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EFFECTS OF A TOPICAL APPLICATION OF CHLORHEXIDINE 1% CREAM ON CLINICAL SIGNS OF INFECTION IN NEWBORN INFANTS.

F. Bottin
Honours. (Nurs)
1993

USE OF THESIS

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EFFECTS OF A TOPICAL APPLICATION OF CHLORHEXIDINE 1% CREAM ON CLINICAL SIGNS OF INFECTION IN NEWBORN INFANTS.

BY

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ABSTRACT

For the past 40 years midwives and neonatal nurses have been applying antistaphylococcal cream to newborns, to reduce the risk of *Staphylocccus aureus* (*Staph. aureus*) infections. The purpose of this study was to determine whether there was any difference in the incidence of clinical signs of infection in newborns, untreated or treated with a topical application of the currently used antistaphylococcal cream chlorhexidine 1%.

The experimental design compared two groups of randomly assigned newborns, using an observation chart based on indicators of infection. Observations were recorded twice a day for four days. Any specific or non-specific signs of infection that were clearly featured by the newborns were referred to a physician and infections were confirmed by laboratory studies.

The data were analysed using a statistical test of proportions, where the Z statistic was calculated. Overall, clinical signs of infection were detected in seven newborns, four from the chlorhexidine group and three from the non-chlorhexidine group. There was no significant statistical difference in the incidence of signs of clinical infection in the two groups. The withdrawal of the cream from use in healthy newborns

would have the following implications for nursing practice (a) the reduced disturbance to the development of the newborn's protective normal bacterial flora, and (b) the prevention of unnecessary cost in terms of nurses' time and creams.

Further research is recommended with a larger sample to substantiate the present study.

Declaration

"I certify that this thesis does not incorporate, without acknowledgement, any material previously submitted for a degree or diploma in any institution of higher education and that, to the best of my knowledge and belief, it does not contain any material previously published or written by another person except where due reference is made in the text".

Signed: 10.2.1994

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Chapter 1

INTRODUCTION

1.1 Background and Significance of the Problem

As newborns are delivered from their sterile environment within the uterus, they are subject to colonization with bacteria, both internally and externally (Van De Graff & Fox, 1986). Some of these bacteria become part of the newborn's normal flora and are essential in body functioning. Until these normal flora are fully established, the baby is at risk of acquiring pathogens such as *Staph. aureus* (Burton, 1988). In the past this risk was exacerbated by some hospital practices, for example, frequent handling of newborns by different staff (Gillespie, Simpson & Tozer, 1958).

During the early 1950s newborn staphylococcal infections were treated extensively with antibiotics and sulphonamides (Farquharson, Penny, Edwards & Barr, 1952; Gillespie et al., 1958). Overuse of these drugs, however, caused resistant strains of *Staph. aureus* to emerge. An antistaphylococcal agent, hexachlorophene, was therefore introduced, resulting in a decreased incidence of *Staph. aureus* infections in newborns (Corner, Crowther & Eades, 1960). Chlorhexidine was substituted for hexachlorophene from about 1972-3 onwards, following evidence of a possible link between the latter substance and central nervous system damage in rats (Gaines & Kimbrough, 1971) and human newborns (Gowdy & Ulsamer, 1976).

Chlorhexidine has continued to be routinely applied by nursing staff to newborns on Day 1 and 3 after birth. In recent years, however, marked changes have occurred in hospital environments and practices which have reduced the risk of infection. In particular the advent of "rooming-in" has resulted in less handling of newborns by nursing staff. Despite these changes very little research on the effect of chlorhexidine in preventing infections in newborns has been undertaken. It is important then, to determine if the routine application of an antistaphylococcal agent is justifiable in terms of nurses' time and cost of the creams and whether its use should continue as part of nursing practice.

1.2 Purpose

The purpose of the study is to determine whether there is a difference in the incidence of clinical signs of infection (confirmed by laboratory studies) in newborns untreated with chlorhexidine 1% compared with treated newborns.

1.3 Conceptual Framework

The theoretical framework for the research is that of Nightingale's Environmental Theory of Nursing. Nightingale's focus was on "changing and manipulating the environment in order to put the patient in the best possible condition for nature to act" (Stanton & George, 1990, p.351).

This theory is applicable to the study because unfavourable hospital environments in the past led to the introduction of topical antistaphyloc cal agents being applied to newborns. Nightingale believed that for proper nursing care to be carried out, there should be healthy surroundings. Although Nightingale addressed the home situation when confronting health issues, it is accepted that the hospital environment should be acknowledged in her statement:- "There are five essential points in securing the health of houses: (1) pure air; 2) pure water; (3) efficient drainage; (4) cleanliness [and] (5) light. Without these, no house can be healthy" (Marriner-Tomey, 1989, p. 67).

A factor which helps newborns to adapt to their needs and reduce stress is cleanliness. This can be achieved through the meticulous handwashing of all persons handling newborns. Removing soiled matter from the sensitive skin of newborns only requires cleansing with warm water or a pure mild soap. By allowing newborns to "room-in" with their mothers, the hospital is approaching a normal home environment, with less need for nursing staff to handle the newborns, thus reducing the likelihood of staff-newborn cross-infection. Encouraging maternal-newborn contact promotes quick colonization of newborns with maternal microflora, thus preventing colonization by pathogens such as *Staph. aureus.*

Providing an optimal environment similar to that of the home situation ensures that newborns remain in optimal health. Therefore, these newborns should not be at risk of infection. If risk of infection is reduced there should be no need for the prophylactic use of antistaphylococcal creams.

Extrapolating from Nightingale's Theory, the application of chlorhexidine cream in this study is considered to be a manipulation of the newborn's external environment which may be unnecessary if optimal hospital practices and environmental conditions are maintained.

1.4 Hypothesis

There will be no significant difference between the incidence of clinical signs of infection confirmed by laboratory cultures of *Staph. aureus* in newborns untreated with chlorhexidine 1% cream, compared with those treated with chlorhexidine 1% cream.

Independent Variable - chlorhexidine cream 1%.

Dependent Variables - observed specific and non-specific clinical signs of infection, confirmed by laboratory culture of *Staph. aureus*.

1.5 Definition of Terms

APGAR score: A method for determining a newborn's condition at birth by scoring the heart rate, respiratory effort, muscle tone, reflex irritability, and colour. The newborn is rated from zero to two on each of the five items. The APGAR score is an objective way of assessing and describing a newborn's adaptation to extrauterine life (Miller & Keane, 1992).

Gestation: The duration of pregnancy as calculated from the first day of the last normal menstrual period. The normal limits of the human gestation period are from 37 weeks to 42 weeks.

Occiput: The back part of the head.

Specific Signs of Infection

(1) Conjunctivitis:- A yellow/green exudate from the inner canthus of one or both eyes, in conjunction with inflammation of the sclera of the eyes.

(2) Pustulosis:- Appearance of pustules on the surface of newborns skin after the second day.

(3a) Funistitis:- Inflammation of the umbilical cord.

(3b) Oomphalitis:- Inflammation of the base of cord.

(4) Paronychia:- Collection of purulent material at the base of the nail bed (cuticle).

(5) Fever:- A persistent axillary temperature greater than 37.0 Celcius (^{o}C), on two occasions, at hourly intervals not related to overwrapped or being placed next to a window through which the sun may shine.

Non Specific Signs of Infection

(6) Pallor:- Extreme paleness of generalized appearance, not related to loss of foetal/neonatal blood at delivery.

(7) Lethargy/refusal of feeds. Inactive newborn, disinterested in making any effort to suckle or feed, not related to being cold or hypoglycaemic (low sugar levels within the blood).

(8) Hypotonia:- Reduced/poor muscle tone (flaccid). Onset not occurring before five minutes after birth.

(9) Tachycardia:- A heart rate greater than 160 beats per minute (bpm), on two separate occasions at hourly intervals, not related to crying.

(10) Hypothermia:- A persistently low axillary temperature less than 35.5 ^{o}C, on two separate occasions at hourly intervals, not related to being insufficiently wrapped.

(11) Vomiting:- Regurgitation of feeds (previously tolerated). Not related to overfeeding, or passing of wind (burp).

(12) Respiratory distress:- A respiratory rate greater than 60 respirations per minute (rpm) on two separate occasions at hourly interval with nasal flaring, rib recession, and/or grunting. Not occurring at the delivery.

(13) Irritability:- Unexplained restlessness, not related to soiled napkin, hunger or instrumental delivery.

(14) Mottling of Skin:- Loss of body perfusion.

DS:- Day shift.

NS:- Night shift.

Chapter 2.

REVIEW OF LITERATURE

2.1 Development of Newborn Human Skin Flora

Newborn human skin begins to acquire a variety of microbes the moment the newborn enters the birth canal. These microbes, which are known as normal flora, proliferate and establish themselves (colonise) in succeeding days. The colonisation of newborns by normal flora is influenced by contact with the mother, other persons particularly hospital staff, and environmental factors such as heat, cold and clothing.

Normal flora of the skin are mostly comprised of bacteria. Washing only temporarily removes superficial and transient flora, but does not eliminate those in deeper layers, within pores, skin creases and hair follicles. The type of flora varies with body structures such as skin creases, bodily secretions and the extent of sebaceous glands. Resident bacteria of the skin are beneficial to the host because they help to prevent colonisation of pathogenic species, such as *Staph. aureus* (Burton, 1988).

2.2 Protective Mechanisms of Newborns' Skin

There are two factors which regulate the growth of bacteria on newborn skin and prevent overgrowth of harmful bacteria. One is the natural protective substance known as vernix caesiosa, which appears in foetal development. The vernix caesiosa consists of

fatty secretions from sebaceous glands and provides an anti-infective coating on the newborn's skin which is generally absorbed within 24 hours of birth. Due to its anti-infective properties the vernix caesiosa should not be removed other than for aesthetic reasons (American Academy of Pediatrics, (AAP), 1974; Haun, Porter & Chance, 1984). The second protective factor is the pH of the newborn's skin which is 4.95. This skin acidity is very important in maintaining a balanced growth of normal microbial flora on the skin (Bobak, Jansen & Zalar, 1989). The natural skin ecology resists the intrusion of unwanted pathogens (Lisboa, Crowther & Davis, 1986). It is essential, therefore, not to disturb the balance of skin flora during this especially vulnerable time for newborns as they become colonized.

One of the most common groups of bacteria which form part of the normal skin flora is *Staphylococcus*. Staphylococci are currently classified into three major groups; *Staphylococcus aureus, Staphylococcus epidermidis,* and *Staphylococcus saprophyticus*. While *Staph. epidermidis and Staph. saprophyticus* are part of the normal skin flora of most healthy people, *Staph. aureus* is recognized as a pathogenic (disease causing) organism. However, it too, may transiently comprise part of the normal flora of up to 20% of healthy people (Burton, 1988).

2.3 *Staphylococcus* Infection in Newborns

Staph. aureus has been responsible for significant numbers of newborn infections in the past. During the 1950s -1960s swabs were collected from various sites on newborns' skin, and cultures indicated a high colonization rate of *Staphylococcus* which was associated with an increased incidence of staphylococcal infections in hospital nurseries (Gehlbach, Gutman, Wilfred, Brumly & Katz, 1975). In one study, identical strains of *Staph. aureus* resistant to antibiotics were present in nursing personnel and newborns (Farquharson et al., 1952), indicating that cross infection was occurring between nursing personnel and newborns. The high rate of staphylococcal infections in newborns in the 1950s-1960s is now thought to be due to overcrowded nurseries and cross infection through overhandling of newborns by nursing staff (Haley & Bregman, 1982).

2.4 Treatment of Staphylococcal Infection in Newborns

Once the problem was identified, research initially focused on methods of reducing *Staph. aureus* colonization to decrease infections with this organism in newborns. The most widely practised method to control *Staph. aureus* epidemics in newborn nurseries was the use of antibiotics and sulphonamides. Excessive use of these agents in treating newborn staphylococcal infections in the 1950s, however, contributed to the development of resistant strains of *Staph. aureus* (Farquharson et al., 1952). This in turn led to an increased incidence of

staphylococcal infections which were harder to treat. Hexachlorophene was introduced to combat the problem of resistant strains of *Staph. aureus* (Plueckhahn & Banks, 1958), and was subsequently widely used in hospitals as a topical lotion added to bath water or applied after bathing.

During the mid 1960s hexachlorophene was used in combination with detergents as a bathing solution (Infa-Care) and was used routinely by nursing staff and mothers instead of baby soap (Gregory & Frick, 1967; Lisboa, Crowther & Davis, 1966). Infa-Care is still used today in some maternity units instead of bath soap, although hexachlorophene has been removed, and the Infa-Care solution is now purely detergent based.

Although hexachlorophene was effective in decreasing staphylococcal colonization and infection rates (Corner, Crowther & Eades, 1960; Gluck & Wood, 1961), rat studies by Gaines & Kimbrough (1971) found that hexachlorophene caused central nervous system damage. Subsequent studies in humans suggested that hexachlorophene may cause similar harmful effects in newborns (Gowdy & Ulsamer, 1976). Based on these findings the United States Federal Drug Administration (FDA) and the (AAP) in 1972 recommended that the use of hexachlorophene for newborn bathing be discontinued. In Australia hexachlorophene has been replaced by the chemically unrelated agent chlorhexidine 1%, which is routinely applied following

the bath at the initial examination of the newborn, and again on Day 3. In some maternity and paediatric institutions, chlorhexidine is used on alternate days until the discharge of the newborn.

In recent years the need for antistaphylococcal treatment has been questioned, as hospital environments and nursing practices have changed. Since the routine application of an antistaphylococcal cream was introduced, conditions in maternity units have improved, with less crowding of rooms, provision of better natural lighting, improved ventilation and air-conditioning. Moreover, changing hospital practices such as the now common "rooming-in" of healthy newborns with their mothers and the reduction in time that newborns spend in hospital (2-5 days instead 10-12 days) have resulted in far less handling of newborns by nursing staff and therefore the risk of cross infection has been greatly reduced (Henningsson, Nystrom, & Tunnell, 1981; Memberg & Schoyen, 1985, and Rush, 1986).

Cowan & Frost (1986) found a low incidence of potentially harmful pathogens in healthy term newborns and Wang, Elder & Mishkel (1987) concluded that there was no relationship between staphylococcal colonization and the development of clinical illness in the nursery. A lowered incidence of clinical illness in newborns was demonstrated when persistent carriage of the same strains

of *Staph. aureus* was present, compared to those newborns who demonstrated a transient carriage of *Staph. aureus*.

2.5 Alternative Ways of Reducing Staphylococcal Infections

Recent public awareness about the dangers of chemicals within the environment and the effect that they have on our bodies, has generated research comparing the use of different bathing substances and techniques, and the effect they have on newborn skin flora. In a laboratory setting Smeenk (1969) tested the reaction of adult human skin to nine different detergents and found that regular contact with particular detergents can cause skin damage. As newborn skin is likely to be more sensitive to chemicals than adult skin, it is possible that Smeenk's findings would be relevant to newborns' skin.

Memberg & Schoyen (1985) studied the effects of skin and umbilical disinfection on the relationship between bacterial colonization and neonatal infection in the nursery. They compared the use of soap wash, Benzine, chlorhexidine 0.5% and Hibiscrub (4% chlorhexidine) within the nursery. Of these cleaning regimens, only Hibiscrub reduced the rate of colonization of *Staph. aureus*. The observed reduction from 5.4% to 2% however, was not statistically significant and no difference in infection rates occurred between the Hibiscrub treated group and the control group (normal soap wash) after discharge.

More recently, Cowan & Frost (1986) conducted a trial in which the effectiveness of the two products, liquid detergent and baby soap was compared to detect differences in the transmission rate of pathogenic or resistant species. They suggested that the current trend of using liquid detergents and soaps in newborns' baths, resulted in the removal of some of the valuable amino acid content from the cells of the skin surface, which may increase vulnerability to infection. During the study period mothers were discouraged from using any topical antiseptic creams. Although the sample size of 22 was small and a bigger sample may have lead to different findings, no infections occurred during the trial period. Their findings indicated that the two different products were safe and had no effect on the normal skin flora of newborns, and made no difference to the transmission rate of pathogenic or resistant species. However, no antiseptic creams were used to disturb the balance of normal flora on newborns' skin. The skin's natural bacteriostatic effect therefore, was sufficient to prevent infection.

Rush (1986) compared routine newborn bathing practices with "dry skin" practice (the 'spot' cleansing of the newborn's skin, when soiled, without bathing) to determine the effect on *Staph. aureus* colonization. Of the sample of 186 newborns, 99 were bathed with soap and water and 87 were not bathed after the initial bath until discharged from hospital. The mean length of stay in

hospital for the bath group was 4.7 days, and the mean length of stay for the non-bathed group was 4.6 days. A total of 71 newborns became colonized, 36% of the bathed babies and 35% of the non-bathed newborns. Infection developed in four cases, all of which occurred between the fourth and sixth day in hospital. The specific group in which the infections occurred was not identified.

Although the author does not state in which group the infections occurred, Rush (1986) concluded that there was no significant difference in infection rates between groups using the routine bathing practice and the "dry skin" technique. Despite the high colonization rate with *Staph. aureus*, there were very few reported infections. The method of cleansing had no effect on the infection rate, even though there was no antistaphylococcal agent used. Therefore it is reasonable to assume that the newborns' n ıral bacteriostatic processes were adequate to protect them from harmful pathogen invasion.

2.6 Summary

The results of recent research, (Cowan & Frost, 1986; Memberg & Schoyen, 1985; Rush, 1986 and Wang, Elder & Mishkel, 1987) suggest that colonization with *Staph. aureus* does not inevitably lead to clinical infection in healthy full term newborn infants. Current thinking has recognized the beneficial effects of the newborns' natural flora, together with a reduced risk of infection associated with improvements in nursing practice and hospital environments. Thus, the need for the continued

application of chlorhexidine cream as part of routine care of healthy full term newborns is now questioned. A recent informal survey (Bottin, 1992) of a convenience sample of 26 maternity units in Australia, found that 82% had discontinued the use of antistaphylococcal creams, based on their claims to have no increase in infection rates. It is not known if these reports on infection rates were derived from controlled studies or personal observation.

In conclusion, whilst acknowledging the necessity of the routine use of antistaphylococcal agents in the past, its present use is questionable. This study will determine whether the practice of chlorhexidine 1% application on healthy full term newborns has any effect on the incidence of staphylococcal infection.

Chapter 3.

METHODS

3.1 Design

A randomized double blind experimental design was used to compare two groups of newborns for observed signs of clinical infection. The independent variable for this study was the application of Chlorhexidine 1% cream by nursing staff to newborns on Day 1 and Day 3 after birth.

3.2 Sample and Setting

The setting was a maternity unit within a public hospital in Perth, Western Australia. Of the 437 newborns born during the data collection period, 299 (68.5%) were not included because they participated in the Early Discharge Program (EDP). All other newborns were included in the study if they were full term and weighed 2500-4500 grams, with an APGAR score of no less than eight at five minutes and if their mothers remained in hospital for at least four days after birth. newborns born by emergency caesarian section were included if the birth was unrelated to foetal distress.

Newborns were excluded from the study if they exhibited signs of foetal distress during labour as demonstrated by meconium stained liquor. This, in conjunction with a persistent increase in foetal heart rate above 160 beats per minute (bpm), or a persistent decrease in foetal heart rate below 100bpm, which was not

related to the second stage of labour. Newborns who displayed prolonged decelerations as depicted on a Cardio-tocograph machine were also excluded, as were those where the paediatrician refused to give permission. All mothers with known harmful vaginal pathogens as confirmed by laboratory tests. Finally, all mothers who were unable to speak or read English were also excluded.

Figure 1 shows the number of newborns born during the study period. Of the 437 newborns born a large proportion failed to meet the inclusion criteria.

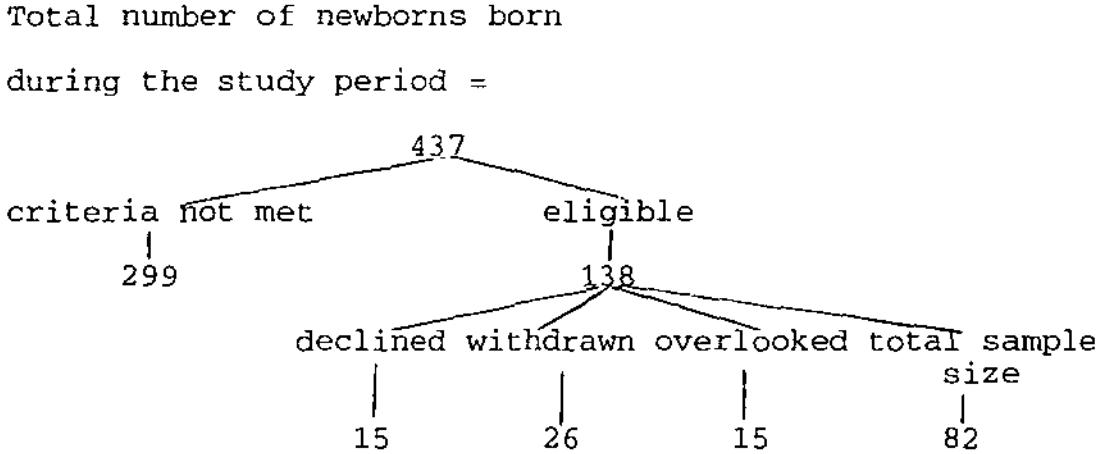

Figure 1. Sample breakdown.

Of the 138 newborns eligible for inclusion into the study, 25 were withdrawn as their mothers chose to go home early from hospital. Fifteen mothers declined to participate. Their reasons included a) maternal partners declined permission for their newborns to take part in research, b) mothers were hesitant about the context of

the word research, even when they were given additional information and explanation by the researcher, and c) mothers wanted to select the group to which their newborn was allocated. Fifteen infants were accidently overlooked by staff, and one newborn was withdrawn from the study when it was known that the mother had harmful vaginal pathogens. This left a total sample size of 82 healthy full term newborns who were randomly assigned to two groups.

3.3 Instrument

The dependent variables were measured by observing infants for specific and non-specific signs of infection and recording results of laboratory cultures of swabs taken.

Although a thorough search of all possible research tools was made, none was found. A data collection sheet was designed for the purpose of this study, based on indicators of infection described in the literature (Tudehope & Thearle, 1984; Valman, 1989), and observed in clinical practice. (Signs of Clinical Infection in Newborns (S.C.I.N.) Sheet (APPENDIX B). The S.C.I.N. sheet incorporated sections for observation of clinical signs of infection in neonates, collection of demographic data such as sex, gestation, type of delivery, APGAR score and weight, and for recording the results of laboratory findings.

The instrument classifies signs of infection as specific and non-specific. An example of a specific sign of infection is conjunctivitis. Examples of non-specific signs of infection are lethargy/refusal of feeds (Section 1.5).

Content validity was assessed by three experts in the fields of clinical microbiology and neonatal infections. The review panel recommended changes and they were incorporated into the instrument before use.

To increase the reliability of the instrument, prior to the commencement of data collection, four independent raters, (one of whom was the researcher) trialed the scale. Comparisons made between the results of the three raters and the researcher indicated that there were no observed differences in the reporting of clinical signs of infection. Further comparisons between the three raters and the researcher using the instrument were obtained at regular intervals during the data collection period, with 90-95% agreement.

3.4 Procedure

A pilot study was conducted using 11 newborns so that problems in recruitment procedures and observation techniques could be detected and corrected for the main study. Information sheets were given to all involved nursing staff (APPENDIX A) which included background information on the use of antistaphylococcal creams,

selection criteria, guide-lines to assist the researcher and suggestions and remarks.

The pilot study took two weeks to complete, and resolved all minor procedural problems. The data from the pilot study were not incorporated into the main study's findings.

Before the main study commenced a single nurse from the unit placed 10 numbers between zero and nine in an envelope. The nurse randomly withdrew the numbers allocating them to the chlorhexidine group or the non-chlorhexidine group until all the numbers were equally distributed between both groups. The specifically grouped numbers were then entered into a log book for unit staff to use once the study began. When the study commenced, ward staff gave parent information sheets to all mothers after they had been transferred to the ward following delivery and obtained consent (witnessed and dated by a staff member) from mothers whose newborns met the inclusion criteria. Unit staff matched the last digit of the newborns' identification bracelet to the corresponding number in the log book. This procedure predetermined if the newborn was allocated to the chlorhexidine group or the non-chlorhexidine group. Each newborn was then given an identification code by the researcher, which was known only to her. The researcher was not involved in bathing any of the newborns during

the study period and therefore was blinded to the experimental treatment.

Using the S.C.I.N. Sheet, the researcher observed all newborns assigned to the study twice a day, morning and night, with the time span roughly 12 hours apart. The researcher performed all observations on the newborns.

Newborns were observed at a time when they were settled which commonly occurred after feeding (APPENDIX B). Their apex beats, respiration rates and axillary temperatures were taken prior to loosening blanket wraps and newborns' clothing. The newborns' general appearance was observed for signs of pustules, oomphalitis and funistitis (APPENDIX B). The same procedure was followed by the researcher with every newborn in the sample.

When specific or non-specific signs of infection were present, the physician was notified, the specific investigative tests were performed and the causative micro-organisms were identified by laboratory tests (APPENDIX B).

3.5 Ethical considerations

Mothers were provided with written and verbal information about the study before being asked for written permission for their newborns to participate (APPENDIX C).

Confidentiality was maintained at all times. No names were displayed on the observation sheet and unit record numbers were the only means of identification. During data collection a master list was kept, which allocated a code to each newborn. The master list was kept separate from the data collection sheets, and only the code was entered in the computer.

The application of chlorhexidine 1% cream to the newborn is regarded as normal practice in maternity and neonatal institutions in this state. It is not regarded as routine practice in other states in Australia. Close observation of the newborns was carried out by the researcher, and at no time were any of the newborns in the control group placed at risk. Any clinical evidence indicating specific or non-specific signs of infection was reported to the appropriate medical officer. There was no disturbance to the normal routines of mothers and newborns during the study.

Authorization from the head of the hospital's obstetric unit, hospital executive, and at least one of the attending paediatricians was given prior to commencement of the study.

Chapter 4.

RESULTS

4.1 Maternal and Newborn Characteristics

Of the 82 mothers in the sample, 62% were married, 24% lived in a defacto relationship and 13% were single. Their ages ranged from 18 to 42 years with a mean age of 29 years, (S.D. = 5.33). Table 1 shows the frequencies and percentages of the gestational period for both groups. Newborns involved in the study were of term gestation, ranging between 37 - 42 weeks (M = 39.84, S.D. = 1.87).

Table 1

Gestational Period

Gestation (Weeks)	Chlorhexidine Group Freq (%)	No Chlorhexidine Group Freq (%)	Total (N =82)
37	2 (5)	0 (0)	2 (2)
38	8 (20)	1 (2)	9 (11)
39	6 (15)	3 (7)	9 (11)
40	20 (49)	25 (61)	45 (55)
41	3 (7)	11 (27)	14 (17)
42	1 (2)	2 (5)	3 (4)

There were six methods of childbirth, of which spontaneous vaginal births were the largest group, and Keilland rotation forceps were the smallest (Table 2).

Table 2

Methods of Childbirth

Type of Delivery	Chlorhexidine Group Freq (%)	No Chlorhexidine Group Freq (%)	Total (N = 82)
Spontaneous vaginal delivery (76)	32 (80)	30 (71)	62
Keilland's rotation forceps (1)	0 (0)	1 (2)	1
Neville Barne's forceps (4)	0 (0)	3 (7)	3
Vacuum extraction (7)	2 (5)	4 (10)	6
Elective caesarean section (9)	4 (10)	3 (7)	7
Non-elective caesarean section (4)	2 (5)	1 (2)	3

Characteristics of the newborns are summarized in Table 3. A chi square test indicated that there was no difference in the gender distribution between the groups, X^2 (1, N = 82) p> .05. APGAR scores ranged from 8-10 at five minutes of age and the Wilcoxon-Mann-Whitney test showed that there was no significant difference in APGAR scores between each group, (Z = -1.6238, p> .05). There was no significant difference in the birth weights of newborns between the chlorhexidine group (M = 3518) and the non-chlorhexidine group (M = 3600), t (80) =.91, p>.05.

Table 3

Characteristics of Newborns in the Two Groups

Variable	Chlorhexidine Group Freq (%)	No Chlorhexidine Group Freq (%)	(N = 82) Freq (%)
Sex			
Males	21 (51)	20 (49)	41 (50)
Females	19 (46)	22 (54)	41 (50)
APGAR Score			
8	4 (10)	0 (0)	4 (5)
9	23 (54)	23 (54)	46 (56)
10	13 (33)	19 (45)	32 (39)
Birth Weight (grams)			
Mean	3518	3600	3560
Range	2700-4360	2740-4400	2700-4400
Standard deviation	387	430	409

4.2 Clinical Signs of Infection in the Two Groups

The research hypothesis stated that there would be no statistical difference in the incidence of clinical signs of infection, as confirmed by laboratory culture of *Staph. aureus*, between the group of healthy full term newborns receiving chlorhexidine, and the group not receiving chlorhexidine.

The total number of newborns who showed clinical signs of infection during the study period was seven; four from the non-chlorhexidine group, and three from the chlorhexidine group.

Statistical analysis was based on a parametric test of proportions (Harrison & Tamaschke, 1984). This was used to determine whether there was a higher proportion of clinical signs of infection in the group not receiving chlorhexidine compared to the group receiving chlorhexidine. The results for the one tailed test were $Z = 0.33$ and $p>.05$. These findings indicated no statistical difference between the two groups. The sample size of the chlorhexidine group was 40 and the sample size of the non-chlorhexidine group was 42. Therefore, the incidence of clinical signs of infection for the chlorhexidine group and non-chlorhexidine group was 7.5% and 9.5% respectively. On the basis of using a one tailed test, a critical Z value of 1.645, a significance level set at $p=.05$., the smallest difference that would be detectable with a statistical power of .80 is eight newborns (showing clinical signs of infection) between the two groups. For example, if there were three infections detected in one group, there would have to be 11 infections detected in the other group.

4.3 Description of clinical signs of infection.

The seven newborns who showed clinical signs of infection could be grouped into four categories which are summarized in Table 4 and discussed below. All but one of the observed clinical signs of infection were investigated by a physician.

4.4 Conjunctivitis.

One newborn (Case 1) from the non-chlorhexidine group developed conjunctivitis in the left eye. The clinical signs appeared 12 hours after birth, and persisted for 36 hours. No swabs were taken from this newborn.

Two other cases (Cases 2 & 3) of conjunctivitis from the chlorhexidine group developed 48 hours after birth and persisted for 36-48 hours. The results of the swabs taken from these newborns are shown in Table 5.

One swab indicated an occasional Gram positive coccus and Gram negative bacillus but culture showed no growth of *Staph. aureus*. The other swab showed moderate numbers of Gram positive cocci and a few leukocytes on microscopy with a heavy growth of mixed skin flora on culture. Such growth is not indicative of *Staph. aureus* infection.

Table 4

Signs of Clinical Infection

	Chlorhexidine Group (N = 40)	No Chlorhexidine Group (N = 42)	Total (N = 82)
Conjunctivitis.	2	1	3
Pustules & Elevated Temperature.	0	1	1
Elevated Temperature & Respiration.	1	1	2
Elevated Temperature & Lethargy/Refusal of feeds.	0	1	1
Total	3	4	7

Table 5

Laboratory Findings

		Microscopy	Culture
Eye Swab			
Case 1	No Chlorhexidine	No swab	No swab
Case 2	Chlorhexidine	Occasional Gram +ve cocci & Gram -ve bacillus	No growth
Case 3	Chlorhexidine	Moderate Gram +ve cocci A few leukocytes	Heavy mixed flora only
Urine			
Case 4	No Chlorhexidine	<5 leukocytes per ml	*E. coli* *Enterococcus faecalis*
Case 5	No Chlorhexidine	a) 5 leukocytes per ml	a) *Staph. aureus* *E. coli*
		b) <5 leukocytes	b) Mixed growth of doubtful significance Colony count 10^3 organisms per ml
Case 7	No Chlorhexidine	Absence of microbes	No growth
Blood			
Case 6	Chlorhexidine	Absence of microbes	No growth
Case 7	No Chlorhexidine	Absence of microbes	No growth

This table lists the organisms that were identified by the various laboratory tests performed. All of the micro-organisms identified are considered part of the normal flora of human skin, or bowel.

4.5 Pustulosis and Elevated Temperature

One newborn (Case 4) from the non-chlorhexidine group displayed signs of an elevated temperature (37.1-37.2, ^{o}C) and a pustular rash. The temperature preceded the rash by 12 hours. The rash appeared at 48 hours after birth and was centrally located on the trunk, with a few spots located in the skin creases of the groin and elbow. Urine analysis identified *E. coli* and *Enterococcus faecalis* with a colony count of $>10^5$ organisms/ml. Since the leukocyte count was within normal limits, this growth was not considered significant. The paediatrician diagnosed dehydration and erythema toxicum neonatorum, a non-infectious condition which manifests as a macular rash with or without pustular vesicles and develops within 2-3 days after birth. Although pustulosis and erythema toxicum neonatorum manifest in similar ways, microscopy would show neutrophils rather than eosinophils if infection was present (Valman, 1989). The cause for this phenomenon is unknown.

4.6 Elevated Temperature and Increased Respiratory Rate

Two newborns, one from each group, developed febrile conditions in conjunction with an increase in respiratory rate. The newborn not receiving chlorhexidine (Case 5), developed an elevated temperature (37.3-38.0 ^{o}C) and an increased respiratory rate (64-68 rpm) on the second day which persisted for 24 hours.

The other newborn from the chlorhexidine group (Case 6) developed an increased temperature (37.1-37.6 ^{o}C) and respiratory rate (64-70 rpm) within 12 hours of birth, which persisted only during the day over a period of three days. The raised respiratory rate lasted for 24 hours and then recurred again on Day 3.

Both newborns had laboratory tests performed. The baby from the non-chlorhexidine group (Case 5) had a urine specimen analysed which showed *Staph. aureus* and *E. coli* (Table 5). A repeat urine specimen taken the following day showed a mixed growth of micro-organisms, the significance of which was not determined. No *Staph. aureus* was isolated from the second specimen. Further tests were considered unnecessary by the paediatrician, as both urine specimens contained leukocyte counts that were within normal limits, indicating that no infection was present. The newborn receiving chlorhexidine (Case 6) who displayed a persistent fluctuating temperature and an increased respiratory rate had blood taken for analysis. This showed no evidence of infection on microscopy or culture.

4.7 Elevated Temperature and Lethargy/Refusal of Feeds

One newborn (Case 7) from the non-chlorhexidine group showed signs of disinterest in feeds and lethargy requiring oro-gastric tube feeds of an artificial formula within 12 hours of birth. This was followed by an increase in temperature (37.2-37.6 ^{o}C) within 24 hours of

birth. Analysis of blood and urine samples showed no growth on culture. By the third day the temperature had resolved, the newborn was more active and alert and was taking oral feeds from a bottle.

4.8 Summary.

Mothers of newborns eligible for inclusion into the study were between 37-42 weeks gestation and 62% of the 82 mothers had normal vaginal births.

Gender of the newborns was evenly distributed between the two groups. Most had an APGAR score of nine at five minutes and birth weights ranged between 2700-4400 grams. Clinical signs of infection were observed in seven babies, three from the chlorhexidine group and four from the non-chlorhexidine group. The significance of these signs is discussed in section 5.2.

Statistical analysis using a test of proportions, was unable to detect a significant difference in clinical signs of infection between the two groups.

Chapter 5.

DISCUSSION

The purpose of this study was to test the hypothesis that there would be no significant difference between the incidence of clinical signs of infection confirmed bt laboratory cultures of *Staph. aureus* in newborns untreated with chlorhexidine 1% cream, compared with those treated with chlorhexidine 1% cream. The results indicated no significant difference between the two groups.

Due to sample size the study ran the risk of a Type II error of probability. A larger sample size may have concluded with more certainty that there was no difference between the two groups. It was not possible to estimate the sample size needed prior to the commencement of this study as there were no statistical data on the incidence of infection rates in newborns at that time. However, the study has provided the hospital with some baseline statistical information on newborn infection rates. In addition, based on the present data for the incidence of clinical signs of infection in newborns, it is possible to calculate how many subjects it would take to detect a significant difference with adequate statistical power. With the desired power set at .80, a significance level of .05 and an effect size of 15%, the number of subjects required to detect a statistically significant difference in infection rates in newborns would be 687 in each group.

5.1 Patterns of Clinical Infections

There were clinical signs of infection detected in seven newborns, four in the non-chlorhexidine group and three in the chlorhexidine group. These signs of infection presented in four distinctive patterns: conjunctivitis; pustulosis with elevated temperature; elevated temperature with raised respiratory rate; and elevated temperature with lethargy, poor feeding and refusal of feeds.

Conjunctivitis.

Three newborns with clinical signs of conjunctivitis, two in the chlorhexidine group and one in the non-chlorhexidine group, were identified according to clinical signs, but none were confirmed by laboratory cultures. Two of the three cases did not respond to routine eye toilets. The two newborns with persistent conjunctivitis were from the group receiving chlorhexidine. These newborns were commenced on Chloramphenicol eye drops and both conditions resolved quickly. A likely cause for the signs of conjunctivitis could be the result of the newborns having rubbed their eyes causing an irritation or inflammation of the conjunctiva to develop, resembling an infection. Irritation of the conjunctiva could also be due to dust or pollen particles inducing a similar reaction.

The overall incidence of conjunctivitis for the present study was low (4%), and no *Staph. aureus* was

cultured. These results are consistent with those of Wang et al. (1987) and Memberg & Schoyen (1985). Wang et al. (1987) detected signs of conjunctivitis in 10 of a sample of 178 newborns (6%). Newborns in this study were not treated with a topical antistaphylococcal agent and only one newborn was found to have *Staph. aureus* on culture. Memberg and Schoyen (1985) showed that from their sample size of 549 newborns, 23 (4%) cases of conjunctivitis were identified. *Staph. aureus* was identified as the causative organism responsible for 96% of all recognized infections in this latter study, despite the use of Hibiscrub (4% chlorhexidine) for bathing newborns. However, differentiation between infections acquired in hospital and those acquired after discharge was not made.

Pustulosis and Elevated Temperature.

One newborn in the non-chlorhexidine group exhibited pustulosis and an elevated temperature. The pustular rash was diagnosed as an erythema toxicum neonatorum that did not warrant swabbing. However, in view of the newborn's poor urinary output and elevated temperature, urine was sent for analysis. *Staph. aureus* was not isolated from this urine specimen, but *E. coli* and *Enterococcus faecalis* were identified from culture results. Since these micro-organisms are part of normal bowel flora, their presence as mixed flora rather than pure culture is suggestive of contamination during

specimen collection, particularly in view of the fact that the leukocyte count was within normal limits.

Dehydration was diagnosed by the paediatrician as the probable cause of the elevated temperature and pustular rash. Treatment consisted of increasing the newborn's oral fluid intake through the introduction of artificial formula after breast feeds until lactation was established. The elevated temperature settled within 24 hours of onset (48 hours after birth), and the pustular rash had dissipated within 36 hours of onset (72 hours after birth).

The results from the present study are congruent with the findings of Wang et al. (1987). The latter study reports that from a sample size of 178 newborns, only five (3%) had pustulosis. This low rate was part of the sum total of 25 (14%) newborns who displayed signs of clinical illness. Of those five newborns, two were colonised by *Staph. aureus* and three were not. The results of Memberg and Schoyen's (1985) study report a slightly higher number of similar infections. From their sample size of 549 newborns, 52 cases (9%) of pemphigus neonatorum (a more severe form of newborn skin infection) were identified. It is not known how many cases of pemphigus neonatorum were acquired in hospital, or what percentage of these infections were due to *Staph. aureus*. However, Memberg and Schoyen documented that 25 (4%) of all registered infections, including pemphigus

neonatorum, were acquired whilst in hospital and *Staph. aureus* was cultured from 96% of all infections.

The findings of the present study are also consistent with those of Gehlbach et al. (1975). These researchers reported that only 11 cases (3%) of pustulosis were identified over a two month period during which antistaphylococcal agents were not used. Re-introduction of antistaphylococcal agents saw an initial decline in staphylococcal and streptococcal colonization rates. However, six to eight weeks later a further three cases of staphylococcal skin disease were recognized, and staphylococcal colonization rates increased. Strains of *Staphylococcus* isolated from the newborns differed from those isolated from hospital personnel, suggesting that there were other sources of contamination. The hospital elected to discontinue antistaphylococcal agents as it made no difference to their *Staph. aureus* colonization rates.

Elevated Temperature and Raised Respiratory Rate.

Two newborns, one from each group, displayed an increase in temperature and respiratory rate. Blood cultures showed no growth of *Staph. aureus*. A possible explanation for these signs in one newborn is that the birth was assisted with a vacuum extractor. A birth of this nature can cause trauma to the newborn's head depending on the amount of pressure that is applied to the suction cup and the number of pulls on the head.

Although the vacuum extractor caused bruising and swelling to the occiput, trauma was not reflected in the newborn's APGAR score which was 10 at five minutes. A second explanation for the elevated temperature and raised respiratory rate was the reduced oral fluid intake and poor urinary output. This led the paediatrician to a diagnosis of dehydration as the likely cause of the clinical signs. During this period the newborn was given complementary feeds of milk formula after each breast feed until the mother's lactation was established. All symptoms had resolved by the third day after birth.

The other newborn (who did not receive chlorhexidine) developed an elevated temperature and increased respiratory rate on the second day after birth and these signs persisted for 24 hours. This newborn had a urine specimen sent for analysis which identified *S. aureus* and *E. coli*. A repeat specimen of urine for analysis the following day showed a mixed growth of micro-organisms, the significance of which was questioned by the paediatrician. A possible explanation for the variable results could have been that the specimen was contaminated by the specimen collector. The staff member collecting the sample could have accidently contaminated the specimen with *Staph. aureus* from her own normal flora or that of the newborn. Another possible cause for conflicting results could have been variability in laboratory technique.

The likely cause of the clinical signs was dehydration, since the newborn's urinary output was poor and the mother's lactation was not established. Treatment involved increasing the newborn's oral fluid intake through the introduction of milk formula until the mother's lactation was established. Urinary output improved within hours and the clinical signs of elevated temperature and raised respiratory rate had subsided by the next day (third day).

Elevated Temperature, Lethargy and Refusal of Feeds.

One newborn developed clinical signs which are characteristic of staphylococcal bacteremia. Haley and Bregman (1982) define staphylococcal bacteremia as a condition occurring in a previously stable newborn who develops "lethargy, poor feeding habits and other signs of sepsis" (p.p. 876). The newborn had an unassisted vaginal birth, with an APGAR score of nine at five minutes and was considered to be in a stable condition at birth by the attending doctor. However, the newborn made no effort to suckle at the breast soon after birth, and therefore oro-gastric tube feeds of an artificial formula were initiated at 12 hours of age. The paediatrician ordered urine and blood samples for analysis. These samples showed no growth on culture. After three days of attempted breast feeds with oro-gastric feeds afterwards, the mother elected to suppress lactation and successfully fed her baby from a bottle.

As this newborn was receiving feeds from 12 hours of age, and urinary output was good, dehydration was dismissed as a probable cause of these symptoms. There were no other environmental causes for the factors which would have led to overheating. Once the newborn commenced bottle feeds no further problems were encountered. Thus, while reasons for the lethargy were not apparent, the observed signs appeared to be unrelated to infection.

5.2 Significance of Clinical Signs of Infection

Of the seven cases that exhibited clinical signs of infection, three cases showed only one specific sign of infection (conjunctivitis), one case showed two specific signs (pustulosis and elevated temperature) and three showed a combination of one specific sign with one non-specific sign (elevated temperature with raised respiratory rate X 2; and elevated temperature with lethargy and refusal of feeds). All newborns had at least one specific sign of infection as defined on the S.C.I.N. sheet (APPENDIX B). The results showed that only one case of *Staph. aureus* was isolated from culture out of all the clinical signs of infection investigated and this was not diagnosed as an infection. Overall, clinical signs of infection that were identified during the study period were of a non-serious nature. The two cases of conjunctivitis were treated with antibiotic eye drops. One other newborn who had an elevated temperature

and increased respiratory rate (case 6) was treated with oral antibiotics as a precautionary measure.

5.3 Theory Application in the Control of Infection

Recent neonatal nursing practices based on current research have attempted to provide an optimal environment similar to that of the home situation. This situation helps to reduce the risk of acquiring nosocomial infections, as set down in Nightingale's Environmental Theory of Nursing. A number of researchers have commented on the benefits of "rooming-in" as a means of reducing staphylococcal colonization (Campbell & Pitkewicz, 1978; Gooch & Britt, 1982; Hargiss & Larson, 1978; Gehlbach et al., 1975, and Wang et al., 1987). However, few of the hospitals in those studies practised "rooming-in" during the night. Most newborns were returned to nurseries overnight. Mothers of newborns in the present study were encouraged to "room-in" with their newborns unless they were unable to settle them, or they were incapable of looking after them through illness. "Rooming-in" is viewed as an ideal way of reducing infection through less handling of newborns by staff. However, there is the possibility of visitors handling newborns, thereby increasing the risk of infection from a source other than the hospital environment. Nevertheless, there is less risk to the newborns from visitors who are unlikely to be colonised with harmful hospital bacteria.

Another factor which is generally believed to have reduced the rate of neonatal infections has been the length of stay in hospital. Most researchers now advocate a short stay in hospital, with an average length of stay after vaginal birth of 3-5 days and 5-7 days after caesarean birth (Campbell & Pitkwicz, 1978; Gehlbach et al., 1975; Hargiss & Larson, 1978 & Wang et al. 1987). Rush (1986) reports that there is a definite trend towards increased infection rates with prolonged lengths of stay in hospital. In Rush's study there were no reported infections up to the fourth day, thereafter, from the fifth to sixth days there were four infections recorded. Gooch & Britt (1978) showed that as the length of stay increases, so do the number of reported infections. For example, during the first week of hospitalization there were no reported infections. From weeks 1-10, however, there were two cases where one or more infections had occurred and from weeks 11-20 there were 13 cases when one or more infections had occurred and five cases when two or more infections occurred. These findings suggest that there is a correlation between the length of stay and the rate of infections acquired in hospital. Still, reduced lengths of stay in hospital may result in misleading data on infection rates if there is no method of post discharge surveillance.

Nightingale's Environmental Theory is based on five essential points, one of which is cleanliness. In the past it was not uncommon for nursing staff to wear scrub

dresses, hair nets or caps and to change gowns between handling each infant. Other hospitals advocated the use of gowns only to cover the street clothes of hospital personnel and parents (Campbell & Pitkewicz, 1978; Gooch & Britt, 1978; Williams & Oliver, 1969). All hospital staff were instructed on the importance of handwashing technique. This routine varied from a 3-5 minute scrub with a recommended cleanser (hexachlorophene 3% or chlorhexidine 4%) on entering and leaving the nursery and between handling each newborn. Hospitals have now dispensed with hairnets, caps, scrub dresses and gowns other than for protection of uniforms against infant soiling. Past research has shown that these measures were ineffective or made no difference to the rate of staphylococcal colonization rates in newborns (Williams & Oliver, 1969). Rather, research has supported that handwashing is of major importance in the control of *Staph. aureus* infections (Campbell & Pitkewicz, 1978; Gehlbach et al., 1975; and Rush, 1986). Rush (1986) noticed a 20% reduction in the incidence of staphylococcal colonization when hospital staff were reminded of the importance of handwashing technique. Hospital personnel were encouraged to act as role models for students, parents and visitors, in the hope that they would do the same. Thus, rather than applying topical antiseptics to newborns' skin, nurses should be paying more attention to careful handwashing.

5.4 The Instrument as an Effective Tool

The instrument was a valuable tool in its ability to enhance recognition of any clinical problems exhibited by the babies. The tool was designed to detect all possible complications resulting from withholding antistaphylococcal treatments. However, it was not a reliable indicator of infection rates as it lacked specificity. The tool would be useful for monitoring purposes for the detection of complications in newborns. For the tool to be useful as an indicator of infection rates it would have to be more stringent. For example, for a temperature to be classified as a febrile condition, the newborn had to have had a persistent axillary temperature greater than 37.0 ^{o}C., on two separate occasions, not related to environmental factors (Section 1.5). To ensure that this sign is a true indicator of infection, the level might need to be increased to a temperature which is greater than 38.0 ^{o}C on two separate occasions, at one hour apart not related to environmental factors.

Midwives and neonatal nurses use their powers of observation based on their knowledge and expertise to recognize what is normal and abnormal in newborns. The instrument assisted the researcher and enhanced her competence in this area by providing the foundations from which to build a reliable assessment guide.

In the present research, from the sample of 82 newborns, only seven displayed clinical signs of infection, and of these, only four displayed specific signs of infection; three with conjunctivitis and one with an elevated temperature and pustulosis. The other three displayed combinations of a specific with non-specific signs; two newborns with an elevated temperature with an increased respiratory rate and one with an elevated temperature with lethargy and refusal of feeds. Of those seven cases, only two cases were shown to have potential pathogens present, but these findings were not diagnosed as true infections and were not treated. Both these newborns came from the non-chlorhexidine group.

One possible explanation for the low infection rate in both groups could be attributed to the use of an antistaphylococcal agent, as the approximate ratio of treated newborns to untreated was 395 to 42, which included a high percentage (47%) of newborns who went home on the early discharge program. Thus, since approximately 90% of the newborns might have obtained a protective effect from the application of chlorhexidine 1%, it is possible that the remaining newborns could have also acquired an associated protection as the reservoir of colonized newborns could have been reduced. Further research would be required to test this hypothesis.

Chapter 6.

CONCLUSIONS

Optimal health of the newborns was achieved by adhering to Nightingale's five essential points in maintaining a healthy environment, providing high standards of nursing practice and a hospital setting similar to that of the home situation. This enabled the natural bacteriostatic processes of the newborn's skin to act without putting them at risk of infection.

In this study there was no significant difference in clinical signs of infection between healthy full term newborns in the group receiving chlorhexidine and the group not receiving chlorhexidine. Thus, chlorhexidine 1% appears to be of limited value as a topical antistaphylococcal agent on healthy newborns' skin. However, caution must be expressed due to the limitations of the present study.

6.1 Implications for Nursing Practice

The findings of the present study suggest that midwives and neonatal nurses can no longer justify the continued application of chlorhexidine 1% on newborn's skin as part of nursing practice. This procedure is no longer performed by nursing staff in most Eastern states of Australia (Bottin,1992). Even though the present study's sample size was small, and a larger sample size may have produced different results, a trial period of withdrawal of chlorhexidine 1% with strict surveillance

program monitoring rates of newborn infections is suggested. This would eliminate the potential problem of the protective effect of chlorhexidine 1% on the newborns not receiving antistaphylococcal treatments.

Neonatal nurses' and midwives' time management in the implementation of care to patients is a very important part of their job. Being able to discontinue a procedure which provides no obvious benefits would allow nursing staff more time to spend on other aspects of patient care.

In addition, hospital management would benefit from the withdrawal of this cream as the product would no longer be required. Management could re-allocate those funds which would otherwise have been budgeted for the cream.

Finally, newborns may benefit from the withdrawal of chlorhexidine 1% cream because their skin will naturally acquire normal flora necessary to prevent the growth of pathogenic micro-organisms.

6.2 Limitations of the Study and Recommendations for Future Research

Due to time constraints, reduced numbers of births and an increase in the number of EDP bookings, it was not within the scope of an Honours thesis to recruit more than 82 newborns for this study. However, for the

future, a larger sample size based on current infection rates would allow more detailed statistical analysis to be performed.

A replication of the present study using the same design, combining all public hospitals with neonatal services, could provide a sample from which to draw further significant conclusions. However, prior to the commencement of such a study, it would be appropriate to first calculate the incidence of infection rates before the withdrawal of any antistaphylococcal treatments. The data would then indicate if there were any trends in the incidence of infection rates of *Staph. aureus*. In this study the observations were performed by a single researcher. If a larger sample were to be studied it would be beneficial to enlist the help of research assistants to reduce the workload.

In this study it was only possible to observe for clinical signs of infections. No attempt was made to identify the incidence of colonization of newborns with *Staph. aureus*, as this would have required culturing swabs from various locations on the skin of all newborns. Nevertheless, because high colonization rates may be the precursors of infections in newborns, a surveillance program on the incidence of colonisation rates could provide information on possible pathogenic micro-organisms, the emergence of any new strains and their sensitivity to antibiotics. The relationship between the

colonization rates and the incidence of infection rates could also be monitored. Recently, however, there has been some doubt as to the significance or usefullness of colonization rates as indicators of staphylococcal infection (Cowan & Frost, 1986). *Staphylococcus* forms part of the skins' normal flora and Wang et al. (1987) reported that there was no relationship between staphylococcal colonization and the onset of clinical illness.

Due to large numbers of newborns being discharged from the hospital on their third day or before, it is possible that newborns could have acquired infections just prior to discharge or shortly thereafter. These infections would not have been apparent to the researcher. Follow up of these newborns at home was beyond the scope of this study. However, a replication of the study with a follow up at home for newborns within two weeks of age, would enable the researcher to obtain a more accurate measure of the incidence of infections acquired in hospital.

As there was no significant difference in the incidence of clinical signs of infection in healthy full term newborns, a similar study involving healthy premature newborns, such as those not requiring ventilation or surgery could also be undertaken.

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APPENDIX A

Staff Information Sheet

Dear Colleagues,
I am presently studying for my Bachelor of Health Science Nursing (Honours) at Edith Cowan University. For my thesis I am required to perform research in an area of interest to myself. The area I have chosen is the topical application of an antistaphylococcal cream to newborns.

Antistaphylococcal agents have been used since the 1950s. Chlorhexidine 1% is the currently used agent in our hospital.

Although midwives have been applying an antistaphylococcal agent as part of nursing practice for the last 40 years, there is evidence to support the claim that the antistaphylococcal agent may be of dubious value, in terms of expense, increased workload and midwives time. Conditions in maternity hospitals have also changed for the better, both environmentally and hygienically.

The study involves randomly assigning newborns into two groups. One group will have the antistaphylococcal cream applied the other group will not. This will be done after the initial examination of the newborn and again on Day 3. I will be observing all infants twice a day for any signs of infection.

Birthsuite staff will be asked to hand out the mother's information sheet and consent form once labour is over. Once the mother gives permission, the signed consent form is separated from the information form and is placed into the mother's nursing notes.

Staff in birthsuite will select random numbers 0-9 from an envelope. Neonates will be randomly assigned to either the control group or the treatment group, using these random numbers on neonatal identification bracelets. These numbers will be recorded in a private diary. This ensures that the researcher is blind to both groups to avoid researcher bias when checking the infants for infection.

Midwives receiving babies allocated to the study on the ward will place a piece of paper with either "FOR ANTISTAPH" or "NO ANTISTAPH" on the back of feeding charts. This will ensure that all ward staff will know which baby belongs to which group.

Staff will be required to apply the antistaphylococcal cream to all the babies in the antistaphylococcal group at initial examination and on Day three. Please ensure that the babies' heads are not covered with the

antistaphylococcal cream, as it takes too long to absorb, and I will be able to establish which baby is in each group.

This study has been approved by Edith Cowan University, the Executive of Osborne Park Hospital, and the head of Obstetric Department.

If you have any questions regarding this study either before commencement or during the study, please do not hesitate to contact me at work or phone number listed below. Thank you for your assistance.

Yours sincerely

Fiona Bottin. 4010387.

APPENDIX B

Signs Of Clinical Infection In Newborns Scale.

Instrument Sheet

I.D. NUMBER: **WEIGHT:**

SEX: **TYPE OF DELIVERY:**

GESTATION: **APGAR SCORE:**

Answer Yes (Y) or No (N).

SPECIFIC SIGNS OF INFECTION.	Day 1 DS.	Day 1 NS.	Day 2 DS.	Day 2 NS.	Day 3 DS.	Day 3 NS.	Day 4 DS.	Day 4 NS.
(1) conjunctivitis								
(2) pustulosis. >2nd day.								
(3a) funistitis. (3b) oomphalitis.								
(4) paronychia.								
(5) fever > 37.0 ^{o}C								
NON-SPECIFIC SIGNS OF INFECTION.								
(6) pallor.								
(7) lethargy/refusal of feeds.								
(8) hypotonia.								
(9) tachycardia.								
(10) hypothermia <35.5 ^{o}C.								
(11) vomiting.								
(12) respiratory distress.								
(13) irritability.								
(14) mottling of skin.								

Laboratory Confirmed Infections

Type of Tests.	No Swabs	Swab + ve for *S. aureus*	Swab -ve for *S.aureus*
Blood Cultures.			
Eye Swab.			
Ear Swab.			
Gastric Aspirate.			
Urine Specimen.			

APPENDIX C
Information Sheet

My name is Fiona Bottin. I am a registered midwife currently employed at Osborne Park Hospital and work in the maternity ward. I am presently studying for my Bachelor of Health Science Nursing (Honours) at Edith Cowan University. For my thesis I am required to perform research in an area of interest to myself. The area I have chosen is the application of an antibacterial cream to newborns.

When your baby is born, bacteria start to grow on its body. Some bacteria are good, but sometimes they can be harmful to your baby and cause infection. To reduce this effect a special cream is applied to your baby's body.

Hospital conditions have changed for the better. In fact a survey of Australian maternity units performed by myself, showed that 82% of maternity units have already stopped using the cream with no increase in infections.

However, the cream is still being used in this hospital. Therefore, a study is being conducted in this hospital to determine whether the cream has any effect on the number of infections occurring in healthy babies.

Babies participating in this study will be placed into one of two groups. Each baby will have an equal chance of being placed in either group. One group will have a topical cream applied; the other will not. There is no discomfort to your baby as applying this cream is routine practice in this hospital. I will be observing your baby and the information will be recorded on the observation sheets provided. (It is normal routine care to check your baby once a day. In this study your baby is observed twice). If there is any sign of infection I will report it to the doctor immediately.

Participation of your baby in this study is purely voluntary. If you do not wish your baby to participate or decide to withdraw your baby from the study, the standard of care offered to you and your baby will not change. Once the research data is collated and documented, all information sheets will be destroyed ensuring confidentiality.

This study has been approved by the Higher Degrees Ethics Committee at Edith Cowan University and Management staff at Osborne Park Hospital.

If you have any questions regarding this study, please do not hesitate to contact me at work or on the phone number listed below. Thank you for your assistance with this study.

Yours sincerely, Fiona Bottin. 4010387.

CONSENT FORM

I agree for my baby to participate in this study.

_____	_____	____
signature of participant	signature of witness	date

EDITH COWAN UNIVERSITY
PERTH WESTERN AUSTRALIA
CHURCHLANDS CAMPUS

Pearson Street Churchlands
Western Australia 6018
Telephone (09) 383 8333
Facsimile (09) 387 7095

12 October 1992

Student No. 0890965

Ms F Bottin
7 Palari Road
OCEAN REEF WA 6027

Dear Fiona

I am pleased to advise that your Research proposal "Effects of a topical application of chlorhexidine 1% cream on newborns" for Bachelor of Nursing - Honours has been approved.

This approval means that the Faculty Higher Degrees Committee believes that you have developed the proposal to a stage where worthwhile research can be conducted on your topic. It does not guarantee successful examination of your research thesis.

Copies of reviewers' comments on your research proposal have been forwarded to your supervisor. These comments are offered as a guide for further discussion between you and your supervisor. More detailed comments have been made in the margins of the actual proposal which can be picked up from your supervisor.

You may now proceed to conduct the research and prepare your thesis. In doing so, you should be guided by the information contained in the University booklet "Information for Honours, Masters and Doctoral candidates on Research Policies and Procedures".

Your supervisor will be asked to consult with you in recommending examiners for your thesis. It is important that this is done well before you submit the thesis, so that arrangements can be made to have your thesis examined without unnecessary delay. Therefore would you please ensure that this is finalised at least six working weeks before you submit your thesis. Your supervisor has the required proforma on which these details should be provided.

I wish you every success with your research.

Yours sincerely

Anne McMurray

ASSOCIATE PROFESSOR ANNE McMURRAY RN PhD FRCNA
CHAIRPERSON, FACULTY HIGHER DEGREES COMMITTEE
FACULTY OF HEALTH AND HUMAN SCIENCES

cc Supervisor
Student Services

8005N:AMcM:IR

Your Ref:
Our Ref:
Address Correspondence
To Administrator

Ms. Fiona Bottin,
7 Palari Road,
OCEAN REEF. 6027

20th November, 1992

Dear Ms. Bottin,

Thank you for your letter, as well as the letter from Associate Prof. Anne McMurray concerning your Research proposal on the "Effects of a topical application of chlorhexidine 1% cream on newborns".

I am quite happy for you to carry on with this project, provided you tell the mothers beforehand what you are doing to their babies.

With best wishes.

Yours sincerely,

S. O. Lim

DR. JACQUELINE SCURLOCK
M.R.C.P.(U.K.), D.C.H.(LOND.), F.R.A.C.P.
DR. ANNETTE FINN
M.R.C.P.(U.K.), D.C.H.(LOND.), F.R.A.C.P.

PAEDIATRICIANS

DR. CORRADO MINUTILLO
M.B.B.S., F.R.A.C.P.
DR. JACK VERCOE
M.B.B.S.(ADEL.), F.R.A.C.P.

SUITES 3-4 1st FLOOR,
25 HAMILTON STREET, SUBIACO 6008.
PHONE: 381 7211.

3rd December, 1992.

Ms. F. Bottin,
7 Palari Road,
OCEAN REEF 6027

Dear Fiona,

Thank you for your letter regarding your proposed research in the nursery at Osborne Park Hospital.

I am certainly happy for you to conduct this study on neonates under my care. I wish you all the best and look forward to seeing the results.

Yours sincerely,

JACK VERCOE