

# The role of Chlorhexidine in *Staphylococcal aureus* prophylaxis

Elizabeth Corcoran, Anne Pollock, Narelle Stoddart & Leanne Monterosso

## Abstract

The use of routine anti-bacterial lotions for staphylococcus aureus (*S.aureus*) prophylaxis was introduced in the study setting in the 1970s to prevent skin infection in newborn infants. In 1981 the Australian College of Paediatrics recommended use of simpler measures (such as strict handwashing and reduced infant handling) to prevent cross infection with organisms such as *S.aureus*. However, unlike many Australian neonatal intensive care nurseries, practice remained unchanged in the study setting (the sole tertiary perinatal referral centre in Western Australia). A lack of empirical evidence to support this practice prompted this two-phase study. In Phase I, an Australia-wide survey of hospitals offering Level I, II and III neonatal care was undertaken to determine current practice regarding routine 'antistaphing' regimens and bathing procedures. Findings from this Phase I survey showed that prophylactic application of Chlorhexidine 1% was not practiced by any hospital other than the study setting.

In Phase II, a quasi experimental study using an historical control group was undertaken to determine whether cessation of the standard prophylactic use of Chlorhexidine 1% would increase the incidence of *S.aureus* rates in newborn infants. Findings from Phase II showed no change in the incidence of staphylococcal aureus infections following cessation of this practice. These compelling findings, together with a lack of empirical evidence resulted in a review of the study setting's neonatal intensive care's manual titled 'Operational Instructions for the Management of Newborn Infants' and cessation of the routine practice of antistaphylococcal prophylaxis.

Newborn infants are particularly susceptible to staphylococcal infections due to their immature immune system and because renal immaturity leads to defective toxin clearance. They are also more likely to be exposed to infection because of the increased staphylococcal prevalence in hospitals<sup>1</sup>. 'Antistaphing' is the term applied to the sparse application of lotion to the skin of a newborn infant as prophylaxis against *Staphylococcal aureus* (*S.aureus*). *S.aureus* is a gram-positive organism that commonly colonises the skin, eyes, umbilical stump and gastrointestinal system of newborn infants soon after birth<sup>1</sup>. *S.aureus* can cause skin infections, conjunctivitis and meningitis in some newborn infants.

The first documented outbreaks of *S.aureus* infections in newborn nurseries occurred in the 1950s where the infections proved difficult to eradicate<sup>2</sup>. These outbreaks were associated with an increased number of women delivering babies in hospitals, newborn infants were nursed in large open nurseries in close proximity to one another. In addition, hygiene practices were inferior in comparison with contemporary standards<sup>2</sup>. The practice of 'antistaphing' with Hexachlorophane<sup>®3</sup> was introduced in response to outbreaks of *S.aureus* infections in newborn nurseries.

Hexachlorophane<sup>®</sup> was shown to reduce the incidence of *S.aureus* infections by 25%<sup>1,3</sup>. It was widely used

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throughout the 1950s and 1960's however, by the end of this decade the safety was beginning to be questioned. Herter<sup>4</sup> had previously described an infant who developed convulsions and other signs of brain damage after treatment with Hexachlorophane® 3%. In a study by Kopelman<sup>5</sup>, rats were found to have oedema and cystic changes in the white matter of their brain after applications of Hexachlorophane®. Other studies found that Hexachlorophane® increased colonisation and infection with gram negative organisms and the reduced normal flora<sup>6</sup>. In 1972, the American Academy of Paediatrics recommended that Hexachlorophane® should not be used routinely as prophylaxis against *S.aureus*<sup>7</sup>. Similar changes in policy occurred in Australia in 1981 when the Australian College of Paediatrics deemed the use of Hexachlorophane® unacceptable. Chlorhexidine® was recommended as a safer alternative to Hexachlorophane® if routine antibacterial application was required<sup>2</sup>.

Chlorhexidine® is an antiseptic and disinfectant effective against a wide range of bacteria, fungi and some viruses<sup>8</sup>. However percutaneous absorption of Chlorhexidine® occurs when applied topically, especially in preterm infants who are at greater risk than term infants due to their very thin epidermal skin layer in which there is a lack of keratin, very little subcutaneous fat and increased peripheral blood flow<sup>9</sup>. Common newborn practices such as phototherapy and the use of added humidity in incubators may also enhance absorption of Chlorhexidine®<sup>10</sup>. Irritant dermatitis, contact allergy dermatitis and anaphylaxis can also be triggered by application of Chlorhexidine®<sup>11</sup>. Of major concern also is the possibility that cold stress may be induced by conduction and evaporation following application of Chlorhexidine® to an infant's skin. There are a number of potential serious complications associated with cold stress including hypoglycaemia, metabolic acidosis, hypoxia, increased oxygen requirements, and apnoea<sup>12</sup>. Additional concerns include the premature removal of vernix and negative physiological and behavioural responses demonstrated by the washing of preterm infants<sup>13</sup>.

A study by Bottin<sup>14</sup>, in a large Western Australian hospital, compared the rate of staphylococcal skin infections in term infants who were treated with a body application of Chlorhexidine® 1% solution on the first and third days, with term infants not treated with Chlorhexidine® 1%. No significant difference in staphylococcal skin infections was detected.

In keeping with the majority of hospital-acquired infections, prevention of cross infection through use of 'Standard Precautions'<sup>15</sup> is considered to be a more effective approach to reducing the incidence of *S.aureus* infections in infants. As recommended by the Australian College of Paediatrics policy statement on the 'Use of

Hexachlorophane on the Skin of the Neonate'<sup>2</sup>, this can be successfully achieved by mothers rooming in with their infants, restricted handling of infants by parents and carers, strict hand washing, avoidance of communal nurseries, and monitoring of *S.aureus* outbreaks.

At the sole tertiary perinatal referral hospital offering Levels I, II and III neonatal care in Western Australia, Chlorhexidine® 1% had been routinely applied to all full term infants on the first and third days of life and on alternate days for extremely low birth weight and/or sick infants until they were stable enough to be bathed. There was a general consensus among nurses and midwives at the study setting that this practice should be ceased. An informal survey on 100 nurses and midwives, conducted by the Infection Control Clinical Nurse Consultant, indicated that only 37% of nurses actually carried out the routine 'antistaphing' regimen when caring for newborn infants. The 'antistaphing' practice had been in place at the study setting since the early 1970s. A lack of evidence to support this practice, together with anecdotal evidence suggesting the practice was outdated, prompted this study.

The aim of this study was to determine current practice regarding use of Chlorhexidine® skin preparation as prophylaxis against *Staphylococcus aureus* (*S. aureus*) in Australian Neonatal Intensive Care Units (NICUs). Use of prophylactic skin treatments for *S.aureus* was compared between hospitals offering Level II and III neonatal nursery care and current practice in the study hospital's Level II and III nurseries. Current hygiene practices for preterm infants, nursed both in incubators and open cots, were also compared.

## Study background

A prospective two-phase study was conducted. In Phase I, an Australia-wide survey of hospitals offering Level II and III neonatal nursery care was undertaken to determine current practice regarding routine 'antistaphing' regimens and bathing procedures. In Phase II, a quasi experimental study using an historical control group, was undertaken in the study setting to determine whether cessation of the standard prophylactic use of Chlorhexidine® 1% would increase the incidence of *S.aureus* rates in newborn infants.

## Ethics

Approval to conduct this study was granted by the Ethics Committee of the study setting. In Phase I, completion of questionnaires implied participant consent. In Phase II, patient unit record numbers were replaced with a number code on all data collection sheets. Raw data were securely stored in a locked cupboard in the study setting. Computer files were password protected. In accordance with NHMRC guidelines, all data will be destroyed five years after publication of study findings.

## Phase I

### Method

Phase I was conducted over a six month period from September 1998 to January 1999. A questionnaire was mailed to 20 Australian neonatal intensive care units (NICUs) that provided Level II or III care. The questionnaire consisted of seven open and closed questions regarding routine use of Chlorhexidine® 1% as prophylactic management against *S.aureus* infection in newborn preterm and term infants. Questions also addressed nursery policies regarding use of other routine skin preparations as prophylaxis against *S.aureus* infection, as well as the evidence on which practice was based. The content, internal consistency and clarity of the questionnaire was verified using the method described by Imle and Atwood<sup>16</sup> for assessing the validity and internal consistency of the questionnaire. An *a priori* criteria of 83% was set for clarity, apparent internal consistency and content validity for each question. In keeping with the recommendation by Lynn<sup>17</sup>, raters were drawn from the context within which the original data were generated. Six nurses with at least five years of neonatal intensive care nursing experience were recruited and informed about the testing procedures. All seven items achieved 100% agreement and the preset criteria for content, internal consistency, and clarity<sup>16</sup>.

Following a further review of the literature, the researchers decided to administer an additional questionnaire by telephone regarding bathing procedures of ventilated and non-ventilated infants in incubators and open cots, use of bathing solutions, and evidence on which practice was based. Nine open and closed questions were included in the questionnaire. The previously described questionnaire verification procedures were also used for the telephone questionnaire. The telephone interviews were conducted by a sole researcher to ensure consistency and reliability of data collection methods.

### Statistical Analysis

Descriptive statistics were used for data from closed questions. Data from open-ended questions were analysed for content, sorted and categories identified.

### Results of written survey

Of the twenty units surveyed, 17 returned completed questionnaires, indicating a response rate of 85%. Chlorhexidine, 1% was not used by any NICU for *S.aureus* prophylaxis. Only one NICU used a preparation (Triclosan,) for *S.aureus* prophylaxis. In this instance, Triclosan, was used for bathing when an infant was sufficiently stable enough to be bathed or sponged. There was no reported use of skin antiseptics for *S.aureus* prophylaxis by any NICU.

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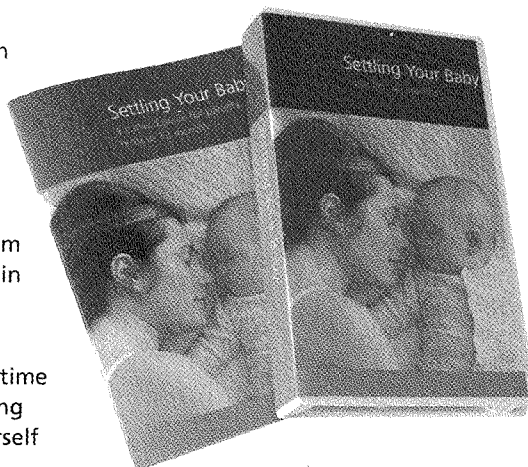
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### Results of telephone questionnaire

The telephone questionnaire was administered to the 17 NICUs who responded to the written questionnaire. Of the 17 NICUs approached, 15 NICUs participated; a response rate of 88%. As previously described, questions focused mainly on bathing procedures. In all NICUs, infants nursed in incubators or under overhead warmers were washed. In six (40%) NICUs, infants were washed on alternate days and, in three (20%) NICUs, infants were washed daily. In nine (59%) NICUs varied washing protocols (eg, bottom washes eight hourly or as required) were used. In one of these NICUs, extremely low birthweight infants were not washed until two weeks of age when the keratin skin layer was likely to have developed. Some NICUs responded to more than one category.

In the majority of NICUs (n=12), partial body washes were preformed. Full body washes (n=6) were described as being performed on small stable infants. A partial body wash included a 'top and tail', or a bottom wash only for sick unstable infants or extremely low birthweight infants until they were considered stable. Johnson and Johnson Baby Bath® was the most common solution used for washing infants. Some NICUs used a variety of at least two solutions depending on age and gestation of infants.

Of particular interest was the finding that all participants were unsure about whether their 'antistaphing' and bathing practices were evidence based. All stressed there were no preset guidelines regarding bathing practices and that infants were assessed on an individual basis based on gestation, weight and state of wellness.

In summary, the key finding from the Phase I survey was that Chlorhexidine® 1% was not used by any other Australian NICU for prophylaxis against *S.aureus* other than the study setting at the sole perinatal tertiary referral centre of Western Australia. Also of significance, there was no empirical evidence supporting either use or non-use of Chlorhexidine 1% in the NICUs surveyed. It was also clear that individual assessment of infants regarding bathing and use of *S.aureus* prophylaxis was important.

### Phase II

The findings from Phase I were presented to the Head of the Microbiology Department and the Infection Control Clinical Nurse Consultant at the study setting for consideration. The decision was then made to present the findings to the study settings of the Infection Control Medical Advisory Scientific Sub Committee as well as the Western Australian Infection Control Advisory Committee in May 1999. Both committees agreed that prophylactic use of Chlorhexidine® 1% should cease and that the solution be used only as the treatment of choice for *S.aureus* infection. However, prior to this change of practice it was recommended that supportive empirical

evidence be obtained if possible, hence the decision to undertake Phase II of this study. It would have been desirable to conduct a randomised controlled study in order to obtain rigorous empirical evidence but, since the routine practice of 'antistaphing' was to cease, this was not possible.

### Method

A quasi experimental study using an historical control group was conducted to examine whether ceasing use of Chlorhexidine® 1% affected the incidence of *S.aureus* infections in newborn infants at the study setting.

### Setting

The study was undertaken between July 1999 and August 2000 at the sole tertiary perinatal referral centre that cares for approximately 95% of all preterm and sick infants in the state of Western Australia.

### Sample

A convenience sample was used that consisted of two independent groups of newborn infants admitted to the study setting in each of two time periods. The first group (historical control group) comprised all term and preterm infants born or admitted to the study setting during the six-month period of July 1999 and January 2000 (n=3061). Infants in this group received the standard 'antistaphing' regimen (ie, application of Chlorhexidine® 1% on the first and third day of life to all fullterm healthy infants and on alternate days for extremely low birth weight and/or sick infants until they were stable enough to be bathed). The second group comprised all infants born or admitted to the study setting during the six-month period of February 2000 and August 2000 (n=2886). Infants in this group did not receive the standard 'antistaphing' regimen.

### Outcome variables

Umbilical stump infections caused by *S.aureus* were considered to be the most common *S.aureus* infections that occurred in infants in the study setting. Therefore, umbilical infections attributed to *S.aureus* were chosen as the primary outcome variable. The secondary outcome variable was all other neonatal infections caused by

Table 1. Mean gestational age (weeks) of infants with a documented infection with *S.aureus* before and after cessation of routine Chlorhexidine 1% application.

Group	Gestational age (weeks)	n	p
Routine Chlorhexidine 1% (N=3061)	37.9	10	0.265
No Chlorhexidine (N=2886)	37.1	5	

Table 2. Frequency of *S.aureus* umbilical stump infections in infants pre and post cessation of routine Chlorhexidine 1% application.

Group	Frequency of infection	p
Routine Chlorhexidine 1% (N=3061)	10	0.238
No Chlorhexidine (N=2886)	5	

*S.aureus* (ie, other skin infections such as scalp pH monitoring wounds and presence of skin pustules in varying areas of the body). The Infection Control Clinical Nurse Consultant employed at the study setting identified all cases of *S.aureus* from the hospital's pathology database system. Infants with *S.aureus* infections were included if the infant was also clinically symptomatic and had a skin swab positively identified as *S.aureus*. Skin swabs were only performed if an infant had clinical signs of *S.aureus* skin infection.

### Sample size and power

A review was undertaken of all recorded *S.aureus* skin infections (from the study setting's microbiology department database) during the previous 12 month periods (July 1998 to June 1999). Ten infections were recorded during this time period. A sample size calculation determined that enrolling 2,500 babies in each of the Chlorhexidine® treated and untreated groups would have an 80% power (with a significance level of 0.05), to detect a clinically significant increase in the number of *S.aureus* infections from ten to twenty in the group of infants who did not receive the routine application of Chlorhexidine® 1%.

Differences in mean gestational age and infection rates between the two groups were analysed using the Chi Square test. Given the large total sample size (N=5947) and the lack of a hospital wide computerised database system that would allow easy access to demographic variables of all infants born in the hospital, it was not logistically possible to obtain any other demographic variables that could be used for group comparisons. Despite this limitation, the research team was confident (from a clinical perspective) that infants in both groups would be demographically similar for two reasons – first, the study setting is the sole perinatal referral centre for Western Australia, caring for approximately 5,000

women who deliver newborn babies annually, and second, clinical evidence suggested there were no marked changes in routine practice, maternal admissions, or infection outbreaks during either of these time periods that could have potentially affected the incidence or non-incidence of *S.aureus* infection rates in infants.

### Results

Table 1 shows there was no significant difference ( $p=0.265$ ) between the mean gestational age of infants who developed *S.aureus* skin infections in the standard 'antistaph' regimen group compared with infants who did not receive the standard 'antistaph' regimen.

As shown in Table 2, there was no significant difference ( $p=0.238$ ) in the frequency of the primary outcome of interest, umbilical *S.aureus* infection, between the groups of infants who received and did not receive the standard 'antistaph' regimen.

Table 3 shows there was no significant difference ( $p=0.906$ ) between the rate of all other *S.aureus* skin infections between the group of infants who received the standard 'antistaph' regimen compared with the group of infants who did not receive the standard 'antistaph' regimen.

### Discussion

This was a two-phase study to determine current 'antistaphing' practice as well as to provide empirical evidence on which to critically evaluate this practice. This study was undertaken in response to a growing concern by nurses and midwives at a perinatal tertiary referral of Western Australia that the routine practice of 'antistaphing' infants was outdated. Additionally, anecdotal evidence suggested that many nurses and midwives at the study setting did not always adhere to the nursing and midwifery guidelines recommending prophylactic 'antistaphing' with Chlorhexidine® 1%. Despite this fact, it was assumed the majority of nurses and midwives did adhere to the guidelines. Use of this historical control group was, therefore, deemed appropriate as it constituted the best possible control group available at the study setting and was representative of standard practice.

This concern was justified both by literature that clearly supported there was little justification for routine use of Chlorhexidine<sup>2,7</sup>, as well as the difficulty in evaluating a possible association of hexachlorophane with longer term sequelae<sup>2,4,7</sup>.

Phase I provided the first Australian empirical data regarding use of Chlorhexidine, 1% and other forms of *S.aureus* prophylaxis in Australian NICUs. Findings showed that routine prophylactic application of Chlorhexidine® 1% was not practiced by any hospital other than the study setting.

Table 3. Frequency of other *S.aureus* infections pre and post cessation of routine Chlorhexidine 1% application.

Group	Frequency	p
Routine Chlorhexidine 1% (N=3061)	9	0.906
No Chlorhexidine (N=2886)	9	

The researchers noted with interest the apparent lack of knowledge regarding whether *S.aureus* prophylaxis was evidence based, as shown in findings from the telephone interviews. It was apparent there was a lack of knowledge regarding evidence to support current practice (ie, non-use of antistaphylococcal prophylaxis). Specifically, the researchers were concerned because the practice had ceased in the majority of maternity units and neonatal nurseries across the United States and Australia because of recommendations for meticulous adherence to measures that prevent cross infection, rather than use of routine antibacterial preparations<sup>2,7</sup>. The researchers recommend the implementation of nursing education regarding this issue.

Phase I results also demonstrated a commitment and flexibility of NICU nurses to individualise practice regarding bathing and *S.aureus* prophylaxis according to factors such as neonatal age, gestation and state of wellness.

Phase II results concurred with a previous nursing study by Bottin<sup>11</sup> that showed no difference in *S.aureus* infection rates in term infants treated with prophylactic Chlorhexidine, compared with term infants not treated with Chlorhexidine. These findings also support the recommendations from the American Academy of Pediatrics<sup>7</sup> and the Australian College of Paediatrics<sup>2</sup>.

While the quasi experimental design used for Phase II lacked the rigour of a randomised controlled trial, the findings were based on a large sample size with 80% power to detect any differences in *S.aureus* infection rates. Sample size calculations were based on the assumption that *S.aureus* umbilical stump infections were the most common forms of *S.aureus* infections in the study setting. This assumption was confirmed by the findings that showed approximately equal numbers of *S.aureus* umbilical stump infections compared with the number of all other *S.aureus* infections.

### Limitations

A limitation of this study was that the sample consisted of infants from two consecutive time periods and outcomes may have been influenced by other factors. However, anecdotal evidence from the study setting suggested there were no marked changes in routine practice, maternal admissions, or infection outbreaks during either of these time periods that could have potentially affected the incidence or non-incidence of *S.aureus* infection rates in infants. While the study had sufficient power to detect a clinically significant difference in incidence rates of *S.aureus* infections before and after cessation of the routine 'antistaphing' regimen, the results should be viewed with caution given the inability of the researchers to compare demographic variables other than mean gestational age, between groups.

### Conclusion

Findings from Phase I of this study resulted in a major change to practice in the study setting. The practice of prophylactic 'antistaphing' that had been in place for approximately 25 years was ceased. Findings from Phase II confirmed the change to practice was appropriate and no adverse increase in the incidence of *S.aureus* infection in infants was detected. It is recommended the incidence of *S.aureus* infections continue to be monitored in the study setting.

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