Abstract of thesis entitled

A Clinical Guideline of Skin Care Management for Newborns with Diaper Dermatitis
Submitted by

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Diaper dermatitis is one of the most common skin conditions in neonates, infants, and toddlers. To date, there is no formal data that reports on the prevalence of diaper dermatitis in Hong Kong, but an informal observation made by nurses in one public hospital reported that approximately 4 in 10 neonates in both neonatal intensive care unit (NICU) and special care baby unit (SCBU) suffer from diaper dermatitis. Diaper dermatitis causes discomfort or pain, and in some cases, alters the neonates’ vital sign, nutritional intake, and quality of life. This leads to prolonged hospitalization, increased manpower, and reduced bonding between neonates and mothers. Without standardized treatment and practices, nurses may deal with diaper dermatitis in varying ways, which means that the healing process will also vary. Therefore, it is imperative to develop an evidence-based guideline that will inform physicians, nurses, and caregivers alike of the best management of diaper dermatitis.

This dissertation is a translational research that aims to review current available evidence of applying cream to reduce the severity level and increase the cure rate of diaper dermatitis. By processing the electronic searches from Pubmed, CINAHL, MEDLINE and British Nursing Index with several sets of keywords using an inclusion and exclusion criteria, seven articles were selected for the study. These selected articles were rated for their internal validity, risk of bias and overall quality by a critical appraisal tool, *Scottish Intercollegiate Guideline Network, (SIGN)*. The transferability
of findings generated from these seven articles, and the feasibility of a project implementation were then assessed, with the conclusion that a similar guideline, as proposed in these articles, can be implemented in a hospital setting in Hong Kong.

The implementation plan was then developed, comprising a communication plan with key stakeholders. This was followed by a pilot study, designed to test the feasibility of the proposed skin care management guideline, and expected to last for five weeks. Finally, an evaluation plan was constructed with the purposes to assess the effectiveness of the guideline by measuring the primary and secondary outcome variables.
A Clinical Guideline of Skin Care Management for Newborns with Diaper Dermatitis

By

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Declaration

I declare that this thesis represents my own work, except where due acknowledge is made, and that it has not been previously included in a thesis, dissertation or report submitted to this University or to any other institution for a degree, diploma or other qualification.

Signed:______________________________

CHIU GEE SHUEN
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Background

Diaper dermatitis is a common dermatologic disorder in neonates. According to Furber, Bedwell, and Campbell (2012, p.14), “the skin of the newborn is immature at birth and vulnerable to contaminants that may cause diaper dermatitis”. This is because the stratum corneum of a newborn is thin, less hydrated, has a neutral pH, and is ineffective in handling water (Bonifazi, 2011).

Skin serves as a protective layer to prevent the loss of water, heat and electrolyte, and also provides protection from infection and toxic substance that may adversely affect the babies’ body (Bonifazi, 2011). The presence of diaper dermatitis has been found to be associated with discomfort, irritation, and pain, which affects neonates’ quality of life (Stamatas & Tierney, 2014). At the same time, an irritable baby may also increase caregiving stress, thus reducing the bonding between the baby and his or her caregiver (Furber et al., 2012).

Studies have identified certain conditions that increase neonates’ susceptibility to diaper dermatitis, including high humidity, maceration, contact with urine and feces, and friction (Rowe, McCall, & Kent, 2008) (Alonso et al., 2013). In particular, excessive humidity in diapers may decrease the function of the stratum corneum, which may cause the skin surface to become fragile and sensitive to frictional damage.
Excessive humidity may also weaken the barrier function of the skin, thus making it easier for microorganism to enter the skin.

Excessive contact with urine and feces has been associated with diaper dermatitis, as it has been documented that ammonia from urine contributed to a higher pH value, creating an alkaline environment that is favorable for bacteria to grow (Bonifazi, 2011). Likewise, it has been found that faecal enzyme in the stool also increased the pH value, and provided a fertile environment for bacteria to grow (Ibid.). Together, excessive exposure to urine and feces may cause, and also exacerbate, diaper dermatitis in neonates. Given that neonates typically pass urine out between 10 to 20 times on a daily basis (Stamatas, Zerweck, Grove, & Martin, 2011), excessive contact with feces and urine is a critical contributing factor toward diaper dermatitis.

Studies by Bonifazi, (2011), Hoeger, Stark, and Jost (2010) and Sparker et al. (2006) found that Candida albicans is the leading microorganism that causes diaper dermatitis, whereby the colonization by Candida albicans occurs in over 70-80% of diaper dermatitis. Generally, Candida albicans may be treated with a board spectrum of antibiotics, but these antibiotics may also worsened the incidence of diaper dermatitis (Spraker et al., 2006).
Affirming Needs

To date, research has shown that the incident rate of diaper dermatitis varied from 7% to 35%, with the highest prevalence occurring between 6 and 12 months old (Alonso et al., 2013; Stamatas et al., 2011; Gozen, Caglar, Bayraktar & Atici, 2012). The study by Shin et al. (as cited in Alonso et al., 2013, p.124) reported the earliest onset of diaper dermatitis was developed on the fourth day of life. However, these figures may be underestimated because some cases may not have been reported to physicians for treatment (Stamatas, 2011). To illustrate the wide discrepancy pertaining to the prevalence of diaper dermatitis, a study from UK found that as many as 52% of babies suffered from diaper dermatitis and its associated symptoms, including oral thrush and diarrhea (Panahi et al., 2011).

The effects of diaper dermatitis have also been documented. For instance, Stamatas and Tierney (2014) asserted that neonates’ vital signs were irritated by the painful sensation caused by diaper dermatitis. Visible signs of discomfort including excessive crying, and abnormal heart rates and body temperatures have also been identified as results of diaper dermatitis (Stamatas & Tierney, 2014). Studies also showed that the feeding of neonates may be adversely affected by the discomfort resulting from diaper dermatitis, and subsequently altered the nutritional intake of neonates (Adam, 2008). Babies with diaper dermatitis are generally more agitated and
therefore require more attentive care. In many cases, this places a high demand on manpower and other resources to care for these babies during their hospital stay (Stamatas & Tierney, 2014). Additionally, caring for babies with diaper dermatitis may also lead to higher anxiety levels and exacerbating caregiving-related stress (Baldwin et al., 2012).

Different preventative measures aimed to reduce the prevalence of diaper dermatitis were recommended by nurses and doctors in the neonatal intensive care unit (NICU) and special care baby unit (SCBU) where I worked. However, mild to severe diaper dermatitis remained unresolved. Therefore, the development of a skin care management guideline for different level of diaper dermatitis among the newborns is direly needed.

**Significance**

As mentioned previously, diaper dermatitis is one of the most common dermatological problems that significantly affects the quality life of both newborns and their caregivers. Thus far, evidence has shown that the vital signs and nutritional intake may be altered in newborns with diaper dermatitis, thereby prolonging their hospital stay, and adversely affecting the bonding with their caregivers. Caregiver anxiety may also be increased resulting from the need to care for a more agitated baby.
Diaper dermatitis is recognized to be relatively common among patients in the hospital where I work, although there is no formal data on the incidence rate. By obtaining data from admission book and by observing babies in my hospital, 4 out of 10 babies suffered from varying degree of diaper dermatitis. Moreover, the various practice of the nurses to babies who suffered from diaper dermatitis were observed. However, there were no standardized practice or guideline pertaining to the proper treatment of diaper dermatitis. As such, an evidence-based guideline will be beneficial not only to babies with diaper dermatitis, but to their caregivers, nurses and hospitals. Findings generated from this study may contribute to the development of a skin care management guideline for treating different levels of diaper dermatitis among newborns.

Objectives

The objectives of this study are: (1) to conduct a literature research on the effectiveness intervention of reducing the severity of diaper dermatitis; (2) to conduct quality assessment for the selected studies, and to summarize and synthesize the data; (3) to assess the implementation potential of the proposed guideline for the skin care management project; and (4) to develop the implementation plan, pilot study and evaluation plans for the skin care management project.
The first step of developing an evidence-based practice is to generate a viable research question. By adopting the PICO framework, the research question was formulated as follows:

“How can a standardized skin care management guideline be more effective to reduce the severity of diaper dermatitis?”

Under the PICO framework, the patient population of interest (P) is newborn babies with diaper dermatitis. The intervention of interest (I) is skin care management guideline for the reduction of the severity of diaper dermatitis. The comparison of interest (C) is the current nursing care practice (e.g. daily routine care of ward practice), and the outcome of interest (O) is the prevention and reduction of diaper dermatitis.
Chapter 2: Critical Appraisal

Search and Appraisal Strategies

Search Strategies

A Prisma Flow diagram is introduced to perform a structural screening for selecting relevant articles that examined diaper dermatitis in newborns. To identify relevant articles, an electronic search was conducted from July 2014 to October 2014 in four different electronic databases, comprising CINAHL (EBSCOhost), MEDLINE (Ovid), Pubmed (ProQuest), and British Nursing Index. Three sets of keywords (identifiers) were used to conduct the literature searches, including (1) “neonatal, infant, baby, and newborn”; (2) “diaper, napkins, and nappy”; and (3) “dermatitis and rash”. These three sets of keywords were entered into databases using both “or” to include all possible findings, and “and” to generate more specific findings. Exclusion criteria were also applied to narrow down the number of articles, for example, the publication date of the articles.

Under these sampling criteria, 20 articles were selected from CINHAL, 14 articles were selected from Medline, 23 articles were selected from Pubmed, and 32 articles were selected from British Nursing Index. With the same sets of keywords additional searches in sources, such as Google Scholar and Yahoo Search, were conducted, with a total of 28 articles generated. By screening the selected article manually, duplicated
articles were removed. Titles, abstracts, and full texts of the remaining articles were scanned and reviewed according to the inclusion and exclusion criteria. At the end, seven articles were selected for this study. The detail of the search result and the Prisma flow diagram were illustrated in Appendixes A and B. The following sections provided a detailed account on the inclusion and exclusion criteria, and search results.

**Inclusion Criteria**

Articles were included if they (1) were published in 2003 or onwards to ensure that information acquired was up to date and accurate; (2) used randomized controlled trial (RCT) and clinical trial as research methods to validate empirical evidence; (3) focused on infants and neonates with diaper dermatitis, and who were using pharmaceutical treatment or natural remedies were included; (4) were conducted in either in-patient or outpatient; and (5) were written in English.

**Exclusion Criteria**

Studies were excluded if (1) they exclusively examined the treatment of diaper dermatitis due to congenital dermatological disorder or abnormality, and critically ill babies with intubation, sedative or inotropes. This is because critically ill babies required minimal handling, which decreased their mobility and increased the incident
rate of diaper dermatitis (Bonifazi, 2011); and (2) focused solely on preventative measures for diaper dermatitis.

**Search Result**

A total of 89 articles were retrieved from the four databases, CINAHL, MEDLINE, Pubmed and British Nursing Index, and another 28 articles were retrieved from Google Scholar and Yahoo Search. By manually screening with the inclusion and exclusion criteria, and the duplication articles removed, 38 articles remained. Finally, a total of seven full-text articles were selected. The search result and search flow diagram are shown in Appendixes A and B. There were six randomized controlled trial studies (Gozen et al., 2012; Farahani, Ghobadzadeh, Yousefi, 2014; Hoeger et al., 2010; Panahi et al., 2011; Spraker et al., 2006; Wananukul, Limpongsanuruk, Singalavaniya, Wisuthsarewong, 2006), and one quasi-experimental study (Gunes, Akin, Sarici, Hallac, Kurtoglu, Hashimoto, 2013). All studies were published between 2006 and 2014.

**Appraisal Strategies**

Level of evidence of all selected studies (Gozen et al., 2012; Farahani, Ghobadzadeh, Yousefi, 2014; Hoeger et al., 2010; Panahi et al., 2011; Spraker et al., 2006; Wananukul, Limpongsanuruk, Singalavaniya, Wisuthsarewong, 2006; Gunes,
Akin, Sarici, Hallac, Kurtoglu, Hashimoto, 2013) was evaluated and rated by the critical appraisal tool, the Scottish Intercollegiate Guideline Network (SIGN). This methodological checklist was also used to rate the studies’ internal validity and overall quality. The result was summarized in Appendix C, whereas the following section provided a comprehensive analysis.

**Quality assessment of the reviewed articles.**

By using SIGN checklist, one article was rated 1++ (Spraker et al., 2006), 4 articles were rated 1+ (Farahani et al., 2014; Hoeger et al., 2010; Panahi et al., 2011; Wananukul et al., 2006), 1 article was rated 2+ (Gunes et al., 2013), and 1 article was rated 1- (Gozen et al., 2012). The symbols “1++, 1+, 1-” reflected the risk of bias, where 1++ represented lowest risk, and 1- represented highest risk. Moreover, the numbers 1 and 2 represented the level of evidence among different types of articles. Six selected articles (Farahani et al., 2014; Gozen et al., 2012; Hoeger et al., 2010; Panahi et al., 2011; Spraker et al., 2006; Wananukul et al., 2006) were randomized controlled trials, and obtained a higher level of evidence among other articles, while one article (Gunes et al., 2013) was quasi-experimental, and obtained a level 2 evidence compared to other studies.

In the internal validity assessment, all selected articles addressed an appropriated
and clearly focused question by using the PICO framework (Farahani et al., 2014; Gozen et al., 2012; Gunes et al., 2013; Hoeger et al., 2010; Panahi et al., 2011; Spraker et al., 2006; Wananukul et al., 2006). The research question of all seven articles (Farahani et al., 2014; Gozen et al., 2012; Gunes et al., 2013; Hoeger et al., 2010; Panahi et al., 2011; Spraker et al., 2006; Wananukul et al., 2006) focused on the effectiveness of different intervention on the improvement of diaper dermatitis and its resultant conditions.

Moreover, six articles using RCT design have assigned their subjects by randomization. Gozen et al. (2013) used a simple randomization method, toss up; Hoeger et al. (2010) applied a validated automated system that randomly assigned the treatment group; and Wananukul et al. (2006) applied block randomization method. However, the randomization methods of the other three articles were not clearly stated.

Three articles (Hoeger et al., 2006; Spraker et al., 2006 and Wananukul et al., 2006) utilized the concealment method to minimize the risk of allocation bias, to ensure that neither the researcher nor the subjects can identify the treatment group before the study began. The article by Hoeger et al. (2010) used a validated automated system to allocate the subjects to the study group. Both Spraker et al. (2006) and Wananukul et al. (2006) used centralized allocation as their concealment method.

Four studies (Farahani et al., 2013; Gozen et al., 2013; Hoeger et al., 2010; and
Panahi et al. (2011) were single blinded to the investigators. It was difficult to blind the subjects, because the application of cream was documented in the medication record. Studies conducted by Spraker et al. (2006) and Wananukul et al. (2006) were double blinded, with the researchers repackaging the cream used for the intervention and control groups into identical appearance tubing. Moreover, the article by Gunes et al. (2013) was a quasi-experimental design, and did not address issues pertaining to the concealment and blinding process.

Similar baseline demographic characteristics between the intervention and control groups were noted in four studies, which maintained the internal validity. Four articles by Gozen et al. (2012), Gunes et al. (2013), Hoeger et al. (2010), and Spraker et al. (2006) have clearly stated the demographic data at the beginning of the trial, including participants’ age, gender, therapeutic treatment used, and the severity of the diaper dermatitis. There was no significance difference in demographics between the intervention and control group in these studies. On the other hand, three articles by Farahani et al. (2013), Panahi et al. (2011) and Wananukul et al. (2006) had poor demographic data on the recruited subjects.

All seven articles measured the relevant outcomes in a standard, valid and reliable way (Farahani et al., 2014; Gozen et al., 2012; Gunes et al., 2013; Hoeger et al., 2010; Panahi et al., 2011; Spraker et al., 2006; Wananukul et al., 2006). Studies by
Farahani et al. (2014); Gozen et al. (2012), Panahi et al. (2011) and Wananukul et al. (2006) used SPSS as the statistical analysis tool, while the other three studies, the studies by Gunes et al. (2013), Hoeger et al. (2010) and Spraker et al. (2006) did not detail the use of statistical analysis tool. Paired t test, Wilcoxon signed ranks test and chi-square test were used for analyzing the quantitative variables in all studies (Farahani et al., 2014; Gozen et al., 2012; Gunes et al., 2013; Hoeger et al., 2010; Panahi et al., 2011; Spraker et al., 2006; Wananukul et al., 2006).

Only one article by Gunes et al., (2013) did not report the dropout rate. The other six studies stated the dropout rate, which ranged from 5.3 to 17%. Among the articles, Farahani et al. (2014) had the lowest dropout rate (5.3%), whereas Wananukul et al. (2006) had the highest dropout rate (17%). The major reason of dropout among these reviewed studies was that caregivers withdrew from the studies, claiming that the reduction of the severity score for treating diaper dermatitis were in slow or no progression (Gunes et al., 2013; Farahani et al., 2014; Hoeger et al., 2010; Spraker et al., 2006; Wananukul et al., 2006). In addition, the study by Hoeger et al. (2010) reported that subjects were lost to follow up and thereby dropped from the study.

There were two articles (Spraker, 2006; Wananukul, 2006) that addressed the use of intention-to-treat method in handling the missing value. The other articles did not clearly mention the method in handling missing data.
From all selected articles, three articles (Hoeger, 2010; Spraker, 2006; Wananukul, 2006) were multi-center randomized controlled trials, which increased their generalizability. Others performed the studies in a single center (Farahani et al., 2014; Gozen et al., 2012; Gunes et al., 2013; Panahi et al., 2011).

In general, five articles (Farahani et al., 2014; Gunes et al., 2013; Hoeger et al., 2010; Panahi et al., 2011; Wananukul et al., 2006) were considered to have medium level of evidence, and low risk of bias in data analysis.

**Summary**

The articles were selected worldwide, with some studies conducted in developed countries and others in developing countries. Two articles, Sparker et al. (2006) and Hoeger et al. (2010), were conducted in United States and Germany, respectively. Other five articles were from developing countries, such that the study conducted by Farahani et al. (2014) was in Iran, both studies conducted by Gozen et al. (2012) and Gunes et al. (2013) were in Turkey, the study by Panahi et al. (2012) was in Iran, and the study by Wananukul et al. (2006) was in Thailand. All articles were either conducted in hospital or clinic. Three articles (Gozen et al., 2012; Gunes et al., 2013; Panahi et al., 2012) targeted the in-patient group and the other four articles (Farahani, 2014; Hoeger, 2010; Spraker, 2006; Wananukul, 2006) targeted the out-patient group.
Subject characteristics

Both male and female were recruited in all studies, and no study mentioned any significant difference between both sexes. The age of the subjects ranged from newborn to 24 months old in five the articles (Farahani, 2014; Gozen et al., 2012; Gunes et al., 2013; Hoeger et al., 2010; Wananukul et al., 2006). Another two articles by Panahi et al. (2011) and Spraker et al. (2006) recruited children who were aged between newborn to 4 years old.

Pre-assessment were performed in all articles (Gozen et al., 2012; Gunes et al., 2013; Farahani et al., 2014; Hoeger et al., 2010; Panahi, 2011; Spraker et al., 2006; Wananukul et al., 2006), with 90% of recruited subjects reported to have a mild to moderate severity of diaper dermatitis. However, different articles used different classification scale to determine the grading or severity of the diaper dermatitis. In Farahani et al. (2014), Gozen et al. (2012) and Wananukul et al. (2006), a simple method 6-point scale (0= no erythema; 1= slight, diffuse, or partial erythema; 2= marked, sharply demarcated erythema; 3= severe erythema without infiltration; 4= severe erythema with infiltration; 5= vesiculation or epidermal defect (p.726)) was used to assess the severity. A five-point visual scale was used in Gunes et al. (2013) while a Total Symptoms Score (TSS) assessment tool was used in the study by Hoeger et al. (2010). In Hoeger et al. (2010), the TSS assessed the severity of five common
symptoms that could be observed on the buttock of diaper dermatitis newborn, including maceration, erythema, desquamation, papules and oedema. With each observed symptom, a 4 point scale would be used to score the severity of each symptom (0= normal, 1= mild, 2= moderate, 3= severe). Another assessment tool, Severity Index Score, was used in Spraker et al. (2006), which calculated the score by grading the level of erythema, numbers of papules or pustules and the presence of erosion (p.114).

All these different assessment tools focused on the same symptoms of diaper dermatitis: erythema, maceration, papules and desquamation. Therefore, the level of severity was quite similar among the studies. However, the reliability and validity of these tools were not mentioned in all articles.

**Products used to treat diaper dermatitis**

There were various products used in these studies intended to reduce the severity of diaper dermatitis and to promote healing.

*Barrier cream*

The article by Wananukul et al. (2006) focused on barrier cream products by comparing the use of dexapanthenol mixed with zinc oxide ointment in the intervention group, and the use of bee wax and liquid paraffin in the control group. The dexapanthenol mixed with zinc oxide is a pantothenic acid that acts as a moisturizer to improve stratum corneum hydration and to reduce transepidermal water loss (TEWL)
Antifungal cream

Two articles by Hoeger et al. (2010) and Spraker et al. (2006) focused on antifungal cream, clotrimazole and miconazole, in the intervention group. These two cream shared similar properties and are common prescribed antifungal agents for treating diaper dermatitis.

Natural products

Studies by Farahani et al. (2013) and Gozen et al. (2012) examined the effectiveness of hind milk on treating diaper dermatitis. Hind milk is breast milk produced at the end of each breastfeeding session, which is higher in fat content. Hind milk was used in the intervention group, the result of which was compared to the use of hydrocortisone cream in the control group. The article by Gozen et al. (2012) suggested to apply human breast milk to affected areas that exhibit mild to moderate signs of erythema after each diaper change. Gunes et al (2013) applied guaiazulene, a natural product that is extracted from the oil of guaiacum officinale tree, as an anti-inflammatory, antiseptic, and antifungal agent to babies’ buttocks. Guaiazulene is approved by the Food and Drug Administration (FDA). Finally, the article by Panahi et al. (2011) suggested applying Aloe vera ointment to the intervention group, and Calendula officinalis ointment to the control group after each diaper change.
and drying the buttock were required before applying the ointment to the buttock.

Methods

Barrier cream

Wanaukul et al. (2006) suggested applying a thin layer of either dexapanthenol mixed with zinc oxide or bee wax with paraffin. Cleansing and pat drying the buttock area was recommended prior to applying these remedies.

Antifungal cream

Hoeger et al. (2010) applied clotrimazole paste to the babies’ affected area twice a day in the intervention group while nystatin paste was applied in the control with the same frequency. Pastes were re-administered if the pastes were accidentally removed from diaper changing. In Spraker et al.’s (2006) study, small amounts of miconazole cream was applied with fingertips on babies’ affected area after each diaper change or bath for seven days.

Natural products

The study by Farahani et al. (2013) recommended applying hind milk of mothers on their own babies’ affected area after each breastfeeding and let it dry before wearing the diaper. Simultaneously, applying the hydrocortisone cream on the affected area twice a day was instructed in the same study.
**Frequency**

These studies also made suggestions with regards to the frequency of applying skin care products on affected areas. The studies by Wananukul et al. (2006) and Farahani et al. (2013) suggested applying barrier cream or breastmilk to the intervention group after each diaper change. The study by Gunes et al. (2013) suggested applying guaiazulene cream three times a day, and the Hoeger et al. (2010) suggested applying clotrimazole cream twice a day.

**Amount**

Studies also instructed on the appropriate amount of skin product to be applied on affected areas. A thin layer (Wananukul et al., 2006) or fingertips amount (Spraker et al., 2006) was identified as the appropriate amount to apply to the affected area. If the cream is removed accidentally during diaper changing, re-administering the same amount of cream is suggested (Hoeger et al., 2010).

**Length of follow up**

Six articles by Gozen et al. (2012); Gunes et al. (2013); Farahani et al. (2014); Hoeger et al. (2010); Spraker et al. (2006); and Wananukul et al. (2006) assessed the affected buttock area on days 0, 3, 7 and 14, while the article by Panahi et al. (2011) assessed the affected buttock area at a different time intervals: days 0, 5 and 10.

**Effectiveness**
**Barrier cream**

Wananukul et al. (2006) measured and compared the effectiveness between using dexpanthenol mixed with zinc oxide, and using paraffin and bee wax in the reduction of TEWL. Results showed a dramatic decline of decreasing the TEWL on the third day of treatment (36.0±17.9 and 41.1±17.6, respectively). This means that dexpanthenol was more effective in reducing TEWL. However, the severity score was also evaluated at this study, with no significance found between two groups (p > 0.157) over a 7 days treatment.

The article by Gozen et al. (2012) reported zinc oxide had a better effect to cure mild diaper dermatitis than breast milk. The cure rate was 93.6% among those who used zinc oxide compared to the corresponding rate of 60% among those who used breast milk. Thus, zinc oxide barrier cream was more effective in treating mild diaper dermatitis compared with breast milk. But zinc oxide barrier cream is not as effective as clotrimazole and miconazole in treating fungal infection (Hoeger et al., 2010; Spraker et al., 2006).

**Antifungal cream**

In the study by Hoeger et al. (2010), a good effect was found in the within-group for both clotrimazole and nystatin paste after 7 days of treatment (p<0.0001). The total symptom score was decreased to 6.1±1.87 for those who used clotrimazole and to
5.4±2.37 for those who used nystatin. Aside from studying the effectiveness of antifungal paste on diaper dermatitis, Hoeger et al. (2010) also assessed the clinical microbiological cure rate, the result of which showed that the clotrimazole group exhibited a higher cure rate compared to the nystatin group on day 14 (p =0.0496).

In the study by Spraker et al. (2006), it was found that the overall cure rate of miconazole in the intervention group was 23%, as compared to the cure rate of 10% in the control group using zinc oxide. In addition, the recovered babies were also characterized by the absence of rash, and the absence of **Canadida** culture, while the severity score of diaper dermatitis was equal to zero (p= 0.005).

Both studies by Hoeger et al. (2010) and Sparker et al. (2006) showed that two antifungal agents, clotrimazole and miconazole, provided a better cure rate and reduced the severity score compared to their respective control groups. Moreover, no threatening adverse effect was reported in both studies. Only common adverse effects like diarrhea and fever were reported in the studies.

*Natural products*

In Farahani et al. (2013), both the breast milk group and the hydrocortisone group had significant improvement on the severity scores after seven days of treatment (p<0.001). However, there was no significant difference in terms of the severity score between the breast milk group and the hydrocortisone group. The study accepted the
null hypothesis (p=0.32), in that there was no treatment difference between the two groups. However, muscle atrophy and Cushing syndrome were found with prolonged use of hydrocortisone while, breast milk had no side effects.

In the study by Panahi et al. (2011), both the intervention group using Aloe vera, and the control group using Calendula officinalis demonstrated a clear decrease in the severity score of diaper dermatitis. However, the group using Calendula officinalis had a significant higher reduction rate of diaper dermatitis (p=0.001).

In Gunes et al. (2013), significant difference was found in the effect of the use of natural product, Guaiiazulene, compared to the petrolatum and zinc oxide ointment used in the other group. Gunes et al. suggested there is a significant effectiveness of reducing the severity score in guaiiazulene group compared to the group using petrolatum and zinc oxide.

In the control group using petrolatum and zinc oxide, the initial mean score was 3.3± 0.67, and declined to 2.50±0.52 (p=0.46) by day 7. In the study group using guaiiazulene, the initial mean score was 3.5±0.67 and decreased to 0.2±0.41 (p=0.001) on day 7, suggesting that guaiiazulene was more effective in mitigating the conditions resulting from diaper dermatitis.
Synthesis

The majority of the articles included in this study was conducted in developing countries (Gunes et al., 2013; Gozen et al., 2012, Farahani et al, 2014; Panahi et al., 2012; and Wananukul et al., 2006), where the hospital setting is similar to the neonatal intensive unit and special care baby unit in the hospital where I work.

The sample age was selected between newborn to 24 months old of term babies (gestation age greater than 36 weeks), because individuals in this age group still wore diapers and tended to have diaper dermatitis (Gozen et al., 2012; Gunes et al., 2013; Farahani et al., 2014; Hoeger et al., 2010; Spraker et al., 2006; Wananukul et al., 2006). Body weight was not the major factor considered among the studies (Gunes et al., 2013; Farahani et al., 2014; Hoeger et al., 2010; Spraker et al., 2006; Wananukul et al., 2006), but the article by Gozen et al. (2012) examined the difference between preterm and term baby, because the development of the skin maturity of preterm baby is different from the term baby, with the skin among preterm babies more prone to develop diaper dermatitis (Furber et al., 2012).

The majority of the articles showed effectiveness for their intervention on diaper dermatitis. Clotrimazole and miconazole were found to be common antifungal treatment for mild to severe diaper dermatitis if applied twice a day or after every diaper change. Moreover, clotrimazole was also a common treatment for recurrent diaper
dermatitis and is available in my hospital.

Finally, the study by Farahani et al. (2013) found that breast milk had similar effectiveness as hydrocortisone cream on treating mild to moderate diaper dermatitis but breast milk was safe and convenient, whereas hydrocortisone cream may induce adverse effect such as Cushing syndrome with prolonged usage (Farahani et al., 2013). However, Gozen et al. (2012) reported that the zinc oxide had a better effect to cure mild diaper dermatitis than breast milk.

By summarizing the effectiveness and availability of different intervention in Hong Kong, zinc oxide and clotrimazole were selected as the intervention cream. The zinc oxide is to be applied to the buttock area with mild to moderate levels of erythema buttock area. Doing so provides barrier function to help protect the buttock area from urine and fecal substance. Clotrimazole is to be applied to the buttock area with moderate to severe levels of erythema with maceration and fungal infection.

A thin layer of zinc oxide and clotrimazole is to be applied in the affected area. While zinc oxide will be applied after every diaper change, clotrimazole will be applied twice daily.

Pre-assessment and post-assessment are required to compare the improvement of the severity level of diaper dermatitis. Although different studies have used different assessment tools to measure the severity of diaper dermatitis, they all assessed the
similar symptoms of diaper dermatitis, including erythema, maceration, papules and desquamation. Nevertheless, the five-point visual scale adopted by Gunes et al. (2013) provided a more objective assessment, whereby the severity score could be clearly defined and classified by the provided picture. Therefore, this study adopted the five-point visual scale.

In most of the studies, post assessment was either conducted on day 7 or day 14. Post assessment on day 14 was selected for the proposed study, which could provide a better picture on the improvement and cure rate of the diaper dermatitis since diaper dermatitis is mostly curable within 14 days (Farahani et al., 2014; Gozen et al., 2012; Gunes et al., 2013; Hoeger et al., 2010; Panahi et al., 2011; Spraker et al., 2006; Wananukul et al., 2006)
Chapter 3: Interpretation and Application of the Findings

The previous chapter described the impact of diaper dermatitis, and examined existing empirical evidence to support various intervention strategies that aimed to reduce and cure diaper dermatitis. In this chapter, the implementation potential of an intervention was reviewed, along with the possibility of transferring the findings, feasibility, cost and benefit ratio. The results generated from these assessment would contribute to the development of an evidence-based guideline of skin management.

Target setting

The target setting is the neonatal intensive care unit (NICU) and special care baby unit (SCBU) of a public hospital in Hong Kong.

Target Audience

The target audiences were babies admitted to NICU and SCBU who suffered from diaper dermatitis. Taking stock of the reviewed articles (Farahani et al., 2014; Gozen et al., 2012; Gunes et al., 2013; Hoeger et al., 2010; Panahi et al., 2011; Spraker et al., 2006; Wananukul et al., 2006), the majority of the target population’s age was selected between newborn to 24 months old of term babies. Babies with congenital dermatological disorder or abnormality, and critically ill babies with intubation, sedative or inotropes were excluded. Body weight was not considered in this study because it was not a contributing factor to diaper dermatitis (Gunes et al., 2013;
Farahani et al., 2014; Hoeger et al., 2010; Spraker et al., 2006; Wananukul et al., 2006).

Transferability of the Findings

Setting

Fifteen NICU beds and thirty-five SCBU beds are available in the place where I work, usually with a 90-120% occupancy rate. Babies admitted to NICU were commonly diagnosed with respiratory problems, and therefore required ventilator support, or with nutritional problem. The intra-uterine growth retardation resulting from nutritional problem required nutrient support, such as total parental fluid. Babies admitted to SCBU are commonly diagnosed with hypoglycemia and neonatal jaundice problem. The length of stay in hospital of a baby varied from 3-60 days.

The hospital in Hong Kong had a similar setting of NICU and SCBU observed in the majority of the reviewed studies (Gunes et al., 2013; Gozen et al., 2012, Farahani et al, 2014; Panahi et al., 2012; and Wananukul et al., 2006). Therefore, it was possible to transfer the data to the proposed project.

Philosophy of care

The objective of the proposed project was to develop an effective intervention for newborn who suffered from different severity levels of diaper dermatitis and to construct a standardized nursing care guideline. The philosophy underscoring these
goals resonated with the reviewed articles (Gozen et al., 2012; Gunes et al., 2013; Farahani et al., 2014; Hoeger et al., 2010; Spraker et al., 2006; Wananukul et al., 2006). Furthermore, an important goal of the Hospital Authority in Hong Kong was to promote patients’ quality of life, which in turn enhances clinical outcomes (Hospital Authority, 2012). Thus, the objectives of this study aligns with the goals outlined by the Hospital Authority.

**Number of Patient benefit from the innovation**

A significant number of newborns can benefit from the proposed project. According to the Hospital Authority (2012), the total number of admission of newborns per month to either NICU or SCBU was approximately 2,100. About 100-125 babies were admitted to our ward monthly and approximately 30-40% of the babies developed diaper dermatitis. Therefore, approximately 600 babies can directly benefit from this proposed project every year in the target NICU and SCBU units.

**Duration of implementation and evaluation**

The full-scale implementation of the proposed project will take a period of thirty-eight weeks. The project will be divided into three major phases: (1) preparation; (2) implementation, and (3) evaluation phases. A skin care working group will be established within the first week, who will be responsible to plan and implement the whole proposed project. The planning will include communication and coordination
logistics, and will take about two weeks. This will be followed by staff training, which will take two weeks. A pilot study will commence afterwards for five weeks. Finally, the implementation period will last for twenty-four weeks and the evaluation period will take around four weeks. Evaluation will include entering and analyzing collected data. The details are shown in Appendix E.

Feasibility

Right to carry out or terminate the intervention

Ward managers and doctors will support the nurses to carry out the skin care management project for babies who suffered from diaper dermatitis. This project is a nursing intervention designed to apply cream to babies with diaper dermatitis, with the substantiation of existing evidence. Therefore, it was met with little objections from hospital seniors. Participating staff have the right to continue or terminate the intervention should any undesirable outcome occur that may put the patients at risk.

Interference with current staff function

The implementation project will have minimal interference to the current routine duty. An advanced practice nurse (APN) with at least 5 years’ experience in neonatal care will be invited to lead the project. Five registered nurse (RN) with at least three years’ experience in neonatal care with the competence of Post-registration Certificate
Course in Neonatal Intensive Care will be invited to be the member of the project. With their consent, these registered nurses will assist the APN to facilitate the implementation and document of this intervention. No additional manpower or facilities will be required for this project.

**Administration support**

Ward managers (WM) and the Departmental Operation Manager (DOM) usually support evidence-based practice in the clinical area to improve patients’ quality of care. As mentioned previously, a leader (APN) with 5 team members (RN) will form a skin care working group and manage the skin care management project. Two identical two-hours workshops will be conducted, addressing issues including the implementation and documentation of the proposed project to other nursing staff. During the implementation period, this skin care working group will coordinate with other nursing staffs on the implementation and documentation. The daily routine duties of the ward will be minimally affected. Ward staffs were supportive and had positive attitude toward the proposed intervention. They are also familiar with integrating evidence-based practice to promote patient outcome, satisfaction, and wellbeing. For example, ward staffs were eager to promote breastfeeding and oxygen titration practices having learned of evidence-based guidelines.

**Availability of skills and facilities**
Nurses should be competent in assessing neonatal skin condition, and in administering different skin care products to the local area. These are basic nursing skills, and therefore a two-hour workshop will be adequate to equip nurses with the necessary knowledge and skills to implement the skin care management project.

Evaluation tools

A five-point visual scale used in Gunes et al. (2013) will be adopted in this project, since it provided a subjective assessment, whereby the severity score could be clearly defined and classified by the provided picture. During the project implementation period, all nurses will be familiarized with this five-point visual scale so as to identify the severity of the diaper dermatitis, and to adhere to the standardized guideline.

Cost-benefit ration of the Guideline

Potential risk of maintaining current practice

The potential risk is low for both target population and the ward staff, since there were minimal side effect or adverse effect reported from selected studies (Gozen et al., 2012; Gunes et al., 2013; Hoeger et al., 2010; Panahi et al., 2011; Spraker et al., 2006; Wananukul et al., 2006). However, the condition of the diaper dermatitis could deteriorate if remain untreated, which in turn, would prolong the length of hospital stay and alter the quality of life of the patient (Bonifazi, 2011).
Potential benefits of the proposed project to patients

If the project is implemented successfully, it is expected that the severity score of the diaper dermatitis will decrease while the cure rate will increase (Gozen et al., 2012; Gunes et al., 2013; Farahani et al., 2014; Hoeger et al., 2010; Panahi, 2011; Spraker et al., 2006; Wananukul et al., 2006). Successful implementation of this project is also expected to improve the babies’ quality life and the bonding between babies and their respective caregivers, at the same time reducing the length of hospital day, and healthcare expenditure.

Material costs of implementing the innovation

The material costs incurred will include manpower cost, assessment form, and the skin care product. The details of the budget plan are shown in Appendix F.

Two identical two-hour workshops will be held by the skin care working group, team leader (APN) and 2 team member (RN) in the conference room of the paediatric department. The room is free of charge, and technical support, such as computers and projectors, are provided by the ward. Each attending nurse would be given a handout that would cost approximately $25. 25 nurses are expected to attend the workshops. The hourly mean salary of the RN is $181, which means that the total cost of the workshop is $1211.

By the estimated calculation from the reviewed studies, 30 babies will be recruited
to the diaper dermatitis skin care management project as a pilot study, and 240 participants will be recruited in the implementation period for the proposed project. During the pilot study, each team member will oversee 6 patients, with each nurse spending 5 minutes to assess and treat the skin condition every shift, and 5 minutes spend on documentation. The nurses’ salary in this part is not counted in the cost, because they are routinely required to assess babies’ skin condition. Other expenses including the printout of the assessment form and evaluation form, the zinc oxide and clotrimazole creams, and the application equipment such as gloves and spatulas, wipes will be calculated. Taken together, the total expenditure on the diaper dermatitis skin care management project is estimated to be $13,931.

**Nonmaterial cost**

Upon successful implementation of this project, this project can potentially minimize the severity score of the diaper dermatitis and improve the quality of life for both caregivers and babies’ quality of life and satisfaction. Relief from diaper dermatitis and its associated discomfort will enable babies to sleep and settle for a longer period of time and cry less frequently. The caregiver will be more confident in taking care of their babies. Additional, it can also increase the professionalism of nurses by adhering to a standardized, and structured guideline in treating babies with different severity level of diaper dermatitis.
Chapter 4: Evidence-based Practice Guideline

According to the evidence retrieved from the review in chapter 2, an evidence-based guideline of skin care management for newborns with diaper dermatitis will be developed in this chapter, where each recommendation will be graded with the tool, the Scottish Intercollegiate Guidelines Network (SIGN).

**Guideline Title**

A clinical guideline of skin care management for newborns with diaper dermatitis

**Intended Users**

Registered nurses working in the NICU and SCBU settings

**Aim**

To develop an evidence-based skin care management guideline for reducing the severity score of infants with diaper dermatitis in local hospitals

**Objectives**

The objectives of the evidence based guideline were:

(1) To promote evidence-based skin care management;

(2) To provide a standardized practice on different interventions with diaper dermatitis

(3) To enhance staff competency on managing infants with different severity of diaper dermatitis
Major Outcomes Considered

Target population

Term babies who are age between newborn to 24 months old and admitted to NICU or SCBU with different severity score of diaper dermatitis are considered as target population. Babies with congenital dermatological disorder or abnormality, and critically ill babies with intubation, sedative or inotropes are excluded.

Recommendation

The Scottish Intercollegiate Guidelines Network (SIGN, 2012) was used to grade the recommendation and the levels of evidence. As mentioned in chapter 2, the highest level of evidence is the 1++ and the lowest is 4, whereas the symbol of “++, +, -” represented the quality of the articles with very low, low and high risk of bias respectively, and the numerical number represented the different types of study. Best practice recommended was presented with a grade score of either “A”, “B,” “C” and “D”, where “A” reflected the highest grade for recommendation and “D” reflected the lowest grade for recommendation. The detail description of the SIGN grading system is shown in Appendix G.

The recommendation of this guideline will be divided into three major parts: the assessment, implementation and evaluation, the details of which are explained in the following.
Recommendation 1)

Assess the babies who are eligible to receive the skin care management project

- Babies who were newborns to 24 months old with diaper dermatitis, who are
  neither critically ill with intubation, sedative or inotropes, nor diagnosed with
  congenital dermatological disorder or abnormality. Babies who fulfill these
  criteria are then eligible for the skin care management project.

*(Grade of Recommendation: A)*

Supporting Evidence

- The sample of all retrieved articles were term babies’ age below 24 months,
  who did not harbor any congenital dermatological disorder (Farahani et al.,
  2013; Gozen et al., 2012; Wananukul et al., 2006) (1+; 1-; 1+)

Recommendation 2)

Initial assessment

- An initial skin assessment with a five-point visual scale (see Appendix G)
  would be administered as a baseline measurement, whenever mild erythema
  is detected in infants’ buttocks (score = 1).

*(Grade of Recommendation: B)*

Supporting Evidence
Although various pre-assessment tools were used in all studies, they all focused on the same characteristic of the diaper dermatitis e.g. the erythema, maceration, papules and desquamation condition (Gozen et al., 2012; Gunes et al., 2013; Farahani et al., 2014; Hoeger et al., 2010; Panahi, 2011; Spraker et al., 2006; Wananukul et al., 2006) (1-; 2+; 1+; 1+; 1++; 1+)

The five point visual scale was adopted in the studies because it provided an objective assessment by including a picture of the affected area. (Gozen et al., 2012; Gunes et al., 2013; Farahani et al., 2014; Wananukul et al., 2006) (1-; 2+; 1+; 1+)

Recommendation 3)

Preparation - Clean the skin

- A gentle cleansing to remove urine or feces, followed by air-dry, and the application of skin care product after each diaper change. *(Grade of Recommendation: A)*

Supporting Evidence

- The pH value contributed by the ammonia from urine and the enzyme in the stool create favorable condition for bacterial growth and affect the skin barrier function. Cleansing the buttock before the skin care product is applied
can minimize the effect of these contributor factors. (Gozen et al., 2012; Gunes et al., 2013; Panahi et al., 2011; Spraker et al., 2006; Wananukul et al., 2006) (1-; 2+; 1+; 1++; 1+)

Recommendation 4)

Implementation

- For skin conditions 1 and 2, mild to moderate erythema, zinc oxide should be applied to the affected buttock area (score = 1 or 2, refer to Appendix H).

  *(Grade of Recommendation: B)*

- For skin condition 3 and 4, moderate to severe erythema with fungal infection, clotrimazole cream should be applied to the affected area (score = 3 or 4, refer to Appendix H)

  *(Grade of Recommendation: B)*

Supporting Evidence

- The clotrimazole had better performance than the zinc oxide on treating fungal-infected diaper dermatitis. Moreover, it had a better cure rate of *Canadida* (Hoeger et al., 2010; Sparker et al., 2006) (1++; 1++)
Recommendation 5)

Implementation - The frequency of cream application

- Applying zinc oxide to the affected area with scores 1 to 2 after every diaper change.  
  *(Grade of Recommendation: A)*

- Applying clotrimazole cream to the affected area with scores 3 to 4 twice a day.  
  *(Grade of Recommendation: A)*

Supporting Evidence

- Applying zinc oxide to the affected area after every diaper change was recommended (Gozen et al., 2012; Farahani et al., 2014; Wananukul et al., 2006) (1-; 1+; 1+)

- Applying clotrimazole cream to the affected area twice a day, and re-administering the cream if accidentally removed during diaper change (Hoeger et al., 2010) (1+)

Recommendation 6)

Implementation – The dosage of cream applied.

- Applying a thin layer of assigned cream to the affected area.  
  *(Grade of Recommendation: B)*
Supporting Evidence

- The dosage of cream applied were not mentioned in majority of the studies.

A thin layer of zinc oxide mixed with dexpanthenol was recommended to apply to the affected area in only one selected study (Wananukul et al., 2006) (1+)

Recommendation 7)

Evaluation

- Assess the skin condition with the five-point visual scale as used in the initial assessment part on day 7 and day 14, and evaluate the reduction of severity score and cure rate of diaper dermatitis after the implementation.

(Grade of Recommendation: B)

Supporting Evidence

- The post-assessment was either evaluated on day 7 or day 14 in most of the studies. Longer assessment times could provide a better understanding on the improvement and cure rate of diaper dermatitis, where complete recovery was mostly achieved within 14 days (Gozen et al., 2012; Gunes et al., 2013;
Farahani et al., 2014; Hoeger et al., 2010; Panahi, 2011; Spraker et al., 2006;

Wananukul et al., 2006) (1-; 2++; 1++; 1++; 1++, 1+)
Chapter 5: Implementation Plan

The implementation plan is a fundamental step in realizing the project objectives, the success of which can promote positive changes to current nursing practices with regards to treating babies with diaper dermatitis. In this chapter, an implementation plan comprising a communication plan with the potential stakeholders, and a pilot test for the trial based on the proposed guideline will be provided.

Communication Plan

A good communication plan must be developed to allow stakeholders to understand the objectives and the content of this evidenced-based skin care management project, and to obtain the approval and support from all stakeholders regarding the proposed project. The communication plan will establish a structured communication channel to enhance the likelihood of success of the intervention. It will provide critical and relevant information to those who will be involved in the project in various aspects such as the duration of project implementation, and the method of implementation. Implementation of this communication plan will start from the top administrative level of the department and filter down to every nurse in the unit.
Identifying key stakeholders

The potential stakeholders will be classified into three different levels: (1) the administrative level of the Department; (2) the management level of the Department; and (3) the users of the guideline.

The administrative level of the Department are the Departmental Operation Manager (DOM), the Ward Managers (WM) and Chief of Service (COS). These are key persons that will approve and affect change in the ward’s policies and standards. In addition, they also provide the human resources and material for implementing the intervention. Although this skin care management project is implemented during routine care, and therefore do not require any extra staff, this project still require their support in providing material resource, and in prescribing clotrimazole if needed. Thus, the proposed project must get the approval from the administrative level of the Department before commencement.

The management level of the Department include the Advanced Practice Nurse (APN), Nurse Specialist (NS) and Nurse Consultant (NC). These are people who will be supporting the implementation of the proposed guideline. Moreover, they are a group of experienced nurses who also regularly update the Ward with new knowledge and nursing skills.

The users of the proposed project are the nurses who work in the NICU and SCBU,
because they are the frontline staff who provide nursing care to the babies. Therefore it is important to get their consent in implementing a new project.

**Communication process**

Effective communication with stakeholders is essential, as it allows for enhanced understanding and collaboration amongst them, which is imperative to ensure the success of project implementation. According to Pierson et al. (2007), successful communication required different strategies of communication and timeline to different stakeholders (Pierson et al., 2007).

DOM and Ward Managers are the first persons to contact, for they are the key decision makers of the ward’s guideline and policy. DOM and Ward Managers have regularly meetings on a monthly basis. Thus, the skin care management project will be present at this regular meeting to obtain their approval. The presentation will include the background, the affirming needs of the project and the guideline of the skin care management with evidence provided from the reviewed studies.

Moreover, DOM and Ward Managers are also responsible for managing the finances of the Ward, and therefore are privy to assess the costs and benefits of the proposed project. Their approval of the project is therefore critical. In sum, the budget plan, the benefit of the protocol, and comparison between current practice and the
The proposed protocol will be clearly explained in the presentation.

After gaining the approval from the administrative level, this project will be introduced to Nurse Consultant, Nurse Specialist, and APNs in the NICU and SCBU. The aim to communicate with DOM, Ward Managers and APN is to get their consensus to the project and to acquire their assistance in developing a working committee. The details of the project will be also presented to them, including project justifications, the proposed evidence-based guideline on using selected skin care products, the implementation plan of the project, and the detailed proposed timeline.

After getting the approval from the management level, the skin care working group will be established for planning and launching the proposed project. This skin care working group will include an APN and 5 Registered Nurses (RN). The APN, who will be the leader of the project, must have at least 5 years of working experience and must have completed the Post-Registration Certification Course in Neonatal Intensive Care Unit program. The 5 RNs, who will be recruited as members of this project, must have at least three years of working experience and must have also completed the Post-Registration Certification Course in Neonatal Intensive Care Unit.

After the skin care working group is formed, the working group will have to communicate with the users of the guideline, including all nurses working in the NICU and SCBU. There are around 50 nurses in both NICU and SCBU, who will be
instrumental in implementing the proposed guideline to the target group as they perform daily nursing care to babies. Therefore, two identical briefing and training workshops will be provided to ensure all nurses understand the proposed guideline. Each identical workshop will be held for 2 hours and around 25 nurses will attend. If nurses are unable to join the sessions due to the operational duty, they will receive the briefing details individually by the members of the skin care working group. The session’s content will include the objectives of the proposed guideline, the application of the assessment tool, and the implementation of selected skin care product. After attending the session, a set of handout will be given to each nurse and a written guideline will be prepared and placed in the ward area as reference. The progress and updated information of the project will be announced every Friday and sent to every nurse via the internal electronic mail, to prevent any important information and message to be missed.

**Pilot testing**

A pilot study is a small-scale preliminary study that aims to test the feasibility of the proposed guideline. This pilot study will provide staff with the time necessary to familiarize with the project, and to determine the needs for any revision before implementing the guideline. Doing so will help minimize unexpected result and difficulties when launching the project.
A pilot study of the proposed guideline will be carried out in a group of babies. Results from the pilot study will serve as a baseline on the severity level of diaper dermatitis.

The primary objectives of this pilot study are:

a) to determine the feasibility of implementing the guideline;

b) to assess the clinical effect of the project;

c) to identify difficulties encountered in implementing the guideline;

d) to determine whether nurses complied with the guideline;

Data gathered from this pilot study will help modify and improve the proposed protocol.

Timeframe, target population, sample size and target setting.

The duration of the pilot study is five weeks. It will be launched after all nurses have attended the two hours briefing and training workshop for assessing the skin and implementing the skin care products. The first three weeks are for recruitment and implementation of the intervention, and the last two weeks are for evaluation. The babies who meet the inclusion and exclusion criteria will be recruited and the intervention will commence immediately. As mentioned in the previous chapter, around 1,200-1,500 babies are admitted each year to both NICU and SCBU in the place I work,
and around 4 out of 10 babies developed different severity levels of diaper dermatitis. Therefore, approximately 30 babies are expected to be recruited to the pilot study. A verbal consent will be obtained from the eligible babies’ parents.

In the first three weeks of the pilot study, the skin care working group will support and facilitate nursing staff on recruiting the subjects, assessing the skin condition, choosing and applying the selected skin care cream, and documenting the result. Nurses will evaluate the babies’ skin condition on Day 0, Day 7 and Day 14 with the five-point visual assessment scale (Appendix H), and a clinical photo will be taken on Day 0 and Day 14 for data collection.

In addition to evaluating the babies’ skin condition, nurses’ comments and opinions toward this intervention will also be solicited via a questionnaire (Appendix I). This questionnaire will measure the staff’s satisfactory level on launching the project, the clarity and precision of the guidelines, and the ease of implementing the project. The nurses will also be able to provide comments at the end of the questionnaire.

Discussion pertaining to data collected from the pilot study

After collecting all data, the effectiveness of skin care management project will be evaluated in relation to the observed, if any, improvements of the babies’ skin condition. Data will be analyzed by the skin care working group, the results of which
will be written into a report for the WM and DOM. The effectives of the project, the level of satisfaction among nurses, the logistic arrangement, and the difficulties arising from the pilot study will be presented to the Nursing Consultant, Nursing Specialist and APN during the meeting. Recommendations and suggestions will also be presented to enhance the sustainability of the skin care management project. After the administrative level reviews the evaluation report, information will be disseminated to all nurses by email.
Chapter 6: Evaluation Plan

An evaluation plan is an important process for implementation of an intervention, for it assesses the effectiveness of the proposed project. The evaluation plan will include outcome measure and details with regards to the methods used for collecting and analyzing the data.

**Outcome measure**

*Primary outcomes*

In light of reviewed articles (Gunes et al., 2013; Gozen et al., 2012; Farahani et al., 2014; Hoeger et al., 2010; Spraker et al., 2006; Wananukul et al., 2006), the primary outcome measure is the reduction rate of the severity score and the curable rate of diaper dermatitis among the babies who are admitted to the NICU or SCBU.

The five point visual scale (Appendix H) will be used for assessing the improvement of skin condition, and the corresponding scores of this scale will be compared across Day 0, Day 7 and Day 14. If the score decreases to zero on Day 7 or Day 14, the primary outcome is achieved. Clinical photo will be taken on Day 0 and Day 14 to provide an objective picture to compare the babies’ skin condition.

In addition, demographic data will also be collected to evaluate the influence of the baby’s data, e.g. gestation age to its skin healing process (Appendix J).
Secondary outcome

The secondary outcome measures are the nurses’ level of compliance and level of satisfaction, as these can directly affect the effectiveness of the guideline. The nurses’ compliance will be assessed by evaluating the documentation of the project data collection form (Appendix I), while the level of satisfaction will be evaluated with a questionnaire (Appendix I) that consists of questions regarding the clarity and precision of the guideline, the ease of project implementation, and the overall level of satisfaction with the project. Nurses will be asked to respond to 7 items on a 5-point likert scale ranging from “strongly disagree” to “strongly agree”.

Nature and Number of client to be involved

The eligibility criteria of clients to be recruited in the evaluation plan are based on previous reviewed studies (Gunes et al., 2013; Gozen et al., 2012; Farahani et al., 2014; Hoeger et al., 2010; Spraker et al., 2006; Wananukul et al., 2006). They are: (i) term babies who are admitted to SCBU or NICU with age between newborn to 24 months; and (ii) who suffered from different severity score of diaper dermatitis in the target ward. Babies with congenital dermatological disorder or abnormality, and critically ill babies with intubation, sedative or inotropes are excluded for this study.

The effectiveness of the project can be assessed by determining the reduction
rate of the severity score of diaper dermatitis after the skin care management project is implemented. By using the online software by Lenth (2006), the one-sample t-test is selected and the sample size can be calculated. It is because our project is measuring the difference between the severity score before and after applying the skin product for a single group of people. According to the Cohen’s d method, the effect size is small class, which is 0.2. With 95% of confidence interval, the power of 80% and the sigma of 1 selected in the skin care management project, the sample size is 198. Furthermore, an average dropout rate of 15% were reported in the reviewed studies. (Gunes et al., 2013; Gozen et al., 2012; Farahani et al., 2014; Hoeger et al., 2010; Spraker et al., 2006; Wananukul et al., 2006). Thus, the total number of recruitment is 240 babies.

**Data collection**

According to the reviewed studies (Gunes et al., 2013; Gozen et al., 2012; Farahani et al., 2014; Hoeger et al., 2010; Spraker et al., 2006; Wananukul et al., 2006), the severity level and cure rate of the diaper dermatitis can be measured by the five point visual scale (Appendix H). The nurses will document the babies’ skin condition score (Appendix J) at A shift on Day 0, Day 7 and Day 14. Clinical photos will also be taken by the nurses and printed out on Day 0 and Day 14 in order to compare the severity level of the babies’ skin condition as described in the reviewed studies (Gunes
et al., 2013; Gozen et al., 2012; Farahani et al., 2014; Hoeger et al., 2010; Spraker et al., 2006; Wananukul et al., 2006).

Furthermore, staff compliance will be measured by their documentation of data collection form (Appendix J) on the A shift on Day 0, Day 7 and Day 14. Nurses will be required to fill in a questionnaire that assesses their level of satisfaction toward the end of the project.

**Data analysis**

The severity score of the diaper dermatitis will be measured using the five-point visual scale assessment tool, with “0” indicating no erythema, and “4” indicating severe erythema (see appendix H). The collected data will be entered into the Statistical Package for Social Science (SPSS) version 21. The one sample t test will be used to measure the mean score of the baby’s condition. The demographic data of the babies will be measured by Chi-square to assess whether it has an effect on the cure rate. The nurses’ feedback and satisfaction survey will also be analyzed by measuring the percentage of each item.

**Basis for an effective change of practice**

The effectiveness of the protocol is determined by the achievement of the
outcomes. With reference to previous literature, the main objectives of this protocol are to reduce the severity score of the diaper dermatitis, and to increase the cure rate of diaper dermatitis after the skin care product is administered.

Patient clinical outcomes

The effectiveness of the skin care management project will be determined by the skin condition of the babies. According to Gunes et al. (2013), if the mean score of the five point visual scale is reduced to less than or equal to 0.6 among affected babies, the project can be concluded as effective.

Nursing Satisfactory

The level of satisfaction among nurses will also determine the effectiveness of the project. If 80% of the nurses stated “strongly agree” or “agree” on overall satisfaction in the questionnaire (Appendix I), the project will be considered effective.

Conclusion

Results from a systematic review indicated that a structured skin care management can reduce the severity score of diaper dermatitis among babies. As mentioned earlier, the presence of diaper dermatitis can affect the babies’ vital sign, nutritional intake and quality of life, and may result in prolonged hospital stay. This
may pose higher demands on manpower and may decrease the bonding between babies and their respective caregivers. Moreover, due to the lack of consistent or standardized practice with regards to the treatment of diaper dermatitis among nurses, the healing and recovery process amongst babies also varied significantly. It was under these circumstances that led the author to develop an evidence-based skin care management guideline, the success of which can potentially generate positive patient and caregiving outcomes.

This study proposed an intervention guideline in response to the need to treat diaper dermatitis in an effective, and standardized manner. The first step is to devise an effective communication plan so as to gain support and approval from the stakeholders by equipping them with the knowledge and understanding of the importance of this project. A pilot study is then expected to be conducted in order to test the feasibility of the proposed guideline. Difficulties and unforeseen challenges arising from this pilot project will help modify and improve the proposed guideline prior to full implementation. Finally, evaluation mechanisms will be used to design and review the effectiveness of the primary and secondary outcomes of this project. Results generated from these findings will be consolidated into a comprehensive report that will serve as a streamlined and structured skin care management guideline for future use across hospitals in Hong Kong in treating diaper dermatitis in babies.
Appendix A – Search History

Searches completed from July 2014 to October 2014
Retrieved on 5th October 2014

<table>
<thead>
<tr>
<th>Search ID</th>
<th>Keywords</th>
<th>CINAHL (EBSCO host)</th>
<th>British Nursing Index (ProQuest)</th>
<th>Medline (ProQuest)</th>
<th>Pubmed (ProQuest)</th>
</tr>
</thead>
<tbody>
<tr>
<td>S1</td>
<td>Neonatal</td>
<td>4624</td>
<td>5902</td>
<td>198066</td>
<td>181284</td>
</tr>
<tr>
<td>S2</td>
<td>Infant</td>
<td>33626</td>
<td>7582</td>
<td>1040885</td>
<td>986914</td>
</tr>
<tr>
<td>S3</td>
<td>Baby</td>
<td>1899</td>
<td>2931</td>
<td>59204</td>
<td>1000624</td>
</tr>
<tr>
<td>S4</td>
<td>Newborn</td>
<td>15414</td>
<td>1139</td>
<td>635393</td>
<td>624829</td>
</tr>
<tr>
<td>S5</td>
<td>Diaper</td>
<td>50</td>
<td>17</td>
<td>1957</td>
<td>1304</td>
</tr>
<tr>
<td>S6</td>
<td>Napkin</td>
<td>3</td>
<td>6</td>
<td>295</td>
<td>185</td>
</tr>
<tr>
<td>S7</td>
<td>Nappy</td>
<td>9</td>
<td>95</td>
<td>220</td>
<td>126</td>
</tr>
<tr>
<td>S8</td>
<td>Dermatitis</td>
<td>952</td>
<td>323</td>
<td>79400</td>
<td>98904</td>
</tr>
<tr>
<td>S9</td>
<td>Rash</td>
<td>472</td>
<td>186</td>
<td>23138</td>
<td>22652</td>
</tr>
<tr>
<td>S10</td>
<td>S1 or S2 or S3 or S4</td>
<td>35991</td>
<td>12573</td>
<td>1235104</td>
<td>1164307</td>
</tr>
<tr>
<td>S11</td>
<td>S5 or S6 or S7</td>
<td>61</td>
<td>113</td>
<td>2340</td>
<td>1528</td>
</tr>
<tr>
<td>S12</td>
<td>S8 or S9</td>
<td>1382</td>
<td>484</td>
<td>100755</td>
<td>117770</td>
</tr>
<tr>
<td>S13</td>
<td>S10 and S11 and S12</td>
<td>20</td>
<td>49</td>
<td>658</td>
<td>613</td>
</tr>
<tr>
<td>S14</td>
<td>S13; limited to publication date from 2003 to 2014</td>
<td>---</td>
<td>32</td>
<td>14</td>
<td>23</td>
</tr>
</tbody>
</table>
Appendix B - Prisma 2009 Flow Diagram

1. **Identification**
   - Articles identified through CINAHL, Medline, Pubmed, British Nursing Index (n=89)
   - Additional articles identified through Google Search Engine and Yahoo search engine (n=28)

2. **Screening**
   - Articles after duplicates removed (n=62)

3. **Eligibility**
   - Records screened (n=38)
   - Non English Articles and articles published before 2003 are excluded (n=24)

4. **Included**
   - Full-text articles assessed for eligibility (n=18)
   - Full-text articles with the exclusion criteria are excluded (n=20)

5. **Studies included in qualitative synthesis (n=9)**

6. **Studies included in qualitative synthesis (Meta-analysis) (n=7)**
**Appendix C – SIGN Critical Appraisal for the Retrieved literature**

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1.2 The assignment of subjects to treatment groups is randomized</td>
<td>Adequately addressed</td>
<td>Adequately addressed</td>
<td>Adequately addressed</td>
<td>Adequately addressed</td>
<td>Adequately addressed</td>
<td>Adequately addressed</td>
<td>Not applicable</td>
</tr>
<tr>
<td>1.3 An adequate concealment method is used</td>
<td>Not addressed</td>
<td>Not addressed</td>
<td>Adequately addressed</td>
<td>Not addressed</td>
<td>Adequately addressed</td>
<td>Adequately addressed</td>
<td>Not applicable</td>
</tr>
<tr>
<td>1.4 Subjects and investigators are kept ‘blind’ about treatment allocation</td>
<td>Unclear; Single blinded</td>
<td>Unclear</td>
<td>Unclear; Single blinded</td>
<td>Not addressed</td>
<td>Well covered; double blinded</td>
<td>Unclear; Single blinded</td>
<td>Not applicable</td>
</tr>
<tr>
<td>1.5 The treatment and control groups are similar at the start of the trial</td>
<td>Poorly addressed</td>
<td>Poorly addressed</td>
<td>Adequately addressed</td>
<td>Adequately addressed</td>
<td>Adequately addressed</td>
<td>Poorly addressed</td>
<td>Adequately addressed</td>
</tr>
<tr>
<td>1.6 The only difference between groups is the treatment under investigation</td>
<td>Well covered</td>
<td>Well covered</td>
<td>Well covered</td>
<td>Well covered</td>
<td>Well covered</td>
<td>Well covered</td>
<td>Well covered</td>
</tr>
<tr>
<td>1.7 All relevant outcomes</td>
<td>Adequately</td>
<td>Adequately</td>
<td>Adequately</td>
<td>Adequately</td>
<td>Adequately</td>
<td>Adequately</td>
<td>Adequately</td>
</tr>
<tr>
<td></td>
<td></td>
<td>are measured in a standard, valid and reliable way</td>
<td>addressed</td>
<td>addressed</td>
<td>addressed</td>
<td>addressed</td>
<td>addressed</td>
</tr>
<tr>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>1.8</td>
<td>What percentage of the individual or clusters recruited into each treatment arm of study dropped out before the study was completed?</td>
<td>5.3% dropout (n=150)</td>
<td>10% dropout (n=70)</td>
<td>15% drop out (n=102)</td>
<td>Not addressed (n=66)</td>
<td>20% drop out (n=330)</td>
<td>17 % drop out (n=46)</td>
</tr>
<tr>
<td>1.9</td>
<td>All the subjects are analyzed in the groups to which they are randomly allocated (often referred to as intention to treat analysis)</td>
<td>Not addressed</td>
<td>Not addressed</td>
<td>Not addressed</td>
<td>Not addressed</td>
<td>Adequately addressed</td>
<td>Adequately addressed</td>
</tr>
<tr>
<td>1.10</td>
<td>Where the study is carried out at more than one site, results are comparable for all sites.</td>
<td>Poorly addressed, single site.</td>
<td>Poorly addressed, single site</td>
<td>Adequately addressed</td>
<td>Poorly addressed, single site</td>
<td>Adequately addressed</td>
<td>Adequately addressed</td>
</tr>
<tr>
<td>2.1</td>
<td>How well was the study done to minimize bias? Code ++, +, or -</td>
<td>1+</td>
<td>1-</td>
<td>1+</td>
<td>1+</td>
<td>1++</td>
<td>1+</td>
</tr>
<tr>
<td>2.2</td>
<td>Taking into account clinical</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>
considerations, your evaluation of the methodology used, and the statistical power of the study, are you certain that the overall effect is due to the study intervention?

<table>
<thead>
<tr>
<th>2.3</th>
<th>Are the results of this study directly applicable to the patient group targeted by this guideline?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Yes</td>
</tr>
</tbody>
</table>

Remarks: Section 2 relates to the overall assessment of the paper. It starts by rating the methodological quality of the study, based on your responses in Section 1 and using the following coding system to assess the levels of evidence:

<table>
<thead>
<tr>
<th>1++</th>
<th>All or most of the criteria have been fulfilled. Where they have not been fulfilled the conclusion of the study or review, based on unlikely to alter</th>
</tr>
</thead>
<tbody>
<tr>
<td>1+</td>
<td>Some of the criteria have been fulfilled. Those criteria that have not been fulfilled or not adequately described are thought unlikely to alter the conclusion</td>
</tr>
<tr>
<td>1-</td>
<td>Few or no criteria fulfilled. The conclusion of the study are thought likely or very likely to alter.</td>
</tr>
</tbody>
</table>
Appendix D - Table of Evidence

<table>
<thead>
<tr>
<th>Bibliographic citation</th>
<th>Study Type</th>
<th>Patient Characteristics</th>
<th>Intervention</th>
<th>Comparison</th>
<th>Length of follow up</th>
<th>Outcome measures</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Farahani et al., 2013</td>
<td>Randomized controlled trial</td>
<td>Infants age between birth to 24 months</td>
<td>Hind milk applied to the affected area after each breastfeeding</td>
<td>Hydrocortisone 1% applied to affected area twice a day</td>
<td>7 days</td>
<td>Primary (1) effectiveness of human breast milk and hydrocortisone ointment after 7 days treatment Secondary (2) Compare severity scores after 0, 3 and 7 days.</td>
<td>(1) ( p&lt;0.001 ) (2) ( P=0.32 ), no significant difference</td>
</tr>
<tr>
<td>Gozen et al, 2012</td>
<td>Randomized controlled trial</td>
<td>Term and preterm newborns</td>
<td>Human breast milk</td>
<td>Barrier cream of 40% zinc oxide and cod liver oil</td>
<td>7 days</td>
<td>(1) The effectiveness of human breast milk and zinc oxide with cod liver oil after 10 days treatment.</td>
<td>(1) ( p&lt;0.01 )</td>
</tr>
<tr>
<td>Gunes et al, 2013</td>
<td>Quasi-experimental</td>
<td>Newborns aged &lt;10 weeks old</td>
<td>Guaiazulene alone applied 3 times per day</td>
<td>Continue barrier cream with antifungal agents applied 3 times per day</td>
<td>7 days</td>
<td>(1) Reduction of mean rash score after 7 days</td>
<td>(1) In control group, ( P=0.46 ), no significant difference; in study group, ( p&lt;0.001 ), 80% of patient completely resolved</td>
</tr>
<tr>
<td>Hoeger et al., 2010</td>
<td>Randomized controlled trial</td>
<td>Infants age between 4 months to 2</td>
<td>1% clotrimazole applied to the affected area</td>
<td>Nystatin with zinc oxide applied to the</td>
<td>14 days</td>
<td>Primary (1) Improvement of the total symptom score</td>
<td>(1) ( P=0.043 ), no significant difference (2) ( P=0.0496 )</td>
</tr>
</tbody>
</table>
Panahi et al., 2011  | Randomized controlled trial  | Infants age under 3 years old  | Topical Aloe vera applied to the affected area three times a day  | Calendula ointment applied to the affected area three times a day  | 10 days  | Primary  
(1) Effectiveness of Aloe vera and Calendula officinalis on treating diaper dermatitis  
Secondary  
(2) Compare the effects of calendula with aloe  | (3) P=0.5141  
(1) p<0.001  
(2) P=0.001 |

Spraker et al., 2006  | Randomized Controlled Trial  | Infants younger than 4 years old  | Miconazole nitrate 0.25% ointment were applied after every diaper change  | Zinc oxide / petrolatum were applied after every diaper change  | 14 days  | Primary  
(1) Therapeutic response of overall cure rate on day 14  
Secondary  
(2) Assessment of  | (1) 38% with study group, and 11 % with control group, p<0.001  
(2) 93% of patient were clinically cured;
<table>
<thead>
<tr>
<th>Study</th>
<th>Design</th>
<th>Participants</th>
<th>Intervention</th>
<th>Duration</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wananuku et al., 2006</td>
<td>Randomized Controlled Trial</td>
<td>Infants age between 4 months to 2 years old</td>
<td>Ointment base alone (bee wax, liquid paraffin) were applied</td>
<td>7 days</td>
<td>Clinical cure and microbiologic eradication on day 14</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Culture test negative in 50% in study group and 23% in control group</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

(1) Effectiveness of study group compared to control group to reduce transepidermal water loss (TEWL) (1) P=0.07, no significance
### Appendix E- Time schedule for implementing the innovation

<table>
<thead>
<tr>
<th>Item</th>
<th>Schedule</th>
</tr>
</thead>
<tbody>
<tr>
<td>Formation of the skin care working group</td>
<td>One week</td>
</tr>
<tr>
<td>Planning for the innovation including communication plan</td>
<td>Two weeks</td>
</tr>
<tr>
<td>Staff training</td>
<td>Two weeks</td>
</tr>
<tr>
<td>Pilot study for the project</td>
<td>Five weeks</td>
</tr>
<tr>
<td>Implementation period</td>
<td>Twenty-four weeks</td>
</tr>
<tr>
<td>Evaluation</td>
<td>Four weeks</td>
</tr>
</tbody>
</table>
### Appendix F – Cost and Expenditure Table

#### Expenditure:

2 hours workshop:

<table>
<thead>
<tr>
<th>Category</th>
<th>Calculation</th>
<th>Sub-total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Training hour (per nurse)</td>
<td>$181 \times 2</td>
<td>$362</td>
</tr>
<tr>
<td>Total training fee (3 nurse)</td>
<td>$362 \times 3</td>
<td>$1086</td>
</tr>
<tr>
<td>Printed material for workshop</td>
<td>$5 \times 25</td>
<td>$125</td>
</tr>
</tbody>
</table>

On Skin care management project

<table>
<thead>
<tr>
<th>Category</th>
<th>Calculation</th>
<th>Sub-total</th>
</tr>
</thead>
<tbody>
<tr>
<td>240 eligible patients/ month</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Printed Material for nurse implementation</td>
<td>$3/\text{patient} \times 240 \text{patient/month}</td>
<td>$720</td>
</tr>
<tr>
<td>Assessment form + evaluation form</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expense for equipment and facilities</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Skin care products</td>
<td>$50 \times 240 \text{patient/month}</td>
<td>$12,000</td>
</tr>
</tbody>
</table>

Total expenditure on skin care management project

\[
= \$1086 + \$125 + \$720 + \$12000 = \$13,931 \text{ (per month)}
\]
Appendix G- Level of Evidence and Grade of Recommendation

SIGN grading system: Level of evidence
(Scottish Intercollegiate Guidelines Network, 2014)

<table>
<thead>
<tr>
<th>Grade</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1++</td>
<td>High quality meta-analyses, systematic reviews of RCTs, or RCTs with very low risk of bias</td>
</tr>
<tr>
<td>1+</td>
<td>Well-conducted meta-analyses, systematic reviews of RCTs, or RCTs with low risk of bias</td>
</tr>
<tr>
<td>1-</td>
<td>Meta analyses, systematic reviews of RCTs, or RCTs with a high risk of bias</td>
</tr>
<tr>
<td>2++</td>
<td>High quality systematic review of case-control or cohort studies with a very low risk of confounding-, bias, or chance and a high probability that the relationship is causal</td>
</tr>
<tr>
<td>2+</td>
<td>Well-conducted case control or cohort studies with a low risk of confounding or bias and a moderate probability that the relationship is causal</td>
</tr>
<tr>
<td>2-</td>
<td>Case control or cohort studies with a high risk of confounding or bias and a significant risk that the relationship is not causal</td>
</tr>
<tr>
<td>3</td>
<td>Non-analytic studies, e.g. case reports, case series</td>
</tr>
<tr>
<td>4</td>
<td>Expert opinion</td>
</tr>
</tbody>
</table>

SIGN grading system: Grade of Recommendation
(Scottish Intercollegiate Guidelines Network, 2014)

<table>
<thead>
<tr>
<th>Grade</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>At least one meta-analysis, systematic review, or RCT rate as 1++, and directly applicable to the target population; or A body of evidence consisting principally of studies rated as 1+, directly applicable to the target population, and demonstrating overall consistency of results</td>
</tr>
<tr>
<td>B</td>
<td>A body of evidence including studies rated as 2++, directly applicable to the target population, and demonstrating overall consistency of results; or Extrapolated evidence from studies rated 1++ or 1+</td>
</tr>
<tr>
<td>C</td>
<td>A body of evidence including studies rated as 2+, directly applicable to the target population and demonstrating overall consistency of results; or Extrapolated evidence from studies rated as 2++</td>
</tr>
<tr>
<td>D</td>
<td>Evidence level 3 or 4; or Extrapolated evidence from studies rated as 2+</td>
</tr>
</tbody>
</table>


Appendix H – Five Point Visual Scale - skin condition assessment tool

<table>
<thead>
<tr>
<th>Score</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>None</td>
</tr>
<tr>
<td>1</td>
<td>Mild erythema</td>
</tr>
<tr>
<td>2</td>
<td>Moderate erythema</td>
</tr>
<tr>
<td>3</td>
<td>Moderate erythema plus maceration</td>
</tr>
<tr>
<td>4</td>
<td>Severe erythema plus pustules or ulceration</td>
</tr>
</tbody>
</table>
### Appendix I -

**A clinical guideline of skin care management for newborns with diaper dermatitis Questionnaire - Staffs’ Satisfaction level**

<table>
<thead>
<tr>
<th>Please choose the best answer on the right side</th>
<th>Strongly disagree</th>
<th>Disagree</th>
<th>Neutral</th>
<th>Agree</th>
<th>Strongly agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. The information in briefing session was clear for carrying out the project</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. The length of briefing session was appropriate</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. The skin care management guideline is suitable for babies affected by diaper dermatitis</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Applying the guideline will not increase any workload</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. Applying the guideline is not time consuming</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6. The guideline is easy to follow</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7. Overall, I am satisfied with the skin care management project</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

8. Any other comment on the skin care management project?

_____________________________________________________________
Appendix J - Skin Care Management Project Data Collection Form
Please fill in the form in **A shift on Day 0, 7, 14**

<table>
<thead>
<tr>
<th>Name: [GUM LABEL]</th>
<th>Gestational Age: ___ weeks</th>
<th>BW: ___ kg</th>
<th>Gender: F / M</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Ethnicity:</th>
<th>Feeding Plan: Exclusive BF / BF &amp; AF / AF</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Admission Diagnosis:</th>
<th>Antenatal History (+/- social problem):</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Please fill in the following columns in every shift:

<table>
<thead>
<tr>
<th>(Day) Date</th>
<th>(D0)</th>
<th>(D7)</th>
<th>(D14)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bowel Open</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Times</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Stool Texture</td>
<td>(loose/watery/ soft/seedy)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Napkin Brand</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baby’s swipe Brand</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Any special Treatment applied: (E.g. phototherapy)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medication (if antibiotics, please specify Day_)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Five Point Visual Scale (score 0-4)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Skin care products applied
(1) Zinc oxide
(2) Clotrimazole

Remarks

Signature
Reference


