2.

3.

4.

5.

APPENDIX H
Skin Condition Evaluation Form

SKIN CONDITION EVALUATION FORM

ID# _____

Evaluated twice per week on Monday and Friday afternoons.

Skin Condition Rating Scale

0=normal	No sign of dry skin.
1,2,3=mild	Dry skin with fine white, thin scales barely raised along margins. Skin may be slightly rough to touch. No fissures or inflammation.
4,5,6=moderate	Dry skin with white to tan or light brown scales with definite margins. Skin rough to touch with white appearance. Few fissures may be present but are shallow and not hemorrhagic. There may be faint erythema, not due to extrinsic causes such as excoriations, rubbing, irritants, or other skin disorders.
7,8,9=severe	Very dry skin with well-demarcated heavy scaling and clearly discernible patches. Skin very rough to touch. Deep fissures may be present, some hemorrhagic to the extreme of eczema craquele. Erythema is usually present.

1) DURING THE FIRST WEEK OF LIFE

A) Date: _____

Dorsum of hand _____ Dorsum of foot _____ Abdomen _____

Comment _____

B) Date: _____

Dorsum of hand _____ Dorsum of foot _____ Abdomen _____

Comment _____

SKIN CONDITION EVAL CONTINUED

ID#_____

2) DURING THE SECOND WEEK OF LIFE

A) Date:_____

Dorsum of hand_____ Dorsum of foot_____ Abdomen_____

Comment_____

B) Date:_____

Dorsum of hand_____ Dorsum of foot_____ Abdomen_____

Comment_____

3) DURING THE THIRD WEEK OF LIFE

A) Date:_____

Dorsum of hand_____ Dorsum of foot_____ Abdomen_____

Comment_____

B) Date:_____

Dorsum of hand_____ Dorsum of foot_____ Abdomen_____

Comment_____

PHOTOGRAPHSSITEDATE

APPENDIX I
Culture Results Sheet

CULTURE RESULTS SHEET

ID# _____

CULTURE #1DATE _____Before BathAfter Bath_____

_____CULTURE #2DATE _____Before BathAfter Bath_____

_____CULTURE #3DATE _____Before BathAfter Bath_____

APPENDIX J

Bedside Vital Sign Data Collection Sheet

BEDSIDE VITAL SIGNS DATA COLLECTION SHEET

ID # _____

DATE _____

Type of Bed: Radiant Warmer / Isolette

Time	AX Temp	HR	RR	O ₂ Sat	MAP
starting	_____	_____	_____	_____	_____
½ min		_____	_____	_____	_____
1 min		_____	_____	_____	_____
1½ min		_____	_____	_____	_____
2 min		_____	_____	_____	_____
2½ min		_____	_____	_____	_____
3 min		_____	_____	_____	_____
3½ min		_____	_____	_____	_____
4 min		_____	_____	_____	_____
4½ min		_____	_____	_____	_____
5 min		_____	_____	_____	_____
5½ min		_____	_____	_____	_____
6 min		_____	_____	_____	_____
6½ min		_____	_____	_____	_____
7 min		_____	_____	_____	_____
7½ min		_____	_____	_____	_____
ending	_____	_____	_____	_____	_____

Did you increase FiO₂ during bath? YES / NO

Did baby cry during the bath? YES / NO

COMMENTS _____