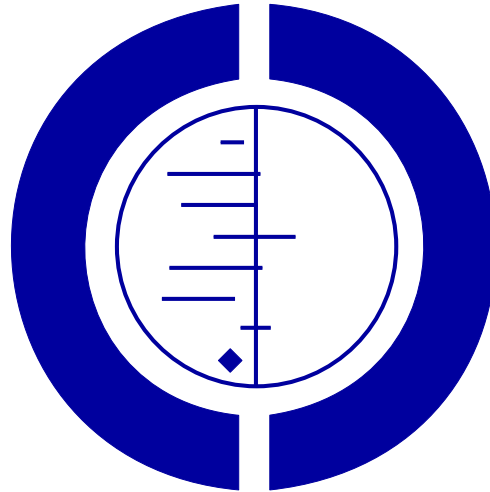


# Disposable nappies for preventing napkin dermatitis in infants (Review)

Baer EL, Davies MW, Easterbrook KJ



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## A B S T R A C T

### Background

Napkin dermatitis is a common condition that occurs in otherwise healthy infants. It causes discomfort to infants, anxiety to parents and caregivers and contributes to the load on the health care system. A large variety of napkins, both disposable and non-disposable, are available. Evidence is required to assist carers and health care workers in making informed decisions when balancing the pros and cons of different napkin choices.

### Objectives

To assess whether disposable napkins prevent napkin dermatitis in infants.

### Search strategy

We searched the Skin Group Specialised Register (up to June 2003), the Cochrane Central Register of Controlled Trials in (*The Cochrane Library*, Issue 3, 2004), MEDLINE (from 1966 to November 2004), EMBASE (from 1980 to February 2003) and CINAHL (from 1982 to November 2004). We searched reference lists of articles. We contacted lead investigators in the area and companies that manufacture disposable napkins for access to unpublished trials.

### Selection criteria

Randomised controlled trials in which disposable napkins were compared with other types of disposable napkins or non-disposable napkins, in infants up to two years of age, for preventing napkin dermatitis.

### Data collection and analysis

Two authors independently extracted data. The same two authors independently assessed trials for methodological quality. Attempts were made to contact trial authors of the trials identified for clarification of methods and results of published trials.

### Main results

We identified 28 studies of the effects of various napkin types on napkin dermatitis. Seventeen studies from nine reports were included. Eleven studies were excluded due to methodology that did not fit the inclusion criteria of this review. Due to the poor reporting of methodology and results of the studies found in this review, there were no quantitative data available for analysis (or meta-analysis). Although the included studies appeared to favour cellulose-core disposable napkins over cloth, absorbent gelling material over cellulose-only core napkins, breathable outer shell over occlusive outer shell napkins and linings impregnated with formulations over plain linings, all of these studies were open to bias due to flawed methodology.

### Authors' conclusions

There is not enough evidence from good quality randomised controlled trials to support or refute the use and type of disposable napkins for the prevention of napkin dermatitis in infants.

## PLAIN LANGUAGE SUMMARY

The role of disposable napkins for preventing napkin dermatitis in infants is not yet clear.

Although generally not a serious condition, napkin dermatitis is common and causes discomfort for infants, anxiety for carers and burdens the health care system. A variety of napkins are available. Carers and health care workers require evidence to assist in the choice of napkins used. This review found that there was not enough evidence from good quality randomised controlled trials to support or refute the use and type of disposable napkins for the prevention of napkin dermatitis in infants. Better studies need to be done.

## BACKGROUND

### Definition and epidemiology

Napkin dermatitis (also known as nappy rash or diaper rash) is a non-specific term used to describe any inflammatory eruption of the skin in the napkin area (this is the definition that will be used for the purpose of this review). Rashes in the napkin area can be classified into three main groups: conditions that occur whether napkins are worn or not (e.g. skin conditions like epidermolysis bullosa or acrodermatitis enteropathica); latent predisposition to dermatitis exacerbated by napkins (e.g. psoriasis, seborrhoeic dermatitis); dermatitis directly attributable to the napkin (e.g. allergic contact dermatitis, direct irritant contact dermatitis) (Koblentz 1973). The majority of napkin dermatitis occurs in otherwise healthy children and is caused by direct irritant contact, therefore this is the group of major focus in this review.

Jordan 1986 demonstrated the regressive nature of napkin dermatitis, with severe rashes tending to improve and mild rashes tending to deteriorate towards the mean. This supports the need for properly controlled studies when dealing with this condition.

Irritant contact napkin dermatitis is a relatively modern affliction of the developed world, resulting from widespread napkin use. The use of modern day cloth napkins developed over the eighteenth and nineteenth centuries, and only became widespread in Europe and the USA in the early twentieth century (Levin 1970). In 1963 Pampers (Procter & Gamble Co, Cincinnati, Ohio, USA) was the first nationally marketed disposable napkin released in the USA, after which disposable napkin use became widespread in the USA and Europe.

The incidence and prevalence of napkin dermatitis varies greatly between reports, and with new developments in napkins, older studies may not reflect the current situation (Odio 2000). Clinical observation suggests that it remains a relatively frequent occurrence. Jordan 1986 reported a frequency of 50% of infants studied (but the recruitment method was unknown), with 5% meeting the criteria for severe rash, with a peak frequency at age nine to twelve months. Their data suggested that 7% of all rash episodes were drawn to the attention of physicians. In a large population study in the UK, the incidence of any grade of napkin rash (as self-reported by mothers) in infants during the first four weeks of life

was 25%, with 6% reporting 'very' or 'quite' bad rashes (Phillipp 1997).

### Causes

Napkin dermatitis is caused by a combination of factors. Moist occlusion following urination in the napkin causes over-hydration of the skin which predisposes it to mechanical injury by increasing the coefficient of skin friction - ie. prolonged wetness of the skin makes it more prone to damage. Skin pH is increased in the napkin area as faecal bacteria produce ammonia from urinary urea, thereby increasing skin permeability to low molecular weight irritants and increasing the activity of faecal enzymes. These factors predispose the skin to opportunistic infection by faecal microbes such as *Candida albicans* thereby causing a more severe and chronic napkin dermatitis (Berg 1987).

The vulnerability of newborn infants (especially pre-term infants) skin to mechanical injury and napkin dermatitis makes this group worthy of separate consideration. Pre-term infants have a relatively thin stratum corneum (the outermost layer of the skin), a smoother epidermal-dermal interface lacking the projections of mature skin, and a thinner, less collagenised dermis. Their skin is therefore more fragile and they have a lower threshold for irritant contact dermatitis, including napkin dermatitis (Williams 2001).

### Impact

Although the incidence varies between populations with different environments and napkin practices, napkin dermatitis continues to be a common condition. Although it is rarely serious enough to have long-term or life-threatening effects, napkin dermatitis causes a large amount of discomfort to infants, as well as anxiety to carers and contributes to the load on the health care system.

### Prevention

Napkins that maintain normal skin pH and hydration should theoretically prevent the development of napkin dermatitis (Berg 1987).

Napkins can be categorized into two main categories: disposable and non-disposable (or reusable). Both come in a large variety of forms and new napkins continue to evolve. The basic components of napkins are an inner lining, an absorbent core and an outer shell.

Disposable napkins can have a variety of inner linings, with recent variants even delivering topical dermatological formulations. The

core of disposable napkins was conventionally an absorbent cellulose pulp, however in the 1980s the addition of super-absorbent gel to the core has produced a new generation of disposable napkins. The outer layer can be either breathable fabric or a waterproof material (Odo 2000a).

Reusable napkins come in a large variety of shapes and compositions. Commonly they consist of multi-layered cloth, but varieties include cloth with a fiber-filled centre. Reusable napkins may be lined with disposable inner cloths. They may also have a waterproof shell but more commonly are covered by a waterproof over pant. A variety of pins, ties, self-adhering closures or clasps are available to secure the cloth in place.

Wilson and colleagues studied the effect of a wide variety of available napkins on skin hydration using adult skin and found that disposable napkins containing super-absorbent gel kept the skin driest and that conventional and reusable napkins were comparably inferior in terms of skin dryness (Wilson 1990). Campbell and colleagues studied a smaller variety of napkins used in infants and had also demonstrated superior dryness with super-absorbent gel napkins, as well as less increase in skin pH and less napkin dermatitis when compared to conventional and cloth napkins (Campbell 1987a).

Other methods of preventing napkin dermatitis such as topical skin treatments, nappy-free time and frequent changing of nappies are not directly addressed in this review.

#### **Why is it important to do this review**

The best choice of napkin for use in infants is a controversial issue. It is a commonly held belief that disposable napkins are more likely to prevent napkin dermatitis than reusable napkins, but this needs to be established. This will allow carers and health care workers to make informed decisions when balancing the pros and cons of different napkin choices. Other considerations used when comparing relative advantages of the variety of napkins available may include: accuracy of measurement of urine output, infection control, environmental and safety considerations, time and cost (Wong 1992). Parents also consider convenience, napkin failure, availability of different sizes and whether the napkins can be removed by the child to be important aspects of napkin choice.

## **OBJECTIVES**

#### **Primary objective:**

To assess whether disposable napkins prevent napkin dermatitis. If there were no other additional benefits of disposable nappies, then a 10% decrease in the occurrence would seem to be clinically relevant given the high prevalence and incidence of napkin dermatitis. However, if there were any additional benefits of disposable nappies (e.g., increased parental satisfaction/convenience or decreased cost) then an equal occurrence would be clinically relevant.

#### **Secondary objective:**

To assess whether the use of disposable napkins was associated with any other significant benefit or harm, either to the infant, the infants caregivers or the environment.

## **CRITERIA FOR CONSIDERING STUDIES FOR THIS REVIEW**

#### **Types of studies**

All randomised controlled trials (RCTs) in which disposable napkins were compared with other types of disposable napkins or non-disposable napkins. Cross over studies will be included but only data regarding outcomes assessed at the end of the first study period (before the first cross over) will be used.

#### **Types of participants**

Infants from birth to two years, including pre-term neonates.

#### **Types of intervention**

Disposable napkins versus non-disposable napkins.  
Disposable napkins versus other types of disposable napkins.

#### **Types of outcome measures**

##### **Primary outcomes**

- (1) Occurrence of napkin dermatitis
- (2) Severity of napkin dermatitis (with severe defined as any occurrence of skin breakdown)

##### **Secondary outcomes**

- (1) Treatment rates for napkin dermatitis
- (2) Napkin dermatitis free days (ie. the number of days free of any dermatitis in the napkin area) per week, two weeks or four weeks/month
- (3) Failure/leakage - soiling or wetting of environment versus no leakage
- (4) Parental satisfaction
- (5) Injury or trauma to infant or caregiver
- (6) Environmental impact

## **SEARCH METHODS FOR IDENTIFICATION OF STUDIES**

See: Skin Group methods used in reviews.

#### **(1) Electronic databases**

We identified relevant trials from:

- the Skin Group's Specialised Register (up to June 2003);
- the Cochrane Central Register of Controlled Trials (CENTRAL) in (*The Cochrane Library*, Issue 3, 2004);
- MEDLINE (from 1966 to November 2004);

- EMBASE (from 1980 to February 2003);
- CINAHL (from 1982 to November 2004).

#### ***Search Strategy for the Skin Group Specialised Register***

The Skin Group Specialised Register was searched in June 2003 using these terms:  
(napkin\* or napp\* or diaper\*) and (dermatitis or rash\*)

#### ***Search strategy for CENTRAL (OVID)***

We identified RCTs of disposable nappies from CENTRAL using:

MeSH heading 'INFANT' OR the textword 'infant' OR the textword 'baby',

AND the MeSH heading 'DIAPER RASH' OR the textwords 'diaper rash', 'napkin rash', 'napkin dermatitis', 'diaper dermatitis' OR 'nappy rash',

AND the textwords 'nappy', 'napkin' OR 'diaper'.

See additional Table 1 (Table 01).

#### ***Search strategy for MEDLINE (OVID)***

We identified RCTs of disposable nappies from MEDLINE using:

MeSH heading 'INFANT' OR the textword 'infant' OR the textword 'baby',

AND the MeSH heading 'DIAPER RASH' OR the textwords 'diaper rash', 'napkin rash', 'napkin dermatitis', 'diaper dermatitis' OR 'nappy rash',

AND the textwords 'nappy', 'napkin' OR 'diaper'.

See additional Table 2 (Table 02).

#### ***Search Strategy for EMBASE***

We searched EMBASE using the search in additional Table 3 (Table 03).

#### ***Search strategy for CINAHL (OVID)***

We identified RCTs of disposable nappies from CINAHL using: CINAHL subject heading 'INFANT' OR the textword 'infant' OR the textword 'baby',

AND the CINAHL subject heading 'DIAPER RASH' OR the textwords 'diaper rash', 'napkin rash', 'napkin dermatitis', 'diaper dermatitis' OR 'nappy rash',

AND the textwords 'nappy', 'napkin' OR 'diaper'.

See additional Table 4 (Table 04).

### **(2) References from published studies**

We checked references from published studies for further trials.

### **(3) Unpublished literature**

We attempted to identify unpublished trials, ongoing trials, and grey literature by contacting the lead authors of the included and excluded studies and companies that make disposable nappies (Kimberly-Clark Corporation, Procter & Gamble Co).

### **(4) Other**

No language restrictions were applied.

## **METHODS OF THE REVIEW**

### **(1) Study selection**

Two authors (ELB and MWD) checked titles and abstracts identified from the searches; then they obtained and independently assessed the full text of all studies of possible relevance. The same two authors decided which trials fitted the inclusion criteria, and recorded their methodological quality. Any disagreement was resolved by discussion between the two authors. If any data were missing from the study reports, attempts were made to obtain that data by contacting the trial authors.

### **(2) Assessment of methodological quality**

Two authors (ELB and MWD) independently assessed trials for inclusion and methodological quality. The quality assessment for each included study contained a description of the following components as there is some evidence that inadequacies in these components are associated with biased estimates of treatment effect (Juni 2001):

- allocation concealment (blinding of randomisation) (adequate when clinicians and participants are unaware of allocations);
- blinding of intervention (whereby neither clinician, caregiver or parent knows which treatment group they are in);
- completeness of follow up (adequate when there is minimal loss to follow up and participants are followed up and analysed in the groups to which they were originally randomised);
- blinding of outcome measurement (adequate when the outcome assessor is unaware of the allocation).

### **(3) Data extraction**

Two of the authors (ELB and MWD) independently extracted data. Differences were resolved by discussion and consensus of the two authors. If necessary, trial authors were contacted for additional information or data.

### **(4) Analysis**

For individual trials, where possible, mean differences and 95% confidence intervals were to be reported for continuous variables. For categorical outcomes, the risk ratio and 95% confidence interval were to be reported.

For the meta-analysis, where possible, weighted mean differences and 95% confidence intervals were to be reported for continuous variables. The pooled risk ratio and 95% confidence intervals were to be reported for binary categorical outcomes. Random effect models were to be used to pool the data from the individual trials.

Crossover studies were analysed using outcomes at the end of the first study period (before the cross-over). Cross-over and parallel trials were to be pooled together where appropriate.

Heterogeneity between studies was to be assessed using  $I^2$ . Where moderate levels of heterogeneity ( $I^2 > 50\%$ ) were seen for the primary outcome, subgroup analysis were planned to determine whether the results differed by:

## Population

- Pre-term neonates, term neonates, or infants from 28 days to two years of age
- Male or female
- Predisposing skin condition or not (e.g., atopic dermatitis)

## Intervention

- Disposable napkin - type of lining, type of absorbent material, type of outer shell
- Non-disposable napkin - type of cloth, use of disposable liners, use of re-usable liners, type of over pant

A sensitivity analysis was planned to assess the effect of excluding poor quality studies.

Non-randomised controlled studies are listed but not discussed further. Studies relating to side effects are described qualitatively.

## 5. Other

Trial authors were contacted for clarification where there was uncertainty.

## DESCRIPTION OF STUDIES

We identified twenty-eight studies of the effects of various napkin types on napkin dermatitis. Seventeen studies from nine reports were included. Eleven studies were excluded due to methodology that did not fit the inclusion criteria of this review. One study that may be relevant to this review is pending translation (Janda 1993). Of the included studies, three compared napkins with different linings, eleven compared napkins with different absorbent materials, two compared napkins with different outer shells, and one compared napkins without clarifying differences between them.

### Included studies

#### *Studies comparing different types of napkin linings (3 studies)*

Baldwin 2001 reported a randomised trial on infants evaluating the change in the severity of napkin dermatitis using a disposable napkin that had an inner lining impregnated with a petrolatum, stearyl alcohol and zinc oxide formulation compared with an otherwise identical control disposable napkin. The report also included results of studies evaluating the ability of the napkin to transfer the formulation onto infant skin and to prevent skin irritation in an adult forearm model, outcomes not relevant to this review. Children in good health who routinely used disposable napkins were recruited to the study. Children found to have severe napkin rash (as defined by appearing to require physician treatment) were excluded from the study. The recruitment method and targeted age range were not specified. The initial six days of the study, all children used the control product. Following this, 304 children were randomised with stratification by sex and severity of napkin dermatitis, with results presented for 268 of these. The

children were evaluated twice weekly for four weeks and a napkin rash scale was used to record the severity of rash in four different anatomical regions. Five of the six study authors were of Procter & Gamble Co.

Odio 2000a reported a randomised trial on sixty-four infants 8 to 24 months old evaluating the change in skin erythema using a disposable napkin that had an inner lining impregnated with a formulation containing petrolatum, stearyl alcohol and aloe vera extract compared with an otherwise identical control disposable napkin. Children in good health who routinely used disposable napkins were recruited to the study. The recruitment method was not specified. Children with severe or moderately severe erythema in the napkin area were excluded. The children were evaluated on day four, five and six of the study using a napkin erythema scale. The study authors were of Procter & Gamble Co.

Odio 2000b reported a randomised trial on 308 infants 8 to 24 months old evaluating the change in napkin dermatitis and skin erythema using a disposable napkin that had an inner lining impregnated with a formulation containing petrolatum, stearyl alcohol and aloe vera extract compared with an otherwise identical control disposable napkin. 327 children in good health who routinely used disposable napkins were recruited to the study. The recruitment method was not specified. The initial six days of the study, all children used the control product. Following randomisation, the children were evaluated twice weekly for four weeks and a napkin rash and erythema scale was used to record the severity of rash and erythema. The study authors were of Procter & Gamble Co.

#### *Studies comparing different types of napkin absorbent material (11 studies)*

Campbell and colleagues reported four separate studies (Campbell 1987a; Campbell 1987b; Campbell 1987c; Campbell 1987d) in a single report. All four studies had a similar design but it was impossible from the single report to separate the data. The studies compared the effects on infant skin condition of a variety of disposable napkins (nine in total) and cloth napkins. The napkins were grouped into categories: absorbent gelling material disposables, conventional disposables, home laundered cloth. One thousand six hundred and fourteen healthy infants (weighing 12 to 20 lbs) were recruited from the local community, assessed fortnightly for 4 to 6 weeks in their usual napkins, then placed in a test product and assessed fortnightly for eight weeks and then followed up for a further four weeks of fortnightly assessments. Infants were assessed using a rash severity score by trained nurses to give an overall 'subjective rash grade'. The recruitment method and age range were not reported. The study also evaluated transepidermal water loss and skin pH, outcomes irrelevant to this review. The study authors were of Procter & Gamble Co.

Davis 1989 performed a randomised cross-over study on 150 infants 4 to 12 months old (weighing 12 to 24lbs) evaluating the effects on infant skin condition of four different disposable nap-

kins (two containing cellulose fluff cores and two with cellulose fluff combined with absorbent polymers). The infants used one of the cellulose fluff napkins for one week at the beginning, middle and end of the study, and underwent two six week blocks using a randomly allocated one of the three other napkins. The assessment involved grading any napkin rash on a rating scale. Parents/caretakers were also requested to keep a daily diary. The study also gathered data on infant skin pH, transepidermal water loss and skin electrical conductance, none of which were relevant outcomes to this review. The infants were withdrawn from the study while diaper dermatitis was being treated. Two of the four study authors were of Kimberly-Clark Corporation.

Jordan and Blaney reported four separate studies (Jordan 1982a; Jordan 1982b; Jordan 1982c; Jordan 1982d) in a single report. All four studies had a similar design. They were randomised studies on healthy infants 3 to 24 months age comparing cloth napkins with cellulose core disposable napkins. Two studies (Jordan 1982a; Jordan 1982b) were performed in the United States and compared multilayered cotton cloth napkins with plastic or rubber over pants with cellulose core disposable napkins with plastic outer shells. Results from 147 (Jordan 1982a) and 163 (Jordan 1982b) infants were reported for these studies. Two studies (Jordan 1982c; Jordan 1982d) were performed in Japan and compared cloth napkins with porous water-repellent synthetic fabric over pants with cellulose core disposable napkins with plastic outer shells. Results from 150 (Jordan 1982c) and 169 (Jordan 1982d) infants were reported for these studies. The infants in all studies were evaluated fortnightly using a rash severity score. An initial observation period of four weeks was used to evaluate baseline rash, while the infant used a 'control' napkin that was not described. This was followed by randomisation to a test product and further fortnightly evaluations for a study period of four to six weeks. The study authors were of Procter & Gamble Co.

Lane 1990 performed a randomised study on 204 newborn infants (38 to 42 weeks gestation) comparing the prevalence and severity of napkin dermatitis using disposable napkins with cellulose cores with and without absorbent gelling material. Exclusion criteria included systemic disease, skin disorders, skin diseases, birthmarks in napkin area and growth parameters outside the 10th to 90th centile. The infants were randomised within 24 hours of birth and were assessed by a physician day one, then daily until discharge, then at two weeks, then four-weekly until fourteen weeks of age using a rash severity score.

Seymour 1987 reported a randomised trial on infants with atopic dermatitis and infants without atopic dermatitis less than 20 months old comparing the effects on napkin rash and skin microbiology of napkins with cellulose core with and without absorbent gelling material. The studies also included a comparison with cloth napkins, however this allocation was not randomised and therefore the results of this comparison were not considered in this review. The study included 61 infants with atopic dermatitis

and 57 infants without atopic dermatitis. The infants were assessed fortnightly for six weeks, then four weekly up until 26 weeks. The assessment involved one of two dermatologists grading the napkin area on a napkin rash scale and an atopic dermatitis scale. Swabs were also collected for microbiological culture, but these results were not relevant to this review. Three of the five authors were of Procter & Gamble Co.

#### ***Studies comparing different types of napkin outer shells (2 studies)***

Akin and colleagues performed two randomised clinical trials at independent laboratories on infants 3 to 15 months old (weighing 16 to 18lbs) evaluating the effects on napkin dermatitis of two different disposable napkins with breathable outer shells (Akin 2001a; Akin 2001b). The studies were controlled using otherwise identical napkins with non-breathable outer shells. Between 230 and 260 infants of both sexes were recruited for each study. The infants were assessed twice weekly for seven weeks following napkin allocation. The assessment involved grading any rash present using a rash severity score and a clinical signs score incorporating regional assessment. The publication included data comparing the different napkin types ability to inhibit *candida* growth when used to occlude skin on adult forearms, an outcome not relevant to this review. Three of the six study authors were of Kimberly-Clark Corporation.

#### ***Other studies (1 study)***

Stein 1982 reported a randomised trial on healthy infants (age not specified but napkins were newborn size) evaluating the incidence of napkin dermatitis using three varieties of disposable napkins (differences between napkins were not described). The study also included a non-randomised comparison with cloth napkins. The recruitment method was not stated, except to say that infants with fair skin were preferentially recruited. Exclusion criteria included systemic disease, severe napkin dermatitis or infants on medication. One hundred and fifty infants were included in the disposable arms of the study. The infants were assessed for the presence and grade of napkin dermatitis once a week for six weeks by the author. The study was supported by a grant from Johnson & Johnson Baby Products Company.

#### **Excluded studies (11 studies)**

See 'Characteristics of Excluded Studies' table.

## **METHODOLOGICAL QUALITY**

#### **Studies comparing different types of napkin linings**

Baldwin 2001. The randomisation method was not stated, except to say that it was performed after stratification of the infants for sex and napkin rash score. Subsequent concealment of the randomisation sequence was unclear. The study was described as double blind. Outcome assessment was blind. Completeness of follow-up was not described in detail and drop-outs were not accounted



for, and in the absence of clarity of how many children were evaluated, the proportion followed up was not able to be calculated. The data suggests that 88% of those enrolled were evaluated (268 children out of 304) and between 95 and 105% of those children were evaluated at each visit. This is awaiting further clarification by the study authors.

Odio 2000a. The randomisation method and subsequent concealment of the randomisation was not stated. The studies were described as double-blind. Outcome assessment was blind. Follow-up was reported as 100% complete.

Odio 2000b. The randomisation method and subsequent concealment of the allocation was not stated. The study was described as double-blind. Outcome assessment was blind. Completeness of follow-up was not described in detail and drop-outs were not accounted for, and in the absence of clarity of how many children were evaluated, the proportion followed up was not able to be calculated. The data suggests that between 86% and 99% of the study groups were evaluated at each visit.

#### **Studies comparing different types of napkin absorbent material**

Campbell 1987a; Campbell 1987b; Campbell 1987c; Campbell 1987d. Randomisation was computer-generated and stratified for type of napkin usually used, breast feeding, degree of baseline napkin dermatitis and a calculated "maturity index". Infants previously using cloth napkins were exclusively recruited to the cloth napkin test group, thereby making the group left for randomisation into the varied disposable groups unclear (were some cloth users randomised to disposables?), and excluding the non-randomised cloth group from the results of this review. Allocation concealment was unclear. The intervention was blinded, except for the cloth napkin group. Outcome assessment was blinded. Completeness of follow-up was not reported, and the number of children that participated in each arm of the four studies was not reported.

Davis 1989. Randomisation was computer-generated and stratified for age, sex and race and that twins were randomised together. The degree of blinding of allocation, intervention and outcome assessment were not reported. Although the total number of infants that dropped out of the study was reported, there is no report of which group they belonged to. Also, the number of infants on whom incomplete data was obtained was not reported.

Jordan 1982a; Jordan 1982b; Jordan 1982c; Jordan 1982d. The randomisation method and subsequent concealment of the randomisation code was unclear. The intervention was not able to be blinded, given that the study compared cloth and disposable napkins. Outcome assessment was blinded. The number of infants recruited was not reported, except to say that the mothers of infants who failed to complete the study were questioned to assure that their withdrawal was unrelated to the effects of the test product. Also, the number of infants on whom incomplete data was obtained is not reported.

Lane 1990. Randomisation was performed after stratification of the infants for sex and diet (breast versus bottle fed), although the method for generating the allocation sequence was unclear. Allocation concealment was not reported and blinding of intervention was implied but unclear. Completeness of follow-up was only >80% at the day 2 and day 14 assessments. Outcome assessment was blinded.

Seymour 1987. Randomisation (method not stated) was performed after stratification of the infants for preceding napkin rash, preceding atopic dermatitis rash and an age/weight/sex maturity factor. Exclusion criteria were not stated. Allocation concealment was unknown and blinding of intervention was implied but unclear. Follow-up was 94% of atopic infants studied and 99% of normal infants studied and the drop outs were accounted for. Outcome assessment was blinded.

#### **Studies comparing different types of napkin outer shells**

Akin 2001a. For both studies, randomisation was performed after stratification of the infants by napkin dermatitis history, sex, age, weight, feeding method and race. Allocation concealment was adequate. The intervention was reported as blind and outcome assessment was also blinded. Completeness of follow-up, number of exclusions and (most importantly) the number of infants actually studied were not reported.

#### **Other studies**

Stein 1982. The carers of infants randomised to the various disposable nappies had a preference for using disposables over cloth, thereby excluding the results of the cloth napkin group from this review as it was not randomised adequately. Blinding of allocation and intervention was unclear. Completeness of follow-up was unclear as only the infants completing the study were included in results and the total number recruited was not reported. Outcome assessment was blinded.

## **RESULTS**

No results from the included studies in this review can be pooled because of the extreme disparity between studies and the general inadequacy of the reporting of the studies. It is still useful, however, to review the results of the individual studies (described below).

#### **Studies comparing different types of napkin linings**

The results of Baldwin 2001 were presented as mean napkin rash scores and proportion of visits with napkin rash. Mean napkin rash scores were found to be significantly reduced in the children allocated test napkins relative to those using the controls napkins. Mean rash scores were not an outcome considered in the method of this review; they are not consistently defined across studies and the data are not distributed normally. It is impossible to determine the proportion of babies with any nappy rash or with severe nappy rash from mean rash scores. The authors noted a marked variation in individual rash scores over time, further evidence that mean

rash scores are not an appropriate outcome measure. Between 127 and 141 children from each group were evaluated at each visit, even though the methodology suggests each group contained only 134 children. The proportion of visits where the children were assessed as not having 'no napkin rash' was reported as being significantly less for the children allocated test napkins in three of the four anatomical areas, however actual results were only presented for two of the anatomical areas. In the absence of knowledge of how many infants from each group were assessed at each visit, and whether each individual infant had rash or not, none of these results could be presented numerically. These results must be treated with caution as they are prone to bias. No other results considered relevant for this review were reported.

The results of Odio 2000a were presented as mean erythema scores in the perianal and genital areas covered by the napkin. Evaluation of different anatomical areas was not described in the study methodology and results from other anatomical areas covered by the napkin were not reported. A significantly lower mean erythema score was found in the children using the test product relative to the control on all three evaluation days. Mean erythema scores were not an outcome considered in the method of this review, as discussed above. No other results considered relevant for this review were reported.

The results of Odio 2000b were presented as mean napkin rash scores in the perianal and genital areas covered by the napkin, although evaluation of different anatomical areas was not described in the study methodology and results from other anatomical areas covered by the napkin were not reported. Between 132 and 153 children from each group were evaluated at each visit. A significantly lower mean rash score was found in the children using the test product relative to the control on almost all visits. The authors noted a marked variation in individual rash scores over time. Mean rash scores were not an outcome considered in the method of this review, as discussed above. No other results considered relevant for this review were reported.

#### **Studies comparing different types of napkin absorbent material**

The results of Campbell 1987a; Campbell 1987b; Campbell 1987c and Campbell 1987d were presented graphically as "ranges of percent of babies with overall subjective rash grades >1.0" (considered to be parent perceptible) for each of the four studies (n not defined, presented graphically), and the overall average napkin rash grade for each of the three test napkin categories. The results of the cloth napkin group are not relevant to this review as this group was not randomised. The ranges of percent of babies with subjective rash grade >1.0 was lower for the absorbent gelling material napkins than the conventional napkins in three out of the four studies. However, no absolute figures were reported and no calculation of statistical significance was possible. The overall subjective rash grade average (results of all studies combined graphically) was lower for absorbent gelling material napkins than

conventional disposable napkins, which was reported as a significant difference, however, average rash scores were not an outcome considered in the method of this review for reasons stated above. No other results considered relevant for this review were reported.

The results of Davis 1989 were presented as average rash severity for each napkin type, without reporting the time in the study at which the measurements were taken. Pre- and post-crossover data were reported together. The number of infants randomised to each study group was not reported. The mean rash severity scores were lower for the napkins containing absorbent gelling material compared with the cellulose fluff only napkin, but this did not reach statistical significance and is not an outcome considered relevant for this review. No differences were reported in the severity of napkin dermatitis in each group as reported by the parent/caregiver. No other results considered relevant for this review were reported.

The results of Jordan 1982a; Jordan 1982b; Jordan 1982c and Jordan 1982d were presented as number of infants in each study group with none to slight rash, slight to moderate rash and moderate to severe rash, as well as what appeared to be a mean napkin rash score. The numerical results were not adequately defined to allow further analysis. It was stated that the results indicated that disposable napkins and cloth napkins did not differ in their influence on napkin dermatitis, regardless of the occlusiveness of the over pant used in the cloth group. No other results considered relevant for this review were reported.

The results of Lane 1990 were presented as frequency of napkin dermatitis at each visit, and mean rash scores at each visit. No statistical difference in mean rash scores was found in the study and mean rash scores were not an outcome considered relevant for this review for reasons stated above. Follow-up was complete for 73% of the 204 infants enrolled. The results at two weeks, ten weeks and fourteen weeks demonstrated higher frequency of napkin rash for infants in conventional napkins, while at six weeks there was a higher frequency in the absorbent gel group. The results at fourteen weeks were the only data reaching statistical significance. No other results considered relevant for this review were reported.

The results of Seymour 1987 were presented as mean napkin rash scores, an outcome that was not considered in the method of this review for reasons stated above. The findings in infants with atopic dermatitis demonstrated significantly lower mean rash scores in those infants wearing disposable napkins relative to cloth, however no difference between the two types of disposable napkins was reported. The findings in infants with normal skin demonstrated significantly lower mean rash scores in infants wearing disposable napkins with cellulose cores relative to cloth and cellulose with absorbent gelling material napkins at one of the eight grading visits. This trend was not apparent at the other grading visits with crossovers in mean napkin rash scores in all three napkin groups.

No other results that we considered relevant for this review were reported.

#### **Studies comparing different types of napkin outer shells**

The results of Akin 2001a and Akin 2001b were presented in terms of the number of exam visits in which rash was present in each of the study groups in each of the studies. This was further subdivided into whether moderate/severe versus mild rash was present. In the absence of knowledge of how many infants were randomised to each group and followed-up, how many were assessed at each visit and at which visits the rashes were diagnosed, these data need to be treated with caution as they are open to bias. The results show that there was a reduction in both the number of visits in which a rash was present and in the severity of the rash in the infants randomised to highly breathable napkins in both studies. The statistical significance of the findings was not stated, and there was not enough raw data reported to calculate significance. Another result stated in the study was that the regional assessments of the napkin area demonstrated a lesser degree of dermatitis in the highly breathable napkin group, however no quantitative data was presented to support this. No other results considered relevant for this review were reported.

#### **Other studies**

The results of Stein 1982 were presented in terms of the number of return visits in which rash was present. In view of the lack of any described difference between the three napkins studied, the results were not included in the analysis. Infants using cloth napkins had a significantly larger number of assessments with rash than those using disposables, however allocation to cloth was not randomised, therefore this result is not relevant to this review. No other results considered relevant for this review were reported.

## **DISCUSSION**

In studies comparing various napkin types for the prevention of napkin dermatitis, there will always be some limitations in methodology. For example, in a randomised controlled trial comparing cloth and disposable napkins many parents/caregivers would have a personal preference that may limit compliance and create bias. It would also be difficult to fully blind the intervention given that the parent/caregivers handle the napkins. The need for an adequate control group is important given the regressive nature of napkin dermatitis. For that reason, it would be important that an outcome measure of napkin dermatitis be fully blinded to limit any bias. Assessing napkin dermatitis in an objective way also would need careful consideration. As with any study of prevention of harm, adequate follow-up and accounting for drop outs would be necessary to remove the chance of this biasing results.

In general, the sub-optimal methodology descriptions, and poor follow-up and outcome data, limited the interpretation of the included studies for the purposes of this review. None of the studies

gave any quantitative data comparing the study groups at baseline. All of the studies contained reasonable rash grading systems to define rash to some reproducible degree, however, averaging the results of these scores was not logical, especially as the distribution of napkin dermatitis does not follow the normal curve.

Due to the poor reporting of methodology and results of the studies, no quantitative data was available for analysis (or meta-analysis) in this review. This is an important point for investigators to consider when designing, implementing and reporting future studies. Although missing data was sought to improve the results available from these studies by contacting trial authors, no further data was obtained. This emphasizes the importance of reporting results thoroughly on initial publication.

Although the included studies appeared to favour cellulose-core disposable napkins over cloth; absorbent gelling material over cellulose-core napkins; breathable outer shell over occlusive outer shell napkins; and linings impregnated with formulations over plain linings: all of these studies were open to significant bias. Any interpretation of the results of the studies included in this review would be extremely unreliable.

It is particularly important to consider the possibility of publication bias, given that negative studies and results (particularly those done by companies that manufacture disposable napkins) are less likely to be published. The under-reporting of RCTs due to publication bias has been well described (Dickersin 1987; Dickersin 1990; Dickersin 1993). In a systematic review of pharmaceutical industry sponsorship and research outcome Lexchin 2003 found that research funded by drug companies was less likely to be published.

The generalisability of the available results is also limited. Internationally there is a wide variety of available disposable napkins and an even wider variety of reusable napkins. The included studies were all performed in the USA, and although there were some Japanese data and a few European studies in the excluded studies, the majority of the literature on the topic is generated in the USA. Therefore, the results will have only a limited application internationally, where there is a huge range of napkin practices and alternative infant toileting techniques. After all, no napkin is the best prevention for napkin dermatitis.

## **AUTHORS' CONCLUSIONS**

### **Implications for practice**

There is not enough evidence from good quality randomised controlled trials to support or refute the use and type of disposable napkins for the prevention of napkin dermatitis in infants. The implications of this for practice are that health care workers, parents and infant caregivers are left to balance the many considerations in napkin choice without this evidence.

## Implications for research

A good quality, adequately powered randomised controlled trial needs to be done assessing the use of disposable napkins in the prevention of napkin dermatitis. With the continuing evolution of disposable napkins, ongoing comparative research will be required. Outcomes in such a study would ideally include the presence and severity of napkin dermatitis as well as cost analysis, parent/caregiver satisfaction and environmental impact .

## POTENTIAL CONFLICT OF INTEREST

None known.

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\*Indicates the major publication for the study

## TABLES

### Characteristics of included studies

Study	Akin 2001a
Methods	Randomised controlled clinical trial; infants stratified into two groups, then each group randomly assigned one type of napkin; participants, clinician and outcome assessors blinded
Participants	Recruitment method not described, 3-15 month old infants weighing 16-28 pounds. Exclusion criteria: symptoms of systemic disease; skin lesions other than mild napkin dermatitis Number randomised: between 230 and 260 (exact n not specified)
Interventions	a: super absorbent gel containing disposable napkin with a non-breathable outer shell (Huggies Ultratrim) b: identical napkin with a breathable outer shell
Outcomes	Rash severity score utilised to determine the number of exam visits in which rash was present, subdivided into mild vs mod/severe rash
Notes	
Allocation concealment	A – Adequate

Study	Akin 2001b
Methods	Randomised controlled clinical trial; infants stratified into two groups, then each group randomly assigned one type of napkin; participants, clinician and outcome assessors blinded
Participants	Recruitment method not described, 3-15 month old infants weighing 16-28 pounds. Exclusion criteria: symptoms of systemic disease; skin lesions other than mild napkin dermatitis Number randomised: between 230 and 260 (exact n not specified)
Interventions	a: super absorbent gel containing disposable napkin with a non-breathable outer shell (Huggies Supreme) b: identical napkin with a breathable outer shell

### Characteristics of included studies (Continued)

Outcomes Rash severity score utilised to determine the number of exam visits in which rash was present, subdivided into mild vs mod/severe rash

Notes

Allocation concealment A – Adequate

#### Study **Baldwin 2001**

Methods Randomised controlled clinical trial; infants stratified, then randomised into two treatment groups, method not further described; blinded participants and outcome assessors.

Participants Recruitment method not described, average age 9.9 months but range not given. exclusion criteria: serious or chronic disease, severe napkin rash. Number randomised: 304

Interventions a: super absorbent gel containing disposable napkin with a breathable shell  
b: identical napkin with a lining containing zinc oxide/ petrolatum formulation

Outcomes Rash and erythema scoring scale was utilised to determine the mean napkin rash score as well as the proportion of visits where rash was present.

Notes

Allocation concealment B – Unclear

#### Study **Campbell 1987a**

Methods Randomised controlled clinical trial; infants stratified, then randomised via computer program; participants and outcome assessors blinded.

Participants Healthy infants of napkin wearing age weighing 12-20lbs recruited from local community. Number randomised: approximately 100 in each arm of study, specific number not reported.

Interventions a: super absorbent gel containing disposable napkin  
b: cellulose only core disposable napkin  
c: super absorbent gel containing disposable napkin  
d: cellulose only core disposable napkin

Outcomes Subjective rash grades utilised to determine ranges of percent of babies with rash present.

Notes

Allocation concealment B – Unclear

#### Study **Campbell 1987b**

Methods Randomised controlled clinical trial; infants stratified, then randomised via computer program; participants and outcome assessors blinded.

Participants Healthy infants of napkin wearing age weighing 12-20lbs recruited from local community. Number randomised: approximately 100 in each arm of study, specific number not reported.

Interventions a: absorbent gel containing disposable napkin  
b: cellulose only core disposable napkin  
c: cellulose only core disposable napkin  
d: cloth (excluded)

Outcomes Subjective rash grades utilised to determine ranges of percent of babies with rash present.

Notes

Allocation concealment B – Unclear

#### Study **Campbell 1987c**

Methods Randomised controlled clinical trial; infants stratified, then randomised via computer program; participants and outcome assessors blinded.

### Characteristics of included studies (Continued)

Participants	Healthy infants of napkin wearing age weighing 12-20lbs recruited from local community. Number randomised: approximately 100 in each arm of study, specific number not reported.
Interventions	a: absorbent gel containing disposable napkin b: cellulose only core disposable napkin c: cellulose only core disposable napkin d: cloth (excluded)
Outcomes	Subjective rash grades utilised to determine ranges of percent of babies with rash present.
Notes	
Allocation concealment	B – Unclear

#### Study **Campbell 1987d**

Methods	Randomised controlled clinical trial; infants stratified, then randomised via computer program; participants and outcome assessors blinded.
Participants	Healthy infants of napkin wearing age weighing 12-20lbs recruited from local community. Number randomised: approximately 100 in each arm of study, specific number not reported.
Interventions	a: absorbent gel containing disposable napkin b: cellulose only core disposable napkin c: cloth (excluded)
Outcomes	Subjective rash grades utilised to determine ranges of percent of babies with rash present.
Notes	
Allocation concealment	B – Unclear

#### Study **Davis 1989**

Methods	Randomised controlled clinical trial with crossover; infants stratified and randomised using computer generated schedule; blinding not reported.
Participants	Healthy infants between 4-12 months weighing 12-24lbs. Number randomised: 150 with 22 drop-outs.
Interventions	a: cellulose core plus 5g of absorbent gel disposable napkin b: cellulose core plus 6.5g of absorbent gel disposable napkin c: cellulose core only disposable napkin
Outcomes	Napkin rash grading scale used to calculate average rash severity.
Notes	
Allocation concealment	B – Unclear

#### Study **Jordan 1982a**

Methods	Randomised controlled clinical trial; randomisation method not stated; outcome assessor blinded.
Participants	Healthy infants between 3-24 months. Number randomised: 147
Interventions	a: cloth napkin with occlusive overpant b: disposable napkin
Outcomes	Napkin rash grading scale used to calculate mean napkin rash scores and number of infants with none-mild, mild-mod or mod-severe rash.
Notes	
Allocation concealment	B – Unclear

#### Study **Jordan 1982b**

Methods	Randomised controlled clinical trial; randomisation method not stated; outcome assessor blinded.
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### Characteristics of included studies (Continued)

Participants	Healthy infants between 3-24 months. Number randomised: 163
Interventions	a: cloth napkin with occlusive overpant b: disposable napkin
Outcomes	Napkin rash grading scale used to calculate mean napkin rash scores and number of infants with none-mild, mild-mod or mod-severe rash.
Notes	
Allocation concealment	B – Unclear

#### Study **Jordan 1982c**

Methods	Randomised controlled clinical trial; randomisation method not stated; outcome assessor blinded.
Participants	Healthy infants between 3-24 months. Number randomised: 150
Interventions	a: cloth napkin with breathable overpant b: disposable napkin
Outcomes	Napkin rash grading scale used to calculate mean napkin rash scores and number of infants with none-mild, mild-mod or mod-severe rash.
Notes	
Allocation concealment	B – Unclear

#### Study **Jordan 1982d**

Methods	Randomised controlled clinical trial; randomisation method not stated; outcome assessor blinded.
Participants	Healthy infants between 3-24 months. Number randomised: 169
Interventions	a: cloth napkin with breathable overpant b: disposable napkin
Outcomes	Napkin rash grading scale used to calculate mean napkin rash scores and number of infants with none-mild, mild-mod or mod-severe rash.
Notes	
Allocation concealment	B – Unclear

#### Study **Lane 1990**

Methods	Randomised controlled clinical trial; randomisation stratified, method not stated; participants and outcome assessors blinded.
Participants	Healthy term newborn infants with growth parameters between 10th-90th centiles. Number randomised: 204 with 149 followed up completely.
Interventions	a: cellulose core disposable napkin b: absorbent gel disposable napkin
Outcomes	Napkin rash grading scale used to calculate frequency of presence of rash and mean rash grades.
Notes	
Allocation concealment	B – Unclear

#### Study **Odio 2000a**

Methods	Randomised controlled clinical trial: randomisation method not stated. Participants and outcome assessors blinded.
Participants	Healthy infants 8-12 months age. Number randomised: 64
Interventions	a: absorbent gel disposable napkin b: identical absorbent gel disposable napkin with lining containing petrolatum formulation

### Characteristics of included studies (Continued)

Outcomes Napkin rash and erythema scale used to calculate mean napkin rash scores.

Notes

Allocation concealment B – Unclear

#### Study Odio 2000b

Methods Randomised controlled clinical trial: randomisation method not stated. Participants and outcome assessors blinded.

Participants Healthy infants 8-12 months age. Number randomised: 308

Interventions a: absorbent gel disposable napkin  
b: identical absorbent gel disposable napkin with lining containing petrolatum formulation

Outcomes Napkin rash and erythema scale used to calculate mean napkin rash scores.

Notes

Allocation concealment B – Unclear

#### Study Seymour 1987

Methods Randomised controlled clinical trial: randomisation stratified, method not stated; participants and outcome assessors blinded.

Participants Infants under 20 months age, healthy infants and infants with atopic dermatitis recruited to the study. Number randomised: atopic infants 85 with 80 followed-up completely, normal infants 87 with 86 followed-up completely.

Interventions a: infants with atopic dermatitis wearing cellulose core disposable napkins  
b: infants with atopic dermatitis wearing absorbent gel disposable napkins  
c: normal infants wearing cellulose only disposable napkins  
d: normal infants wearing absorbent gel disposable napkins.

Outcomes Atopic dermatitis grading scale and napkin rash grading scale used to calculate mean rash grades.

Notes

Allocation concealment B – Unclear

#### Study Stein 1982

Methods Randomised controlled clinical trial: randomisation method not stated: blinding of participants and outcome assessors not reported.

Participants Healthy infants with median age of 28 days. Number randomised: 150 with complete follow-up.

Interventions a: disposable napkin (Pampers)  
b: disposable napkin (Johnson's disposable diapers)  
c: disposable napkin (prototype from Johnson & Johnson)

Outcomes Napkin rash scale used to calculate the number of return visits with rash present.

Notes

Allocation concealment B – Unclear

### Characteristics of excluded studies

Berg 1994 Not a randomised controlled trial. The authors reported four separate clinical trials comparing the effects on infant skin wetness, pH and napkin dermatitis of a number of disposable napkins and cloth napkins. The disposable napkins

### Characteristics of excluded studies (Continued)

used were not described. The report did not describe any randomization, thereby excluding the studies from this review. The study authors were of Procter & Gamble Co.

Campbell 1988	The authors reported a study comparing disposable napkins with and without absorbent gelling material on napkin dermatitis associated with diarrhoea and antibiotic use in children in day-care centers. The children were only evaluated for napkin dermatitis if they had an episode of antibiotic use or diarrhoea, so only a subset of the children who entered the study were evaluated, thereby excluding the study due to incomplete evaluation of an outcome relevant to this review. Two of the four study authors were of Procter & Gamble Co.
De Prost 1987	Not a randomised clinical trial. The authors reported the results of a clinical trial comparing the effects on skin condition, transepidermal water loss and skin pH of two disposable napkins (cellulose core with or without absorbent gelling material) in 102 infants in French day-care centres. The study was not reported to be randomised and the outcome of skin condition was not defined, two reasons the study was excluded from this review.
Grant 1973	Not a randomised clinical trial. A retrospective study using a questionnaire to compare the effect of disposable and cloth diapers, laundered by various methods, on the incidence of napkin dermatitis.
Jordan 1986	Not a randomised clinical trial. The authors reported a cross-sectional population study using questionnaires and clinical examinations of infants to determine the frequency and severity of napkin dermatitis as well as to investigate its relationship with infant age, sex, diet and napkin practices. The study authors were of Procter & Gamble Co.
Longhi 1992	Not a randomised clinical trial. An observational study looking at the incidence of napkin dermatitis in a sample of Italian infants, also aimed at identifying factors related to the development of napkin dermatitis. Although the study group were using one of two different disposable napkins, the napkin use was not reported to be randomised, therefore excluding this study from this review.
Oranje 1987	Not a randomised clinical trial. The authors reported a trial on Dutch infants 6 to 15 months old comparing disposable napkins containing absorbent gelling material with cloth napkins. The study was not reported to be randomised, thereby excluding it from this review.
Ueda 1986	Not a randomised clinical trial, no relevant outcomes reported. The authors reported studies of the effect of disposable and reusable napkins on adult forearm skin and also on the water content of infants skin. The studies were excluded as they were not randomised controlled trials and had no outcomes that were relevant to this review.
Van 1991	A randomised crossover study in day-care centers of the effect of disposable compared with cloth napkins on the rates of fecal contamination of the environment. The study was excluded as it did not address napkin rash as an outcome. The study demonstrated that use of disposable napkins reduced the rate of faecal contamination of the environment relative to cloth.
Weiner 1979	Not a randomised clinical trial. An observational study of napkin dermatitis, taking a retrospective napkin history on 146 one-month-old infants.
Zimmerer 1986	A clinical study of the effect of disposable and reusable napkins on adult forearm skin. The study was excluded as it was not a randomised controlled trial and had no outcomes that were relevant to this review. The study authors were of Procter & Gamble Co.

## ADDITIONAL TABLES

**Table 01. Search strategy for CENTRAL (OVID)**

1 infant.mp. [mp=title, original title, abstract, mesh headings, heading words, keyword]

2 baby.mp. [mp=title, original title, abstract, mesh headings, heading words, keyword]

3 1 or 2

4 diaper rash.mp. [mp=title, original title, abstract, mesh headings, heading words, keyword]

5 ('napkin rash' or 'napkin dermatitis' or 'diaper dermatitis' or 'nappy rash').mp. [mp=title, original title, abstract, mesh headings, heading words, keyword]

6 exp Diaper Rash/

**Table 01. Search strategy for CENTRAL (OVID)** (Continued)

7 4 or 5 or 6  
8 (nappy or napkin or diaper).mp. [mp=title, original title, abstract, mesh headings, heading words, keyword]  
9 3 and 7 and 8

**Table 02. Search strategy for MEDLINE (OVID)**

1 infant.mp. [mp=title, original title, abstract, name of substance word, subject heading word]  
2 baby.mp. [mp=title, original title, abstract, name of substance word, subject heading word]  
3 1 or 2  
4 diaper rash.mp. [mp=title, original title, abstract, name of substance word, subject heading word]  
5 ('napkin rash' or 'napkin dermatitis' or 'diaper dermatitis' or 'nappy rash').mp. [mp=title, original title, abstract, name of substance word, subject heading word]  
6 exp Diaper Rash/  
7 4 or 5 or 6  
8 (nappy or napkin or diaper).mp. [mp=title, original title, abstract, name of substance word, subject heading word]  
9 3 and 7 and 8

**Table 03. Search Strategy for EMBASE**

1 random\$.mp.  
2 crossover\$.mp.  
3 cross-over\$.mp.  
4 factorial\$.mp.  
5 exp PLACEBO/ or placebo\$.mp.  
6 1 or 2 or 3 or 4 or 5  
7 Clinical Trial/  
8 (double blind or double-blind).mp. [mp=title, abstract, subject headings, drug trade name, original title, device manufacturer, drug manufacturer name]  
9 random\$ controlled trial.mp.  
10 Controlled Study/  
11 6 or 7 or 8 or 9 or 10  
12 Infant/  
13 exp BABY/  
14 12 or 13  
15 diaper rash.mp. or exp Diaper Dermatitis/  
16 napkin rash.mp. or napkin dermatitis/  
17 nappy rash.mp.  
18 15 or 16 or 17  
19 (napp\$ or napkin\$ or diaper\$).mp. [mp=title, abstract, subject headings, drug trade name, original title, device manufacturer, drug manufacturer name]  
20 18 and 19  
21 11 and 14 and 20

**Table 04. Search strategy for CINAHL (OVID)**

1 infant.mp. [mp=title, subject heading word, abstract, instrumentation]  
2 baby.mp. [mp=title, subject heading word, abstract, instrumentation]

**Table 04. Search strategy for CINAHL (OVID) (Continued)**

3 1 or 2  
 4 diaper rash.mp. [mp=title, subject heading word, abstract, instrumentation]  
 5 ('napkin rash' or 'napkin dermatitis' or 'diaper dermatitis' or 'nappy rash').mp. [mp=title, subject heading word, abstract, instrumentation]  
 6 exp Diaper Rash/  
 7 4 or 5 or 6  
 8 (nappy or napkin or diaper).mp. [mp=title, subject heading word, abstract, instrumentation]  
 9 3 and 7 and 8

## GRAPHS AND OTHER TABLES

This review has no analyses.

### COVER SHEET

<b>Title</b>	Disposable nappies for preventing napkin dermatitis in infants
<b>Authors</b>	Baer EL, Davies MW, Easterbrook KJ
<b>Contribution of author(s)</b>	ELB - searched for studies, assessed studies for inclusion and wrote the review MWD - searched for studies, assessed studies for inclusion and revised the review KJE - consumer input in revising review
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<b>Date new studies found but not yet included/excluded</b>	Information not supplied by author
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<b>Date authors' conclusions section amended</b>	Information not supplied by author
<b>Contact address</b>	Dr Erica Baer Paediatric Registrar Herston Road Royal Children's Hospital Herston Brisbane Queensland 4029 AUSTRALIA

E-mail: Erica\_Baer@health.qld.gov.au

Tel: +61 73 63 68111

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